14 October 2016
EMA/CHMP/680764/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 12-15 September 2016

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

Health and safety information

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

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

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

Note on access to documents

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

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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) September 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 to be held 15-18 September 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 welcomed the new Dutch alternate member Paula Boudewina van Hennik. Johann Lodewijk Hillege became the member from the Netherlands replacing Pieter de Graeff. The Committee also noted that Belgian alternate member Bart van der Schuren was changed to the member position due to resignation of Daniel Brasseur. The Committee also noted that Jan Mazag from Slovakia resigned.

1.2. Adoption of agenda

CHMP agenda for 12-15 September 2016

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 18-21 July 2016.

The CHMP adopted the minutes.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. - venetoclax - Orphan - EMEA/H/C/004106

AbbVie Ltd.; treatment of patients with CLL who have failed a B-cell receptor inhibitor due to

intolerance or progression

Scope: Oral explanation

Action: Oral explanation to be held on Tuesday 13 September 2016 at 9:00

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

An oral explanation was held on Tuesday 13 September 2016 at 9:00.

2.1.2. - cediranib - Orphan - EMEA/H/C/004003

AstraZeneca AB; treatment of platinum sensitive relapsed (PSR) ovarian cancer relapsed (PSR) ovarian cancer

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday 14 September 2016 at 11:00

List of Outstanding Issues adopted on 28.04.2016. List of Questions adopted on 19.11.2015.

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

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

Post-meeting note: the applicant submitted a letter dated 19.09.2016 informing of the decision to withdraw the MAA.

2.2. Re-examination procedure oral explanations

2.2.1. Ninlaro - ixazomib - Orphan - EMEA/H/C/003844

Takeda Pharma A/S; multiple myeloma

Scope: oral explanation, opinion, Report from SAG Oncology meeting held on 5 September 2016

Action: Oral explanation to be held on Tuesday 13 September 2016 at 14:00

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

Opinion adopted on 26 May 2016.

An oral explanation was held on Tuesday 13 September 2016 at 14:00.

See also 3.5.1

2.3. Post-authorisation procedure oral explanations

2.3.1. Jardiance - empagliflozin - EMEA/H/C/002677/II/0014

Boehringer Ingelheim International GmbH

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Dolores Montero Corominas

Scope: Oral explanation to be held on Wednesday 14 September 2016 at 09:00

"Extension of indication to include a new indication on prevention of cardiovascular events, based on the final data of the cardiovascular safety phase III clinical trial EMPA-REG OUTCOME. As a consequence, section 4.1 of the SmPC is updated. The Package Leaflet is also updated accordingly.
In addition, the Marketing authorisation holder (MAH) took the opportunity to make some editorial changes."

Action: For adoption

Request for Supplementary Information adopted on 23.06.2016, 25.02.2016.

An oral explanation was held on Wednesday 14 September 2016 at 09:00.

See also 5.1.4

2.4. Referral procedure oral explanations

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Chenodeoxycholic acid sigma-tau - chenodeoxycholic acid - Orphan - EMEA/H/C/004061

Sigma-tau Arzneimittel GmbH; treatment of inborn errors of primary bile acid synthesis

Scope: Opinion

Action: For adoption

Hybrid application (Article 10(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 21.07.2016, 28.04.2016. List of Questions adopted on 25.02.2016.

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.

The CHMP adopted the updated CHMP assessment report on similarity.

3.1.2. Emtricitabine - Tenofovir disoproxil Zentiva - emtricitabine / tenofovir disoproxil - EMEA/H/C/004137

Zentiva k.s.; treatment of HIV-1

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 23.06.2016. List of Questions adopted on 25.02.2016.

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 CHMP noted the letter of recommendation dated 12.09.2016.

The summary of opinion was circulated for information.

3.1.3. Glyxambi - empagliflozin / linagliptin - EMEA/H/C/003833

Boehringer Ingelheim International GmbH; 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 23.06.2016. List of Questions adopted on 25.02.2016.

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.

3.1.4. Granpidam - sildenafil - EMEA/H/C/004289

Accord Healthcare Ltd; treatment of patients with pulmonary arterial hypertension

Scope: Opinion

Action: For adoption

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

List of Questions adopted on 01.04.2016.

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 restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendation dated 14.09.2016.

The CHMP adopted the CHMP assessment report on similarity

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

Pfizer Limited; treatment of breast cancer

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 23.06.2016. 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.

Furthermore, the CHMP considered that palbociclib 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 summary of opinion was circulated for information.

The CHMP noted the letter of recommendation dated 13.09.2016.

3.1.6. Ivabradine JensonR (previously known as Ivabradine Mylan) - ivabradine - EMEA/H/C/004217

JensonR+ Limited; treatment of angina pectoris

Scope: Opinion

Action: For adoption

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

List of Questions adopted on 01.04.2016.

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.

3.1.7. Ivabradine Zentiva - ivabradine - EMEA/H/C/004117

Zentiva, k.s.; treatment of angina pectoris

Scope: Opinion

Action: For adoption

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

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

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.

3.1.8. Lartruvo - olaratumab - Orphan - EMEA/H/C/004216

Accelerated assessment

Eli Lilly Nederland B.V.; treatment of soft tissue sarcoma

Scope: Opinion

Action: For adoption

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

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

Furthermore, the CHMP considered that olaratumab 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 summary of opinion was circulated for information.

The CHMP adopted the CHMP assessment report on similarity

The CHMP adopted the BWP report.

3.1.9. Parsabiv - etelcalcetide - EMEA/H/C/003995

Amgen Europe B.V.; treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy, treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 23.06.2016. List of Questions adopted on 28.01.2016.

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 etelcalcide 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; Day 180 list of outstanding issues

3.2.1. - aceneuramic acid - Orphan - EMEA/H/C/004176

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.01.2016.

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

treatment of haemophilia A

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.

The CHMP adopted the BWP report

3.2.3. - alectinib - EMEA/H/C/004164

indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive.

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.01.2016.

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

The Committee adopted a list of outstanding issues.

The CHMP agreed to the request for an extension to the clock stop to respond to the Day 180 list of outstanding issues with a specific timetable.

3.2.4. - adalimumab - EMEA/H/C/004212

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatri Crohn's disease and Ulcerative colitis

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.

The CHMP adopted the BWP report.

3.2.5. - adalimumab - EMEA/H/C/004373

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease and Ulcerative colitis

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.

The CHMP adopted the BWP report.

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

moderate to severe plaque psoriasis

Scope: Day 180 list of outstanding issue

Action: For adoption

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 list of outstanding issues with a specific timetable.

The CHMP adopted the BWP report.

3.2.7. - darunavir - EMEA/H/C/004068

treatment of HIV-1

Scope: Day 180 list of outstanding issue

Action: For adoption

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

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.

3.2.8. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004215

treatment of HIV-1

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.

3.2.9. - insulin aspart - EMEA/H/C/004046

treatment of diabetes mellitus in adults

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.

The CHMP adopted the BWP report.

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

ERYTECH Pharma S.A.; treatment of leukaemia

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.01.2016.

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.

The CHMP adopted the BWP report.

The CHMP adopted the CHMP assessment report on similarity.

3.2.11. - insulin glargine - EMEA/H/C/004101

treatment of diabetes mellitus

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.

The CHMP adopted the BWP report.

3.2.12. - chlormethine - Orphan - EMEA/H/C/002826

Actelion Registration Ltd.; treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 24.09.2015.

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.

The CHMP agreed to the request for an extension to the clock stop to respond to the Day 180 list of outstanding issues with a specific timetable.

3.2.13. - teriparatide - EMEA/H/C/004368

treatment of osteoporosis

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.

The CHMP adopted the BWP report

3.2.14. - parathyroid hormone - Orphan - EMEA/H/C/003861

NPS Pharma Holdings Limited; treatment of hypoparathyroidism

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016, 28.04.2016, 24.09.2015. List of Questions adopted on 26.03.2015.

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

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 during the July 2016 meeting.

The Committee adopted a 4th list of outstanding issues with a specific timetable.

The CHMP adopted the BWP report.

3.2.15. - nonacog beta pegol - Orphan - EMEA/H/C/004178

Novo Nordisk A/S; treatment of haemophilia B

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.05.2016.

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

It was agreed to involve an ad hoc expert group.

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

The CHMP adopted the BWP report.

The CHMP adopted the SWP report.

3.2.16. - obeticholic acid - Orphan - EMEA/H/C/004093

Intercept Pharma Ltd; treatment of primary biliary cirrhosis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016. List of Questions adopted on 22.10.2015.

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.

3.2.17. - tadalafil - EMEA/H/C/004297

treatment of pulmonary arterial hypertension (PAH)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.05.2016.

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.

The CHMP adopted the CHMP assessment report on similarity

3.2.18. - tenofovir alafenamide - EMEA/H/C/004169

chronic hepatitis B in adults

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.

3.2.19. - teriparatide - EMEA/H/C/003916

treatment of osteoporosis

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.

The CHMP adopted the BWP report.

3.2.20. - edotreotide - Orphan - EMEA/H/C/004140

Diagnosis of gastro-entero-pancreatic neuroendocrine tumours

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016. List of Questions adopted on 25.02.2016.

Post-meeting note: The Committee adopted a 2nd List of Outstanding issues with a specific timetable via written procedure on 23.09.16.

3.3. Initial applications; Day 120 list of questions

3.3.1. - inotuzumab ozogamicin - Orphan - EMEA/H/C/004119

Pfizer Limited; Treatment of ALL

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.

The CHMP adopted the CHMP assessment report on similarity

3.3.2. - pacritinib - Orphan - EMEA/H/C/004193

Baxalta Innovations GmbH; treatment of myelofibrosis

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. - febuxostat - EMEA/H/C/004374

treatment of hyperuricaemia

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.

3.3.4. - lutetium (177 Lu) dotatate - Orphan - EMEA/H/C/004123

Advanced Accelerator Applications; Treatment of gastro-entero-pancreatic neuroendocrine tumours

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

It was agreed to revert back to the standard timetable.

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

3.3.5. - masitinib - Orphan - EMEA/H/C/004159

AB Science; treatment of mastocytosis

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. - ocrelizumab - EMEA/H/C/004043

treatment of adult patients with multiple sclerosis,
treatment of multiple sclerosis

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. - rituximab - EMEA/H/C/003903

treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL), Rheumatoid arthritis and Granulomatosis with polyangiitis and microscopic polyangiitis

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.

3.3.8. - atezolizumab - EMEA/H/C/004143

treatment of metastatic urothelial, treatment of urothelial carcinoma and non-small cell lung cancer (NSCLC)

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.

3.3.9. - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/004051

prevent invasive meningococcal disease caused by Neisseria meningitidis serogroup B

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee agreed to involve the Vaccines Working Party and adopted list of questions to the VWP to be addressed during the clock stop.

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

The CHMP adopted the BWP report.

3.3.10. - carglumic acid - EMEA/H/C/004019

treatment of hyperammoniemia

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.

3.3.11. - patiromer sorbitex calcium - EMEA/H/C/004180

treatment of hyperkalaemia

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. - bezlotoxumab - EMEA/H/C/004136

indicated for the prevention of Clostridium difficile infection (CDI) recurrence

Scope: amended timetable

Action: For adoption

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

The CHMP adopted an amended timetable.

3.4.2. - etanercept - EMEA/H/C/004192

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis, plaque psoriasis and paediatric plaque psoriasis

Scope: Request for an extension to the clock stop to respond to the Day 120 List of questions adopted during the March 2016 meeting.

Action: For adoption

List of Questions adopted on 01.04.2016.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the Day 120 List of questions adopted during the March 2016 meeting.

3.4.3. - tivozanib hydrochloride monohydrate - Orphan - EMEA/H/C/004131

EUSA PHARMA; treatment of adult patients with advanced renal cell carcinoma (RCC)

Scope: Request for an extension to the clock stop to respond to the Day 120 List of questions adopted during the July 2016 meeting.

Action: For adoption

List of Questions adopted on 21.07.2016.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond

to the Day 120 List of questions adopted during the July 2016 meeting.

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

3.5.1. Ninlaro - ixazomib - Orphan - EMEA/H/C/003844

Takeda Pharma A/S; multiple myeloma

Scope: oral explanation, opinion, Report from SAG Oncology meeting held on 5 September 2016

Action: For discussion

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

Opinion adopted on 26 May 2016.

List of experts for the SAG Oncology as well as the list of questions to this group was adopted via written procedure on 02.09.2016.

The CHMP noted the report from the SAG. The SAG considered that the data submitted on the basis of the ITT analysis of PFS, together with the corroborative data from the China Continuation Study, the trends in terms of OS, the clinical rationale, the low toxicity and the possibility of effective triple-combination therapy, resulting in a clearly positive benefit-risk balance in a broad indication, is consistent with the studies' main entry criteria. According to the SAG, the fact that a subsequent secondary analysis showed some uncertainty about the level of statistical significance, was not considered sufficient to change the conclusions about a clear beneficial effect in terms of PFS.

An oral explanation was held on Tuesday 13 September 2016 at 14:00. The Company explained that benefit-risk balance in the pre-specified subgroup (at least 2 prior therapies) could be positive. The Company also discussed and explained a benefit-risk assessment in the overall ITT population. The presentation included the efficacy and safety comparison of Ninlaro to recently approved treatments in the same patient population. Oral dosing was presented as major added value to ixazomib as it could be the first agent to allow effective oral triple-combination therapy.

The Committee discussed, whether conditional marketing authorisation can be granted and it was agreed that possible post-authorisation measures should be investigated further.

The Company made a proposal for post-authorisation measures and the committee discussed the possible conditional marketing authorisation.

The Committee adopted a positive opinion recommending the granting of a conditional marketing authorisation by majority (18 positive out of 27 votes) together with the CHMP assessment report and translation timetable.

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

The divergent position (Bruno Sepodes, Concepcion Prieto Yerro, Daniela Melchiorri, David Lyons, Greg Markey, Ines Baotic, Johann Lodewijk Hillege, Pierre Demolis and Robert Hemmings) was appended to the opinion.

The summary of opinion was circulated for information.

The re-examination question and answers document was circulated for information.

The CHMP adopted the CHMP assessment report on similarity

See also 2.2.1

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Cokiera - dasabuvir / ombitasvir / paritaprevir / ritonavir - EMEA/H/C/004235

AbbVie Ltd.; treatment of hepatitis C

Rapporteur: Kristina Dunder, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Margarida Guimarães

Scope: Withdrawal of initial marketing authorisation application

Action: For information

The CHMP noted the letter from the applicant informing of the decision to withdraw the MAA.

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. Stelara - ustekinumab - EMEA/H/C/000958/X/0049/G

Janssen-Cilag International N.V.

Rapporteur: Greg Markey, Co-Rapporteur: David Lyons, PRAC Rapporteur: Julie Williams

Scope: “Extension application to introduce a new pharmaceutical form (concentrate for solution for infusion), a new strength (130mg) and a new route of administration (intravenous use) and a type II variation (C.1.6.a) to amend section 4.1 of the Summary of Product Characteristics (SmPC) to extend the indication for the treatment of adult patients with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies. As a consequence, sections 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC were updated. The Package Leaflet and the RMP are updated in accordance”

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016. 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 by consensus together with the CHMP Assessment

Report and translation timetable.

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

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

The summary of opinion was circulated for information.

4.1.2. Zytiga - abiraterone - EMEA/H/C/002321/X/0039

Janssen-Cilag International N.V.

Rapporteur: Aranzazu Sancho-Lopez,

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (500mg film-coated tablets)."

Action: For adoption

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

4.2.1. Tivicay - dolutegravir - EMEA/H/C/002753/X/0018/G

ViiV Healthcare UK Limited

Rapporteur: Filip Josephson, Co-Rapporteur: Joseph Emmerich, PRAC Rapporteur: Julie Williams

Scope: "An extension application to add two new strengths (10mg and 25mg tablets) to support the extension (variation type II C.I.6) of the target population covered by the authorised therapeutic indication for Tivicay to treat paediatric patients from 6 years of age infected with HIV. Data from cohort I and II A of the clinical trial ING112578 are presented in support of the new therapeutic indication."

Action: For adoption

List of Questions adopted on 26.05.2016.

The Committee discussed the issues identified in this application. The main discussion was on clinical pharmacology specifically on the data provided for bridging between the tablet

strengths and the proposed posology in children aged 6 – 12 years.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

4.2.2. 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 Questions adopted on 26.05.2016.

The Committee discussed the issues identified in this application. Some issues on the quality and the clinical parts of the dossier as well as the RMP were raised.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

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. Brilique - ticagrelor - EMEA/H/C/001241/X/0034

AstraZeneca AB

Rapporteur: Johann Lodewijk Hillege

Scope: “To add new pharmaceutical form (orodispersible tablets 90 mg) to the currently approved presentations for Brilique.”

Action: For adoption

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

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

4.3.2. Esbriet - pirfenidone - Orphan - EMEA/H/C/002154/X/0035/G

Roche Registration Limited

Rapporteur: Greg Markey, Co-Rapporteur: David Lyons, PRAC Rapporteur: Julie Williams

Scope: “Extension application to introduce a new pharmaceutical form associated with 3 new strengths (267mg, 534mg and 801mg film-coated tablets).
In addition, the following manufacturing sites are also introduced for the currently approved 267mg hard capsules presentations (EU/1/11/667/001-003):
B.I.b.1.f - To add an alternative site responsible for quality control of the active substance.

B.I.b.1.f - To add an alternative site responsible for quality control of the active substance."

Action: For adoption

The Committee discussed the issues identified in this application, which were related to a number of other concerns on quality, clinical and RMP aspects.

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

4.3.3. Ilaris - canakinumab - EMEA/H/C/001109/X/0045/G

Novartis Europharm Ltd

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Grouped application comprising an extension application covering an additional formulation (150 mg/ml solution for injection) and a type II variation (C.I.6.a) to add a new indication.
The proposed new indication is based on the results of the pivotal phase 3 study CACZ885N2301 and covers the treatment of adults and children of 2 years of age and older with one of the following Periodic Fever Syndromes:
- Tumour Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS);
- Hyperimmunoglobulin D Syndrome (HIDS) / Mevalonate Kinase Deficiency (MKD);
- Familial Mediterranean Fever (FMF) in patients in whom colchicine is contraindicated, is not tolerated, or does not provide an adequate response.
As a consequence sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are proposed to be updated and the Package Leaflet is proposed to be updated accordingly. In addition, the annexes have been aligned with the latest QRD template v.10. A revised RMP version 11 was provided as part of the application."

Action: For adoption

The Committee discussed the issues identified in this application. The main discussion concerned the use of the product in patients with contraindication or intolerance to colchicine.

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. 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."

Clockstop extension requested to respond to LoQ,

Action: For adoption

List of Questions adopted on 21.07.2016.

The CHMP agreed to the request by the MAH for an extension to the clock stop to respond to the list of questions adopted in July 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. Abilify - aripiprazole - EMEA/H/C/000471/II/0110

Otsuka Pharmaceutical Europe Ltd

Rapporteur: Bruno Sepodes, Scope: "Extension of Indication to include treatment of schizophrenia in adolescents between 13 – 15 years of age based on paediatric studies 31-09-266 and 31-09-267 submitted according to Article 46 of the paediatric regulation. As a consequence sections 4.1, 4.2 and 4.8 of the SmPC have been updated and the Package Leaflet has been updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 23.06.2016, 25.02.2016, 24.09.2015.

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 summary of opinion was circulated for information.

5.1.2. Cinryze - C1-esterase inhibitor, human - EMEA/H/C/001207/II/0045

Shire Services BVBA

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include children with hereditary angioedema (HAE) in the treatment and pre-procedure prevention of angioedema attacks.

As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 6.5 and 6.5 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance.
In addition, an update of regional information in module 3.2.R due to the proposed dose recommendation for children is submitted."

Action: For adoption

The Committee discussed the issues identified in this application. The main discussion focused on the clinical data in children below 6 years. Further data for this age group was requested from the MAH.

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

5.1.3. Inovelon - rufinamide - Orphan - EMEA/H/C/000660/II/0037

Eisai Ltd

Rapporteur: Pierre Demolis, PRAC Rapporteur: Claire Ferard

Scope: "Extension of Indication to include treatment of seizures associated with Lennox-Gastaut Syndrome in paediatric patients 1 year of age and older, based on the results of study E2080-G000-303 (Study 303); a randomized, controlled, open-label study to evaluate the cognitive development effects and safety, and pharmacokinetics of adjunctive rufinamide treatment in paediatric subjects 1 to less than 4 years of age with inadequately controlled Lennox-Gastaut Syndrome. This study was conducted to fulfil the long-term (2 years) safety and efficacy objectives required as part of the Paediatric Investigation Plan (PIP) EMEA-000709-PIP01-09. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are proposed to be updated and the Package Leaflet is proposed to be updated accordingly. In addition, the MAH took the opportunity to make minor editorial changes in the annexes, to implement changes in line with the latest QRD template and to combine the SmPCs, labelling and Package Leaflets for the three authorised strengths of the tablet formulation in line with the current version of the QRD template. The application included an updated RMP version 9.0."

Action: For adoption

The Committee discussed the issues identified in this application. Further explanation is expected by the applicant on the population PK model to support extrapolation from older children, adolescents and adults to the proposed extended target population to include children aged 1 to less than 4 years of age.

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

5.1.4. Jardiance - empagliflozin - EMEA/H/C/002677/II/0014

Boehringer Ingelheim International GmbH

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Dolores Montero Corominas

Scope: Oral explanation to be held on Wednesday 14 September 2016 at 09:00

"Extension of indication to include a new indication on prevention of cardiovascular events,

based on the final data of the cardiovascular safety phase III clinical trial EMPA-REG OUTCOME. As a consequence, section 4.1 of the SmPC is updated. The Package Leaflet is also updated accordingly.
In addition, the Marketing authorisation holder (MAH) took the opportunity to make some editorial changes."

Action: For adoption

Request for Supplementary Information adopted on 23.06.2016, 25.02.2016.

An oral explanation was held on Wednesday 14 September 2016 at 09:00.

The Committee discussed the issues identified in this application mainly focusing on the wording of the indication.

The presentation by the MAH focused on the clinical trial design and outcome data in support of the requested new distinctive indication for reduction of cardiovascular death.

The Committee adopted a 3rd request for supplementary information with a specific timetable.

See also 2.3.1

5.1.5. 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 28.04.2016.

The Committee discussed the issues identified in this application. The discussion focused on the assay performance data as well as some changes proposed to the SmPC and patient leaflet.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.6. NovoRapid - insulin aspart - EMEA/H/C/000258/II/0112

Novo Nordisk A/S

Rapporteur: Kristina Dunder

Scope: "Extension of Indication to include the use of NovoRapid in children from 1 to 2 years of age.
As a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.
Furthermore, the PI is brought in line with the latest QRD template version 10."

Action: For adoption

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.

5.1.7. Opdivo - nivolumab - EMEA/H/C/003985/II/0012

Bristol-Myers Squibb Pharma EEIG

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

Scope: "Extension of Indication to include the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL):
- after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin, or
- after at least two prior therapies in patients who are not candidates for ASCT,
for OPDIVO as monotherapy.
As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated in order to add the proposed new indication, add a warning that patients with active autoimmune disease and symptomatic interstitial lung disease were excluded from clinical trials of cHL, and update the safety and pharmacodynamic information. The Package Leaflet is updated in accordance. Furthermore, the PI is brought in line with the latest QRD template version 10.0.
Moreover, the updated RMP version 5.0 has been submitted"

Action: For adoption

Request for Supplementary Information adopted on 23.06.2016.

The Committee discussed the issues identified in this application. The Committee noted that there is a safety concern related to patients with alloSCT after nivolumab treatment which should be addressed by the applicant.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

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

Santhera Pharmaceuticals (Deutschland) GmbH

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

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

is contraindicated."

Action: For adoption

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

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

5.1.9. Revlimid - lenalidomide - Orphan - EMEA/H/C/000717/II/0089/G

Celgene Europe Limited

Rapporteur: Pierre Demolis, PRAC Rapporteur: Claire Ferard

Scope: "Extension of indication to add treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who have undergone autologous stem cell transplantation (ASCT). Consequently SmPC sections 4.1, 4.2, 4.4, 4.8 and 5.1 have been updated with the efficacy and safety data. The Package Leaflet and the RMP have been updated accordingly. Furthermore, the MAH introduced 7-day pack sizes for the 10 mg and 15 mg strengths with subsequent changes to the Product Information."

Action: For adoption

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

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

5.1.10. Synjardy - empagliflozin / metformin - EMEA/H/C/003770/II/0015

Boehringer Ingelheim GmbH

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Dolores Montero Corominas

Scope: "Extension of Indication to include treatment with Synjardy as adjunct to standard care therapy in adult patients with type 2 diabetes mellitus and high cardiovascular risk when treatment with empagliflozin and metformin is appropriate and empagliflozin is needed to reduce the risk of all-cause mortality by reducing cardiovascular death and cardiovascular death or hospitalization for heart failure. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated based on the final CSR of study EMPA-REG OUTCOME. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes/corrections in the SmPC. Moreover, the updated RMP version 5.0 has been submitted."

Action: For adoption

Request for Supplementary Information adopted on 26.05.2016.

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

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

5.1.11. 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 - Extension of Indication to add a new indication as monotherapy in the treatment of partial-onset seizures. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly.
In addition, the applicant took the opportunity to update the PI in line with the latest QRD template."

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016.

The Committee discussed the issues identified in this application. The discussion reflected on the proposed posology for the monotherapy indication.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.12. Votubia - everolimus - Orphan - EMEA/H/C/002311/II/0041

Novartis Europharm Ltd

Rapporteur: Harald Enzmann, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Martin Huber

Scope: "Extension of Indication to include adjunctive treatment of patients aged 2 years and older with refractory seizures associated with tuberous sclerosis complex (TSC) for Votubia 2 mg, 3 mg and 5 mg dispersible tablets.
Sections 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated in parallel based on the results from the pivotal study. In addition, sections 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 are also updated for the 2.5 mg, 5 mg and 10 mg tablets to reflect on data relevant to these formulations.
The Package Leaflet is updated in accordance.
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. The main discussion focused on the wording of the indication with regard to different seizure types.

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

5.1.13. Renvela Sevelamer carbonate Zentiva - sevelamer sevelamer - EMEA/H/C/WS0965

Genzyme Europe BV

Lead Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Veerle Verlinden

Scope: "Extension of indication for Renvela and Sevelamer carbonate Zentiva to include the control of hyperphosphataemia in paediatric patients (>6 years of age and a Body Surface Area (BSA) of >0.75 m2) with chronic kidney disease.
As a consequence, section 4.2 of the SmPC is updated to detail posology in the paediatric

patients.
The Package Leaflet is updated in accordance."

Action: For adoption

The Committee discussed the issues identified in this application. The main discussion related to the observed response rates for the paediatric population in comparison to the adult population.

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

No items

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

No items

6. Ancillary medicinal substances in medical devices

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

No items

6.2. Update of Ancillary medicinal substances in medical devices

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Ribociclib - H0004213

Treatment of breast cancer,

Scope: Letter from the company dated 29.07.2016 requesting an accelerated assessment.

Action: For adoption

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

The CHMP did not agree to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

8.1.2. Nusinersen - Orphan - H0004312

Biogen Idec Ltd, Treatment of Spinal Muscular Atrophy (SMA),

Scope: Letter from the company dated 05.08.2016 requesting an accelerated assessment.

Action: For adoption

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

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

8.1.3. Naloxone HCl Dihydrate – H0004325

Emergency use for the complete or partial reversal of respiratory depression induced by natural or synthetic opioids,

Scope: Letter from the company dated 07.07.2016 requesting an accelerated assessment.

Action: For adoption

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

The CHMP did not agree 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

The CHMP noted the list of applications received.

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

The CHMP adopted the recommendation for PRIME eligibility. The CHMP reviewed 9 recommendations for eligibility to PRIME: 2 were granted and 7 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. Helicobacter Test INFAI - 13C-urea - EMEA/H/C/000140/II/0019

MAH: INFAI GmbH, Rapporteur: Andrea Laslop,

Scope: Request for Supplementary Information / Opinion

"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."

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

Action: For adoption

The Committee discussed the issues identified in this application. The Committee noted that the choice of the cut-off and consequently the interpretation of the diagnostic performance still needs to be addressed by the applicant.

The CHMP adopted a 5th request for supplementary information with a specific timetable.

9.1.2. Soliris - eculizumab - Orphan - EMEA/H/C/000791/II/0086/G

MAH: Alexion Europe SAS, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia

Scope: Request for Supplementary Information / Opinion

Type II (C.I.4): Update of section 4.8 of the SmPC with the ADR frequencies to reflect overall exposure to eculizumab in clinical trials. The Package Leaflet (section 4) is updated accordingly.
Type II (C.I.3.b): update of section 4.4 of the SmPC with warning and precautions on meningococcal vaccination timing as recommended by PRAC. The Package Leaflet (sections 2 and 3) Annex II.D and the RMP (ver. 13) are updated accordingly.
In addition, the MAH took the opportunity of this RMP update to implement the PRAC recommendation suggesting to remove the off label use from the missing information, to provide the exposure data from PSUR 13 and to update the epidemiology sections with more complete and recent scientific literature data.
Moreover, the MAH took the opportunity of this submission to add editorial changes and to bring the PI in line with the latest QRD template."

Action: For adoption

The Committee discussed the issues identified in this application.

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

The CHMP agreed to the PRAC advice.

9.1.3. Iressa - Gefitinib - EMEA/H/C/001016/LEG 021 & EMEA/H/C/001016/LEG 022

MAH: AstraZeneca AB

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: PRAC advice

(LEG/21): Submission of a detailed literature review on resistance mechanism to gefitinib by transformation of non-small cell lung cancer (NSCLC) and lung adenocarcinoma to small cell carcinoma as requested in the conclusions of PSUSA/00001518/201507 procedure adopted by PRAC and CHMP in January 2016

(LEG/22): Submission of a detailed analysis on a safety meta-analysis reporting a higher frequency of gefitinib-related hepatotoxicity of grade ≥ 3 in Asians compared to non-Asians (Takeda et al, Lung Cancer. 2015, Apr;88(1):74-9) as requested in the conclusions of PSUSA/00001518/201507 procedure adopted by PRAC and CHMP in January 2016

Action: For adoption

The CHMP agreed to the PRAC advice.

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

MAH: PTC Therapeutics International Limited,

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus,

Scope: List of experts to the SAG

Type II variation

“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 21.07.2016, 01.04.2016.

Renewal of Marketing Authorisation

Scope: List of experts to the SAG Neurology
Request for Supplementary Information adopted on 21.07.2016, 28.04.2016.

Action: For adoption

The CHMP adopted the list of experts to the SAG Neurology meeting to be held on 29 September 2016.

9.1.5. Cresemba – Isavuconazole - EMEA/H/C/002734/MEA/004

MAH: Basilea Medical Ltd

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski

Scope: Updated assessment report.

Action: For adoption

The CHMP adopted the updated assessment report.

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 - EMEA/H/A-20/1438

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

Scope: List of experts to the SAG HIV/viral meeting on 10 October 2016

Action: For adoption

The CHMP adopted the List of experts for the SAG HIV/viral diseases meeting on 10 October 2016.

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: amended timetable

Prescription status of desloratadine-containing products

Action: For adoption

List of outstanding issues adopted on 26 May 2016

The CHMP adopted an amended timetable.

Furthermore the CHMP agreed to request PRAC advice.

Rapporteur/co-rapporteur joint assessment report circulated to CHMP:13.10.2016

PRAC advice to CHMP: 24-27.10.2016

Comments: 27.10.2016

Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 2 November 2016

CHMP discussion/opinion: November 2016 CHMP

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

No items

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

10.5.1. Clenil and associated names - Beclometasone dipropionate - EMEA/H/A-30/1418

Chiesi group of companies and associated companies

Rapporteur: Daniela Melchiorri, Co-Rapporteur: Martina Weise

Scope: Possible oral explanation to be held on 13 September 2016 at 11:00, Opinion

Harmonisation exercise for Clenil and associated names (beclometasone dipropionate). The review was triggered by Italy due to the need to harmonise the product information across all Member States, including the therapeutic indication, the target populations and the posology recommendations.

Action: For adoption

List of Questions adopted on 25.06.2015. List of outstanding issues adopted 19 November 2015, 1 April 2016 and 21 July 2016.

An oral explanation was cancelled.

The committee discussed the therapeutic indication.

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

The Committee adopted a positive opinion by majority (21 positive out of 25 votes) together with the CHMP Assessment Report.

The Icelandic CHMP member was in agreement with the CHMP recommendations.

The divergent position (Sinan B. Sarac, Piotr Fiedor, Pierre Demolis, Jana Schweigertova) was appended to the opinion.

10.5.2. Haldol and associated names (EMEA/H/A-30/1393) (haloperidol),

Janssen-Cilag Group of companies and associated companies

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

Scope: List of experts to the SAG Psychiatry meeting on 3 October 2016

Action: For adoption

The CHMP adopted the List of expert to the SAG Psychiatry meeting.

10.5.3. Haldol decanoate and associated names (EMEA/H/A-30/1405) (haloperidol) Janssen-Cilag Group of companies and associated companies

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

Scope: List of expert to the SAG Psychiatry meeting on 3 October 2016

Action: For adoption

The CHMP adopted the List of expert to the SAG Psychiatry meeting.

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

10.6.1. Pharmaceutics International – EMEA/H/A-31/1444

Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: David Lyons,

Scope: Opinion

Article 31 triggered by the European Commission

Action: For adoption

List of Questions adopted on 23.06.2016. List of Outstanding Issues adopted on 21 July 2016.

The CHMP adopted an opinion by consensus concluding that:

a. For Ammonaps, the marketing authorisation should be varied and subject to the condition that the marketing authorisation holder for Ammonaps provides evidence by 30 June 2017 that the manufacturing process complies with the requirements of Commission Directive 2003/94/EC laying down the principles and guidelines of GMP as provided for in Article 8(3) of Directive 2001/83/EC.

   In the EU Member State(s) where Ammonaps is not considered critical, the supply of Ammonaps manufactured at Pharmaceutics International Inc. should be prohibited and all batches should be recalled.

b. For Lutinus (and associated names) and Dutasteride Actavis (and associated names), at present the particulars and documents provided for in Article 8(3) of Directive 2001/83/EC are incorrect and therefore the marketing authorisations for these medicinal products should be varied to remove Pharmaceutical International Inc. from their marketing authorisations, as alternative manufacturing sites are listed in the respective marketing authorisations.

   The CHMP is also of the opinion that all batches of Lutinus (and associated names) from Pharmaceutics International Inc. should be recalled.

   No batches of Dutasteride Actavis (and associated names) from Pharmaceutics international Inc. are currently available on the EU market.

c. For SoliCol D3, at present the particulars and documents provided for in Article 8(3) of Directive 2001/83/EC are incorrect and therefore, pursuant to Article 116 of Directive 2001/83/EC the marketing authorisation of SoliCol D3 should be suspended, as no other manufacturing site is currently listed in the marketing authorisation.

The CHMP assessment report was adopted by CHMP.

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

The CHMP noted the EMA public health communication.

10.6.2. Dienogest/Ethinylestradiol containing products indicated in acne - Dienogest / Ethinylestradiol - EMEA/H/A-31/1435

Rapporteur: Martina Weise, Co-Rapporteur: Nithyanandan Nagercoil,

Scope: Opinion or List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 23 June 2016.

The Committee discussed different indication wordings and the views of the MAH.

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

Submission of responses: 08.11.2016

Re-start of the procedure: 22.11.2016

Rapporteur/co-rapporteur joint assessment reports circulated to CHMP: 30.11.2016

Comments: 05.12.2016

Updated Rapporteur/co-rapporteur joint assessment reports circulated to CHMP: 08.12.2016

CHMP Opinion: December 2016 CHMP

Post-meeting note: the amended list of outstanding issues with a specific timetable was adopted via written procedure on 20 September 2016.

10.6.3. Metformin and metformin containing fixed-dose combinations – metformin containing products – EMEA/H/A-31/1432

Rapporteur: Kristina Dunder, Co-Rapporteur: Johann Lodewijk Hillege, Scope: Opinion

Review of use in patients with renal impairment and precautions regarding lactic acidosis

Action: For adoption

List of Questions adopted 28 January 2016. List of Outstanding Issues adopted on 23 June 2016

The CHMP discussed different sections of the SmPC and adopted a list of outstanding issues with a specific timetable.

Submission of responses: 21.09.2016

Re-start of the procedure: 26.09.2016

(Co-)Rapporteur assessment report(s) circulated to CHMP: 30.09.2016

Comments: 05.10.2016

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:07.10.2016

CHMP Opinion: October 2016 CHMP

10.6.4. 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 outstanding issues

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.

Answer from EMA to the section 'historical and legal background' concerning the marketing authorisation for Symbioflor and MAH's conclusion from a legal perspective presented in the response to the list of questions.

Action: For adoption

List of Questions adopted on 1 April 2016.

The Committee discussed the indications for the product and the available clinical data.

The CHMP adopted a list of outstanding issues 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: 8.02.2017

Comments: 13.02.2017

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

CHMP opinion: February 2017 CHMP

10.7. 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

September 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

ITF Briefing Meeting

Meeting date: 14 September 2016

Action: For discussion and agreement

The CHMP agreed to the meeting.

ITF Briefing Meeting

Meeting date: 19 September 2016

Action: For discussion and agreement

The CHMP agreed to the meeting.

ITF briefing meeting

Meeting date: 30 September 2016

Action: For discussion and agreement

The CHMP agreed to the meeting.

ITF Briefing Meeting

Meeting date: 12 September 2016

Action: For discussion and agreement

The CHMP agreed to the meeting.

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. Review of experience with the Early Background Summary

Scope: An Outcome of a review of experience with the Early Background Summaries. A survey amongst CAT/CHMP/PRAC assessors was conducted following the pilot starting at the end of 2014. The data collection and analysis are completed based on a total 121 responses for the 21 products in scope of the exercise.

Action: For discussion

Postponed from July 2016 Plenary. The CHMP noted the Review of experience with the Early Background Summary. More than 120 individual responses have been analysed covering 21 EBS produced over 1 year thereby allowing for meaningful feedback on the new tool. The vast majority of the respondents appreciated the summary for their assessment work. In addition, concrete proposals for improvement were made. The cascading of information and actual summaries to the assessment teams has been identified as an issue. The review of the experience with the pilot indicates that early background summaries should in principle be continued, however some adaptations may be necessary.

14.1.2. Update on data gathering

Scope: The project started in March 2014 to gather evidence needed by the European Commission in drafting future legislative proposal on fees. The goal was to assemble evidence about the time spent on procedures at EMA and NCA's. An update will be given on the progress.

Action: For information

The CHMP noted the update.

14.1.3. Joint CHMP-PDCO Strategic Review & Learning Meeting to be held in Brussels, 19-21 October 2016 under the Slovakian Presidency of the Council of the European Union

Scope: Agenda topics of the upcoming Strategic Review and Learning meeting

Action: For discussion

The CHMP discussed the possible agenda topics for meeting. It was agreed to finalise the agenda during the September CHMP.

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 **30-02 September 2016**

Action: For information

The CHMP noted the Summary of recommendations.

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

Action: For adoption

The CHMP adopted the List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for September 2016.

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 08-09 September 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 19-20 September 2016

Action: For information

The CHMP noted the report.

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at September 2016 PDCO

Action: For information

The CHMP noted the information.

Report from the PDCO meeting held on 14-16 September 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 06-08 September 2016
Action: For information

The CHMP noted the report.

14.2.6. CMDh

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 12-14 September 2016

Action: For information

The CHMP noted the report.

Letter from the CMDh dated 5th July 2016 to the PGWP on applicability of Art. 31 referral outcome on codeine-containing medicinal products to medicinal products containing morphine derivatives

Action: For information

Postponed to October CHMP

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

14.3.1. Scientific Advice Working Party (SAWP)

Report from the SAWP meeting held on 30 August - 02 September 2016. Table of conclusions

Action: For information

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

The CHMP noted the report.

14.3.2. Name Review Group (NRG)

PRAC advice on potential name-related issue

Potential for name-related confusion identified post-authorisation with 2 CAPs and 1 NAP

Action: For discussion

The CHMP agreed to the PRAC advice.

14.3.3. Central Nervous System Working Party (CNSWP)

Scope: Election of a chair of the CNSWP

Action: For adoption

The CHMP re-elected Karl Broich as Chair to the CNSWP.

14.3.4. Biosimilar Medicinal Product Working Party (BMWP)

Scope: The election of a chair of the BMWP is postponed. It was agreed to first appoint a 10th member and then continue with the chair election procedure.

Action: For information

The CHMP noted the information.

Scope: Call for nomination of a 10th BMWP member in light of expiry of the mandate of Christian Schneider as chair in September 2016 and his intention to become an observer of BMWP.

Action: For information

Nominations for a BMWP member should be sent by 30 September 2016.

The CHMP noted the information.

Scope: Nomination of Christian Schneider as observer after expiry of his chairmanship

Action: For adoption

The CHMP nominated Christian Schneider as observer after expiry of his chairmanship

14.3.5. Vaccines Working Party (VWP)

Scope: Extension of deadline for call for nomination of new VWP chair person

Please send nominations **by 30 September 2016**. Candidates should submit a brief résumé in support of their candidature. Election of the chair is foreseen for the October CHMP plenary.

Action: For information

The CHMP noted the information.

VWP response to the PDCO letter and questions on the PIP

Scope: Responses to PDCO

Action: For information

The CHMP noted the information.

14.3.6. Infectious Diseases Working Party (IDWP)

Scope: Election of a chair of the IDWP

Action: For adoption

The CHMP elected Anders Lignell as Chair to the IDWP.

14.3.7. Oncology Working Party (ONCWP)

Scope: Election of a chair of the ONCWP.

Action: For adoption

The CHMP elected Pierre Demolis as Chair to the ONCWP.

14.3.8. Biostatistics Working Party (BSWP)

Scope: Extension of deadline for call for nomination of new BSWP chair.

Expertise sought: Candidates for the position should be professionally qualified senior assessors within the European regulatory network, with relevant expertise in the field of biostatistics. Experience in co-operation with EMA Committees, Working Parties and Working Groups would be of advantage.

Please send nominations by 31 October 2016. Candidates should submit a brief résumé in support of their candidature. Election of the chair is foreseen for the November CHMP plenary.

Action: For information

The CHMP noted the information.

14.3.9. Radiopharmaceutical Drafting Group (RadDG)

Scope: Election of a chair of the RadDG

Action: For adoption

The CHMP elected Anabel Cortés Blanco as Chair to the Rad DG.

14.3.10. Biologics Working Party (BWP)

CHMP: Sol Ruiz

Scope: BWP report: Viral safety of plasma-derived and urine-derived medicinal products with respect to Zika virus

Action: For adoption

The CHMP adopted the report. The CHMP noted that there is no increased risk of contamination with the Zika virus for patients who take plasma-derived or urine-derived medicines. The report will be published on EMA website.

14.3.11. Quality working party (QWP)

Chair: Jean-Louis Robert

Scope: Q/A on deletion of a non-significant specification parameter

Action: For adoption

The CHMP adopted the Q/A on deletion of a non-significant specification parameter.

14.3.12. Safety Working Party (SWP)

Chair: Jan Willem van der Laan

Scope: Nomination of new member Jasenka Mršić Pelčić to replace Blaženka Jurišić (HR)

Action: For adoption

The CHMP nominated new member Jasenka Mršić Pelčić to replace Blaženka Jurišić (HR).

14.3.13. Pharmacogenomic Workin Party (PGWP)

Scope: Nomination of Katarina Vučić (HR) as observer to PGWP

Action: For adoption

The CHMP nominated new observer Katarina Vučić (HR).

Scope: Nomination of 2 additional experts: Giuseppe Novelli and Ronald van Schaick for the development of the guideline on Good Pharmacogenomics Practice and guideline on companion diagnostics pending progress of the new IVD Regulation.

Action: For adoption

The CHMP appointed 2 additional experts for the development of guideline.

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

CHMP 2017 Work Plan: draft list of proposed topics

Action: For discussion

The CHMP noted the information.

14.8. Planning and reporting

14.8.1. New marketing authorisation applications for 2016 with and without appointed rapporteurs

Action: For information

The CHMP noted the new marketing authorisation applications for 2016 with and without appointed rapporteurs.

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'

Scope: Update. The concept paper was adopted at the July 2016 CHMP Plenary for 2 months public consultation.

Action: For information

The CHMP noted the update. The revision will be finalised.

15.1.2. EMA - internal organisational adjustments

Scope: Update on the internal organisational adjustments

Action: For information

The CHMP noted the changes in EMA organisation.

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 12-15 September 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	
Ines Baotic	Member	Croatia	No restrictions applicable to this meeting	
Katarina Vučić	Alternate	Croatia	No interests declared	
Panayiotis Triantafyllis	Member	Cyprus	No interests declared	
Ondřej Slanař	Member	Czech Republic	No interests declared	
Radka Montoniová	Alternate	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 (Vice-Chair)	France	No interests declared	
Joseph Emmerich	Alternate	France	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Member	Germany	No interests declared	
Martina Weise	Alternate	Germany	No restrictions applicable to this meeting	
Dimitrios Kouvelas	Member	Greece	No interests declared	
George Aislaitner	Alternate	Greece	No interests declared	
Agnes Gyurasics	Member	Hungary	No interests declared	
Kolbeinn Gudmundsson	Member	Iceland	No interests declared	
Hrefna Gudmundsdottir	Alternate	Iceland	No interests declared	
David Lyons	Member	Ireland	No restrictions applicable to this meeting	
Daniela Melchiorri	Member	Italy	No interests declared	
Luca Pani	Alternate	Italy	No interests declared	
Juris Pokrotnieks	Member	Latvia	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	
Carola de Beaufort	Alternate	Luxembourg	No restrictions applicable to this meeting	
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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	
Bruno Sepodes	Member	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Nela Vilceanu	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Jana Schweigertova	Alternate	Slovakia	No restrictions applicable to this meeting	
Stanislav Primožič	Member	Slovenia	No interests declared	
Nevenka Tršinar 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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			meeting	
Koenraad Norga	Co-opted member	Belgium	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Jean-Louis Robert	Co-opted member	Luxembourg	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Nikola Moravcova	Expert - in person*	Slovakia	No interests declared	
Ana Alonso Gutierrez	Expert - in person*	Spain	No interests declared	
Jorge Camarero Jiménez	Expert - in person*	Spain	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert - in person*	Germany	No interests declared	
Kristina Bech Jensen	Expert - in person*	Denmark	No interests declared	
Darius Matusevicius	Expert - in person*	Sweden	No restrictions applicable to this meeting	
Kvetoslava Krizkova	Expert - in person*	Czech Republic	No restrictions applicable to this meeting	
Eleonora Wijnans	Expert - in person*	Netherlands	No interests declared	
Carla Herberts	Expert - via telephone*	Netherlands	No interests declared	
Babs Fabriek	Expert - via telephone*	Netherlands	No restrictions applicable to this meeting	
Patrick Vrijlandt	Expert - in	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
	person*			
Jonas Bergh	Expert - in person*	Sweden	No restrictions applicable to this meeting	
Christophe Focke	Expert - in person*	Belgium	No interests declared	
Tom Lams	Adobe presenter	Belgium	No interests declared	
Nele Berthels	Adobe presenter	Belgium	No interests declared	
Karin Janssen van Doorn	Adobe presenter	Belgium	No interests declared	
Heinz Ludwig	Expert - in person*	Austria	No restrictions applicable to this meeting	
Mair Powell	Expert - via telephone*	United Kingdom	No interests declared	
Karri Penttila	Expert - via telephone*	Finland	No interests declared	
Vesa Kiviniemi	Adobe presenter	Finland	No interests declared	
Laetitia Croux Belgodere	Expert - in person*	France	No restrictions applicable to this meeting	
Amel Camelia Bencherif	Expert - in person*	France	No restrictions applicable to this meeting	
Sophie Barbou des Courieres	Expert - via telephone*	France	No interests declared	
Eva Maria Nadal Elduayen	Adobe presenter	Spain	No interests declared	
Anabel Cortés Blanco	Adobe presenter	Spain	No interests declared	
Janet Schriever	Adobe presenter	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sylvia Kuehn	Adobe presenter	Germany	No restrictions applicable to this meeting	
Regine Magdalene Lehnert	Adobe presenter	Germany	No interests declared	
Bruno De Schuiteneer	Adobe presenter	Belgium	No interests declared	
Barbara Spruce	Expert - via telephone*	United Kingdom	No restrictions applicable to this meeting	
Odoardo Maria Olimpieri	Expert - via telephone*	Italy	No restrictions applicable to this meeting	
Elspeth Gray	Expert - in person*	United Kingdom	No interests declared	
Beatriz Flores	Expert - in person*	United Kingdom	No interests declared	
Cecilia Chisholm	Expert - via telephone*	United Kingdom	No interests declared	
Marie-Christine Bielsky	Expert - via telephone*	United Kingdom	No restrictions applicable to this meeting	
Benoy Daniel	Expert - via telephone*	United Kingdom	No interests declared	
Jan Bogaerts	Expert - via telephone*	Belgium	No restrictions applicable to this meeting	
Susanne Steinecker	Expert - via telephone*	Germany	No interests declared	
Elina Rönnemaa	Expert - via telephone*	Sweden	No interests declared	
Maria Di Marzo	Expert - via telephone*	Italy	No interests declared	
Ricardo Nescatelli	Expert - via telephone*	Italy	No interests declared	

* 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)*

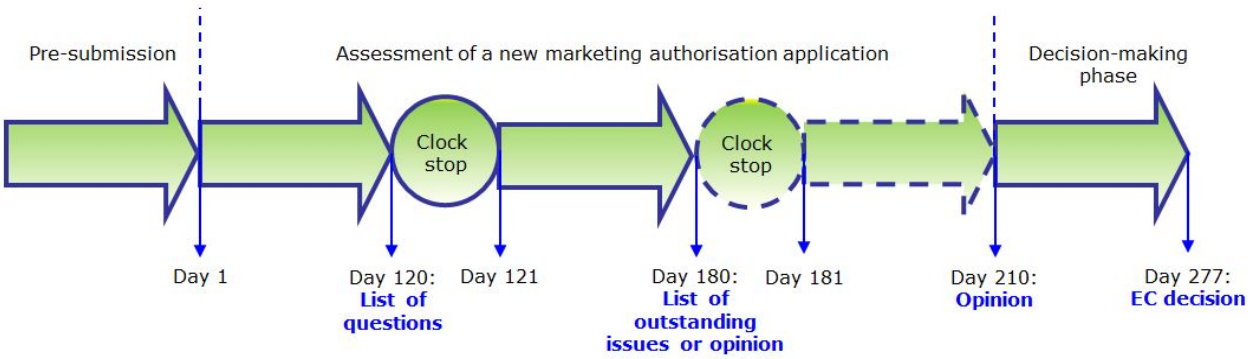
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

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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/