EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2014
EMA/679758/2014

Procedure Management and Business Support Division

Committee for medicinal products for human use (CHMP)

Minutes of meeting held on 20-23 October 2014

Chair: Tomas Salmonson – Vice-chair: Pierre Demolis

Note on access to documents

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

Disclaimers

Some of the information contained in this agenda is considered commercially confidential and therefore not disclosed. With regards to therapeutic indications listed against products it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. The procedures discussed by the CHMP are on-going and therefore are considered confidential. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available. For orphan medicinal products the applicant details are published as this information is already publicly available. Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Further information with relevant explanatory notes can be found at the end of this document.

Agenda (EMA/CHMP/601124/2014 Rev.0) and Annex to CHMP agenda of the CHMP plenary session to be held 20-23 October 2014.	The agenda and annex were adopted with amendments.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Timeschedule of the CHMP plenary session to be held 20-23 October 2014.	The timeschedule was adopted.
Minutes (EMA/CHMP/614190/2014 Rev.0) of the CHMP plenary session held 22-25 September 2014	The Minutes of the CHMP plenary session held 22-25 September 2014 were adopted.
Minutes (EMA/CHMP/580168/2014) of the October 2014 CHMP and ORGAM meeting held on 13 October 2014 (EMA/630679/2014 Rev.0).	The Minutes of the October 2014 CHMP ORGAM meeting held on 13 October 2014, together with all decisions taken at that meeting, were adopted.
Membership Announcement	Jan Mueller-Berghaus was elected by the Committee for another 3 year term as co-opted member.
Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held on 20-23 October 2014.	See October 2014 Minutes (to be published post November 2014 CHMP meeting) The pre-meeting list was noted.
Draft Agenda of 17-20 November 2014 CHMP meeting	The draft agenda was noted.

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1. Oral explanations

1.1. Pre-authorisation procedure oral explanations

(EMEA/H/C/003687), (naltrexone / bupropion), (indicated for the management of obesity)
List of Outstanding Issues adopted on 24.07.2014.
List of Questions adopted on 20.02.2014.
The CHMP agreed that no Oral Explanation was needed at this time.
See also 2.2. New full applications; Day 180 List of outstanding issues

1.2. Re-examination procedure oral explanation

No items

1.3. Post-authorisation procedure oral explanation

No items

1.4. Referral procedure oral explanation

GVK Biosciences (EMEA/H/A-31/1408)
Rapporteur: Harald Enzmann, Co-Rapporteur: Christian Schneider,
Article 31 procedure triggered by the European Commission concerning GVK Biosciences Private Limited (GVK Bio), Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India
An oral explanation was held on Wednesday 22 October 2014 at 9.00.
See also section 12.6 Article 31 Referral

2. New full applications

2.1. New full applications; Opinions

Duavive (EMEA/H/C/002314), (estrogens conjugated / bazedoxifene), (treatment of oestrogen deficiency and osteoporosis)
Fixed combination application (Article 10b of Directive No 2001/83/EC)
Oral explanation held on 24.09.2014. List of Outstanding Issues adopted on 26.06.2014, 20.03.2014.
List of Questions adopted on 15.11.2012.The CHMP discussed the indication and agreed to delete a reference to prescribe the product based on an assessment of benefit /risk for the individual patient.
The Committee confirmed that all issues previously identified in this application had been addressed.
The Committee adopted a positive opinion by majority (28 positive out of 31 votes) recommending the granting of a marketing authorisation together with the CHMP assessment report and translation timetable.
The legal status was agreed as medicinal product subject to medical prescription.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The divergent position (Harald Enzmann, Pierre Demolis, Radka Montoniova) was appended to the opinion.
The summary of opinion was circulated for information.

Duloxetine Lilly (EMEA/H/C/004000), (duloxetine), (treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder)
Informed consent application (Article 10c of Directive No 2001/83/EC)
Request for Supplementary Information adopted on 24.07.2014.

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 medical prescription.
The summary of opinion was circulated for information.

Lynparza (EMEA/H/C/003726), Orphan, (olaparib), Applicant: AstraZeneca AB (treatment of ovarian cancer)
New active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 26.06.2014.
List of Questions adopted on 23.01.2014.
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 Committee noted the letter of recommendation dated 21.10.2014
The legal status was agreed as medicinal product subject to medical prescription.
The summary of opinion was circulated for information.

Paliperidone Janssen (EMEA/H/C/004066), (paliperidone), , (treatment of schizophrenia)
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.

Rixubis (EMEA/H/C/003771), (nonacog gamma), (treatment of haemophilia B)
Known active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 24.07.2014.
List of Questions adopted on 20.03.2014.
The CHMP discussed the educational material and agreed that educational material was not required at this time.
The Committee confirmed that all issues previously identified in this application had been addressed.
The Committee adopted a positive Opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The legal status was agreed as medicinal product subject to restricted medical prescription.
The summary of opinion was circulated for information.
The Committee adopted the BWP Report.

Scenesse (EMEA/H/C/002548), Orphan, (afamelanotide), Applicant: Clinuvel (UK) Limited, (treatment of phototoxicity)
New active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 23.01.2014, 21.03.2013.
List of Questions adopted on 19.07.2012.
The Committee discussed the wording of the indication, contraindications for children and usage in case of pregnancy.

The Committee confirmed that all issues previously identified in this application had been addressed.
The Committee adopted a positive opinion by majority (24 positive out of 31 votes) recommending the granting of a marketing authorisation under exceptional circumstances together with the CHMP assessment report and translation timetable.
The legal status was agreed as medicinal product subject to restricted medical prescription.
Furthermore, the CHMP considered that afamelanotide is a new active substance, as claimed by the applicant.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The divergent position (Ivana Mikacic, Sol Ruiz, Greg Markey, Hubert Leufkens, Pieter de Graeff, Concepcion Prieto Yerro, Robert Hemmings) was appended to the opinion.
The summary of opinion was circulated for information.

2.2. New full applications; Day 180 List of outstanding issues

(EMEA/H/C/002450), Orphan, ATMP, (ex vivo autologous corneal epithelial cells including stem cells), Applicant: Chiesi Farmaceutici S.p.A., (treatment of limbal stem cell deficiency)
List of Questions adopted on 25.07.2013.
The Committee was reminded of the status of this application and its remaining outstanding issues.
The CHMP agreed on the recommendation and scientific discussion as adopted by CAT, together with the List of Outstanding Issues with a specific timetable.
The Committee adopted the BWP Report.

(EMEA/H/C/003780), (liraglutide), (treatment of obesity)
List of Questions adopted on 22.05.2014.
The Committee was reminded of the status of this application and its remaining outstanding issues.
The Committee adopted a List of Outstanding Issues with a specific timetable.
The Committee adopted the BWP Report.

(EMEA/H/C/003687), (naltrexone / bupropion), (indicated for the management of obesity)
List of Outstanding Issues adopted on 24.07.2014.
List of Questions adopted on 20.02.2014.See also 1.1. Pre-authorisation procedure oral explanations
The Committee was reminded of the status of this application and its remaining outstanding issues.
The Committee adopted 2nd List of Outstanding Issues with a specific timetable.

2.3. New full applications; Day 120 List of Questions

(EMEA/H/C/003984), (bortezomib), (treatment of multiple myeloma)
The Committee discussed the issues identified in this application.
The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions

(EMEA/H/C/003925), (docetaxel), (treatment of breast cancer, non small cell lung cancer, prostate cancer, metastatic gastric adenocarcinoma and head and neck cancer)
The Committee discussed the issues identified in this application.
The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions

(EMEA/H/C/003820), (pembrolizumab), (treatment of melanoma)
The Committee discussed the issues identified in this application.
The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions
The Committee adopted the BWP Report.

(EMEA/H/C/003822), Orphan, (glycerol phenylbutyrate), Applicant: Hyperion Therapeutics Limited, (treatment of patients with urea cycle disorders)
The Committee discussed the issues identified in this application
The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions

(EMEA/H/C/003858), (insulin human), (treatment of diabetes)
The Committee discussed the issues identified in this application.
The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions
The Committee adopted the BWP Report.

(EMEA/H/C/003971), (sevelamer), (control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis)
The Committee adopted a revised list of questions with a revised timetable.

(EMEA/H/C/003968), (sevelamer), (control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis)
The Committee adopted a revised list of questions with a revised timetable.

2.4. Update on on-going new full applications for Centralised procedure

(EMEA/H/C/002801), Orphan, ATMP, (allogeneic t cells genetically modified to express suicide gene), Applicant: MolMed SpA (treatment in haploidentical haematopoietic stem cell transplantation)
List of Questions adopted on 24 July 2014.
The CHMP noted that the CAT had agreed to the request by the applicant for an additional extension to the clock stop to respond to the Day 120 List of Questions adopted in July 2014.

(EMEA/H/C/002661), Orphan
(recombinant l-asparaginase), Applicant: medac Gesellschaft fuer klinische Spezialpraeparate mbH, (combination therapy for B/T cell lymphoblastic leukaemia (ALL) or B/T cell lymphoblastic lymphoma (LBL))
The CHMP agreed to the request by the applicant for extension to the clock stop.

(EMEA/H/C/003702), (phenylephrine hydrochloride / ketorolac trometamol), , (maintenance of mydriasis, prevention of miosis and reduction of ocular pain replacement (ILR).)

List of Outstanding Issues adopted on 22.05.2014.
List of Questions adopted on 23.01.2014.The Committee adopted the revised List of Questions to Ad hoc expert group meeting
(EMEA/H/C/003800), Orphan (ketoconazole), Applicant: Agenzia Industrie Difesa-Stabilimento Chimico Farmaceutico Militare, (treatment of Cushing's syndrome)
The Committee agreed to the request from the applicant for an additional extension of clock stop to respond to the Day 120 List of Questions adopted in April 2014.

(EMEA/H/C/002616), Orphan, (pitolisant hydrochloride), Applicant: BIOPROJET PHARMA, (treatment of narcolepsy)
The Committee agreed to the request from the applicant for an additional extension of clock stop to respond to the Day 120 List of Questions adopted in September 2014.

(EMEA/H/C/003773), (cangrelor), (inhibitor indicated for the reduction of thrombotic cardiovascular events)
List of Outstanding Issues adopted on 25.09.2014.
List of Questions adopted on 25.04.2014.The Committee agreed to the request from the applicant dated 24 October 2014 for an additional extension of clock stop to respond to the Day 180 List of Outstanding Issues adopted in September 2014.

2.5. Products in the Decision Making Phase

Vantobra (EMEA/H/C/002633)(Tobramycin), Applicant: PARI Pharma GmbH,Hybrid application (Article 10(3) of Directive No 2001/83/EC)
The CHMP adopted a List of Question with a specific timetable.

Cyramza (EMEA/H/C/002829), Orphan, (ramucirumab), Applicant: Eli Lilly Nederland B.V., (treatment of gastric cancer)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion in September 2014. List of Outstanding Issues adopted on 26.06.2014. List of Questions adopted on 23.01.2014.
The CHMP noted the final product information.

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

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

No items

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

Orfadin (EMEA/H/C/000555/X/0041), Orphan, (nitisinone), MAH: Swedish Orphan Biovitrum International AB, Rapporteur: Luca Pani, PRAC Rapporteur: Carmela Macchiarulo "To add an oral suspension 4 mg/ml as additional pharmaceutical form"
List of Questions adopted on 19.12.2013.

The Committee was reminded of the status of this application and its remaining outstanding issues.
The Committee adopted a List of Outstanding Issues with a specific timetable.

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

Norvir (EMEA/H/C/000127/X/0127), (ritonavir), MAH: AbbVie Ltd., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus, "line extension of a new oral powder formulation of Norvir (ritonavir) as a replacement for the currently marketed Norvir oral solution for a more suitable ritonavir formulation for the paediatric population."
The Committee discussed the issues identified in this application
The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions.

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

No items

4. Type II variations - Extension of indication procedures according to Annex I of Commission Regulation (EC) No 1234/2008

4.1. Type II variation; Extension of indication; Opinions or Requests for supplementary information

Humira (EMEA/H/C/000481/II/0134), (adalimumab), MAH: AbbVie Ltd., Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Ulla Wändel Liminga, "Extension of Indication to add treatment of chronic plaque psoriasis in children and adolescents from 4 years of age, based on data from study M04-717 'A multicentre, randomised, double-dummy, double-blind study evaluating two doses of adalimumab versus methotrexate in paediatric subjects with chronic plaque psoriasis.' As a consequence sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC have been updated and the Package Leaflet has been updated accordingly. In addition, the MAH proposed minor editorial changes in the SmPC and Package Leaflet.
A revised RMP version 11.2 was included as part of this application."
The Committee discussed the issues identified in this application concerning the lower age limit
The Committee adopted a Request for Supplementary Information with a specific timetable.

Kalydeco (EMEA/H/C/002494/II/0027), Orphan, (ivacaftor), MAH: Vertex Pharmaceuticals (U.K.) Ltd., Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Miguel-Angel Macia "Extension of indication for Kalydeco to include the treatment of cystic fibrosis in patients aged 18 years and older who have a R117H mutation in the CFTR gene. Consequently, changes are proposed to sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and to the Package Leaflet."
The Committee discussed the issues identified in this applicationThe Committee discussed whether the submitted data supports the approval of extended indication and whether subgroup analysis is appropriate.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Prevenar 13 (EMEA/H/C/001104/II/0111), (pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)), MAH: Pfizer Limited, Rapporteur: Kristina Dunder, Co-Rapporteur: Daniel Brasseur, PRAC Rapporteur: Qun-Ying Yue, "Extension of indication to add "pneumonia" to the authorised indication for adults (≥18 years of age), based on data from the recently completed Community–Acquired Pneumonia Immunization Trial in Adults
(CAPiTA), which studied the efficacy of Prevenar 13 in preventing vaccine-serotype pneumococcal community-acquired pneumonia (CAP) and vaccine-serotype invasive pneumococcal disease (IPD) in adults aged 65 years and older. As a consequence the MAH proposes to update sections 4.1, 4.8 and 5.1 of the SmPC and to update the Package Leaflet accordingly. The provision of the CAPiTA study addresses MEA 045."The Committee discussed the issues identified in this application, concerning some clinical aspects.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Rebetol (EMEA/H/C/000246/II/0074), (ribavirin), MAH: Merck Sharp & Dohme Limited, Rapporteur: Joseph Emmerich, "Change of the indication of Rebetol to reflect that ribavirine is indicated in the treatment of hepatitis C in combination with other medicinal products and remove reference to the peginterferon used (2a or 2b) in line with the PRAC recommendation in the PSUR assessment (EMEA/H/C/PSUSA/000100007/201307). As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.7, 4.8, 4.9 and 5.1 of the SmPC are updated. The package leaflet is updated accordingly."
The Committee discussed the issues identified in this application, mainly concerning the wording of different sections of the SmPC/PIL, but also to the posology and the environmental risk assessment.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Sustiva (EMEA/H/C/000249/II/0126/G), (efavirenz), MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Margarida Guimarães, "Grouped variation consisting of two consequential variations. A type II variation to extend the therapeutic indication to include children 3 months of age to less than 3 year of age and weighing at least 3.5kg. A type IB, consequential to this update, to remove the Oral Solution pharmaceutical form for Sustiva (efavirenz) and as such upgrade the already approved "capsule sprinkle" dosing method as primary means of dosing for young patients and those that cannot swallow capsules and/or tablets"
Request for Supplementary Information adopted on 22.05.2014.
The Committee discussed the issues identified in this application, which were related to changes to the SmPC and the RMP, as well as to the communication strategy.
The Committee adopted a 2nd Request for Supplementary Information with a specific timetable.

Tamiflu (EMEA/H/C/000402/II/0110/G), (oseltamivir), MAH: Roche Registration Ltd, Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Bruno Sepodes, , "A group of a type II extension of indication to include the treatment of influenza in infants below one year of age and a type IAIN to add a 3 ml plastic oral dispenser (for the Tamiflu 6mg/ml strength)"
The Committee discussed the issues identified in this application, which were related to safety and efficacy in less than 1 year old infants. In addition the Committee discussed the resistant viral mutants emerged in this age group.
The Committee agreed to the request by the applicant for an additional extension to the clock stop.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Teysuno (EMEA/H/C/001242/II/0018), (tegafur / gimeracil / oteracil), MAH: Nordic Group B.V., Rapporteur: Pieter de Graeff, PRAC Rapporteur: Sabine Straus, "Update of sections 4.1, 4.2 and 5.1 of the SmPC in order to add combination therapy of Teysuno with oxaliplatin (with or without epirubicin) with consequential updates to sections 4.3, 4.4, 4.5, 4.6, 4.8. The Package Leaflet is updated accordingly.
In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 9.0."
The Committee discussed the issues identified in this application.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Xtandi (EMEA/H/C/002639/II/0008), (enzalutamide), MAH: Astellas Pharma Europe B.V., Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Dolores Montero Corominas, "Extension of indication for the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. Consequently, changes are proposed to sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC. The package leaflet is updated accordingly. The MAH also propose to update the contact details of local representatives in the package leaflet."
Request for Supplementary Information adopted on 24.07.2014.
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)
The Committee discussed the issues identified in this application.
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.
The CHMP agreed by consensus on the one year extension of the market protection.

4.2. Update on on-going type II variation; extension of indications

Ceprotin (EMEA/H/C/000334/II/0079), (human protein c), MAH: Baxter AG, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of sections 4.1, 4.2 and 5.1 of the SmPC in order to extend the indication to treatment of patients with Purpura fulminans due to severe acquired protein C deficiency with consequential updates of sections 4.8 and 5.2. Additionally, section 4.6 information has been revised. The PL is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 9.0."
The Committee noted the letter from the MAH dated 16 October 2014 informing of the decision to withdraw the procedure.

Eylea (EMEA/H/C/002392/II/0013), (aflibercept), MAH: Bayer Pharma AG, Rapporteur: Pierre Demolis, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Arnaud Batz, "Update of the Product information to introduce new indication : the treatment of macular oedema following branch retinal vein occlusion (BRVO). New clinical and nonclinical data is being introduced to the SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2. The PL is being updated accordingly. Furthermore, minor editorial changes have been introduced to the PI." Request for Supplementary Information adopted on 25.09.2014.

The CHMP agreed to the request by the applicant for an additional 1-month extension of timeframe to submit responses to Request for Supplementary Information adopted on 25.09.2014.

5. Ancillary medicinal substances in medical devices

5.1. Ancillary medicinal substances in medical devices - Opinions / List of outstanding isues / List of Questions

(EMEA/H/D/003740), (human serum albumin), (the storage, manipulation, in-vitro culture and transfer of human gametes)
List of Questions adopted on 23.01.2014. List of Outstanding Issues adopted on 25.09.2014.
The CHMP agreed to the request by the applicant for an additional extension to the clock stop.

(EMEA/H/D/002831), ((substance to be reviewed) insulin-like growth factor-i (igf-i) segment), (hard-to-heal wounds, primarily venous leg ulcers)
List of Questions adopted on 23.01.2014. List of Outstanding Issues adopted on 25.09.2014.
The CHMP agreed to the request by the applicant for an additional extension to the clock stop.

6. Re-examination procedure (new applications) under Article 9(2) of Regulation no 726/2004

No items

7. Re-examination procedure (Type II variations) under Article 16 of Commission Regulation (EC) No 1234/2008 and 9(2) of Regulation (EC) No 726/2004

No items

8. Withdrawal of full new application

No items

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

No items

10. Pre-submission issues

Some items in this section are considered commercially confidential or sensitive and therefore not disclosed.

(H0003954), Orphan
(Lumacaftor\Ivacaftor), Applicant: Vertex Pharmaceuticals (U.K.) Ltd., (treatment of Cystic Fibrosis in patients aged 12 years and older who are homozygous for the *F508del* mutation in the CFTR gene, The CHMP agreed to the accelerated assessment request and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

Activities related to Ebola

11. Post-authorisation issues

Some items in this section are considered commercially confidential or sensitive and therefore not disclosed.

Evicel (EMEA/H/C/000898/II/0026), (human fibrinogen / human thrombin), MAH: Omrix Biopharmaceuticals N. V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, , "Update of the RMP". Oral explanation held on 22.07.2014. Request for Supplementary Information adopted on 26.06.2014, 20.03.2014.
The Committee confirmed that all issues previously identified in this application had been addressed.
The CHMP adopted an opinion by consensus recommending the variation to the terms of the Marketing Authorisation.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The Committee noted the letter of recommendation dated 23 October 2014.
The CHMP agreed to the wording of the public health communication.

Xofigo (EMEA/H/C/002653)
(Radium-223 Chloride), MAH: Bayer Pharma AG, Rapporteur: Harald Enzmann, Co-Rapporteur: Daniela Melchiorri, (treatment of castration-resistant prostate cancer), New active substance (Article 8(3) of Directive No 2001/83/EC)
The Committee noted the DHPC and communication plan as adopted on 16.10.2014 via written procedure.
The Committee adopted the Rapporteurs' assessment report.

Giotrif (EMEA/H/C/002280/II/0003), (afatinib), MAH: Boehringer Ingelheim International GmbH, Rapporteur: Filip Josephson, "Update of section 4.4 of the SmPC to add a warning with regards to the combination of afatinib with vinorelbine in HER2 positive metastatic breast cancer further to results from a phase III clinical trial"
Request for Supplementary Information adopted on 24.07.2014.
The Committee discussed the issues identified in this application, which were related to effectiveness and safety .
The Committee adopted a Request for Supplementary Information with a specific timetable.

Pradaxa (EMEA/H/C/000829/ LEG2 043.1
dabigatran etexilate), MAH: Boehringer Ingelheim International GmbH, Rapporteur: Jens Heisterberg, Co-Rapporteur: Pierre Demolis, PRAC Rapporteur: Torbjorn Callreus, The CHMP agreed to request PRAC advice

Results of sampling & testing programme 2013
The CHMP noted the results of the sampling and testing programme 2013

12. Referral procedures

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

Iclusig (EMEA/H/C/002695/A-20/0003)

(ponatinib), MAH: Ariad Pharma Ltd, CHMP Rapporteur: Rafe Suvarna, CHMP Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Rafe Suvarna, PRAC Co-Rapporteur: Ulla Wandel-Liminga,
Review of the benefit-risk balance following notification by the European Commission of a referral under Article 20(8) of Regulation (EC) No 726/2004, based on pharmacovigilance data. The Committee discussed the proposed changes in SmPC, key elements to be included in healthcare professional educational materials and studies in the RMP.
The CHMP, having considered the PRAC recommendation, adopted an opinion by consensus, recommending the variation to the terms of the Marketing Authorisations.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The public health communication document was circulated for information.

12.2. Requests for CHMP Opinion under Article 5(3) and 57 (1)p of Regulation (EC) No 726/2004

Polymyxin-based products (EMEA/H/A-5(3)/1384)

(colistin, colistimethate sodium), Rapporteur: Robert James Hemmings, Co-Rapporteur: Martina Weise,
Review of the module 3 (quality) and European Pharmacopeia monograph. Triggered by the EMA Executive Director.
See also section 12.6 Community Interests - Referral under Article 31
The Committee adopted 2nd List of Outstanding Issues with a specific timetable.
CHMP discussion and second list of questions to be addressed by the MAHs: October 2014 CHMP
Submission of responses: 17.11.2014
Joint assessment report: 01.12.2014
Comments from CHMP: 11.12.2014
Updated joint assessment report: 19.12.2014
CHMP discussion/CHMP adoption of opinion: January 2015 CHMP

Activities related to Ebola

The Committee discussed the update on Article 5(3) procedure.

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

No items

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

Seasonique film coated tablets (EMEA/H/A-29(4)/1392)

(levonogestrel 150 µg and ethinylestradiol 30 µg / 10 µg), MAH: Teva Pharma B.V (NL), Rapporteur: Joseph Emmerich, Co-Rapporteur: Martina Weise, , RMS: FR, CMS: AT, BE, DE, IT, PL, RO, SI ,SK,

Procedure number: FR/H/0516/001/DC,
Article 29(4) triggered due to disagreement with regard to the demonstration of contraceptive effectiveness and treatment compliance. Opinion adopted on 26.06.2014.
The Committee discussed the request from the European Commission for clarification in relation to the CHMP Opinion adopted for Seasonique film coated tablets at its June 2014 meeting.

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

Amoxil (EMEA/H/A-30/1372) (amoxicillin), MAH: GlaxoSmithKline, Rapporteur: Robert James Hemmings, Co-Rapporteur: Concepcion Prieto Yerro, ,
Amoxil was included in the list of products for SmPC harmonisation, drawn up by the CMDh, in accordance with Article 30(2) of Directive 2001/83/EC. List of Questions adopted on 25.07.2013. List of Outstanding Issues adopted 25.04.2014.
The CHMP discussed the proposed SmPC wording and agreed that further clarification should be sought on different sections of the SmPC.
The Committee adopted a 2nd List of Outstanding Issues with a specific timetable:
Second list of outstanding issues: October 2014 CHMP; Responses to list of outstanding issues: 05.01.2015; Restart of the procedure: 27.01.2015; Assessment report: 11.02.2015; Comments from CHMP: 16.02.2015; Third list of outstanding issues or CHMP opinion: February 2015 CHMP

Nasonex (EMEA/H/A-30/1374) (mometasone), nasal spray suspension, MAH: Merck Sharp & Dohme, Rapporteur: Kristina Dunder, Co-Rapporteur: David Lyons,
Nasonex was included in the list of products for SmPC harmonisation, drawn up by the CMDh, in accordance with Article 30(2) of Directive 2001/83/EC. List of Questions adopted on 19.09.2013. List of Outstanding Issues adopted on 25.09.2014, 20.02.2014.
The CHMP discussed the proposed SmPC and PL wording . The Committee agreed that further clarification should be sought on different sections of the SmPC and PL and adopted a 3rd List of Outstanding Issues with a specific timetable.
List of outstanding issues 3: 23.10.2014; Responses to LoOI 3: 30.10.2014; Joint Assessment report: 07.11.2014; Comments from CHMP members: 12.11.2014; CHMP opinion: November 2014 CHMP

Novantrone and associated names (EMEA/H/A-30/1399) (mitoxantrone), MAH: MEDA group of companies and associated companies. Rapporteur: Pieter de Graeff, Co-Rapporteur: Robert Hemmings,
Novantrone was included in the list of products for SmPC harmonisation, drawn up by the CMDh, in accordance with Article 30(2) of Directive 2001/83/EC. The CHMP noted the letter from the European Commission notifying of an official referral under Article 30.
The CHMP adopted a list of questions with a specific timetable.
Start of procedure (CHMP): October, 2014; List of Questions: 23.10.2014; Submission of responses: 02.02.2015; Re-start of the procedure: 24.02.2015; Rapporteur/co-rapporteur assessment reports circulated to CHMP: 11.03.2015; Comments: 16.03.2015; List of outstanding issues/CHMP opinion: March 2015 CHMP

Plendil (EMA/H/A-30/1385)
(felodipine), Astra Zeneca group of companies and associated companies, Rapporteur: Kerstin Oselin, Co-Rapporteur: Martina Weise,

Harmonisation exercise for Plendil 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 States.
List of Questions adopted in 21.11.2013. List of Outstanding Issues adopted on 25.04.2014, 24.07.2014.
The CHMP adopted an opinion by consensus, recommending the variation to the terms of the Marketing Authorisations.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The public health communication document was circulated for information.

Article 30 list for SmPC harmonisation, to be triggered by the EC in 2015. CHMP adopted article 30 list for SmPC harmonisation. CHMP agreed on the call for expression of interest in Rapporteurship.
Letter from CMDh to EC seeking agreement on the proposed list, dated 8 October.
List of products identified by CMDh, with proposed starting dates.
Agreement letter from the EC, dated 10 October 2014.
List of products:
Durogesic (fentanyl), Janssen-Cilag, Start: September 2015 The CHMP appointed Johann Lodewijk Hillege as Rapporteur and Martina Weise as Co-Rapporteur.
Etopophos (etoposide phosphate), BMS, Start: October 2015 The CHMP appointed Greg Markey as Rapporteur and Pieter de Graeff as Co-Rapporteur.

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

Polymyxin-based products (EMEA/H/A-31/1383)
(colistin, colistimethate sodium), Rapporteur: Robert Hemmings, Co-Rapporteur: Joseph Emmerich, Full benefit-risk review and update and harmonisation of the product information triggered by European Commission.
See also section 12.2 Requests for CHMP Opinion under Article 5(3)
The Committee discussed the Rapporteurs' assessment of the MAHs responses and agreed on final changes to the product information.
The CHMP adopted an opinion by consensus, recommending the maintenance of the Marketing Authorisation for Colobreathe and the variation to the terms of the Marketing Authorisations for nationally authorised products.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The public health communication document was circulated for information.

Adrenaline auto injectors (EMEA/H/A-31/1398)
Rapporteur: Alar Irs, Co-Rapporteur: Robert Hemmings
Article 31 triggered by the MHRA due to the lack of robust evidence that the devices deliver the adrenaline intramuscularly in all patients.
Call for nomination of experts:

- Radiologists and/or ultrasonographers with expertise in special imaging techniques – particularly contrast ultrasonography.
- Pharmacokineticists with expertise in:
    - PK modelling
    - Micro-dosing

    - Scintigraphy
- Consultant allergists, particularly in tertiary referral centres dealing with patients with severe allergies.

GVK Biosciences (EMEA/H/A-31/1408)
Rapporteur: Harald Enzmann, Co-Rapporteur: Christian Schneider,
Article 31 procedure triggered by the European Commission concerning GVK Biosciences Private Limited (GVK Bio), Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India
See also section 1.4 Oral Explanations
An oral explanation was held on Wednesday 22 October 2014 at 9.00.
During the oral explanation, the company explained the different clinical processes.
The Committee adopted a List of outstanding issues to GVK Bio as well as a list of questions to the MAHs with a specific timetable:
Notification: 04.08.2014; Start of the procedure (CHMP): September 2014 CHMP; List of questions to GVK Bio: 25.09.2014; Submission of responses: 03.10.2014; Rapporteur and co-rapporteurs' assessment reports circulated to CHMP: 13.10.2014; Comments: 15.10.2014; Updated rapporteur and co-rapporteurs' assessment reports circulated to CHMP: 16.10.2014; List of questions to MAHs: 23.10.2014; List of outstanding issues to GVK Bio: 23.10.2014; Submission of responses: 04.11.2014
Re-start of the procedure: 11.11.2014; Rapporteur and co-rapporteurs' assessment reports circulated to CHMP: 13.11.2014; Comments: 14.11.2014; List of outstanding issues/CHMP opinion: November 2014 CHMP

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

No items

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

No items

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

No items

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

No items

12.11. 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)

Oxynal 10mg/5mg, 20mg/10mg
Targin 10mg/5mg, 20mg/10mg, 40mg/20mg, 5mg/2.5mg
(EMEA/A-13/1402)
(oxycodone/naloxone), Mundipharma GmbH, Rapporteur: Martina Weise, Co-Rapporteur: Johann Lodewijk Hillege, Mutual Recognition Procedure number: DE/H/XXXX/WS/044.
Article 13 procedure triggered by Germany on the following grounds: the benefit risk balance for the claimed indication is considered negative as the available clinical data, the proposed product information and the proposed risk minimisation measures are insufficient to assure that the risks of iatrogenic drug dependence and drug prescription abuse outweigh the benefits.
The Committee discussed the benefit-risk balance of the product in second line treatment and the safety issues related to it. However some CHMP members emphasized the unmet need in treatment of restless leg syndrome and the careful patient selection for this treatment.

The CHMP adopted an opinion by majority (21 out of 24 votes) recommending that the objections raised by the Netherlands, France and Italy should not prevent the approval of the variation to the marketing authorisations.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The divergent position (Pierre Demolis, Pieter de Graeff, Daniela Melchiorri) was appended to the opinion.
The public health communication document was circulated for information.

13. Pharmacovigilance issues

Summary of recommendations and advice of PRAC meeting held on 6-9 October 2014: **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 October 2014: **For adoption**	The EURD list was adopted.
Early Notification System: October 2014 Early Notification System on Envisaged CHMP Recommendations for Regulatory Action (based on Identified Safety Concerns) Accompanied by Communication to the General Public: **for information**	See individual items

14. Inspections

14.1. GMP inspections

14.2. GCP inspections

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

14.3. Pharmacovigilance inspections

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

14.4. GLP inspections

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

15. Innovation Task Force

15.1. Minutes of Innovation Task Force: For information

15.2. Briefing meetings (Innovation Task Force)

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

15.3. Eligibility to EMA scientific services

No items

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

Request from EDQM for EMA scientific Opinion under Art. 57 (1)P of Regulation (EC) No 726/2004	The CHMP adopted the final report.

15.5. Nanomedicine activities

No items

16. Scientific Advice Working Party (SAWP)

Report from the SAWP meeting held on 6-8 October 2014. Table of conclusions: **For information**	The CHMP noted the report.
Scientific advice letters:	*Disclosure of information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.*

17. Satellite Groups

17.1. Coordination Group for Mutual Recognition and Decentralised Procedures

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 20-22 October 2014: **For information**	The CHMP noted the report.
Request from CMDh to CHMP and PDCO regarding Guidance on the development of parenteral nutrition in the paediatric population: **For information**	The CHMP noted the request from CMDh.
QWP response to CMDh request for advice concerning the droplet size distribution of Azelastin nasal spray (EMA/CHMP/QWP/606171/2014): **For adoption** • Letter from CMDh and background document: **For information**	The CHMP adopted the QWP response to CMDh.

18. Other Committees

18.1. Committee for Orphan Medicinal Products (COMP)

Press release of the COMP meeting held on 7-8 October 2014: **For information**	To be sent in the Post-mail.

18.2. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 29-30 September 2014: **For information**	The CHMP noted the report.

18.3. Paediatric Committee (PDCO)

PIPs reaching D30 at October 2014 PDCO: **For information**	To be sent in the Post-mail.
Report from the PDCO meeting held on held on 10-12 October 2014: **For information**	The CHMP noted the report.

18.4. Committee for Advanced Therapies (CAT)

Table of Decisions of CAT meeting held on 16-17 October 2014: **For information**	The CHMP noted the table of decisions.

19. Invented name issues

20. Any other business

Election of CHMP Co-opted member	Jan Mueller-Berghaus was elected as CHMP co-opted member for another 3-year term with expertise in quality and safety of biological medicinal products, including biotechnology derived medicines, cell therapy and gene therapy.
Election of Vice Chair of Central Nervous System Working Party	Greg Markey was elected as vice-chair of the CNS Working Party.
Facilitation of registration of centrally authorised products in developing countries – pilot scheme: **For discussion**	WHO proposed EMA to cooperate in a pilot scheme. As regulatory requirements are quickly developing in developing countries, whose competent authorities do not have the right resources to fully operate their key regulatory functions, therefore sharing regulatory outcomes and scientific grounds for regulatory decisions taken by Competent Authorities in more developed countries, can facilitate their regulatory decision making, thus enabling faster access to medicines by patients. The CHMP agreed to the pilot scheme
Discussion Paper on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias: **For adoption**	The Committee adopted the discussion paper.

Guideline on Medicinal Products for the Treatment of Multiple Sclerosis: **For discussion**	The CHMP discussed the guideline. Guideline has been sent to the WG.
Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues (BMWP)(EMEA/CHMP/BMWP/42832/2005 Rev1): **For adoption** Overview of GCG comments received (EMA/772616/2014): **For information**	Postponed to ORGAM November 2014.
Draft SWP response to request from EDQM for EMA scientific Opinion under Art. 57 (1)P of Regulation (EC) No 726/	Follow-up discussion. The CHMP adopted the final report.See also 15.4. Requests for CHMP Opinion under Article 57 (1)P of Regulation (EC) No 726/2004
Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (EMA/CHMP/SWP/169430/2012): **For adoption**	Postponed to ORGAM November 2014
Guideline on Quality of transdermal patches (EMA/CHMP/QWP/608924/2014): **For adoption for 6-months public consultation**	The CHMP adopted the guideline for 6 months public consultation.
Outcome from ad-hoc QWP CT on Aripiprazole API starting materials: **For discussion**	The Committee was updated on the outcome from ad-hoc QWP CT on Aripiprazole API starting materials.
Call for nominations for the appointment of core members for SAG HIV/viral diseases (current mandate ends in November 2014): **For information**	Nominations or confirmation of existing members should be sent by 31 October 2014.
Guideline on the use of minimal residue disease as an endpoint in chronic lymphocytic leukaemia studies (EMA/629967/2014): **For adoption for 3 months consultation**	The Committee adopted the guideline for 3 months public consultation.
Benefit-Risk project Effects Table Pilot: **For discussion**	The CHMP discussed the project. The overview from the feedback of the pilot phase was given. The next steps of the project were presented.
Reminder to use the most up to date Readers Guidance document (EMA/162093/2008)- also including information on PRAC advice/recommendation and the older population: **For information**	The CHMP was reminded to use the updated Readers Guidance document and adopted the updated version.
Update on RMP activities and review process: **For discussion**	The CHMP noted the update on the RMP activities and review process.

Information on the PROTECT symposium	The CHMP noted the agenda of the PROTECT symposium to be held 18-20 February 2015 at EMA. The main topics will include methods to collect data directly from consumers, signal detection, methods to improve consistency between pharmacoepidemiological studies and benefit-risk integration and representation. It was requested to update the CHMP after the symposium during a Plenary meeting or a presidency meeting.

21. List of participants: including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 20-23 October 2014 meeting.

CHMP Chair	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restrictions applies Product / substance
Tomas Salmonson	Sweden	Full involvement	

CHMP Member	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restrictions applies Product / substance
Andrea Laslop	Austria		
Daniel Brasseur	Belgium		
Mila Vlaskovska	Bulgaria		
Ivana Mikačić	Croatia		
Panayiotis Triantafyllis	Cyprus		
Jens Heisterberg	Denmark	No participation in final deliberations and voting	Paliperidone Janssen (EMEA/H/C/004066), (paliperidone) Duloxetine Lilly (EMEA/H/C/004000), (duloxetine)
Outi Mäki-Ikola	Finland	No participation in final deliberations and voting	Humira (EMEA/H/C/000481/II/0134), (adalimumab) (EMEA/H/C/003971), (sevelamer) (EMEA/H/C/003968), (sevelamer)
Pierre Demolis	France		
Harald Enzmann	Germany		
Dimitrios Kouvelas	Greece		
Agnes Gyurasics	Hungary		
David Lyons	Ireland		
Daniela Melchiorri	Italy		
Romaldas Mačiulaitis	Lithuania		
John Joseph Borg	Malta		
Pieter de Graeff	Netherlands		
Karsten Bruins Slot	Norway		

CHMP Member	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restrictions applies Product/substance
Piotr Fiedor	Poland		
Bruno Sepodes	Portugal		
Nela Vilceanu	Romania		
Jan Mazag	Slovakia		
Concepcion Prieto Yerro	Spain		
Kristina Dunder	Sweden		
Greg Markey	United Kingdom		
Robert James Hemmings	Co-opted		
Hubert Leufkens	Co-opted		
Jan Mueller-Berghaus	Co-opted		
Sol Ruiz	Co-opted		

CHMP Alternate	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restrictions applies Product/substance
Milena Stain	Austria		
Bart Van der Schueren	Belgium		
Ana Dugonjić	Croatia		
Radka Montoniová	Czech Republic		Replacing CHMP member
Christian Schneider	Denmark	Via TC only	
Kersti Oselin	Estonia		Replacing CHMP member
Joseph Emmerich	France	No participation in final deliberations and voting	Xofigo (EMEA/H/C/002653) (Radium-223 Chloride) Plendil (EMA/H/A-30/1385) (felodipine)
Martina Weise	Germany		
George Aislaitner	Greece		
Melinda Sobor	Hungary		
Hrefna Gudmundsdottir	Iceland		Replacing CHMP member
Patrick Salmon	Ireland		

CHMP Alternate	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restrictions applies Product / substance
Natalja Karpova	Latvia		Replacing CHMP member
Johann Lodewijk Hillege	Netherlands		
Ingunn Hagen Westgaard	Norway		
Dinah Duarte	Portugal		
Jana Klimasová	Slovakia		
Nevenka Tršinar	Slovenia		Replacing CHMP member
Arantxa Sancho-Lopez	Spain		
Filip Josephson	Sweden		
Rafe Suvarna	United Kingdom		

European Commission	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product / substance
	European Commission	Full involvement	

CHMP Expert	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which the expert is invited Product / substance
* Experts were only evaluated against the product they have been invited to talk about.			
Patricia Diaz Ramos	Spain	No participation in discussions, final deliberations and voting on: Duavive (EMEA/H/C/002314), (estrogens conjugated / bazedoxifene) Prevenar 13 (EMEA/H/C/001104/II/0111), (pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed))	
Kristina Bech Jensen	Denmark		
Sean Jones	United Kingdom		

CHMP Expert	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which the expert is invited Product/substance
Greeves Kondowe	United Kingdom		
Olivier Le Blaye	France		
Valerie Lescrainier	Belgium		
Sabine Mayrhofer	Germany		
Ljiljana Milosevic-Kapetanovic	France		
Elena Mostenicka	Slovakia		
Elisabeth Penninga	Denmark		
Karen Slevin	United Kingdom		
Jason Wakelin-Smith	United Kingdom		
Philippe Zamia	France		

CHMP Expert by phone	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which the expert is invited Product/substance
* Experts were only evaluated against the product they have been invited to talk about.			
Valentina Mantua	Italy		
Marion Haberkamp	Germany		
Annette Lommel	Germany		
Yuansheng Sun	Germany		
Regine Magdalene Lehnert	Germany		
Wilma Fischer-Barth	Germany		
Jens Bäte	Germany		
Michael Pfleiderer	Germany		
Sylvia Kuehn	Germany		
Janet Schriever	Germany		
Thomas Grüger	Germany		
Mike Udell	United Kingdom		
Andre Elferink	Netherlands		
Patrick Vrijlandt	Netherlands		

CHMP Expert by phone	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which the expert is invited Product/substance
Maria Jesús Fernandez Cortizo	Spain		

Explanatory notes

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

Oral explanations *(section 1)*

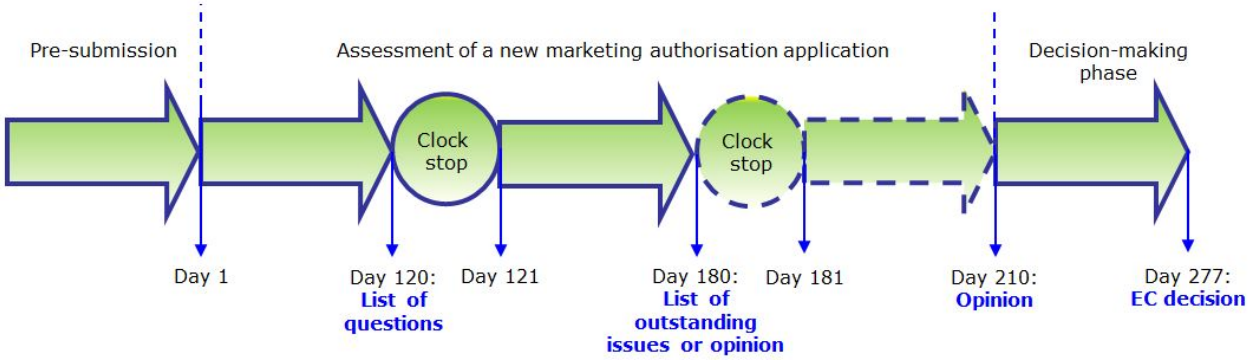
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 2 and 3) or referral procedures (section 12) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

New applications *(section 2)*

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

Section 2.1 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 2.2 (**Day 180 List of outstanding issues**) and 2.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 2.4, **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 2.5, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 *(section 3)*

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 4)*

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 3. 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 5)*

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 6)*

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 *(section 7)*

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 8)*

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 9)*

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 10)*

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 11)*

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 12)*

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 13)*

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 14)*

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 15)*

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 16)*

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 17)*

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 18)*

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.