4 April 2016
EMA/CHMP/244718/2016
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 22-25 February 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) February 2016 CHMP minutes for the pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 22-25 February 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.

1.2. Adoption of agenda

CHMP agenda for 22-25 February 2016.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 25-28 January 2016.

The CHMP adopted the minutes.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Descovy - emtricitabine / tenofovir alafenamide - EMEA/H/C/004094

Gilead Sciences International Ltd; treatment of HIV

Scope: Oral explanation and opinion

Report from SAG HIV/viral diseases held on 15 February 2016.

Action: Oral explanation to be held on Tuesday 23 February 11:00

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

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 24.09.2015.

The CHMP agreed that an oral explanation was not needed at this time.

See also 3.1.6 Initial applications; Opinions

2.1.2. - infliximab - EMEA/H/C/004020

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

Scope: Oral explanation

Action: Oral explanation to be held on 24 February 2016 at 9.00.

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 23.07.2015.

An oral explanation was held on 24 February 2016.

See also 3.2.13 Initial applications; List of Outstanding Issues

2.1.3. - migalastat - Orphan - EMEA/H/C/004059

Amicus Therapeutics UK Ltd; treatment of patients with Fabry disease

Scope: Oral Explanation

Action: Oral explanation to be held on Tuesday 23 February 2016 at 14.15.

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 22.10.2015.

Oral explanation was held on Tuesday 23 February 2016 at 14.15.

See also 3.2.12. Initial applications; Day 180 list of outstanding issues

2.1.4. - opicapone - EMEA/H/C/002790

Parkinson's disease and motor fluctuations

Scope: Oral explanation / Opinion

Action: Possible Oral explanation to be held on Tuesday 23 February 2016 at 9.00.

List of Outstanding Issues adopted on 19.11.2015, 24.09.2015. List of Questions adopted on 23.04.2015.

An oral explanation was held on Tuesday 23 February 2016 at 9.00.

See also 3.2.14 Initial applications; Day 180 list of outstanding issues

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Alprolix - eftrenonacog alfa - Orphan - EMEA/H/C/004142

Biogen Idec Ltd; treatment and prophylaxis of bleeding in patients with haemophilia B

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 28.01.2016. List of Questions adopted on 22.10.2015.

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 eftrenonacog alfa is a new active substance, as claimed by the applicant.

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

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

The summary of opinion was circulated for information.

The Committee adopted the BWP report.

3.1.2. Idelvion - albutrepenonacog alfa - Orphan - EMEA/H/C/003955

CSL Behring GmbH; treatment and prophylaxis of bleeding in patients with haemophilia B

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 19.11.2015. List of Questions adopted on 23.07.2015.

The members discussed a proposed wording on prophylaxis treatment in section 4.2 of the SmPC and agreed on the final wording.

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 albutrepenonacog alfa is a new active substance, as claimed by the applicant.

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

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

The summary of opinion was circulated for information.

The CHMP adopted the BWP report.

3.1.3. Lonsurf - trifluridine / tipiracil - EMEA/H/C/003897

Les Laboratoires Servier; treatment of colorectal cancer

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 23.07.2015.

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 tipiracil is a new active substance, as claimed by the applicant.

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

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

The CHMP noted the letter of recommendation dated 22.02.2016.

The summary of opinion was circulated for information.

3.1.4. Palonosetron Hospira - palonosetron - EMEA/H/C/004069

Hospira UK Limited; prevention of nausea and vomiting associated with cancer chemotherapy

Scope: Opinion

Action: For adoption

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

List of Questions adopted on 24.09.2015.

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

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

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

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

The CHMP noted the letter of recommendation dated 25.02.2016.

The summary of opinion was circulated for information.

3.1.5. Taltz - ixekizumab - EMEA/H/C/003943

Eli Lilly Nederland B.V.; treatment of moderate to severe plaque psoriasis

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 24.09.2015.

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 ixekizumab 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 BWP report.

3.1.6. Descovy - emtricitabine / tenofovir alafenamide - EMEA/H/C/004094

Gilead Sciences International Ltd; treatment of HIV

Scope: Oral explanation and opinion

Report from SAG HIV/viral diseases held on 15 February 2016.

Action: Oral explanation to be held on Tuesday 23 February 11:00

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

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 24.09.2015.

Oral explanation to be held on Tuesday 23 February 11:00 was cancelled.

The CHMP noted the report from the SAG HIV/viral diseases meeting held on 15 February 2016. The SAG report concluded that there is no need for any specific post-authorisation investigations related to HIV replication in the CNS.

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 tenofovir alafenamide is not a new active substance.

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 recommendations dated 23.02.2016.

The summary of opinion was circulated for information.

3.2. Initial applications; Day 180 list of outstanding issues

3.2.1. - amikacin - Orphan - EMEA/H/C/003936

Insmed Limited; treatment of Mycobacterium avium Complex (MAC) lung disease in adult patients who have persistent positive sputum cultures despite the use of medically appropriate first-line therapy

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.06.2015.

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 by the applicant for an extension to the clock stop to respond to the list of outstanding issues with a specific timetable.

3.2.2. - bortezomib - EMEA/H/C/004076

treatment of multiple myeloma

Scope: Revised day 180 list of outstanding issue as adopted by written procedure on 4 February 2016

Action: For information

List of Outstanding Issues adopted on 28.01.2016. List of Questions adopted on 23.07.2015.

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

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

3.2.3. - lutetium (177 lu) chloride - EMEA/H/C/003999

radiolabelling of carrier molecules, which have been specifically developed for radiolabelling with this radionuclide

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 2nd list of outstanding issues with a specific timetable.

3.2.4. - pancreas powder - EMEA/H/C/002070

treatment in exocrine pancreatic insufficiency

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.06.2015.

BWP Report

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. - irinotecan - Orphan - EMEA/H/C/004125

Baxter Innovations GmbH; treatment of pancreatic cancer

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.

3.2.6. - ixazomib - Orphan - EMEA/H/C/003844

Accelerated review

Takeda Pharma A/S; multiple myeloma

Scope: Day 150 list of outstanding issues

Action: For adoption

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 list of outstanding issues with a specific timetable.

3.2.7. - palonosetron - EMEA/H/C/004129

prevention of nausea and vomiting associated with cancer chemotherapy

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.

3.2.8. - saxagliptin / dapagliflozin - EMEA/H/C/004057

treatment of type 2 diabetes

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.

3.2.9. - autologous cd34+ enriched cell fraction that contains cd34+ cells transduced with retroviral vector that encodes for the human ada cdna sequence - Orphan - ATMP - EMEA/H/C/003854

GlaxoSmithKline Trading Services; severe combined immunodeficiency

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 as well as the discussion at the CAT February Plenary.

The CHMP agreed to the list of outstanding issues with a specific timetable, as adopted by the CAT.

The CHMP adopted the BWP report.

3.2.10. - ceftazidime / avibactam - EMEA/H/C/004027

Complicated intra-abdominal infections (cIAI), Complicated urinary tract infections (cUTI), including pyelonephritis, Nosocomial pneumonia, including ventilator-associated

pneumonia, Infections due to aerobic Gram-negative organisms in patients with limited treatment options

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.

3.2.11. - grazoprevir / elbasvir - EMEA/H/C/004126

treatment of chronic hepatitis C (CHC) in adults

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 19.11.2015.

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

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

3.2.12. - migalastat - Orphan - EMEA/H/C/004059

Amicus Therapeutics UK Ltd; treatment of patients with Fabry disease

Scope: Day 195 list of outstanding issue

Action: Oral explanation to be held on Tuesday 23 February 2016 at 14.15.

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 22.10.2015.

An oral explanation was held on Tuesday 23 February 2016 at 14.15.

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

3.2.13. - infliximab - EMEA/H/C/004020

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

Scope: Oral explanation

Action: Oral explanation to be held on 24 February 2016 at 9.00.

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 23.07.2015.

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

An oral explanation was held on 24 February 2016.

The oral explanation focused on the immunogenicity in relation to biosimilarity.

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

The CHMP adopted the BWP report.

3.2.14. - opicapone - EMEA/H/C/002790

Parkinson's disease and motor fluctuations

Scope: Oral explanation / Opinion

Action: Possible Oral explanation to be held on Tuesday 23 February 2016 at 9.00.

List of Outstanding Issues adopted on 19.11.2015, 24.09.2015. List of Questions adopted on 23.04.2015.

An oral explanation was held on Tuesday 23 February 2016 at 9.00.

The CHMP adopted a 3rd list of outstanding issues with a specific timetable.

3.3. Initial applications; Day 120 list of questions

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

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

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application,

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

3.3.2. - alendronic acid / colecalciferol - EMEA/H/C/004172

treatment of postmenopausal osteoporosis

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. - begelomab - Orphan - EMEA/H/C/004144

ADIENNE S.r.l. S.U.; Treatment of graft-versus-host disease

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.4. - bortezomib - EMEA/H/C/004207

treatment of multiple myeloma

Scope: Revised day 120 list of questions as adopted by written procedure on 4 February 2016.

Action: For information

The Committee discussed the issues identified in this application.

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

3.3.5. - chenodeoxycholic acid - Orphan - EMEA/H/C/004061

Accelerated review

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

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. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004137

treatment of HIV-1 infection

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application. The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.7. - ertapenem - EMEA/H/C/004080

treatment of bacterial infections and prophylaxis of surgical site infection following elective colorectal surgery

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.

3.3.8. - empagliflozin / linagliptin - EMEA/H/C/003833

treatment of type 2 diabetes mellitus

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.

3.3.9. - follitropin delta - EMEA/H/C/003994

indicated for controlled ovarian stimulation

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.

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

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

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. - rituximab - EMEA/H/C/004112

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.

3.3.12. - chlorhexidine - Article 58 - EMEA/H/W/003799

Accelerated review; prophylaxis of omphalitis

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application. It was noted that the WHO 4th Model List of Essential Medicines for Children's now includes a recommendation for 7.1% chlorhexidine digluconate for use in umbilical care. 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. - palbociclib - EMEA/H/C/003853

treatment of breast cancer

Scope: Letter from the applicant dated 9 February 2016 requesting a extension of clock stop

Action: For information

List of Questions adopted on 17.12.2015.

The CHMP agreed to the request by the applicant for an extension of clock stop to respond to the list of questions adopted in December 2015.

3.4.2. - rociletinib - EMEA/H/C/004053

treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC).

Scope: Letter from the applicant dated 11 February 2016 requesting extension of clock stop

Action: For information

List of Questions adopted on 17.12.2015.

The CHMP agreed to the request by the applicant for extension of clock stop to respond to the list of questions adopted in December 2015.

3.4.3. - daclizumab - EMEA/H/C/003862

treatment of multiple sclerosis (RMS)

Scope: Letter from the applicant dated 15 February 2016 requesting a delay of the planned oral explanation.

Action: For information

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 23.07.2015.

The CHMP agreed to the request by the applicant to postpone the planned oral explanation.

The CHMP adopted the BWP report.

3.4.4. - sirolimus - Orphan - EMEA/H/C/003978

Santen Oy; treatment of chronic non-infectious uveitis

Scope: List of experts to Ad- hoc expert group meeting

Action: For adoption

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 25.06.2015.

The CHMP adopted a list of experts to an ad-hoc expert group.

3.4.5. Obeticholic Acid - obeticholic acid - Orphan - EMEA/H/C/004093

Intercept Italia s.r.l; treatment of primary biliary cirrhosis

Scope: Communication from the applicant dated 24 February 2016 requesting extension of clock stop.

Action: For adoption

List of Questions adopted on 22.10.2015.

The CHMP agreed to the request by the applicant for extension of the clock stop to respond to the list of questions adopted in October 2015.

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

3.5.1. Dropcys - mercaptamine - Orphan - EMEA/H/C/004038

Lucane Pharma; treatment of corneal cystine deposits

Scope: Grounds for re-examination and procedural timetable

Action: For information

The CHMP noted the grounds for re-examination together with the specific timetable.

3.6. Initial applications in the decision-making phase

3.6.1. Uptravi - selexipag - EMEA/H/C/003774

treatment of pulmonary arterial hypertension (PAH; WHO Group I)

Scope: Letter from the European Commission

Action: For discussion

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

Opinion adopted on 28 January 2016.

The CHMP noted the letter from the European Commission on the opinion adopted in January 2016. Action plan was agreed.

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

No items

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

No items

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

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

Amgen Europe B.V.

Rapporteur: Pieter de Graeff, PRAC Rapporteur: Kimmo Jaakkola

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

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.

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

4.4.1. Zebinix - eslicarbazepine acetate - EMEA/H/C/000988/X/0050/G

Bial - Portela & Cª, S.A.

Rapporteur: Martina Weise, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Martin Huber

Scope: Letter from the MAH dated 6 January 2016 requesting extension of clock stop to respond to Day 120 List of Questions.

"Grouping of a line extension application to add a new pharmaceutical form (50 mg/ml oral suspension) and a type II variation (C.I.6.a New indication (paediatric indication)) to add treatment of children aged 2 years and older. Consequently, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC have been updated and the Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to make minor editorial changes in the SmPC and Package Leaflet.
The application included a revised RMP version 14.0.",

Action: For information

List of Questions adopted on 19.11.2015.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to Day 120 List of Questions adopted in November 2015.

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 24.09.2015.

The Committee discussed the issues identified in this application.

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

5.1.2. Afinitor - everolimus - EMEA/H/C/001038/II/0048

Novartis Europharm Ltd

Rapporteur: Harald Enzmann, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber

Scope: "Extension of Indication to include a new indication for the treatment of unresectable or metastatic, well-differentiated non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease for Afinitor.
As a consequence, sections 4.1, 4.4, 4.8 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 9.1."

Action: For adoption

Request for Supplementary Information adopted on 19.11.2015.

The Committee discussed the issues identified in this application. The main issues discussed concerned the efficacy data in relation to the tumour location and subgroup analysis.

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

5.1.3. Arzerra - ofatumumab - Orphan - EMEA/H/C/001131/II/0041

Novartis Europharm Ltd

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

Scope: "Extension of Indication to include maintenance therapy in Chronic Lymphocytic Leukemia (CLL).
As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
In accordance with the new QRD template version 9.1, the MAH is also taking the opportunity of this procedure to update the Annex II and combine the 2 SmPCs for the 100mg an 1,000mg vials."

Action: For adoption

Request for Supplementary Information adopted on 22.10.2015.

The Committee discussed the issues identified in this application which related to the clinical data in the proposed maintenance therapy indication in particular the primary and secondary endpoints. The Committee also discussed the safety data in the maintenance setting.

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

The CHMP agreed to consult the SAG Oncology and adopted a list of questions to this group.

5.1.4. Ferriprox - deferiprone - EMEA/H/C/000236/II/0103

Apotex Europe BV

Rapporteur: Pierre Demolis, Co-Rapporteur: Concepcion Prieto Yerro

Scope: "Extension of Indication to include a new indication for Ferriprox in combination with another chelator.
As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the MAH took the opportunity of this procedure to update the Product Information in compliance with the QRD template version 9.1 and combine the SmPC for the 500mg and 1000mg tablets. The contact details of France and Portugal have been

updated in the PL."

Action: For adoption

Request for Supplementary Information adopted on 17.12.2015.

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

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

5.1.5. Giotrif - afatinib - EMEA/H/C/002280/II/0012

Boehringer Ingelheim International GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of Indication to include patients with locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy for Giotrif. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet and RMP are updated in accordance. Furthermore, minor editorial changes have been introduced throughout the PI.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 22.10.2015.

The members noted that the applicant withdrew the request for 1 year of market protection for a new indication.

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

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

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

The summary of opinion was circulated for information.

5.1.6. Humira - adalimumab - EMEA/H/C/000481/II/0149

AbbVie Ltd.

Rapporteur: Kristina Dunder

Scope: "Extension of Indication to include 1st line treatment of moderate to severe chronic plaque psoriasis in adult patients. As a consequence SmPC section 4.1 has been updated and the Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement minor changes in sections 4.2 and 5.1 of the SmPC."

Action: For adoption

The Committee discussed the wording of indication and place in therapy.

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

Boehringer Ingelheim International GmbH

Rapporteur: Pieter de Graeff, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Miguel-Angel Macia

Scope: "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

The Committee discussed the issues identified in this application. The members discussed the clinical data provided to support the cardiovascular prevention indication. The Committee debated on the internal and external validity of the results, possible mechanism of action and the clinical relevance to different patient groups.

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

5.1.8. Opdivo - nivolumab - EMEA/H/C/003985/II/0002

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include treatment as monotherapy of locally advanced or metastatic non-squamous NSCLC after prior chemotherapy in adults based on study CA209057. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC have been updated and the Package Leaflet has been updated accordingly. Further, SmPC section 4.8 has been revised with updated combined clinical trial exposure numbers to reflect inclusion of studies in non-squamous NSCLC and in nivolumab in combination with ipilimumab in advanced melanoma. In addition, the MAH took the opportunity to align

the annexes with the latest QRD template version 9.1 and to implement minor editorial changes. A revised RMP version 3.0 was provided as part of the application."

Action: For adoption

Request for Supplementary Information adopted on 28.01.2016, 22.10.2015.

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.

5.1.9. Opdivo - nivolumab - EMEA/H/C/003985/II/0008

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to add treatment as monotherapy of patients with advanced renal cell carcinoma (RCC) after prior therapy in adults, based on Study CA209025; a phase 3 study of nivolumab vs. everolimus in subjects with advanced or metastatic clear-cell RCC who have received prior anti-angiogenic therapy, and the CA209010 addendum study report; phase 2 dose-ranging study of nivolumab in subjects with progressive advanced/metastatic clear-cell RCC who have received prior anti-angiogenic therapy. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 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 editorial changes in the SmPC and Package Leaflet.
An updated RMP version 4.0 was provided as part of the application. Further, the MAH requested one additional year of market protection for a new indication."

Action: For adoption

Request for Supplementary Information 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 by consensus together with the CHMP Assessment Report and translation timetable.

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

The CHMP noted the letter of recommendation dated 22.02.2016

The summary of opinion was circulated for information.

5.1.10. Orencia - abatacept - EMEA/H/C/000701/II/0097

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Kirsti Villikka

Scope: "Extension of Indication to extend the use of Orencia in combination with methotrexate (MTX) in the treatment of adults with rheumatoid arthritis (RA) who have highly active disease with poor prognostic factors (such as ACPA+ and/or RF+, joint erosion) not previously treated with MTX. As a consequence, sections 4.1 and 5.1 of the SmPC are updated based on results from AVERT study (IM101226). The Package Leaflet is updated accordingly. Moreover, the updated RMP version 20 has been submitted."

Action: For adoption

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

The Committee adopted Request for Supplementary Information with a specific timetable.

5.1.11. Ruconest - conestat alfa - EMEA/H/C/001223/II/0031

Pharming Group N.V

Rapporteur: Greg Markey

Scope: "Extension of Indication to include adolescents in the treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency. As a consequence sections 4.1, 4.2, and 5.1 of the SmPC have been updated. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information 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 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.

Furthermore the CHMP adopted the similarity assessment report of Ruconest.

5.1.12. TachoSil - human thrombin / human fibrinogen - EMEA/H/C/000505/II/0057

Takeda Austria GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Greg Markey, PRAC Rapporteur:

Brigitte Keller-Stanislawski

Scope: “Extension of indication for the use of Tachosil as suture line sealing in dura mater closure. As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC and the Package leaflet are updated. The MAH also took the opportunity to make minor editorial corrections to the product information.”

Action: For adoption

Request for Supplementary Information adopted on 24.09.2015, 21.05.2015, 22.01.2015.

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.

5.1.13. Zydelig - idelalisib - EMEA/H/C/003843/II/0011

Gilead Sciences International Ltd

Rapporteur: Kristina Dunder, PRAC Rapporteur: Rafe Suvarna

Scope: “Extension of Indication to include new indication for Zydelig to include the combination of idelalisib with ofatumumab. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives for United Kingdom and Ireland in the Package Leaflet.”

Action: For adoption

Request for Supplementary Information adopted on 17.12.2015, 22.10.2015.

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.

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

5.2.1. Opdivo - nivolumab - EMEA/H/C/003985/II/0003

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Revised timetable

"Extension of Indication to include treatment in combination with ipilimumab of advanced (unresectable or metastatic) melanoma in adults based on interim data from study CA209067 and the final CSR of study CA209069. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated and the Package Leaflet has been revised accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC, Annex II and Package Leaflet. An updated RMP version 3.0 was provided as part of the application as well as a paediatric non-clinical biomarker study provided to fulfil paediatric requirements."

Action: For information

Request for Supplementary Information adopted on 28.01.2016, 22.10.2015.

The CHMP adopted the revised timetable.

5.2.2. Humira - adalimumab - EMEA/H/C/000481/II/0146

AbbVie Ltd.

Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Ulla Wändel Liminga

Scope: List of experts to Ad- hoc expert group meeting

"Extension of Indication to include treatment of non-infectious intermediate, posterior and panuveitis in adult patients for Humira.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 17.12.2015.

The CHMP adopted a list of experts to an ad-hoc expert group.

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. - H0004308

Ancillary human blood derivative incorporated in a medical device: human fibrinogen and human thrombin

Scope: Letter from the company dated 14 January 2016 requesting an accelerated assessment

Action: For adoption

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.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Humalog - Insulin Lispro - EMEA/H/C/000088

Eli Lilly Nederland B.V., treatment of diabetes mellitus

Rapporteur: Robert James Hemmings, Co-Rapporteur: Kristina Dunder

Scope: Humalog Basal (EU/1/96/007/010 and 037) - Cessation for commercial reasons in Lithuania, Italy and Spain

Action: For discussion

The Committee noted the withdrawal of the product in Lithuania, Italy and Spain.

9.1.2. Rapamune - sirolimus - EMEA/H/C/000273/II/0160

Pfizer Limited,

Rapporteur: Kristina Dunder

Scope: Request for Supplementary information / Opinion

Submission of the final Clinical Study Report of study B1741007 ("Planned Transition to Sirolimus-based Therapy Versus Continued Tacrolimus (TAC)-based Therapy in Renal Allograft Recipients"). No changes to the PI are proposed.

Action: For adoption

Request for Supplementary Information adopted on 10.12.2015.

The Committee discussed the issues identified in this application. The members discussed the wording of the indication and other sections of the SmPC in light of the results of the final clinical study report.

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

9.1.3. Tysabri - Natalizumab - EMEA/H/C/000603/R/0091

Biogen Idec Ltd

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Brigitte Keller-Stanislawski,

Scope: Renewal and changes to sections 4.4 and 4.8 of the Summary of Product Characteristics

Action: For adoption

Request for Supplementary Information adopted on 17.12.2015.

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

Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Tysabri in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

In addition, sections 4.4 and 4.8 of the Summary of Product Characteristics (SmPC) were updated to include new safety information on Granule Cell Neuronopathy (GCN), a condition which is also caused by John Cunningham Virus (JCV) and that has occurred in some patients who have been given Tysabri. Symptoms of JCV GCN are similar to symptoms of Progressive Multifocal Leukoencephalopathy (i.e. cerebellar syndrome). The Package leaflet is being updated accordingly.

10. Referral procedures

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

10.1.1. Tysabri - Natalizumab - EMEA/H/A-20/1416/C/000603/0083

Biogen Idec Ltd, treatment of multiple sclerosis

Rapporteur: Jan Mueller-Berghaus, Co-rapporteur: Daniela Melchiorri, PRAC Rapporteur: Brigitte Keller-Stanislawski;

Scope: Opinion

Review of the benefit-risk balance following notification by the European Commission of a referral under Article 20(8) of Regulation (EC) No 726/2004, based on pharmacovigilance data

Action: For adoption

Scientific Advisory Group meeting held on 06.11.2015. The CHMP noted the PRAC recommendation.

The CHMP adopted an opinion by consensus based on the PRAC recommendation.

The CHMP agreed to the DHPC and communication plan.

10.1.2. Sodium-glucose co-transporter-2 (SGLT2) inhibitors: canagliflozin – INVOKANA; canagliflozin, metformin – VOKANAMET; dapagliflozin – FORXIGA; dapagliflozin, metformin – XIGDUO; empagliflozin - JARDIANCE; empagliflozin, metformin – SYNJARDY - EMEA/H/A-20/1419

Applicant: AstraZeneca AB (Forxiga, Xigduo), Boehringer Ingelheim International GmbH (Jardiance, Synjardy), Janssen-Cilag International N.V. (Invokana, Vokanamet)

Rapporteurs for the Article 20 referral: PRAC Overall Rapporteur: Menno van der Elst, PRAC Co-rapporteurs: Valerie Strassmann and Qun-Ying Yue;

Individual products Rapporteurs: Kristina Dunder, Co-Rapporteur: Martina Weise (Forxiga), Rapporteur: Kristina Dunder, Co-Rapporteur: Agnes Gyurasics (Xigduo), Rapporteur: Pieter de Graeff, Co-Rapporteur: Bart Van der Schueren (Jardiance), Rapporteur: Pieter de Graeff, Co-Rapporteur: Daniela Melchiorri (Synjardy), Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder (Invokana), Rapporteur: Martina Weise, Co-Rapporteur: Karsten Bruins Slot (Vokanamet).

Scope: Opinion

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

Action: For adoption

The CHMP noted the PRAC recommendation.

The CHMP adopted an opinion by consensus based on the PRAC recommendation.

The CHMP agreed to the DHPC and communication plan.

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

No items

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

No items

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

10.4.1. Otipax 1% (11 mg/ml) ear drops, solution – lidocaine hydrochloride - EMEA/H/A-29/1426

Biocodex Benelux SA/NV

Rapporteur: Daniel Brasseur, Co-Rapporteur: Martina Weise,

RMS: BE, CMS: AT, CY, DE, DK, EL, ES, FI, IT, NO, PL, PT, SE, Mutual recognition procedure number: BE/H/0213/001/MR

Scope: List of Outstanding Issues / Opinion

Disagreement regarding efficacy and the evidence of well-established use.

Action: For adoption

List of Questions adopted on 22 October 2015.

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

Submission of responses: 25.03.2016

Re-start of the procedure: 31.03.2016

Rapporteur/co-rapporteur report(s) circulated to CHMP: 13.04.2016

Comments: 18.04.2016

Updated Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:21.04.2016

CHMP opinion: April 2016 CHMP

10.4.2. Diclofenac 50 mg Tablets - Diclofenac epolamine - EMEA/H/A-29/1434

Altergon Italia srl

Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: Joseph Emmerich,

RMS: UK, CMS: CZ, FR, SK

Decentralised Procedure number: UK/H/5906/001/DC

Scope: Appointment of (Co)Rapporteur, List of Questions and timetable

Disagreements regarding the demonstration of bioequivalence in the fed state

Action: For adoption

Letter from HMRA in the UK dated 5 February 2016 notifying of official referral under Article 29 (4) and its grounds.

The CHMP noted the letter from MHRA notifying of official referral under Article 29 (4) and its grounds.

The Committee appointed Nithyanandan Nagercoil as Rapporteur (interest level 3) and Joseph Emmerich as Co-Rapporteur (interest level 1).

The CHMP adopted a list of questions with a specific timetable.

Notification: 05.02.2016

Start of procedure (CHMP): 25.02.2016

List of Questions: 25.02.2016

Submission of responses: 24.03.2016

Re-start of the procedure: 31.03.2016

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 13.04.2016

Comments: 18.04.2016

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 21.04.2016

CHMP list of outstanding issues or CHMP opinion: April 2016 CHMP

Post-meeting note: After the Plenary a revised timetable was adopted by written procedure on 3 March 2016:

Submission: 25.04.2016

Clock restart: 28.04.2016

(Co)-rapps AR: 11.05.2016

CHMP comments: 16.05.2016

Updated (Co)-rapps AR: 19.05.2016

CHMP discussion: May 2016 CHMP

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

10.5.1. Cymevene IV and associated names - ganciclovir - EMEA/H/A-30/1406

MAH: F. Hoffmann-La Roche
Rapporteur: Rugile Pilviniene, Co-Rapporteur: Alar Irs,

Scope: Opinion

Harmonisation exercise for Cymevene IV and associated names. The review was triggered by the European Commission in September 2014, due to the need of harmonisation of the Summary of Product Characteristics across Member State.

Action: For adoption

The Committee confirmed that all issues previously identified in this referral had been resolved.

The CHMP adopted an opinion by consensus recommending changes to the SmPCs, labelling and package leaflets. The assessment report was adopted.

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

The CHMP noted the EMA question-and-answer document.

10.5.2. Etopophos and associated names– etoposide - EMEA/H/A-30/1417

MAH: Bristol-Myers Squibb group of companies and associated companies

Rapporteur: Greg Markey, Co-Rapporteur: Pieter de Graeff,

Scope: List of Outstanding Issues

Harmonisation exercise for Etopophos and associated names

Action: For adoption

List of Questions adopted on 22 October 2015.

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

List of outstanding issues: February 2016 CHMP

Submission of responses: 14.04.2016

Re-start of the procedure: 28.04.2016

Joint Rapporteurs assessment report circulated to CHMP: 11.05.2016

Comments: 16.05.2016

Updated Joint Rapporteurs assessment report circulated to CHMP: 19.05.2016

LoOI/ CHMP opinion: May 2016 CHMP

10.5.3. Vepesid and associated names - etoposide - EMEA/H/A-30/1425

MAH: Bristol-Myers Squibb group of companies and associated companies

Rapporteur: Greg Markey, Co-Rapporteur: Pieter de Graeff

Scope: List of Outstanding Issues

Harmonisation exercise for Vepesid and associated names

Letter from the European Commission dated 14 October 2015 notifying of an official referral under Article 30.

Action: For adoption

List of Questions adopted on 22 October 2015.

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

List of outstanding issues: February 2016 CHMP

Submission of responses: 14.04.2016

Re-start of the procedure: 28.04.2016

Joint Rapporteurs assessment report circulated to CHMP: 11.05.2016

Comments: 16.05.2016

Updated Joint Rapporteurs assessment report circulated to CHMP: 19.05.2016

LoOI/ CHMP opinion: May 2016 CHMP

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

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

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

Scope: Appointment of (Co)Rapporteur, List of Questions and timetable

Action: For adoption

Letter from the MHRA in the UK dated 18 February 2016 notifying of official referral under Article 31 and its grounds

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

The CHMP adopted a list of questions with a specific timetable.

Start of the procedure (CHMP): February, 2016 CHMP

List of questions: 25.02.2016

Submission of responses: 14.04.2016

Re-start of the procedure: 28.04.2016

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 11.05.2016

Comments: 16.05.2016

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 19.05.2016

CHMP list of outstanding issues/opinion: May 2016 CHMP

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

Rapporteur: Kristina Dunder, Co-Rapporteur: Pieter de GraeffScope: Letter from Novartis Pharma AG and Sanofi-Aventis Recherche & Development for an extension of timeframe to submit responses to the List of Questions adopted 28 January 2016.

Article 31 triggered by the MEB in the Netherlands

The Committee noted the letter from Novartis Pharma AG and Sanofi-Aventis Recherche & Development and agreed to the request.

The CHMP adopted a specific timetable.

Submission of responses: 12.05.2016

Re-start of the procedure: 26.05.2016

(Co-)Rapporteur assessment report(s) circulated to CHMP: 08.06.2016

Comments: 13.06.2016

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 16 April 2016

CHMP list of outstanding issues/ CHMP opinion: June 2016 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)

10.11.1. Levonelle 1500mcg tablets and associated names – Levonorgestrel - EMEA/H/A-13/1427

MAH: Gedeon Richter Plc Group of companies

Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: Daniela Melchiorri RMS: UK, CMS: AT, BE, CZ, DE, EL, ES, FR, IE, IS, IT, LT, LU, NL, NO, PL, PT, SE, Mutual recognition procedure: UK/H/0803/001/II/022

Scope: Opinion

Action: For adoption

List of Questions adopted on 22 October 2015.

The Committee discussed the available data with regard to a possible interaction with efavirenz and other enzyme inducers and how to best advise the users.

The CHMP agreed to consult patients/consumers and healthcare professionals organisations in order to assess the delivery of information in practice.

The CHMP adopted a list of questions with a specific timetable.

List of outstanding issues: February 2016 CHMP

Submission of responses: 14.04.2016

Re-start of the procedure: 27.04.016

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 11.05.2016

Comments: 16.05.2016

Updated rapporteur/co-rapporteur joint assessment report circulated to CHMP: 19.05.2016

CHMP opinion: May 2016 CHMP

11. Pharmacovigilance issue

11.1. Early Notification System

February 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

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

Action: For adoption

The CHMP adopted the briefing 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

13.4.1. 3rd Teleconference of the International Pharmaceutical Regulators Forum (IPRF) Nano Working Group on 11 February 2016

Action: For information

Agenda

The CHMP noted the agenda.

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Benefit-risk assessment of the CHMP assessment report template

Scope: Revision of section 5, benefit-risk assessment template and guidance revision: second draft

Action: For discussion

The CHMP noted the discussion on the revision of the benefit-risk assessment section of the CHMP assessment report template. The revision of the template is proposed in order to clarify the current benefit-risk template structure; in a subsequent step, training material

(guidance, presentations) for assessors will be further developed. Further comments should be sent by 10 March 2016.

14.1.2. Draft Pilot report Parallel advice Regulators and HTA

Scope: EMA report and annexes on the Pilot of parallel regulatory-HTA scientific advice

Action: For discussion

The CHMP noted the report on the Pilot. The report will be published in full shortly on the EMA website including the responses to the public consultation on the draft Best Practice Guide and the updated guidance.

14.1.3. Proposal for a pre-marketing risk-based model for medicinal product testing – Pilot procedure for human CAPs

Scope: Interim report halfway through the pilot

Action: For discussion

The CHMP noted the report. The report looked at the risk-assessment templates received for the new centralised applications for human products, having a Day 0 between July and November 2015. There were a total of 31 new applications (for medicinal products for human use) during this period.

Scope: List of products to be tested in the sampling and testing programme 2017

Action: For adoption

The CHMP adopted the List of products.

14.1.4. Initial marketing authorisation - revised accelerated assessment procedural timetables

Action: For adoption

The CHMP has adopted the revision of the Accelerated Assessment guideline together with the revised accelerated assessment procedural timetables. The Guideline will come into effect on 1 June 2016. As the request for accelerated assessment is to be submitted 2-3 months prior to the submission of the marketing authorisation application (MAA), the new timetable for accelerated assessment described in section 6 of this guideline will apply for MAA evaluations starting in September 2016.

14.1.5. Risk Management Plan (RMP) revised assessment process in initial marketing authorisation(s) - performance indicators

Action: For discussion

The CHMP noted the information and feedback received. Next steps will be to collect simple quantitative metrics and survey on content/qualitative aspects, informed by the results of the first stage.

14.1.6. Enhanced early dialogue to foster development and facilitate accelerated assessment (PRIME)

Action: For adoption

The CHMP adopted the document, together with related templates and the summary outcome of the public consultation. PRIME (PRIority MEdicines) scheme will come into effect 7 March 2016.

With a view to improving early access tools and regulatory support to promising new medicines, the PRIME scheme introduces the possibility not only to identify products fulfilling the criteria for accelerated review earlier, but also to enhance the regulatory and scientific support for these products through advice at key milestones in development.

Eligibility to the PRIME scheme will depend on the availability of adequate non-clinical and exploratory clinical data to justify a potential major public health interest prior to the initiation of confirmatory clinical studies at proof of concept stage (i.e. where data in patients justify that clinical benefit can be expected). The scheme is expected to lead to better informed development plans, to improve the quality of marketing authorisation applications and to promote regulatory awareness thus allowing for a shortened timeframe for review. Ultimately, this will promote the possibility of earlier patient access to promising new medicines. The Committee noted the training on PRIME, that will be organised for CHMP in the future.

14.1.7. Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004

Scope: CHMP guideline on conditional marketing authorisation, Overview of public consultation comments received

Action: For adoption

The CHMP noted the positive opinion received from the European Commission and, having implemented the comments raised by the European Commission, adopted the guideline. The CHMP also noted the overview of comments received. The guideline will indicate coming into effect date as 1 June 2016. The guideline addresses the granting and renewal of conditional marketing authorisations, as well as the subsequent granting of marketing authorisations not subject to specific obligations following their completion.

14.1.8. Strategic Review & Learning Meeting

Scope: Reflection on OTC switch in the centralised procedure (follow-up item from Luxembourg presidency meeting)

Action: For discussion and appointment of sponsors

The CHMP noted the activities and appointed sponsors.

Scope: Information about the draft agenda topics of the upcoming Strategic Review and Learning meeting

Strategic Review and Learning meeting that will be held in Utrecht, 30 May-1 June 2016 under the Netherland's Presidency of the Council of the European Union. This meeting will be held, in part, jointly with the COMP.

Scope: Preliminary information on the Strategic Review and Learning meeting in the second half of 2016

The Strategic Review and Learning meeting will be held in Brussels, 19-21 October 2016 under the Slovakian Presidency of the Council of the European Union. This meeting will be held, in part, jointly with the PDCO.

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 **08-11 February 2016**

Action: For information

The CHMP noted the Summary of recommendations and advice.

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

Action: For adoption

The CHMP adopted the list.

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 18-19 February 2016
Action: For information

The CHMP noted the draft minutes.

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 1-4 February 2016

Action: For information

The CHMP noted the report.

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at February 2016 PDCO

Action: For information

Report from the PDCO meeting held on 24-26 February 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 16-18 February 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 25-27 February 2016

Action: For information

The CHMP noted the report.

Scope: Response to CMDh request to CHMP/ PKWP regarding exenatide

Action: For adoption

The CHMP adopted the follow-up request from CMDh to the response given in January 2016. It was agreed to develop product-specific guidance, which would go for public consultation.

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 8-11 February 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.

14.3.2. Invented Names Group (NRG)

Scope: Request for PRAC advice

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

Action: For discussion

The CHMP agreed to contact the concerned MAHs of the 2 CAPs requesting an analysis of the situation. The NAP should be contacted via the concerned NCAs.

14.3.3. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke,Scope: Nomination of core members to the Respiratory drafting group

Action: For adoption

New core members Concepcion Prieto Yerro from Spain, Erika Fredriksson from Sweden and observer Susanne Kaul from Germany were adopted.

Scope: Work Plan for 2016

Action: For adoption

The CHMP adopted the work plan.

14.3.4. Cardiovascular Working Party (CVSWP)

Scope: Reflection paper on assessment of cardiovascular safety profile of medicinal products for the treatment of cardiovascular and metabolic diseases (EMA/CHMP/50549/2015)

Action: For discussion

The CHMP adopted the reflection paper. The purpose of the reflection paper is to provide recommendations for the evaluation of the cardiovascular safety profile of new (non-generic, non-biosimilar) medicinal products that are intended for long-term treatment of

certain cardiovascular and metabolic diseases. This paper aims to clarify the requirements for these medicinal products at the time of assessment of the marketing authorisation application with respect to data needed for the evaluation of the cardiovascular safety profile.

14.3.5. Blood Products Working Party (BPWP)

Scope: Work Plan for 2016

Action: For adoption

The CHMP adopted the Work Plan.

14.3.6. Central Nervous System Working Party (CNSWP)

Scope: Overview of comments received on Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy (EMA/30262/2016)

Action: For information

The CHMP noted the Overview of comments.

Scope: Draft guideline on the clinical development of medicinal products for the treatment of Autism Spectrum Disorder (ASD)(EMA/CHMP/598052/2013)

Action: For adoption

The CHMP adopted the guideline for 6-months public consultation. The guideline is intended to provide guidance on the evaluation of new products in Autistic Spectrum Disorder (ASD); it should be read in conjunction with other EMA and ICH guidelines, which may apply to similar conditions and patient populations.

14.3.7. Biologics Working Party (BWP)

Chair: Sol Ruiz

Scope: Revision Guideline on Epidemiological Data on Blood Transmissible Infections and Overview stakeholder comments - (EMA/CHMP/548524/2008 Rev. 1)

Overview of comments (EMA/651460/2015)

Appendices (EMA/735037/2015)

Action: For adoption

The CHMP adopted the revision and noted the overview of comments and appendices. The objective of the revision is to provide additional guidance to Plasma Master File

(PMF) holders on several aspects: residual risk calculation, usefulness of control charts, approaches to identify trends in viral marker rates, epidemiological data requirements for approval of blood/plasma collection centres.

14.3.8. International Council on Harmonisation (ICH)

Scope: The ICH S1 Regulatory Notice Document updated to include minor changes to the workflow and the participation of Canada and Switzerland to the working group.

Action: For adoption

The CHMP adopted the ICH S1 document.

14.4. Cooperation within the EU regulatory network

14.4.1. Letter from the European Commission on a definition for 'principal molecular structural features'

Scope: Update the CHMP on progress

Letter from the European Commission, requesting that a definition for 'principal molecular structural features' as referred to in Art 3(3)c of Reg (EC) No 847/2000 on similar active substance is developed by end of March 2016

Action: For discussion

The CHMP noted the update. Drafting group working on this, involves BWP and QWP experts and 2 CAT members. The deadline was extended until end of March. Adoption is planned in March CHMP.

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Zika virus update

CHMP: Sol Ruiz

Action: For information

The CHMP was updated on the status of the Zika virus. EMA has established a task force of European experts with specialised knowledge in vaccines, infectious diseases and other relevant expertise to contribute to the global response to the threat of the Zika virus infection. This group will be available to give advice on any scientific and regulatory matters for the research and development of medicines or vaccines against the virus. There are currently no vaccines or medicines to protect from or treat Zika virus infection that are approved or undergoing clinical studies.

15.1.2. Update on French clinical trial

Action: For information

The CHMP was updated on the French clinical trial by the French CHMP member.

15.1.3. EMA notification system

Scope: Test of the EMA notification system

The CHMP noted the proposal for a test of the EMA notification system.

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 22-25 February 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	
Daniel Brasseur	Member	Belgium	No interests declared	
Bart Van der Schueren	Alternate	Belgium	No interests declared	
Mila Vlaskovska	Member	Bulgaria	No interests declared	
Ines Baotic	Member	Croatia	No participation in discussions, final deliberations and voting on:	9.1.1. Humalog - Insulin Lispro - EMEA/H/C/000088 Eli Lilly Nederland B.V.,
Katarina Vučić	Alternate	Croatia	No interests declared	
Panayiotis Triantafyllis	Member	Cyprus	No interests declared	
Radka Montoniová	Alternate	Czech Republic	No interests declared	
Jens Heisterberg	Member	Denmark	No restrictions applicable to this meeting	
Sinan B. Sarac	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	
Harald Enzmann	Member	Germany	No interests declared	
Martina Weise	Alternate	Germany	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dimitrios Kouvelas	Member	Greece	No interests declared	
George Aislaitner	Alternate	Greece	No interests declared	
Agnes Gyurasics	Member	Hungary	No interests declared	
Hrefna Gudmundsdottir	Alternate	Iceland	No interests declared	
David Lyons	Member	Ireland	No restrictions applicable to this meeting	
Patrick Salmon	Alternate	Ireland	No interests declared	
Daniela Melchiorri	Member	Italy	No interests declared	
Juris Pokrotnieks	Member	Latvia	No restrictions applicable to this meeting	
Natalja Karpova	Alternate	Latvia	No interests declared	
Rugile Pilviniene	Alternate	Lithuania	No interests declared	
Jacqueline Genoux-Hames	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Helen Vella	Alternate	Malta	No interests declared	
Pieter de Graeff	Member	Netherlands	No interests declared	
Johann Lodewijk Hillege	Alternate	Netherlands	No interests declared	
Karsten Bruins Slot	Member	Norway	No interests declared	
Bjorg Bolstad	Alternate	Norway	No restrictions applicable to this meeting	
Piotr Fiedor	Member	Poland	No interests declared	
Aldona Paluchowska	Alternate	Poland	No interests declared	
Bruno Sepodes	Member	Portugal	No interests declared	
Jan Mazag	Member	Slovakia	No interests declared	
Nevenka Tršinar	Alternate	Slovenia	No interests declared	
Concepcion Prieto Yerro	Member	Spain	No interests declared	
Arantxa Sancho-Lopez	Alternate	Spain	No interests declared	
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			meeting	
Robert James Hemmings	Co-opted member	United Kingdom	No restrictions applicable to this meeting	
Koenraad Norga	Co-opted member	Belgium	No interests declared	
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	
Maria Galindo	Expert - in person*	Spain	No participation in discussions, final deliberations and voting on:	3.3.2. - alendronic acid / colecalciferol - EMEA/H/C/004172
Isabelle Yoldjian	Expert - in person*	France	No interests declared	
Camille Thomassin	Expert - in person*	France	No restrictions applicable to this meeting	
Mette Tranholm	Expert - in person*	Denmark	No interests declared	
Jorge Camarero Jimenez	Expert - in person*	Spain	No restrictions applicable to this meeting	
Anabel Cortés Blanco	Expert - via telephone*	Spain	No interests declared	
Christophe Focke	Expert - in person*	Belgium	No interests declared	
Renee van Binsbergen	Expert - in person*	Netherlands	No interests declared	
Nanna Aaby Kruse	Expert - via telephone*	Denmark	No restrictions applicable to this meeting	
Christian Schneider	Expert - in person*	Denmark	No interests declared	
Hatice Canan Bayar	Expert - via telephone*	Norway	No interests declared	
Ingrid Wang	Expert - via telephone*	Norway	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Daniel Vittecoq	Expert - via telephone*	France	No interests declared	
Mair Powell	Expert - in person*	United Kingdom	No interests declared	
James Swales	Expert - via telephone*	United Kingdom	No restrictions applicable to this meeting	
Susan Cole	Expert - in person*	United Kingdom	No interests declared	
Parvinder Phul	Expert – in person*	United Kingdom	No interests declared	
Ana Juric	Expert - via telephone*	Croatia	No interests declared	
Marta Ivanjko	Expert - via telephone*	Croatia	No interests declared	
Jens Ersbøll	Expert - via telephone*	Denmark	No interests declared	
Brian Dooley	Expert - via telephone*	Ireland	No interests declared	
Malin Filler	Expert - via telephone*	Sweden	No interests declared	
Ingrid Schellens	Expert - via telephone*	Netherlands	No interests declared	
Sabine Mayrhofer	Expert - in person*	Germany	No interests declared	
Henning Brohmann	Expert - via telephone*	Germany	No interests declared	
Marcus Savsek	Expert - via telephone*	Germany	No interests declared	
Karoline Buhre	Expert - via telephone*	Germany	No interests declared	
Janet Schriever	Expert - via telephone*	Germany	No interests declared	
Daniela Philadelphy	Expert - via telephone*	Austria	No interests declared	
Jan Span	Expert - in person*	Netherlands	No interests declared	
Zoran Simic	Expert - via telephone*	United Kingdom	No interests declared	
Michel Kooijman	Expert - via telephone*	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ineke Havinga	Expert - via telephone*	Netherlands	No interests declared	
Sabine Lenton	Expert - via telephone*	United Kingdom	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

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

17. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

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

Oral explanations *(section 2)*

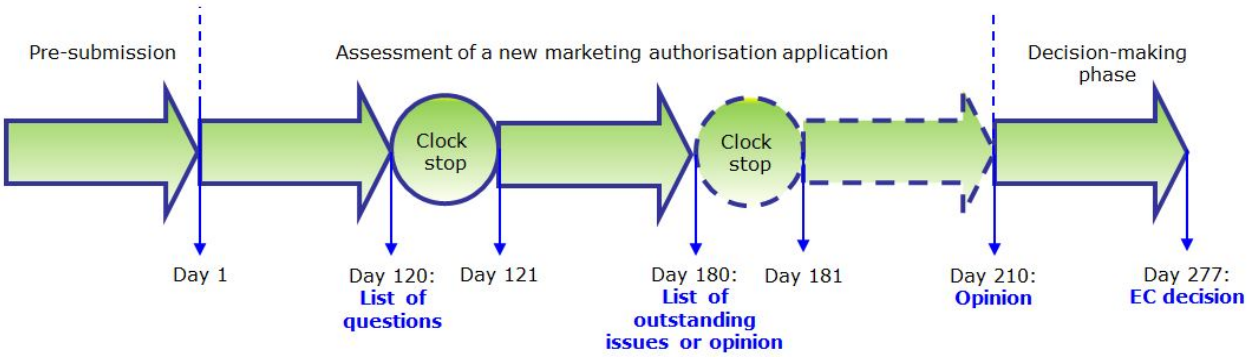
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

a decision are listed under section 3.6, **products in the decision making phase**.

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the

agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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