24 June 2016
EMA/445754/2016
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 23-26 May 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) May 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 23-26 May 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 23-26 May 2016

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 25-28 April 2016.

The CHMP adopted the minutes.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

Insmed Limited; Treatment of Mycobacterium avium Complex (MAC) lung disease

Scope: Oral explanation

Action: Oral explanation to be held on 24 May 2016 at 14.00.

List of Outstanding Issues adopted on 25.02.2016. List of Questions adopted on 25.06.2015.

An oral explanation was held at 15:00. The presentation focused on the efficacy and safety data as well as outlining the claim of fulfilment of unmet medical need.

2.1.2. - drisapersen - Orphan - EMEA/H/C/003846

BioMarin International Limited; treatment of Duchenne muscular dystrophy (DMD)

Scope: Oral explanation

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

List of Outstanding Issues adopted on 01.04.2016. List of Questions adopted on 22.10.2015.

Participation of patients' representatives

An oral explanation was held on 24 May 2016 at 9.00. The presentation focused on the efficacy and safety profile of the drug.

Post meeting note: The CHMP noted that the applicant withdrew the marketing authorisation application for Kyndrisa.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. 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: Opinion / Request for Supplementary Information

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."

Scope: Oral explanation

Action: Oral explanation to be held on 24 May 2016 at 11.00.

Request for Supplementary Information adopted on 28.04.2016, 25.02.2016, 22.10.2015.

SAG Oncology meeting was held on 14 April 2016.

An oral explanation was held on 24 May 2016 at 12:45.

See section 5.1.11

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Bortezomib Hospira - bortezomib - EMEA/H/C/004207

Hospira UK Limited; treatment of multiple myeloma

Scope: Opinion, Similarity assessment report

Action: For adoption

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

List of Questions adopted on 28.01.2016. List of Outstanding Issues adopted on 28.04.2016

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

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the updated CHMP assessment report on similarity for Bortezomib Hospira.

3.1.2. Bortezomib SUN - bortezomib - EMEA/H/C/004076

SUN Pharmaceutical Industries (Europe) B.V.; treatment of multiple myeloma

Scope: Opinion, Similarity assessment report

Action: For adoption

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

List of Outstanding Issues adopted on 01.04.2016, 28.01.2016. 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.

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 for Bortezomib Sun.

3.1.3. Epclusa - sofosbuvir / velpatasvir - EMEA/H/C/004210

Accelerated assessment

Gilead Sciences International Ltd; treatment of chronic hepatitis C virus

Scope: Opinion

Action: For adoption

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

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.

Furthermore, the CHMP considered that velpatasvir 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 CHMP noted the letter of recommendation dated 20 May 2016.

The summary of opinion was circulated for information.

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

Takeda Pharma A/S; multiple myeloma

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 01.04.2016, 25.02.2016. List of Questions adopted on 17.12.2015. Oral explanation was held on 30.03.2016.

The CHMP adopted a negative opinion by consensus recommending the refusal of the granting of the marketing authorisation together with the Assessment Report.

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

The refusal question and answers document was circulated for information.

3.1.5. Pemetrexed Fresenius Kabi - pemetrexed - EMEA/H/C/003895

FRESENIUS KABI ONCOLOGY PLC; treatment of malignant pleural mesothelioma and non-small cell lung cancer

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 01.04.2016. 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.

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

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

The summary of opinion was circulated for information.

3.1.6. Qtern - saxagliptin / dapagliflozin - EMEA/H/C/004057

AstraZeneca AB; treatment of type 2 diabetes

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 28.04.2016, 25.02.2016. 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 summary of opinion was circulated for information.

3.1.7. Zepatier - grazoprevir / elbasvir - EMEA/H/C/004126

Merck Sharp & Dohme Limited; treatment of chronic hepatitis C (CHC) in adults

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 01.04.2016, 25.02.2016. List of Questions adopted on 19.11.2015.

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 grazoprevir and elbasvir are new active substances, 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 CHMP noted the letter of recommendation dated 24 May 2016.

The summary of opinion was circulated for information.

3.2. Initial applications; Day 180 list of outstanding issues

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

treatment of HIV-1

Scope: Day 180 list of outstanding issue

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.

3.2.2. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004050

treatment of HIV

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.

3.2.3. - dinutuximab beta - Orphan - EMEA/H/C/003918

APEIRON Biologics AG; treatment of neuroblastoma

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 adopted the BWP report.

3.2.4. - tenofovir disoproxil - EMEA/H/C/004049

treatment of HIV-1 infection and hepatitis B infection

Scope: Day 180 list of outstanding issue

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.

3.2.5. - tenofovir disoproxil - EMEA/H/C/004120

treatment of HIV-1 infection and hepatitis B infection

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.

3.2.6. - eluxadoline - EMEA/H/C/004098

for the treatment of irritable bowel syndrome with diarrhoea

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.

3.3. Initial applications; Day 120 list of questions

3.3.1. - cabozantinib - EMEA/H/C/004163

Accelerated assessment

treatment of advanced renal cell carcinoma (RCC)

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. - prasterone - EMEA/H/C/004138

treatment of vulvovaginal atrophy

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. - lenvatinib - EMEA/H/C/004224

Accelerated assessment

in combination with everolimus for the treatment of unresectable advanced or metastatic renal cell carcinoma (RCC)

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 similarity assessment report.

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

Novo Nordisk A/S; treatment of haemophilia B

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.

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

treatment of pulmonary arterial hypertension (PAH)

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. - padeliporfin - EMEA/H/C/004182

treatment of prostate cancer

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. - pegfilgrastim - EMEA/H/C/004211

treatment of neutropenia

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.

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

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

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

Scope: Request for an extension to the clock stop to respond to the Day 120 List of questions adopted in February 2016.

Action: For adoption

List of Questions adopted on 25.02.2016

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

3.4.2. - allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2) - Orphan - ATMP - EMEA/H/C/002801

MolMed SpA; treatment in haploidentical haematopoietic stem cell transplantation

Scope: Update on procedure, Oral Explanation held at CAT on 18.05.2016

Action: For information

List of Outstanding Issues adopted on 01.04.2016, 28.01.2016, 26.03.2015. List of Questions adopted on 24.07.2014.

The CHMP was updated on the discussions from the May 2016 CAT meeting. The Committee concluded that additional questions should be sent to CAT on the commitments of the conditional marketing authorisation and finally did not consider the involvement of SAG-O relevant.

The CHMP communicated a list of outstanding issues to the CAT. The CAT adopted this 4th List of Outstanding issues via written procedure with the following timetable.

The CHMP adopted the BWP report.

3.4.3. - vosaroxin - Orphan - EMEA/H/C/004118

Sunesis Europe Ltd; treatment acute myeloid leukaemia

Scope: Request for an extension to the clock stop to respond to the Day 120 List of questions adopted in April 2016.

Action: For adoption

List of Questions adopted on 28.04.2016.

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 in April 2016.

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

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

Scope: Request for an extension to the clock stop to respond to the Day 180 List of Outstanding issues adopted in April 2016.

Action: For adoption

List of Outstanding issues adopted on 28.04.2016. List of Questions adopted on 25.02.2016.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the Day 180 List of Outstanding issues adopted in April 2016.

3.4.5. - abaloparatide - EMEA/H/C/004157

treatment of osteoporosis

Scope: Request for an extension to the clock stop to respond to the Day 120 list of questions adopted in April 2016.

Action: For adoption

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 in April 2016.

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

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

Scope: Request for an extension to the clock stop to respond to the Day 180 List of Outstanding issues adopted in April 2016.

Action: For adoption

List of Outstanding issues adopted on 28.04.2016. 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 the Day 180 List of Outstanding issues adopted in April 2016.

3.4.7. - 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 for an extension to the clock stop to respond to the Day 120 List of questions adopted during the March 2016 meeting.

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

3.5.1. Sialanar - glycopyrronium bromide - PUMA - EMEA/H/C/003883

Proveca Limited; treatment of sialorrhoea

Scope: Letter from the applicant dated May 2016 requesting a re-examination of the Opinion adopted on 28.04.2016. Appointment of re-examination Rapporteurs

Action: Appointment of re-examination Rapporteurs

The Committee appointed re-examination Rapporteur and re-examination Co-Rapporteur by written procedure on 17 May 2016.

The CHMP noted the re-examination procedure timetable.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Opsiria - sirolimus - Orphan - EMEA/H/C/003978

Santen Oy; treatment of chronic non-infectious uveitis

Scope: Letter from the applicant dated 20 May 2016 informing of the decision to withdraw the MAA.

Action: For information

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

The CHMP noted the letter from the applicant dated 20 May 2016 informing of the decision to withdraw the MAA.

3.7.2. Xegafri - rociletinib - EMEA/H/C/004053

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

Scope: Letter from the applicant dated 03 May 2016 informing of the decision to withdraw the MAA.

Action: For information

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

List of Questions adopted on 17.12.2015.

The CHMP noted the letter from the applicant dated 03 May 2016 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

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

4.2.1. Fycompa - perampanel - EMEA/H/C/002434/X/0025

Eisai Europe Ltd.

Scope: "To add a new pharmaceutical form, oral solution, to the one currently approved (EU/1/12/776/024).
To add a new strength of 0.5 mg/ml for Fycompa finished product (EU/1/12/776/024)."

Action: For adoption

List of Questions adopted on 17.12.2015.

The Committee discussed the issues identified in this application.

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

4.2.2. 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

List of Questions adopted on 25.02.2016.

The Committee discussed the issues identified in this application.

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. 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

The Committee discussed the issues identified in this application.

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

4.3.2. 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

The Committee discussed the issues identified in this application. The members discussed the bioequivalence data presented and it was considered that pharmacokinetics data should be provided. Furthermore the Committee looked at the posology data with particular focus on the proposed dosing in children below 12 years of age.

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

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

Janssen-Cilag International N.V.

Rapporteur: Arantxa Sancho-Lopez, Scope: “Extension application to introduce a new pharmaceutical form associated with new strength (500mg film-coated tablets).”

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

No items

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

No items

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

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

5.1.1. Adcetris - brentuximab vedotin - Orphan - EMEA/H/C/002455/II/0025

Takeda Pharma A/S

Rapporteur: Pieter de Graeff, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sabine Straus

Scope: "Extension of Indication to include the treatment of adult patients with Hodgkin Lymphona (HL) at increased risk of relapse or progression following autologous stem cell transplantation (ASCT). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet and the RMP (v.6.3) are updated in accordance.
In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016, 01.04.2016, 22.10.2015, 25.06.2015.

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.

The CHMP agreed by consensus on the one additional year of market protection for a new indication.

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

AbbVie Ltd.

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

Scope: "Extension of Indication to include treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC were updated. The warning in SmPC section 4.4 on neurological events was extended to provide additional advice on the monitoring and possible need for discontinuation in case of demyelinating disorders. The Package Leaflet was updated in accordance. Furthermore, the PI is being brought in line with the latest QRD template version 10 and the MAH took the opportunity to make editorial amendments throughout the PI."

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016, 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 CHMP noted the letter of recommendations dated 20 May 2016.

The summary of opinion was circulated for information.

5.1.3. Kyprolis - carfilzomib - Orphan - EMEA/H/C/003790/II/0001/G

Amgen Europe B.V.

Rapporteur: Arantxa Sancho-Lopez, Scope: "Extension of Indication to include new indication for Kyprolis to be used with either lenalidomide and dexamethasone or dexamethasone alone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and the RMP (version 6.0) is updated in accordance.
In addition, the Marketing authorisation holder (MAH) updated section 6.6 of the SmPC to include the option to administer Kyprolis in a 100 mL intravenous bag containing 5% glucose solution for injection in line with the extension of indication part of this variation. Furthermore the MAH took the opportunity to include some editorial changes and harmonisations in the PI and to update the information of local representatives for Croatia and Cyprus."

Action: For adoption

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

The Committee also adopted the assessment report on similarity
The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The CHMP noted the letter of recommendations dated 25 May 2016.

The summary of opinion was circulated for information.

5.1.4. Lucentis - ranibizumab - EMEA/H/C/000715/II/0061

Novartis Europharm Ltd

Rapporteur: Kristina Dunder, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of Indication to include treatment of visual impairment due to choroidal neovascularization (CNV) based on 6-month data from the pivotal study CRFB002G2301 (MINERVA). Consequential changes are proposed to SmPC sections 4.1, 4.2, 4.8 and 5.1 and the Package Leaflet is proposed to be updated accordingly.
The application included an updated RMP version 16.0."

Action: For adoption

The Committee discussed the issues identified in this application, which were related to long-term efficacy and safety data. The CHMP endorsed the PRAC advice.

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

5.1.5. Revestive - teduglutide - Orphan - EMEA/H/C/002345/II/0020

NPS Pharma Holdings Limited

Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Torbjorn Callreus

Scope: "Extension of Indication to include paediatric population for Revestive.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated in order to update the safety information. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 19.11.2015.

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

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

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

The summary of opinion was circulated for information.

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

Boehringer Ingelheim GmbH

Rapporteur: Pieter de Graeff, 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

The Committee discussed the issues identified in this application. The main discussion focused on the clinical data provided to support the extension of indication. Clarifications on the clinical trial design and analysis of outcome data as well as concerning the mechanism of action were sought.

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

5.1.7. Translarna - ataluren - Orphan - EMEA/H/C/002720/II/0012

PTC Therapeutics International Limited

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Sabine Straus

Scope: "Extension of indication for Translarna to include the treatment of cystic fibrosis resulting from a nonsense mutation in at least one allele of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Consequently, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 5.1, 5.2 of the SmPC were updated. The Package leaflet and RMP are being updated accordingly.
The MAH took also the opportunity to implement the QRD template v9.1. and proposed combined SmPC for Translarna 125 mg, 250 mg and 1000 mg granules for oral suspension. 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 17.12.2015.

The Committee discussed the issues identified in this application. The Committee discussed the outstanding issues related to efficacy and safety and concluded that further information is needed on some aspects of the new proposed indication.

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

Post meeting note: the final timetable was adopted via written procedure on 1 June 2016.

5.1.8. Tysabri - natalizumab - EMEA/H/C/000603/II/0077

Biogen Idec Ltd

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

Scope: "Extension of Indication to include a new indication for Tysabri
As a consequence, sections 4.1 and 4.4 of the SmPC were updated in order to provide physicians with more options for treating RRMS patients with high disease activity who fail a full and adequate course of treatment with disease modifying therapy (DMT).
Consequential changes were also introduced in sections 4.2, 4.3, 5.1 of the SmPC.
The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 19.11.2015, 25.06.2015.

The Committee discussed the design of a PASS study and the need for inclusion of patient data from the EU. The CHMP 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. Xalkori - crizotinib - EMEA/H/C/002489/II/0039

Pfizer Limited

Rapporteur: Pierre Demolis, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Claire Ferard

Scope: "Extension of Indication to include treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC) based on the results of Study A8081001 (a multinational, multicentre, open-label, single-arm study of the safety, pharmacokinetics, pharmacodynamics, and antitumor activity of crizotinib in patients
with advanced cancer). Consequential changes are proposed to SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 and the Package Leaflet is proposed to be updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Annex II. The application included an updated RMP version 7.0."

Action: For adoption

The Committee discussed the issues identified in this application, which were related to indication and place in treatment lines and concluded that the applicant should answer the remaining uncertainties.

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

5.1.10. Trajenta Jentadueto - linagliptin - EMEA/H/C/WS0915

Boehringer Ingelheim International GmbH

Lead Rapporteur: Pieter de Graeff, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of Indication to include use of Trajenta as combination therapy with metformin and an SGLT-2 inhibitor and use of Jentadueto as combination therapy with an SGLT-2 inhibitor. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated based on studies 1245.30, 1275.10 and 1275.1. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to make minor editorial changes in the SmPC for Jentadueto only. Moreover, the updated RMP version 10 (for Trajenta) and version 12 (for Jentadueto) have been submitted."

Action: For adoption

The Committee discussed the issues identified in this application. The discussion focused on the wording of the indication and the added value of the proposed fixed dose combination.

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

5.1.11. 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: Opinion / Request for Supplementary Information

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."

Scope: Oral explanation

Action: Oral explanation to be held on 24 May 2016 at 11.00.

Request for Supplementary Information adopted on 28.04.2016, 25.02.2016, 22.10.2015.

SAG Oncology meeting was held on 14 April 2016.

An oral explanation was held on 24 May 2016 at 12:45. The presentation focused on efficacy and safety of ofatumumab maintenance therapy in high-risk CLL patients. The explanation for high-risk subgroup identification was provided and proposal was made for therapeutic indication wording.

The Committee discussed the proposed criteria for high-risk patients' subgroup and efficacy endpoints. The members expressed different views on the benefit-risk of the product in proposed indication. The Committee concluded that further information is needed from the

applicant.

The CHMP agreed to consult the SAG-Oncology on the totality of data in the newly proposed indication and adopted a list of questions to the SAG-Oncology.

The CHMP adopted a 4th request for supplementary information with a specific timetable.

See also section 2.3.1 post authorisation procedure oral explanation.

5.1.12. Simponi - golimumab - EMEA/H/C/000992/II/0063

MAH: Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga,

Scope: Opinion

"Extension of indication to add a new indication for Simponi in the treatment of polyarticular juvenile idiopathic arthritis in combination with methotrexate in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with methotrexate; consequently, SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1, and 5.2 have been revised to include new efficacy, PK and safety information. The Package Leaflet and RMP have been updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.0."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 19.11.2015, 26.03.2015.

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/0012

Bristol-Myers Squibb Pharma EEIG

Scope: Similarity assessment report

"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

The CHMP adopted the CHMP assessment report on similarity for Opdivo.

The CHMP adopted the BWP report.

5.2.2. Trisenox - arsenic trioxide - EMEA/H/C/000388/II/0058

Teva B.V.

Scope: Similarity assessment report, QWP Report

Scope: "Extension of Indication to include induction of remission, and consolidation in adult patients with newly diagnosed low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤ 10 x 103/µl) characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene for Trisenox.

As a consequence, sections 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated regarding the posology, efficacy and safety information and warnings. In addition, a Risk Management Plan is introduced. The Package Leaflet is updated in accordance."

Action: For adoption

The CHMP adopted the CHMP assessment report on similarity for Trisenox.

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. - Glibenclamide - Orphan - H0004379

AmmTek; Treatment of neonatal diabetes, paediatric formulation (ready to use oral suspension of glibenclamide) to be used in newborns, infants and children.

Scope: Letter from the company dated 30 March 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.

8.1.2. - Etirinotecan Pegol - H0003874

indicated for the treatment of patients with locally recurrent or metastatic breast cancer (MBC). Prior therapy should have included an anthracycline, a taxane and capecitabine (ATC).

Scope: Letter from the company dated 3 May 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. - Midostaurin - Orphan - H0004095

Novartis Europharm Ltd; indicated as a combination therapy for the treatment of patients with newly diagnosed acute myeloid leukaemia who are FLT3 mutation-positive and who are eligible to receive standard induction and consolidation chemotherapy; indicated for the

treatment of patients with aggressive systemic mastocytosis (ASM) or mast cell leukemia (MCL) with or without an associated hematologic non-mast cell lineage disorder (AHNMD).

Scope: Letter from the company dated 4 May 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.

8.2. 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 18 recommendations for eligibility to PRIME: 4 were granted and 14 were denied. The individual outcomes are listed in PRIME Monthly Report on EMA website.

8.2.3. Fee reductions for scientific advice requests on PRIME products for SMEs and applicants from the academic sector

Executive Director decision on fee reductions for scientific advice requests on PRIME products for SMEs and applicants from the academic sector

Action: For adoption

The CHMP adopted the decision.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Revatio - sildenafil - EMEA/H/C/000638/II/0073

MAH: Pfizer Limited, Rapporteur: Pieter de Graeff,

Scope: Opinion

"Following the availability of powder for oral suspension formulation and following the request of CHMP, update of sections 4.2, 6.3, 6.4 and 6.6 of Revatio 20mg film-coated tablets SmPC and section 4.2 of Revatio 10mg powder for oral suspension to delete

information related to the extemporaneously prepared oral suspension. The film-coated tablet PL is updated accordingly."

Action: For adoption

The CHMP discussed the wording of section 4.2 of the SmPC concerning the 10mg dosing in light of the available 20mg film-coated tablet, which was not dividable.

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

9.1.2. Translarna - ataluren - Orphan - EMEA/H/C/002720/II/0020

PTC Therapeutics International Limited,

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus

Scope: List of experts for SAG meeting to be held 16 June 2016

"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."

Action: For adoption

List of questions to the MAH with a specific timetable adopted 1 April 2016.

The CHMP adopted list of experts for SAG meeting to be held 16 June 2016.

9.1.3. WS0771 - aliskiren, aliskiren / hydrochlorothiazide - Rasilez-EMEA/H/C/000780/WS0771/0104 – Rasilez HCT-EMEA/H/C/000964/WS0771/0075

Novartis Europharm Ltd

Lead Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Carmela Macchiarulo, Procedure

Scope: Scope: Opinion / Request for Supplementary Information

"Update of the RMP with regards identified risks, missing information, concomitant use of other medicines, drug-drug interactions, removal of safety issues attributed to the now withdrawn aliskiren/amlodipine (Rasilamlo) and aliskiren/amlodipine/HCTZ (Rasitrio). The variation is supported by Study Report SPA100A: Antihypertensive Effects and Long-Term Safety of Aliskiren in Elderly Patients. No changes to the Product Information are proposed."

Action: For adoption

Request for Supplementary Information adopted on 28.01.2016.

The CHMP discussed the changes to SmPC and considered that further clarifications were needed from the applicant.

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

10. Referral procedures

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

No items

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

10.2.1. Desloratadine-containing products

Rapporteur: Daniel Brasseur, Co-Rapporteur: Andrea Laslop,

Scope: Opinion or List of Outstanding Issues

Prescription status of desloratadine-containing products

Action: For adoption

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

Submission of responses: 04.08.2016

Re-start of the procedure: 18.08.2016

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 31.08.2016

Comments: 05.09.2016

Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 08.09.2016

CHMP opinion/list of outstanding issues: September 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

10.4.1. 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: List of outstanding Issues / Opinion

Disagreements regarding the demonstration of bioequivalence in the fed state

Action: For adoption

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

List of outstanding issues to MAH adopted together with a revised timetable.

Rapporteur/co-rapporteur assessment reports following PKWP consultation: 06.07.2016

Comments: 11.07.2016

Updated rapporteur/co-rapporteur assessment reports following PKWP consultation: 146.07.2016

CHMP opinion: July 2016 CHMP

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

10.5.1. Lovenox and associated names – enoxaparin - EMEA/H/A-30/1429

Sanofi Aventis group of companies and associated companies

Rapporteur: Joseph Emmerich, Co-Rapporteur: Pieter de Graeff,

Scope: Letter from Sanofi Aventis group dated 19.05.2016 requesting extension of timeframe to the list of outstanding issues adopted 28 April 2016.

Harmonisation exercise for Lovenox and associated names. The review was triggered by France, due to the need of harmonisation of the Summary of Product Characteristics across Member States.

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

Action: For adoption

The CHMP agreed to the request by the applicant for an extension of timeframe to respond to the list of outstanding issues adopted during the April 2016 CHMP. The new timetable was adopted:

MAH responses: 01 September 2016

Joint Rapp AR: 28 September 2016

Comments: 03 October 2016

Updated AR:06 October 2016

CHMP Opinion (or 2nd LoOI): October 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: Amended timetable

Action: For information, adopted via written procedure on 03.05.2016

The CHMP noted a 1-month extension to the timetable adopted by written procedure on 03.05.2016

Re-start of the procedure: 28.04.2016

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 08.06.2016

Comments: 13.06.2016

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 16.06.2016

CHMP list of outstanding issues or Opinion: June 2016 CHMP

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

Symbiopharm GmbH,

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

Scope: Letter from the MAH dated 4 May 2016 requesting an extension of timeframe to submit responses to the List of Questions adopted on 1 April 2016.

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

Action: Revised timetable adopted by written procedure

The CHMP noted a 2-month extension to the timetable adopted by written procedure on 10.05.2016.

Submission of responses: 04.08.2016

Re-start of the procedure: 18.08.2016

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 31.08.2016

Comments: 05.09.2016

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 08.09.2016

CHMP LoOI/CHMP opinion: September 2016 CHMP

10.6.3. Semler Research Centre Private Ltd - EMEA/H/A-31/1443

Rapporteur: Pieter de Graeff, Co-Rapporteur: Concepcion Prieto-Yerro,

Scope: Update on the procedure

Article 31 referral triggered by the UK, Germany, Spain, Denmark and the Netherlands in relation to findings of non-compliance with GCP at the Semler bioanalytical and clinical facilities in Bangalore, India.

Action: For information

The CHMP members were updated on the procedure. The CHMP was informed about the national actions to the date and it was reminded member states to keep the network informed on national decisions to suspend MA/MAA. The CHMP noted the draft Annex I.

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 Outstanding Issues adopted on 25 February 2016. List of Questions adopted on 22 October 2015.

The CHMP adopted an opinion by majority that the marketing authorisation(s) should be varied (27 out of 28 votes) together with the CHMP assessment report.

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

The divergent position (John Joseph Borg) was appended to the opinion.

The CHMP agreed to the DHPC and communication plan.

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

11. Pharmacovigilance issue

11.1. Early Notification System

May 2016 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

Scope: ITF Briefing Meeting

Meeting date: 22 June 2016

Action: For adoption

The CHMP agreed to the meeting.

Scope: ITF Briefing Meeting

Meeting date: 1 June 2016

Action: For adoption

The CHMP agreed to the meeting.

Scope: ITF Briefing Meeting

Meeting date: TBD

Action: For adoption

The CHMP agreed to the meeting.

Scope: ITF Briefing Meeting Meeting date: 17 June 2016

Action: For adoption

The CHMP agreed to the meeting.

Scope: ITF Briefing Meeting

Meeting date: 4 July 2016

Action: For adoption

The CHMP agreed to the meeting.

Scope: ITF Briefing Meeting

Meeting date: TBD

Action: For adoption

The CHMP agreed to the meeting.

Scope: ITF Briefing Meeting

Meeting date: 25 May 2016

Action: For adoption

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

Request from EDQM for EMA scientific Opinion under Art. 57 (1)J of Regulation (EC) No 726/2004

Scope: Timetable

Action: For adoption

The CHMP agreed to the request from EDQM together with a timetable.

Request from the European Commission for an EMA scientific Opinion under Article 57

Scope: Timetable

Action: For adoption

The CHMP noted the request from the European Commission and appointed coordinators as well as adopted the procedure timetable.

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Confirmation of area of expertise of Co-opted Member

Action: For discussion

Mandate of Sol Ruiz and Jean-Louis Robert expires in July 2016. Sol Ruiz's area of expertise has been in Quality (biotech and biological), with expertise in advanced therapies (gene, cell and tissue therapies) and Jean-Louis Robert's in Quality (non-biologicals, synthetic chemicals).

The CHMP discussed the current areas of expertise and noted comments from Spanish delegation. The CHMP agreed on the areas of expertise of Co-opted members: Quality (biotech and biological), with expertise in advanced therapies (gene, cell and tissue therapies), Quality (non-biologicals, synthetic chemicals) and epidemiology (specialisation in post-marketing study design, observational study design and registries). Elections will take place at the July 2016 CHMP.

14.1.2. Assessment Report templates for Generic products

Scope: Proposal to amend assessment report templates for Generic products. Proposal for Simplification of Generic templates in line with the CMDh templates

Action: For discussion

The CHMP agreed with the proposal to align the templates for the CAP generics with the templates used by CMDh.

This proposal will be brought back to the Generic Task Force and the Template Review Group for implementation, and agreement at a future ORGAM meeting.

14.1.3. Feedback from recent interactions on evaluation management

Action: For discussion

The CHMP noted the feedback from the joint EMA - HMA Task Force on timetables (TT)

meeting with stakeholders. Uncertainty in the timing of submission of new MAAs or responses to List of Questions (LoQ)/List of Outstanding Issues (LoOI) creates resource planning difficulties for the EMA and National Competent Authorities (NCAs). A Task Force (TF) was set up by the HMA and EMA to address issues with timetables for applications in the CP, MRP and DCP procedures. A survey was performed among stakeholders and common problems were identified related to initial submissions and responses to LoQ/LoOI. Therefore a Best Practice Guide for regulators and industry will be developed to increase predictability in procedures and ensure quality. Preparation of the document involves consultation with the Committees and CMDs. The CHMP also noted the feedback from 3rd Industry stakeholder platform on the operation of the centralised procedure, held on 21 April 2016. Specific follow-up actions from the discussions with direct relevance for CHMP were presented: those were related to accelerated assessment and pre-submission meetings.

EMA survey on Initial Marketing Authorisation Application provides opportunity for feedback also from rapporteurs / assessors on the applications through a specific and focused set of questions: experience after the primary assessment and after opinion finalisation. Draft questions will be circulated to CHMP representatives for review by 6th June.

14.1.4. Confirmation of joint CHMP/PDCO membership for Hungary, Romania, Luxembourg

Hungary - Agnes Gyurasics and Melinda Sobor

Romania - Nela Vilceanu, Dana Gabriela Marin

Luxembourg - Jacqueline Genoux-Hames and Carola de Beaufort

Action: For adoption

The CHMP appointed the CHMP members and alternates from Hungary, Romania and Luxembourg for another 3 year term as CHMP/PDCO joint members. The CHMP was reminded about the legal obligation to appoint two further joint CHMP/PDCO members. The CHMP members should discuss with their NCAs whether they could take this joint membership.

14.1.5. Update on the “CHMP assessment report on the significant clinical benefit in comparison with existing therapies in accordance with Article 14(11) of Regulation (EC) No 726/2004” and “Practical guidance on elements required to grant an additional year of marketing protection due to significant clinical benefit”

Action: For information

The CHMP noted the update on templates.

14.1.6. Best Practice Guide for CHMP plenaries

Action: For adoption

The CHMP adopted the document, which intends to provide guidance to members and experts for preparing CHMP plenary discussions.

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 10-13 May 2016

Action: For information

The CHMP noted the information.

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

Action: For adoption

The CHMP adopted the list.

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 19-20 May 2016
Action: For information

The CHMP noted the draft minutes.

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Not applicable this month

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at May 2016 PDCO

Action: For information

The CHMP noted the information.

Report from the PDCO meeting held on 25-27 May 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 17-19 May 2016
Action: For information

The CHMP noted the report.

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

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 23-25 May 2016

Action: For information

The CHMP noted the report.

Response from PKWP to question from the CMDh on bioequivalence for generic ibuprofen products

Action: For adoption

The CHMP adopted the response.

14.2.7. Committee for Medicinal Products for Veterinary Use (CVMP)

Scope: "Updated advice on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health

Action: For adoption for 1 month public consultation

The CHMP adopted the updated advice for public consultation but asked whether the public consultation period could be extended to one month. The Committee noted that one month deadline for consultation was acceptable.

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 10-13 May 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.

Election of SAWP Vice-Chair

Action: For adoption

Peter Mol and Kolbeinn Gudmundsson were elected as SAWP Vice-Chairs.

14.3.2. Gastroenterology Drafting Group (GDG)

Nomination of observer

Action: For adoption

The CHMP appointed Mari Thorn (Germany) as observer to GDG.

14.3.3. Safety Working Party (SWP)

Pulegone and Menthofuran – SWP responses to HMPC/CHMP questions on the HMPC public statement (EMA/CHMP/SWP/305366/2016)

Action: For adoption

Following a request from HMPC and consultation with SWP, CHMP has adopted new thresholds for all medicinal products containing the substances pulegone and menthofuran (constituents of peppermint oil).

The new recommendations are for a permitted daily exposure for the sum of pulegone and menthofuran of 37.5 mg per day for medicines used long term and 75 mg per day for medicines used for less than one year.

The draft HMPC public statement on pulegone and menthofuran (found here: http://www.ema.europa.eu/docs/en_GB/document_library/Public_statement/2014/12/WC500179556.pdf) will be finalised accordingly.

14.3.4. Radiopharmaceutical Drafting Group (RDG)

Chair: Patrick Salmon,

Scope: Guideline on core SmPC and Package Leaflet for Fluorodopa (EMA/CHMP/337958/2016)

Action: For adoption for 4 months public consultation

The CHMP adopted the guideline for 4 months public consultation.

Scope: Guideline on core SmPC and Package Leaflet for gadoteric acid (EMA/CHMP/337820/2016)

Action: For adoption for 4 months public consultation

The CHMP adopted the guideline for 4 months public consultation.

Scope: Guideline on core SmPC and Package Leaflet for (68Ge/68Ga) generator (EMA/CHMP/337681/2016)

Action: For adoption for 4 months public consultation

The CHMP adopted the guideline for 4 months public consultation.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

14.5.1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

Scope: ICH E11 Addendum R1 to Guideline “Clinical Investigation of Medicinal Products in Pediatric Population”

Presentation by Daniel Brasseur

Action: For information

The CHMP noted the document. The document captures ethical considerations in paediatric studies, which will be further discussed in June in Lisbon ICH meeting. There is the strategy for the paediatric formulation to move much earlier into the development. Next step is to have a dedicated ICH guidance to paediatric formulation. Novel methodologies in Pediatric Drug

Development have been agreed and following methods are involved: Extrapolation in children; Methodologies in clinical trial design and Model for Informed Drug Discovery Development.

Scope: Appointment of Piotr Krauze as an Expert representing EU for ICH Q12, replacing David Cockburn in this role

Action: For adoption

The CHMP appointed Piotr Krauze as an Expert representing EU for ICH Q12.

Scope: Appointment of Andreas Kouroumalis as an Expert representing EU for ICH M4E

Action: For adoption

The CHMP appointed Andreas Kouroumalis as an Expert representing EU for ICH M4E.

Scope: S3A Q&A - Step 2 - Note for guidance on toxicokinetics the assessment of systemic exposure in toxicity studies - questions and answers (EMA/CHMP/ICH/320985/2016)

Action: For adoption

The CHMP adopted the document.

Scope: Guideline on enhancing the format and structure of benefit-risk information in ICH Efficacy - M4E (R2)

Action: For information

The CHMP noted the guideline, which will be further discussed in June in Lisbon ICH meeting. There were changes proposed for specific headings in unmet medical need and in therapeutic areas. The latest draft was circulated to drafting group. Members were invited to send any comments until12th of June.

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

No items

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 23-26 May 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 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	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			this meeting	
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	
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	
Romaldas Mačiulaitis	Member	Lithuania	No restrictions applicable to this meeting	
John Joseph Borg	Member	Malta	No interests declared	

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

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			declared	
Nithyanandan Nagercoil	Alternate	United Kingdom	No restrictions applicable to this meeting	
Robert James Hemmings	Co-opted member	United Kingdom	No restrictions applicable to this meeting	
Koenraad Norga	Co-opted member	Belgium	No 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	
Mette Madsen	Expert - in person*	Denmark	No interests declared	
Dahlia Saccal Diab	Expert - in person*	France	No interests declared	
Thomas Senderovitz	Expert - in person*	Denmark	No restrictions applicable to this meeting	
Maria Escudero Galindo	Expert - in person*	Spain	No participation in discussions, final deliberations and voting on:	3.2.1. darunavir - EMEA/H/C/004068 3.2.4 - tenofovir disoproxil - EMEA/H/C/004049 3.2.2. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004050 3.3.5. - tadalafil - EMEA/H/C/004297
Christophe Focke	Expert - in person*	Belgium	No interests declared	
Pauline Dayani	Expert - in person*	France	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
Sabine Mayrhofer	Expert - in person*	Germany	No interests declared	
Elmer Schabel	Expert - via telephone*	Germany	No interests declared	
Christine Greiner	Expert - via telephone*	Germany	No interests declared	
Gabriele Schlosser-Weber	Expert - via telephone*	Germany	No interests declared	
Jörg Zinserling	Expert - via telephone*	Germany	No interests declared	
Rene Thürmer	Expert - via telephone*	Germany	No interests declared	
Benoy Daniel	Expert - in person*	United Kingdom	No interests declared	
Mair Powell	Expert - in person*	United Kingdom	No interests declared	
Beatriz Flores	Expert - in person*	United Kingdom	No interests declared	
Janet Nooney	Expert - via telephone*	United Kingdom	No interests declared	
Cecilia Chisholm	Expert - via telephone*	United Kingdom	No interests declared	
Marie Bielsky	Expert - via telephone*	United Kingdom	No restrictions applicable to this meeting	
Paula Salmikangas	Expert - via telephone*	Finland	No interests declared	
Johannes Hendrikus Ovelgönne	Expert - via telephone*	Netherlands	No interests declared	
Macarena Rodriguez Mendizabal	Expert - via telephone*	Spain	No interests declared	
Jan Welink	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
Patients' representative		Patient observer	No interests declared	
Patients' representative		Patient mentor	No restrictions applicable to this meeting	
Patients' representative		Patient observer	No interests declared	
Brigitte Keller-Stanislawski	Expert - via telephone*	Germany	No interests declared	
Jorge Camarero Jimenez	Expert - via telephone*	Spain	No restrictions applicable to this meeting	
Olga Kholmanskikh	Expert - via telephone*	Belgium	No interests declared	
Maria Rosa Virto	Expert - via telephone*	Spain	No interests declared	
Luisa Arreaza Lopez	Expert - via telephone*	Spain	No interests declared	
Representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

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

17. Explanatory notes

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

Oral explanations *(section 2)*

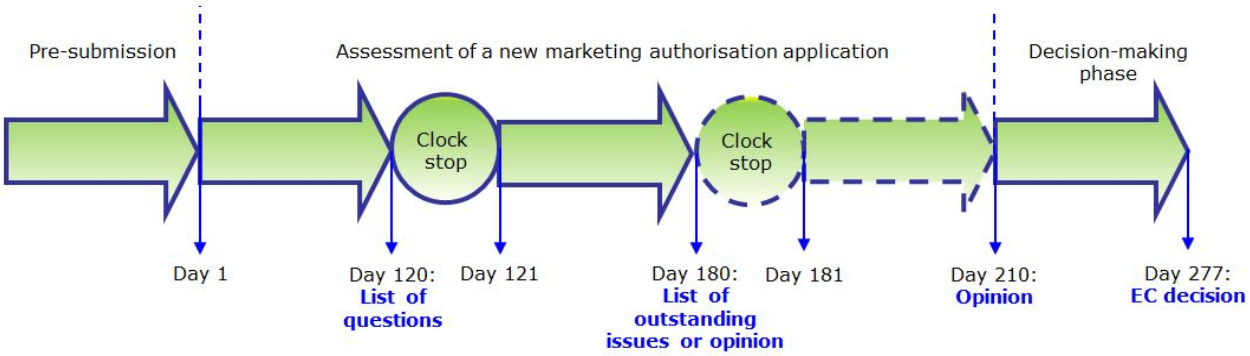
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

The assessment leads to an opinion from the CHMP by day 210. Following a CHMP opinion the European Commission takes usually 67 days to issue a legally binding decision (i.e. by day 277 of the procedure). CHMP discussions on products that have received a CHMP opinion and are awaiting a decision are listed under section 3.6, **products in the decision making phase**.

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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