25 September 2015
EMA/630733/2015
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Minutes of the meeting on 20-23 July 2015

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

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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.

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session held 20-23 July 2015.

1.2. Adoption of agenda

CHMP agenda for 20-23 July 2015.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 22-25 June 2015.

The CHMP adopted the minutes.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Fexeric - ferric citrate coordination complex - EMEA/H/C/003776

Keryx Biopharma UK Ltd.; treatment of hyperphosphataemia

Scope: Oral explanation

Action: Oral explanation, to be held on 21.07.2015 at 9.00, was cancelled.

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

List of Outstanding Issues adopted on 26.03.2015. List of Questions adopted on 24.07.2014.

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

See 3.1.2

2.1.2. Mosquirix™ - p. falciparum circumsporozoite protein fused with hepatitis b surface antigen (rts), and combined with hepatitis b surface antigen (s) in the form of non-infectious virus-like particles (vlps) produced in yeast cells (saccharomyces cerevisiae) by recombinant dna technology - EMEA/H/W/002300

GlaxoSmithKline Biologicals S.A.; indicated for active immunisation against malaria

Scope: Oral explanation and report from the SAG Vaccines

Action: Oral explanation was held on Monday 20 July 2015 at 15.00.

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

Article 58 of Regulation (EC) No 726/2004

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 20.11.2014.

The Committee noted the SAG Vaccines report.

See 3.1.5.

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. Cresemba - isavuconazole - Orphan - EMEA/H/C/002734

Basilea Medical Ltd; treatment of aspergillosis and mucormycosis

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 18.12.2014.

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

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

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

The summary of opinion was circulated for information.

3.1.2. Fexeric - ferric citrate coordination complex - EMEA/H/C/003776

Keryx Biopharma UK Ltd.; treatment of hyperphosphataemia

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 26.03.2015. List of Questions adopted on 24.07.2014.

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

The CHMP agreed that no oral explanation was needed at this time, because some information on quality aspects need to be provided post-approval. Other questions raised during the discussion were related to iron overload risk management and new active substance status. The Committee gave recommendations for future quality development and agreed on obligation to conduct post-authorisation measures.

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 ferric citrate coordination complex is a new active substance, as claimed by the applicant.

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

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

The summary of opinion was circulated for information.

Post meeting note: Revision to the opinion had been done in accordance with discussions at CHMP.

The final documents were adopted via written procedure on 30.07.2015.

3.1.3. Intuniv - guanfacine - EMEA/H/C/003759

Shire Pharmaceuticals Ireland Ltd.; treatment of ADHD

Scope: Opinion

Action: For adoption

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

Oral explanation was held on 23.06.2015. List of Outstanding Issues adopted on 26.03.2015. List of Questions adopted on 24.07.2014.

The Committee discussed the wording of indication, need for educational materials and the need of additional risk minimization tools in order to investigate the long term safety. The Committee concluded that MAH should conduct and submit the results of a comparative safety study, according to an agreed protocol.

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

The Committee adopted a positive opinion by majority (30 positive out of 31 votes) recommending the granting of a marketing authorisation together with the CHMP assessment report and translation timetable.

The Icelandic Member was in agreement with the CHMP recommendation.

The divergent position (Pierre Demolis) was appended to the opinion.

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

The Committee noted the letter of recommendation dated 31.07.2015.

The summary of opinion was circulated for information.

The CHMP agreed to the wording of the EMA press release.

3.1.4. Ivabradine Anpharm - ivabradine - EMEA/H/C/004187

"ANPHARM" Przedsiębiorstwo Farmaceutyczne S.A.; treatment of angina pectoris

Scope: Opinion

Action: For adoption

Informed consent application (Article 10c of Directive No 2001/83/EC)

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.

3.1.5. Mosquirix - plasmodium falciparum and hepatitis b vaccine (recombinant, adjuvanted) - EMEA/H/W/002300

GlaxoSmithKline Biologicals S.A.; indicated for active immunisation against malaria

Scope: Opinion

Action: For adoption

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

Article 58 of Regulation (EC) No 726/2004

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 20.11.2014.

See 2.1.2

The CHMP noted the report from the SAG. The SAG concluded that although the efficacy in the age group 6-12 weeks was relatively low it was considered sufficiently efficacious. It was unknown, how the trial results would translate into field settings with different transmission intensities. For the age group 5-17 months the experts agreed that the clinical data showed a higher efficacy compared to the younger age group. The experts recommended further post-approval studies in severe malaria as well as the optimal timing of a fourth or additional doses and a potential rebound effect. Furthermore the potential risk of meningitis and pneumonia should be followed up after authorisation. The experts did not see a concern using the vaccine in HIV-infected children.

An Oral Explanation was held on Monday 20 July 2015 at 15.00. The presentation of the applicant focused on the efficacy and safety data in the different age groups.

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.

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

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

The summary of opinion was circulated for information.

The CHMP agreed to the wording of the EMA press release.

3.1.6. Obizur - susoctocog alfa - Orphan - EMEA/H/C/002792

Baxter AG; treatment of acquired hemophilia

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 23.04.2015. List of Questions adopted on 20.11.2014.

The CHMP discussed the wording of the indication as well as the post authorisation

measures. 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 under exceptional circumstances 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.

See 3.2.13

3.1.7. Pemetrexed Lilly - pemetrexed - EMEA/H/C/004114

Eli Lilly Netherlands; 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 Questions adopted on 23.04.2015.

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.

3.1.8. Pemetrexed Sandoz - pemetrexed - EMEA/H/C/004011

SANDOZ GmbH; in combination with cisplatin is indicated for the 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 25.06.2015. List of Questions adopted on 26.02.2015.

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.

3.1.9. Praluent - alirocumab - EMEA/H/C/003882

sanofi-aventis groupe; reduction of low-density lipoprotein cholesterol (LDL-C) and increase high-density lipoprotein cholesterol (HDL-C).

Scope: Opinion

Action: For adoption

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

List of Questions adopted on 23.04.2015.

The CHMP was updated on discussions at the PRAC on the RMP. 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 alirocumab 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 Committee noted the letter of recommendation dated 17.07.2015.

The summary of opinion was circulated for information.

3.1.10. Zerbaxa - ceftolozane / tazobactam - EMEA/H/C/003772

Merck Sharp & Dohme Limited; treatment of intra-abdominal urinary tract infections

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 18.12.2014.

The CHMP noted the IDWP report from their meeting held 11 June 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 this fixed-dose combination medicinal product includes a new active substance, ceftolozane, as claimed by the applicant.

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

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

The summary of opinion was circulated for information.

3.1.11. Zalviso - sufentanil - EMEA/H/C/002784

Grunenthal GmbH; indicated for the management of pain

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 20.11.2014.

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 special and restricted medical prescription.

The Committee noted the letter of recommendation dated 20.07.2015.

The summary of opinion was circulated for information.

3.2. Initial applications; Day 180 list of outstanding issues

3.2.1. - aripiprazole - EMEA/H/C/004021

treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 18.12.2014.

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

outstanding issues.

The CHMP adopted a list of Outstanding Issues with a specific timetable.

3.2.2. - blinatumomab - Orphan - EMEA/H/C/003731

Amgen Europe B.V.; treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

The Committee adopted the BWP report.

3.2.3. - pemetrexed - EMEA/H/C/003788

treatment of malignant pleural mesothelioma and non-small cell lung cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

3.2.4. - efmoroctocog alfa - Orphan - EMEA/H/C/003964

Biogen Idec Ltd; treatment of Haemophilia A

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

The Committee adopted the BWP report.

3.2.5. - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042

treatment of HIV-1

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

3.2.6. - fentanyl - EMEA/H/C/002715

treatment of acute moderate to severe post-operative pain

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 22.01.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

3.2.7. - levodopa / carbidopa - EMEA/H/C/002611

treatment of Parkinson's disease

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.03.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

3.2.8. - mepolizumab - EMEA/H/C/003860

treatment of asthma

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.03.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

The Committee adopted the BWP report.

3.2.9. - pegaspargase - EMEA/H/C/003789

indicated as combination therapy in acute lymphoblastic leukaemia (ALL)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 20.11.2014.

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

The CHMP adopted a list of Outstanding Issues and agreed to the request by the applicant for an extension to the clock stop to respond to the LoOI together with a specific timetable.

The Committee adopted the BWP report.

3.2.10. - lumacaftor / ivacaftor - Orphan - EMEA/H/C/003954

Vertex Pharmaceuticals (U.K.) Ltd.; treatment of cystic fybrosis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.03.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

3.2.11. - pemetrexed - EMEA/H/C/003970

treatment of malignant pleural mesothelioma and non-small cell lung cancer (excluding predominantly squamous cell histology)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

3.2.12. - pemetrexed - EMEA/H/C/003905

treatment of malignant pleural mesothelioma and non-small cell lung cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015.

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

The CHMP adopted a list of Outstanding Issues with a specific timetable.

3.2.13. Obizur - susoctocog alfa - Orphan - EMEA/H/C/002792

Baxter AG; treatment of acquired hemophilia

Scope: Opinion

Action: For adoption

See 3.1.6.

3.3. Initial applications; Day 120 list of questions

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

treatment of multiple myeloma

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

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

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the Day 120 list of questions with a specific timetable.

3.3.2. - caspofungin - EMEA/H/C/004134

treatment of invasive candidiasis and invasive aspergillosis

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

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

3.3.3. - albutrepenonacog alfa - Orphan - EMEA/H/C/003955

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

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together

with the List of Questions.

The Committee adopted the BWP report.

3.3.4. - trifluridine / tipiracil - EMEA/H/C/003897

treatment of colorectal cancer

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions

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

treatment of rheumatological and dermatological diseases

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions.

3.3.6. - pandemic influenza vaccine h5n1 (live attenuated, nasal) - EMEA/H/C/003963

prophylaxis of influenza

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application

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

3.3.7. - idarucizumab - EMEA/H/C/003986

Prevention and treatment of dabigatran associated haemorrhage

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application,

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

The Committee adopted the BWP report.

3.3.8. - rasagiline - EMEA/H/C/004064

treatment of idiopathic Parkinson's disease (PD)

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

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

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

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

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

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

The Committee adopted the BWP report.

3.3.10. - enoxaparin sodium - EMEA/H/C/004264

prophylaxis of thromboembolic disorders of venous origin

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

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

3.3.11. - enoxaparin sodium - EMEA/H/C/003795

prophylaxis of thromboembolic disorders of venous origin

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application,

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

The Committee adopted the BWP report.

3.3.12. - miglustat - EMEA/H/C/004016

treatment of Gaucher disease

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together

with the list of questions.

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

treatment of multiple sclerosis (RMS)

Scope: Day 120 list of questions

Action: For adoption

The Committee noted the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions

The Committee adopted the BWP report.

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

3.4.1. insulin human - EMEA/H/C/003858

treatment of diabetes

Scope: Request for an extension of clock stop

Action: For adoption

Day 180 list of outstanding issues adopted 25.06.2015. List of Questions adopted on 23.10.2014.

The CHMP noted the request from the applicant for an extension of clock-stop to respond to Day 180 list of outstanding issues. The Committee discussed this request and agreed for extension to the clock stop with a specific timetable.

3.4.2. sacubitril / valsartan - EMEA/H/C/004062

treatment of heart failure (NYHA class II-IV)

Scope: Need for SAG

Action: For discussion

The Committee noted the previous Day 120 issues of the application.

The CHMP discussed the need for a SAG and agreed that the SAG should be planned following the adoption of the D180 LoOIs in September. Further discussion regarding the LoQs for the planned SAG is expected during the September 2015 CHMP.

Nominations of cardiologists specialised in heart failure to be sent by 11 September 2015.

3.4.3. amikacin - EMEA/H/C/003936

treatment of Pseudomonas aeruginosa lung infection/colonisation in cystic fibrosis patients
treatment of nontuberculous mycobacterial lung infection

Scope: Extension of clock stop for assessment of similarity

Action: For adoption

The CHMP agreed to the request by the applicant for an extension of clock stop to respond to the RSI on similarity adopted in April 2015 with a specific timetable.

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

3.5.1. Heparesc - human heterologous liver cells - Orphan - ATMP - EMEA/H/C/003750

Cytonet GmbH&Co KG; treatment of urea cycle disorders (UCD)

Scope: Request for a re-examination of the Opinion adopted on 25 June 2015 and consultation of SAG

Action: For information and appointment of re-examination CHMP Coordinators

Letter from the applicant dated 9 July 2015 requesting a re-examination of the Opinion adopted on 25 June 2015.

The CAT appointed a re-examination Rapporteur and a re-examination Co-Rapporteur.

The CHMP appointed CHMP Co-ordinators supporting the Rapporteurs teams.

Request for nominations for expert meeting with following expertise:

- Paediatrician and/or Paediatric Intensive Care specialist with expertise in urea cycle disorders

- Paediatrician hepatologist with expertise in liver genetic diseases

- Surgeon with expertise in Paediatric liver surgery

- Preclinical lab specialist with expertise in urea cycle disorders

Nominations of experts should be sent by 11 September 2015.

3.6. Initial applications in the decision-making phase

No items

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

4.2.1. Instanyl - fentanyl / fentanyl citrate - EMEA/H/C/000959/X/0030/G

Takeda Pharma A/S

Rapporteur: Pierre Demolis, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Arnaud Batz

Scope: "Annex I_2.(c) To add the new strength of 400 micrograms/dose in a multi-dose nasal spray in pack size of 10's, 20's, 30's & 40 doses.
Type II cat. B.II.e.4.b) To replace the current multi-dose nasal spray by a new improved child resistant multi-dose nasal spray.
3 X Type IB cat. B.II.e.5.d) To add a new pack size of 30 doses for each current strength (50 micrograms/dose, 100 micrograms/dose & 200 micrograms/dose).
Type IA cat. B.II.d.1.a) – To tighten the assay release limit of the multi-dose finished product to 98.0%-102.0%.
Type IA cat. B.II.f.1.a) 1. – To reduce the shelf life of all strengths of the multi-dose finished product to 24 months.
Additionally, the Applicant took the opportunity to include an editorial change, as to change the wording of the specification footnote regarding the droplet size distribution test from ""The test is performed by the vendor on every pumping system batch" to "The test is performed at release of the pumping system"."

Action: For adoption

List of Questions adopted on 26.02.2015.

Note: The line extension of the application was withdrawn within the responses to the Day 120 List of Questions. The procedure is reverting to a type II-G .

The Committee was reminded of the status of this application and its remaining outstanding issues. The discussion focused on the lock-out system (the proposed container closure system) and the committee agreed that a clinical variation to reconsider the current posology, based on current scientific knowledge, before the new device is marketed, would be necessary.

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

4.2.2. Kalydeco - ivacaftor - Orphan - EMEA/H/C/002494/X/0034/G

Vertex Pharmaceuticals (U.K.) Ltd.

Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Miguel-Angel Macia

Scope: "Line extension to the Marketing Authorisation to include a new pharmaceutical form (granules) in two new strengths (50 mg and 75 mg unit doses) to enable administration of Kalydeco to patients aged 2 to less than 6 years of age. Changes to SmPC sections 4.2, 4.4, 4.5, 4.8 and 5.2 to provide clarity and relevant updates in line with the proposed paediatric extension of application. Consequential changes are made to the Package Leaflet."

Action: For adoption

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 26.02.2015.

The Committee was reminded of the status of this application and its remaining outstanding issues. The main discussion focused on the study design of a post-authorisation study on the long term efficacy and safety in children who initiate treatment from 2-5 years of age.

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

The CHMP agreed by consensus to the request for an additional 1 year of market protection. The CHMP discussed the need for a DHPC and concluded that no DHPC was required at this time.

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

4.3.1. Brilique - ticagrelor - EMEA/H/C/001241/X/0029/G

AstraZeneca AB

Rapporteur: Pieter de Graeff, Co-Rapporteur: Arantxa Sancho-Lopez, PRAC Rapporteur: Menno van der Elst

Scope: "Annex I_2.(c) - extension application for a new strength of 60mg with a new indication: History of Myocardial Infarction.
C.I.4. Type II - To update the product information of the existing Brilique 90mg license with important clinical information from the PEGASUS study."

Action: For adoption

The Committee discussed the issues identified in this application. The discussion concerned the most appropriate target population as well as the long term use of the medicinal product in relation to efficacy.

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

4.3.2. Exjade - deferasirox - Orphan - EMEA/H/C/000670/X/0043

Novartis Europharm Ltd

Rapporteur: Pierre Demolis, PRAC Rapporteur: Corinne Fechant

Scope: "Extension application for a new pharmaceutical form and new strengths (Exjade 90, 180 and 360 mg film-coated tablets)."

Action: For adoption

The Committee discussed the issues identified in this application. The main discussions focused on possible medication errors due to the new formulation. The possibility of a different trade name was evaluated next to other risk minimisation measures.

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

4.3.3. Reyataz - atazanavir / atazanavir sulfate - EMEA/H/C/000494/X/0094/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Joseph Emmerich, Co-Rapporteur: Rafe Suvarna, PRAC Rapporteur: Arnaud Batz

Scope: "An extension application covering a new pharmaceutical form (oral powder), a new strength for the oral powder presentation (50mg), and a new paediatric indication (patients from 3 months of age and weighing at least 5kg); a type II variation (C.1.6) to updated Reyataz capsules in light of new paediatric data; a type IB (C.I.11) variation to make minor revisions to the RMP with regards to nephrolithiasis, following PRAC's assessment of RMP version 7.3."

Action: For adoption

The Committee discussed the issues identified in this application. The main discussion related to the benefit/risk and the possibility to extrapolate data from the adult population to the paediatric age group, with specific focus on the lower weight band.

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

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

4.4.1. REVOLADE - eltrombopag / eltrombopag olamine - EMEA/H/C/001110/X/0022/G

Novartis Europharm Ltd

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Dolores Montero Corominas

Scope: Extension of clock stop

"Extension of indication for paediatric (age 1 year and above) chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients who had an insufficient response to other treatments (e.g. corticosteroids, immunoglobulins). Grouping with the line extension for one new tablet strength (12.5mg) and a new Powder for Oral Suspension formulation (25mg). The Type II variation and the Extension are grouped within this Application. This grouping is justified, as one of the variations in the group is an extension of the marketing authorisation (Annex III of Commission Regulation (EC) No 1234/2008 of November 2008). Agreed justification. 120 day TT follows Line extension."

Action: For adoption

The CHMP agreed to the request by the applicant for an extension to respond to the Request for Supplementary Information adopted in June 2015.

4.4.2. Mabthera - rituximab - EMEA/H/C/000165/X/0101/G

MAH: Roche Registration Ltd,

Rapporteur: Christian Schneider, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Doris Stenver

Scope: Request for extension of clock stop

"Grouping of:

Line extension to add a new strength 1600 mg solution for subcutaneous injection, a new indication is proposed for this strength (different from 1400mg strength).

Type II variation to update the product information of the existing strengths as a consequence to the line extension application

Type II variation to update the RMP"

Action: For adoption

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

The Committee discussed this request and agreed for extension to the clock stop with a specific timetable.

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

No items

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

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

5.1.1. Gilenya - fingolimod - EMEA/H/C/002202/II/0034

Novartis Europharm Ltd

Rapporteur: Pierre Demolis, Co-Rapporteur: Filip Josephson, Scope: "Extension of Indication to update the Gilenya indication in second line use to 'patients with active disease defined by clinical or imaging features despite treatment with at least one disease modifying therapy'
As a consequence, section 4.1 of the SmPC is updated.
In addition, the applicant took the opportunity to relocate documents from section 5.3.5.1 to 5.3.5.2."

Action: For adoption

The Committee discussed the issues identified in this application and concluded that MAH should justify the positive benefit risk ratio of the new proposed indication.

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

5.1.2. Qutenza - capsaicin - EMEA/H/C/000909/II/0039

Astellas Pharma Europe B.V.

Rapporteur: Bruno Sepodes, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Magda Pedro

Scope: "Extension of indication to include treatment of diabetic patients with peripheral neuropathic pain based on the results of studies E05-CL-3004 (STEP) and E05-CL-3002 (PACE). As a consequence sections 4.1, 4.4 and 4.8 of the SmPC have been updated, and Annex II (additional risk minimisation measures) and the Package Leaflet have been updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC, Annex II, labelling and Package Leaflet. An updated RMP (version 18) was provided as part of the application. The provision of studies STEP and PACE addresses MEA 001.4."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2015.

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

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.

5.1.3. Revlimid - lenalidomide - Orphan - EMEA/H/C/000717/II/0079

Celgene Europe Limited

Rapporteur: Pierre Demolis, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Arnaud Batz

Scope: "Extension of Indication to add treatment of adult patients with relapsed and/ or refractory mantle cell lymphoma (MCL). As a consequence, SmPC sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 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. A revised version of the RMP (version 25.0) was provided as part of this application."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2015.

The Committee discussed the issues identified in this application. The members discussed the clinical data on overall survival and progression free survival and the relationship with the tumour burden.

The Committee adopted 2nd Request for Supplementary Information with a specific timetable.

5.1.4. REVOLADE - eltrombopag / eltrombopag olamine - EMEA/H/C/001110/II/0020

Novartis Europharm Ltd

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Dolores Montero Corominas

Scope: "Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to add a new indication on the treatment of adult patients with severe aplastic anaemia (SAA) who have had an insufficient response to immunosuppressive therapy. The package leaflet is updated accordingly. In addition, the MAH has corrected the acronym used for full blood counts (FBC) in the SmPC, Annex II and PL."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2015, 26.02.2015.

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

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.

5.1.5. Volibris - ambrisentan - Orphan - EMEA/H/C/000839/II/0041

Glaxo Group Ltd

Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Radka Montoniová, PRAC Rapporteur: Dolores Montero Corominas

Scope: "Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to include an expanded therapeutic indication for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1)
In addition, the MAH took the opportunity to update Annex II to reflect a change in the PSUR cycle.
The Package leaflet is proposed to be updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2015.

The Committee discussed the issues identified in this application. The main discussion focused on the wording of the indication which was considered too broad with terms of combination therapy.

The Committee adopted 2nd Request for Supplementary Information with a specific timetable.

5.1.6. Xalkori - crizotinib - EMEA/H/C/002489/II/0024

Pfizer Limited

Rapporteur: Pierre Demolis, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Corinne Fechant

Scope: "Extension of indication to the first-line treatment of anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung carcinoma (NSCLC). This variation is based on results taken from Study A8081014. As a consequence, sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been amended. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2015.

The Committee discussed the issues identified in this application. The members discussed the overall survival data and the analysis performed on the clinical data.

The Committee adopted 2nd Request for Supplementary Information with a specific timetable.

The Committee agreed to consult the Biostatistics Working Party.

5.1.7. Zutectra - human hepatitis b immunoglobulin - EMEA/H/C/001089/II/0024

Biotest Pharma GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to Prevention of hepatitis B virus (HBV) re-infection in HBsAg and HBV-DNA negative patients at least one week – instead of the approved at least 6 months - after liver transplantation for hepatitis B induced liver failure.
As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly.
An updated RMP has been provided."

Action: For adoption

The Committee discussed the issues identified in this application. The CHMP discussed the pharmacokinetic and efficacy data in relation to the route of administration.

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

5.1.8. Tafinlar – dabrafenib / Mekinist - trametinib - EMEA/H/C/WS0736

Novartis Europharm Ltd

Lead Rapporteur: Pieter de Graeff, Lead Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: “Extension of indication to add a new therapeutic indication for the use in combination of trametinib and dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.
As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. An updated RMP was also provided.”

Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

The CHMP discussed the wording of the indication as well as the efficacy and safety of the combination versus the monotherapies. The Committee confirmed that all issues previously identified in this application had been resolved.

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

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

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

The summary of opinion was circulated for information.

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. Cimzia - certolizumab pegol - EMEA/H/C/001037/II/0045

UCB Pharma SA

Rapporteur: Kristina Dunder, Co-Rapporteur: Agnes Gyurasics

Scope: Request for an extension of clock stop, revised timetable

“Extension of indication to include treatment of severe, active and progressive rheumatoid arthritis in adults not treated previously with MTX or other disease-modifying antirheumatic drugs (DMARDs).
As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are revised in order to update the efficacy and safety information.”

Action: For adoption

The CHMP agreed to the request by the applicant for an extension of clock stop to respond to the request for supplementary information adopted on 21.05.2015.

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. - eryaspase - Orphan - H0004055

ERYTECH PHARMA - LYON, Treatment of Acute Lymphoblastic Leukaemia (with Philadelphia chromosome negative) in combination with a polychemotherapy

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 6 July 2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note.

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

8.1.2. – Paritaprevir/Ombitasvir/Ritonavir - H0004183

treatment of chronic hepatitis C (CHC) in adults

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 29 June 2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note

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. – ixazomib- Orphan - H0003844

Takeda Pharma A/S, indicated for the treatment of patients with multiple myeloma who have received at least one prior therapy

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 12 June 2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note

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

8.1.4. – Rociletinib - H0004053

treatment of patients with mutant EGFR NSCLC who have received prior EGFR-directed therapy and have T790M-mediated resistant NSCLC.

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 2 July 2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note.

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

8.1.5. - Chenodeoxycholic acid - Orphan - H0004061

Sigma-tau Arzneimittel GmbH, treatment of Cerebrotendinous xanthamatosis (CTX), an inborn error of primary bile acid synthesis due to sterol 27-hydroxylase (CYP27A1) deficiency

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 9 July 2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note.

The CHMP **agreed** 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. TECFIDERA - Dimethyl Fumarate - EMEA/H/C/002601/WS0689/G; NAPs included in WS: Fumaderm, Fumaderm Intial

Biogen Idec Ltd,

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber

Scope: Opinion or Request for Supplementary information

Update of sections 4.4 of the SmPC in order to add a recommendation to consider interruption of treatment in patients with low lymphocyte counts (<0.5 x 109/L) persisting for more than six months and to monitor lymphocyte counts until recovery. Update of section 4.8 of the SmPC with information on observed low lymphocyte counts in clinical studies with Tecfidera and PML (Progressive multifocal leukoencephalopathy) occurrence in the setting of severe and prolonged lymphopenia. Furthermore, the due dates of two commitments as part of the RMP have been revised."

Action: For adoption

Request for Supplementary information adopted on 23.04.2015, 26.02.2015. SAG Neurology was held on 11 June 2015.

The Committee discussed the issues identified in this application and noted that, a new PML case was reported after last CHMP meeting. The committee was reminded the outcome of SAG meeting in June. The main discussion revolved around the need for baseline evaluations (MRI and lymphocites), potential treatment discontinuation based on pre-defined lymphocyte count threshold, enhanced patient monitoring in patients with lymphopenia and its frequency. The committee discussed, how much should PIs on Tecfidera and Fumaderm be aligned.

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

9.1.2. NexoBrid – Bromelain, partially purified - Orphan - EMEA/H/C/002246 - PAM ANX 001.3

MediWound Germany GmbH, removal of eschar

Rapporteur: Harald Enzmann, Co-Rapporteur: Robert James Hemmings,

Scope: The MAH shall conduct a study on enzymatic debridement in burns patients (children and adults): A comparison to standard of care (protocol MW2010-03-02), based on a CHMP approved protocol.

Action: For discussion

The CHMP agreed with the Rapporteurs conclusion that the proposed study protocol is

considered not acceptable. An amended/new study protocol is needed for the Annex II PAM. The MAH should address the listed issues in writing and explain how they plan to address the issues requested in the Annex II condition.

9.1.3. Zontivity - vorapaxar - EMEA/H/C/002814/II/0002

MAH: Merck Sharp & Dohme Limited,

Rapporteur: Greg Markey,

Scope: Opinion

"Update of sections 4.2 and 5.1 of the SmPC in order to update the posology and to include the ATC code respectively. The Package Leaflet section 2 is brought in line with the SmPC in regards to renal problem."

Action: For adoption

Request for Supplementary Information adopted on 21.05.2015.

The Committee concluded that the Applicant did not provide any new evidence that vorapaxar can be equally efficacious, but most importantly equally safe, if initiated earlier than the currently recommended 2 weeks following a MI; the benefit/risk of vorapaxar in such circumstances is unknown. Therefore, the proposed change to section 4.2 cannot be approved.

The Committee adopted a negative opinion by consensus together with the CHMP Assessment Report refusing the variation to the terms of the Marketing Authorisation.

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

9.1.4. Imbruvica - ibrutinib - Orphan - EMEA/H/C/003791/II/0008/G

Janssen-Cilag International NV,

Rapporteur: Filip Josephson, i,

Scope: Opinion or Request of supplementary information

"Following the review of all clinical trials and post-marketing data, update of section 4.4 of the SmPC to add that some fatal bleeding-related events have been reported. Following the cumulative review of hypersensitivity-related cases, update of section 4.8 of the SmPC to add the adverse reactions urticaria, angioedema and erythema. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity of this procedure to update the contact details of the Danish local representative in the PL."

Action: For adoption

The CHMP noted that the applicant has withdrawn the type II variation to propose a change to the SmPC section 4.4 concerning PML.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report recommending the variation to the terms of the Marketing Authorisation.

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

recommendations.

The summary of opinion was circulated for information.

9.1.5. Clarification on SmPC

Rapporteur: Kristina Dunder

Scope: Response letter

Action: For discussion

Letter regarding approved labelling for medicinal products for type 2 diabetes. Follow-up discussion from May 2015 Plenary.

The CHMP discussed and agreed the wording of the response letter to the MAH. The final letter was adopted by written procedure on 28.07.2015.

10. Referral procedures

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

10.1.1. CERVARIX -Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – EMEA/H/A20/1421/C/0721/0071 GARDASIL , SILGARD - Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) – EMEA/H/A20/1421/C/0703/0060 / EMEA/H/A20/1421/C/0732/0054 GARDASIL 9 (Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/A20/1421/C/3852/0001

MAHs: GlaxoSmithKline Biologicals S.A. (Cervarix), Sanofi Pasteur MSD SNC (Gardasil, Gardasil 9), Merck Sharp & Dohme Limited (Silgard)

Rapporteurs for the Article 20 referral: PRAC Rapporteur: Julie Williams, PRAC Co-rapporteurs: Qun-Ying Yue and Jean-Michel Dogne

Individual product Rapporteurs: Rapporteur: Daniel Brasseur, Co-Rapporteur: Jan Mueller-Berghaus (Cervarix), Rapporteur: Kristina Dunder, Co-Rapporteur: Pierre Demolis (Gardasil / Silgard), Rapporteur: Kristina Dunder, Co-Rapporteur: Jan Mueller-Berghaus (Gardasil 9)

Scope: Review of the HPV vaccines to further clarify aspects of their safety profile following notification by the European Commission of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data.

Procedure started at PRAC in July 2015.

Action: For information

The CHMP noted the start of procedure at the PRAC in July 2015

10.1.2. Inductos - Dibotermin alfa – EMEA/H/A-20/1422/C/0408/0082

Rapporteur: Pieter de Graeff, Co-Rapporteur: Outi Mäki-Ikola

Scope: non-compliance of a manufacturing site

The CHMP noted the notification by the European Commission for a referral under Article 20 for Inductos.

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

Notification: 23.07.2015

Start of procedure: 23.07.2015

List of questions: 23.07.2015

Submission of responses: 14.08.2015

Restart of the procedure: 27.08.2015

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 09.09.2015

Comments: 14.09.2015

Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 17.09.2015

List of outstanding issues or CHMP opinion: September 2015 CHMP

The CHMP adopted the DHPC letter and communication plan.

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

10.2.1. Medicinal products under development for the treatment of Ebola (EMEA/H/A-5(3)/1410)

Scope: CHMP discussion

Action: For discussion

The CHMP noted the update on the Ebola epidemiology as well as on the development status of the medicinal products for the treatment of Ebola included in the present review . The CHMP continues its review of all information available on the products included in the procedure.

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

No items

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

No items

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

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

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

List of Questions adopted on 25.09.2014.

Scope: List of Outstanding Issues

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 States.

Action: For adoption

List of Outstanding Issues adopted on 26.02.2015.

The Committee discussed the wording in SmPC sections 4.1, 4.2, 4.3, 4.8, 5.1 and 5.2.

The CHMP adopted a 2nd list of outstanding issues with a specific timetable:

List of Outstanding issues 2: July 2015 CHMP

Submission of responses: 28.09.2015

Re-start of the procedure: 19.10.2015

Joint assessment report circulated to CHMP: 04.11.2015

Comments: 09.11.2015

Joint updated assessment report circulated to CHMP: 12.11.2015

List of outstanding issues/ CHMP opinion: CHMP November 2015

10.5.2. Novantrone and associated names - mitoxantrone - EMEA/H/A-30/1399

MEDA group of companies and associated companies.

Rapporteur: Pieter de Graeff, Co-Rapporteur: Robert Hemmings,

Scope: Opinion or List of Outstanding Issues

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

Action: For adoption

List of Outstanding Issues adopted on 26.03.2015.

The members specifically discussed some of the claimed indications and dose recommendations but also other sections of the SmPC.

The CHMP adopted a list of questions to the SAG Neurology to gain insight into the current clinical use of mitoxantrone in patients with multiple sclerosis.

The CHMP adopted a 2nd list of outstanding issues with a specific timetable:

List of outstanding issues: July 2015 CHMP

Submission of responses: 28.09.2015

Scientific Advisory Group: date to be confirmed

Re-start of the procedure: 20.10.2015

Rapporteur joint assessment report circulated to CHMP: 04.11.2015

Comments: 09.11.2015

List of outstanding issues/CHMP opinion: November 2015 CHMP

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

Chiesi group of companies and associated companiesRapporteur: Daniela Melchiorri, Co-Rapporteur: Martina Weise, Scope: Revised timetable

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

Action: For adoption

The CHMP agreed to the request by the applicant for a 1-month extension of time frame to submit responses to the List of Questions adopted on 25.06.2015.

Submission of responses: 09.10.2015

Re-start of the procedure: 20.10.2015

Rapporteur and co-rapporteur assessment reports circulated to CHMP: 04.11.2015

CHMP member comments: 09.11.2015

Updated rapporteur and co-rapporteur assessment reports circulated to CHMP: 12.11.2015

Adoption of list of outstanding issues / CHMP opinion: November 2015 CHMP

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

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

Lead Rapporteur: Rafe Suvarna,

Scope: Optimark - SAWP / PRAC consultation on a post-authorisation measure (joint study ALS-Gd640001) resulting from the 2010 Article 20 referral procedures for gadolinium-containing contrast agents

Action: For information

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

Action: Timetable for adoption

The CHMP adopted the following timetable for assessment of the Annual cumulative reviews. Start date: 27.07.2015, CHMP Rapporteur AR: 01.09.2015, Comments: 14.09.2015, Updated AR: 17.09.2015, CHMP conclusion: 24.09.2015.

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

July 2015 Early Notification System on Envisaged CHMP Recommendations for Regulatory Action (based on Identified Safety Concerns) Accompanied by Communication to the General Summary of recommendations and advice of PRAC meeting held on 06-09 July 2015.

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

Action: For information

13.2. Innovation Task Force briefing meetings

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

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Call for nominations of a CHMP co-opted member

The Committee agreed at their June 2015 meeting that a co-opted member should be appointed in the area of Epidemiology expertise. The members were informed that Hubert Leufkens will step down as CHMP co-opted member after the July 2015 Plenary meeting.

Action: For information

Nominations should be sent by 1 September 2015, end of business.

14.1.2. Election of CHMP Chair in September 2015

Action: For information

Nominations should be sent by 11 September 2015, end of business.

14.1.3. EMA Q&A on procedural and regulatory aspects for PAES

Action: For discussion

The CHMP discussed the Q&A on procedural and regulatory aspects for PAES. The aim of the document is to clarify practical implementation aspects of the imposition of PAES in accordance with the Commission Delegated Regulation (EU) No 357/2014 (came into force in 30 April 2014). The Q&A complements the existing EMA post-authorisation procedural advice for users of the centralised procedure. The document will be published

14.1.4. 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

Action: For adoption for public consultation

The guideline addresses granting and renewing a conditional marketing authorization, as well as granting of a marketing authorisation not subject to specific obligations following their completion. The guideline has been updated in order to reflect the experiences accumulated with conditional marketing authorisations.

The CHMP adopted the guideline for 2-months public consultation.

14.1.5. Revision of the Guideline on the scientific application and the practical arrangements necessary to implement the procedure for accelerated assessment pursuant to article 14(9) of regulation (EC) No 726/2004 – Rev 1

Action: For adoption for public consultation

Based on the experience gathered by reviewing the approach taken to the assessment of past applications since the last version of the guideline in July 2006, it became apparent that some areas of the guideline would benefit from further clarifications, in particular with regards to the justifications provided by the applicant that the medicinal product falls within the scope of the accelerated assessment.

The CHMP adopted the guideline for 2-months public consultation.

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

Scope: Concept Paper

Action: For discussion

The Committee was informed of development of a new scheme that is designed to facilitate the development and accelerated assessment of innovative medicines of major public health interest, in particular from the viewpoint of therapeutic innovation.

14.1.7. Follow-up discussion from Strategic Review & Learning Meeting in Rome on update of template for assessment of claims of additional year of marketing protection

Action: For discussion

Revised CHMP AR Template for assessment of claims of +1 year marketing protection

Postponed to September ORGAM

14.1.8. NOAC - New oral anticoagulants – workshop to be held on 23 November 2015

Action: For discussion

The CHMP noted the draft agenda of the workshop on the role of PK and PD measurements in the use of the new direct oral anticoagulants (DOACs), to be held on 23 Nov 2015. The presentations and discussions will include experts and impacted stakeholders in the following areas: regulatory field, healthcare professionals and pharmaceutical industry. The CHMP discussed the need for involvement of patient representatives and agreed that patients will be involved.

14.1.9. Guideline on the role of pathological complete response as an endpoint in neoadjuvant breast cancer studies

Action: For adoption

Overview of comments: For information

As new therapies have emerged, disease-free survival (DFS) and ultimately overall

survival (OS) of patients with early breast cancer have improved and thereby the time needed to procure confirmatory data. A new endpoint that would allow the assessment of efficacy at an earlier point in time would therefore be valuable, as it could potentially bring novel and improved therapies faster to the market for the benefit of the patients with high-risk early breast cancer.

The CHMP adopted the guideline.

14.1.10. Peer Review Best Practice

Action: For adoption

The purpose of the "Peer Review" process is to support the rapporteurs in producing high quality assessment reports. The peer reviewer's overall role is seen as quality assurance and not a third level of assessment.

The CHMP adopted the final document.

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 06-09 July 2015
Action: For information
The Committee noted the report.
The members noted the Summary of recommendations and advices of the PRAC meeting.

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for July 2015
Action: For adoption
The EURD list was adopted.

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 16-17 July 2015

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 06-09 July 2015

Action: For information

The CHMP noted the report.

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at July 2015 PDCO
Action: For information
The CHMP noted the report.

Report from the PDCO meeting held on 17-19 July 2015
Action: For information
The CHMP noted the report

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 14-16 July 2015

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 20-22 July 2015
Action: For information
The CHMP noted the report

PKWP/MSWG response to CMDh request on biowaiver justification –
Action: For adoption
PKWP-MSWG joint response to CMDh question
Appendix - draft MSWG report
The CHMP adopted the joint response to CMDh together with the Appendix.

Question to CHMP (BWP) on Biosimilars of Low Molecular Weight Heparins
Action: For discussion
Letter from CMDh dated 7 July 2015 to CHMP (BWP) on Biosimilars of Low Molecular Weight Heparins
RMS Assessment Reports for information.
The CHMP endorsed the response letter to the CMDh requesting further clarification on the questions raised.

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 06-09 July 2015. 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. Excipients Drafting Group

Questions and answers on aspartame in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev.1) (EMA/CHMP/134648/2015)
Action: For adoption for 3-month public consultation
Background review for the excipient aspartame (EMA/CHMP/349452/2014)
The adoption is postponed

Questions and answers on boron (boric acid and borates) in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev. 1) (EMA/CHMP/619104/2013)
Action: For adoption for 3-month public consultation
Background review for the excipient boron (boric acid and borates) (EMA/CHMP/765436/2012)
Draft questions and answers documents on excipients are progressively released for public consultation. They include proposals for new or updated information for the label and package leaflet. The corresponding background report supporting the review is published for information only. When one or several Q&As have been finalised, the new information in the package leaflet will be included in a revised annex of the guideline.
The CHMP adopted the document for 3-months public consultation

Questions and answers on fructose and sorbitol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev. 1) (EMA/CHMP/460886/2014)
Action: For adoption for 3-months public consultation
Background review for the excipients fructose and sorbitol (EMA/CHMP/338441/2014)
The adoption is postponed

Questions and answers on Sodium laurilsulfate in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev.1) (EMA/CHMP/606830/2014)
Action: For adoption for 3-month public consultation
Background review for Sodium laurilsulfate (SLS) used as an excipient (EMA/CHMP/351898/2014)
Draft questions and answers documents on excipients are progressively released for public consultation. They include proposals for new or updated information for the label and package leaflet. The corresponding background report supporting the review is published for information only. When one or several Q&As have been finalised, the new information in the package leaflet will be included in a revised annex of the guideline.
The CHMP adopted the document for 3-months public consultation.

14.3.3. Quality Working Party (QWP)

QWP comments on FDA's draft Near Infrared (NIR) guideline
Action: For adoption
The CHMP adopted the document

Joint BWP/QWP/GMDP IWG – Industry European workshop on Lifecycle Management (ICH Q12) to be held on 28-29 October 2015

Action: For information

The CHMP noted the planned joint workshop to be held at EMA. This workshop is intended to gather input from European stakeholders on the core expectations for the ICH Q12 guideline, the design of the proposed Q12 tools and enablers, and their application to typical post-approval changes.

14.3.4. Respiratory Drafting Group (RDG)

Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Asthma (CHMP/EWP/2922/01 Rev. 1)

Action: For adoption

Overview of comments received.

The guideline provides guidance for the clinical development and evaluation of new medicinal products for the treatment of asthma. The CHMP adopted the guideline.

14.3.5. Cardiovascular Working Party

Draft Guideline on clinical evaluation of medicinal products used in weight management

Action: For discussion

The CHMP discussed the draft guideline and the main issue for discussion was how the reduction of cardiovascular risk should be expressed. The guideline will be updated according to comments and will be sent back to GCG, then to the Cardiovascular Working Party approval. CHMP will adopt the guideline in September.

14.3.6. Guideline consistency group (GCG)

Scope: Update on the GCG

Action: For discussion

The CHMP agreed to revise the mandate (from consistency to quality assurance) and membership of Guideline consistency group (GCG). The Committee noted the positive outcome of GCG work: consistency between guidelines, quality assurance and focused discussion at ORGAM, when necessary. The negative sides were delays in work, the fact that not all the guidelines are going through GCG and that there is sometimes extra burden to members.

14.3.7. Infectious Diseases Working Party (IDWP)

Scope: Priority list of antibiotics for Article 31 referral for SmPC modernisation

Action: For information

The CHMP noted the list prepared by the IDWP.

14.4. Cooperation within the EU regulatory network

14.4.1. Consultation of Scientific committees on EFSA's draft guidance on uncertainty in scientific assessments

Action: To nominate Committee representatives to provide comments by 4 September 2015

EFSA released a draft guidance document for public consultation until 10 September 2015 on the uncertainty in EFSA Scientific Assessment (http://www.efsa.europa.eu/en/consultations/call/150618.pdf).

CHMP members are invited to submit written comments by 4 September 2015.

14.4.2. EFSA's Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) launched public consultation on draft CEF opinion on "Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials"

Action: For discussion and written comments by 7 October 2015

More information about this public consultation is available on this EFSA webpage: http://www.efsa.europa.eu/en/consultations/call/150707.htm

CHMP members are invited to submit written comments before 7 October 2015.

14.4.3. Update on the status of the IMI2 project ADAPT-SMART

The CHMP noted the Information on the status of the IMI2 project ADAPT-SMART (**A**ccelerated **D**evelopment of **A**ppropriate **P**atient **T**herapies: a **S**ustainable, **M**ulti-stakeholder **A**pproach from **R**esearch to **T**reatment-outcomes). The ADAPT-SMART consortium will facilitate and accelerate the availability of Medicines Adaptive Pathways to Patients (MAPPs). MAPPs seeks to foster access to beneficial treatments for the right patient groups at the earliest appropriate time in the product life-span in a sustainable fashion. The partners are public authorities and private companies. The project started in July 2015 and the duration is 30 months.

The official involvement of CHMP was not considered relevant at the moment, however personal involvement was kept in mind.

14.5. Cooperation with International Regulators

14.5.1. WHO consultation on a new concept of reference preparations for biotherapeutics - 21-22 September 2015, Geneva

Action: For adoption

The CHMP agreed on the participation of the BWP vice-chair as CHMP representative at this meeting.

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

14.7.1. CHMP 2016 Work Plan

Scope: List of proposed topics

Action: For adoption

The CHMP discussed and adopted the list of topics for 2016 work plan. Two new topics will be included – PRIME and Wording of the therapeutic indication.

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1.1. Making medicines safer – How legislation contributes to patient safety

EMA's 20th anniversary event to be held on 22 July 2015, Promenade level

Action: For information

The CHMP noted the information.

16. List of participants

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 20-23 July 2015 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Tomas Salmonson	Chair	Sweden	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Milena Stain	Alternate	Austria	No interests declared	
Bart Van der Schueren	Alternate	Belgium	No interests declared	
Mila Vlaskovska	Member	Bulgaria	No interests declared	
Viola Macolić Šarinić	Member	Croatia	No interests declared	
Ana Dugonjić	Alternate	Croatia	No interests declared	
Panayiotis Triantafyllis	Member	Cyprus	No interests declared	
Ondřej Slanař	Member	Czech Republic	No participation in discussions, final deliberations and voting on:	3.2.1. - aripiprazole - EMEA/H/C/004021
Jens Heisterberg	Member	Denmark	No restrictions applicable to this meeting	
Christian Schneider	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	
Dimitrios Kouvelas	Member	Greece	No interests declared	
George Aislaitner	Alternate	Greece	No interests declared	
Agnes Gyurasics	Member	Hungary	No interests declared	
Melinda Sobor	Alternate	Hungary	No interests declared	
Kolbeinn Gudmundsson	Member	Iceland	No interests declared	
David Lyons	Member	Ireland	No restrictions applicable to this meeting	
Patrick Salmon	Alternate	Ireland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Daniela Melchiorri	Member	Italy	No interests declared	
Natalja Karpova	Alternate	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No restrictions applicable to this meeting	
Rugile Pilviniene	Alternate	Lithuania	No interests declared	
John Joseph Borg	Member	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	
Piotr Fiedor	Member	Poland	No interests declared	
Bruno Sepodes	Member	Portugal	No interests declared	
Dinah Duarte	Alternate	Portugal	No interests declared	
Nela Vilceanu	Member	Romania	No interests declared	
Jan Mazag	Member	Slovakia	No interests declared	
Ivana Pankuchova	Alternate	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	
Rafe Suvarna	Alternate	United Kingdom	No interests declared	
Robert James Hemmings	Co-opted member	United Kingdom	No restrictions applicable to this meeting	
Hubert Leufkens	Co-opted member	Netherlands	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	
Kristina Bech Jensen	Expert - in person*	Denmark	No interests declared	
Hanne Lomholt Larsen	Expert - in person*	Denmark	No interests declared	
Isabelle Bekeredjian-Ding	Expert - in person*	Germany	No interests declared	
Sabine Mayrhofer	Expert - in person*	Germany	No interests declared	
Ana Alonso Gutierrez	Expert - in person*	Spain	No interests declared	
Anna Hrabovska	Expert - in person*	Czech Republic	No restrictions applicable to this meeting	
Nathalie Morgensztejn	Expert - via telephone*	France	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Alexandre Moreau	Expert - in person*	France	No interests declared	
Mair Powell	Expert - in person*	United Kingdom	No interests declared	
Valerie Lescrainier	Expert - in person*	Belgium	No interests declared	
Barbara van Zwieten-Boot	Expert - in person*	Netherlands	No interests declared	
Andrew Pollard	Expert - via telephone*	United Kingdom	No restrictions applicable to this meeting	
Paula Salmikangas	Expert - via telephone*	Finland	No interests declared	
John Johnston	Expert - via telephone*	United Kingdom	No interests declared	
Karen Goetz	Expert - via telephone*	Germany	No interests declared	
Volker Öppling	Expert - via telephone*	Germany	No interests declared	
Nithyanandan Nagercoil	Expert - via telephone*	United Kingdom	No restrictions applicable to this meeting	
Sabine Lenton	Expert - via telephone*	United Kingdom	No interests declared	
Maria do Rosário Lobato	Expert - via telephone*	Spain	No interests declared	
Mario Miguel Rosa	Expert - via telephone*	Spain	No interests declared	
Marcellinus Moester	Expert - via telephone*	Netherlands	No interests declared	
Bertil Jonsson	Expert - via telephone*	Sweden	No interests declared	
Walter Janssens	Expert - via telephone*	Belgium	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

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)*

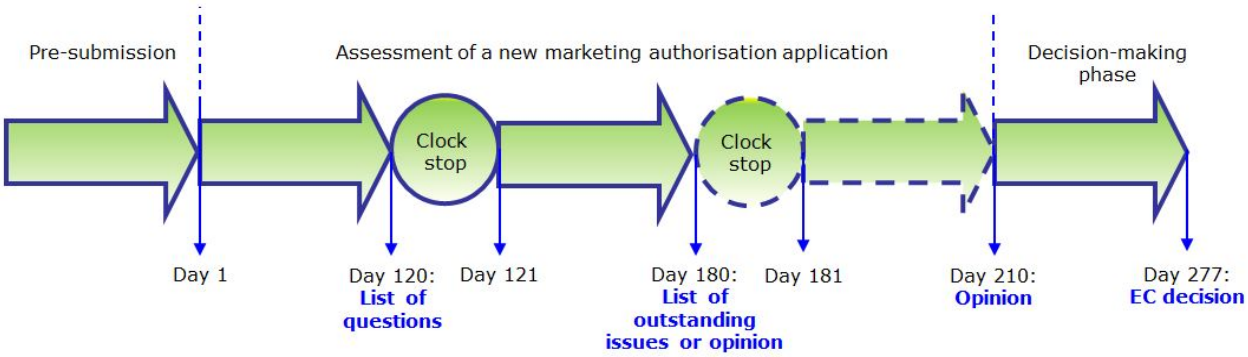
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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