22 September 2014
EMA/CHMP/471144/2014
Procedure Management and Business Support Division

Committee for medicinal products for human use (CHMP)

Minutes of meeting held on 21 - 24 July 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 these minutes is considered commercially confidential or sensitive 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 certain aspects of them are considered confidential. Additional details on some of these procedures is published in the CHMP meeting highlights once the procedures are finalised and start of referrals are also available. For orphan medicinal products and products that received an opinion at this meeting, the applicant details are published as this information is already publicly available. The same applies for the product name for products that received an opinion at this meeting. Documents mentioned in these minutes cannot be released at present as they are currently in draft format or are classified as confidential. They will become public when adopted in their final form or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006). Of note, this set of minutes 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/657038/2013) and Annex to CHMP agenda of the CHMP plenary session to be held 21-24 July 2014	The agenda and annex were adopted with amendments.

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Timeschedule of the CHMP plenary session to be held 21-24 July 2014	The timeschedule was adopted.
Minutes Of The CHMP Plenary Session held on 23-26 June 2014 (EMA/CHMP/413428/2014)	The Minutes of the CHMP plenary session held 23-26 June 2014 were adopted.
Minutes of the July 2014 CHMP ORGAM meeting held on 16 June 2014 (EMA/433531/2014)	The Minutes of the July 2014 CHMP ORGAM meeting held on 16 June 2014 were adopted together with all decisions taken at that meeting.
Membership Announcement	The Committee noted that Hrefna Gudmundsdottir was nominated as the Icelandic CHMP alternate member, replacing Reynir Arngrímsson in this role. Christian Schneider was nominated as the Danish CHMP alternate member, replacing Jens Ersbøll in this role as of 1 August 2014. Furthermore Maria Popova-Kiradjieva was nominated as new Bulgarian alternate replacing Lyubina Racheva Todorova in this role.
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 21-24 July 2014.	See July 2014 minutes (to be published post September 2014 CHMP meeting) The pre-meeting list was noted.
Draft Agenda of August 2014 written procedure CHMP meeting	The draft agenda was noted.

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1. Oral Explanations

1.1. Pre-authorisation procedure oral explanations

Imagify (EMEA/H/C/002347), (perflubutane), (ultrasound imaging agent indicated for the detection of coronary artery disease (CAD))
Oral explanation in May 2014. List of Outstanding Issues adopted on 22.05.2014, 20.03.2014, 21.11.2013. List of Questions adopted on 21.02.2013. An oral explanation was held on Monday 21 July 2014 at 17.15 pm.

See also section 8 Withdrawal of application

1.2. Re-examination procedure oral explanations

No items

1.3. Post-authorisation procedure oral explanations

Busilvex (EMEA/H/C/000472/II/0019), (busulfan), MAH: Pierre Fabre Médicament, Rapporteur: Arantxa Sancho-Lopez, "Extension of indication for fludarabine followed by Busilvex (FB) as conditioning treatment prior to hematopoietic progenitor cell transplantation (HPCT) in adult patients when such combinations are considered the best available option."
Request for Supplementary Information adopted on 20.03.2014, 24.10.2013. An oral explanation was held on Tuesday 22 July 2014 at 9.00.

See also 4.1. Opinions or Requests for Supplementary information - Type II variation; Extension of indication

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"
Request for Supplementary Information adopted on 26.06.2014, 20.03.2014. An Oral explanation was held on Tuesday 22 July 2014 at 14.00.

See also 11. Post-authorisation Issues

1.4. Community procedure oral explanations

No items

2. New applications

2.1. Opinions – New full applications

Accofil (EMEA/H/C/003956), (filgrastim), Applicant: Accord Healthcare Ltd, (reduction in the duration of neutropenia and the incidence of febrile neutropenia)
Similar biological application (Article 10(4) 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 restricted medical prescription. The summary of opinion was circulated for information.

Busulfan Fresenius Kabi (EMEA/H/C/002806), (busulfan), Applicant: FRESENIUS KABI ONCOLOGY PLC, Generic of Busilvex, (conditioning prior to conventional haematopoietic progenitor cell transplantation (HPCT))
Generic application (Article 10(1) of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 22.05.2014. List of Questions adopted on 19.12.2013. The Committee confirmed that all issues previously identified in this application had been addressed. The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The legal status was agreed as medicinal product subject to restricted medical prescription.
The summary of opinion was circulated for information. The CHMP adopted the similarity assessment report.

Imbruvica (EMEA/H/C/003791), Orphan, (ibrutinib), Applicant: Janssen-Cilag International NV, (treatment of mantle cell lymphoma, chronic lymphocytic leukaemia, small lymphocytic lymphoma)
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 20.03.2014. The Committee was reminded of the status of this application and its remaining outstanding issues 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 ibrutinib is a new active substance, as claimed by the applicant. The Icelandic and Norwegian Members were in agreement with the CHMP recommendation. The legal status was agreed as medicinal product subject to restricted medical prescription. The summary of opinion was circulated for information. The CHMP adopted the updated CHMP similarity assessment report for Imbruvica.

Xultophy (EMEA/H/C/002647), (insulin degludec / liraglutide), Applicant: Novo Nordisk A/S, (treatment of type 2 diabetes mellitus)
Fixed combination application (Article 10b of Directive No 2001/83/EC). Oral explanation held in June 2014. List of Outstanding Issues adopted on 26.06.2014, 20.03.2014. List of Questions adopted on 24.10.2013. The CHMP discussed the wording of the indication, and how prescriptive the wording should be. In addition the feasibility of initiation by a medical expert was considered. Furthermore the CHMP

discussed the PRAC recommendation for educational material and the members agreed to the PRAC recommendation. The Committee further discussed the wording of the indication. The Committee confirmed that all issues previously identified in this application had been addressed. The Committee adopted a positive opinion by majority (18 positive out of 31 votes) recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable. The Icelandic Member was in agreement with the CHMP recommendation. The Norwegian member was not in agreement. The legal status was agreed as medicinal product subject to medical prescription.
The divergent position (Alar Irs, Bruno Sepodes, Daniel Brasseur, Daniel Melchiorri, Greg Markey, Hubert Leufkens, Ingunn Hagen Westgaard, Ivana Mikacic, Jacqueline Genoux-Hames, Jan Mazag, Jens Heisterberg, Natalja Karpova, Pieter de Graeff, Robert Hemmings) was appended to the opinion.
The summary of opinion was circulated for information.

Zydelig (EMEA/H/C/003843), (idelalisib), Applicant: Gilead Sciences International Ltd, (treatment of patients with relapsed chronic lymphocytic leukaemia (CLL) and refractory indolent non-Hodgkin lymphoma (iNHL)). 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 20.03.2014. 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 idelalisib is a new active substance, as claimed by the marketing authorisation holder. 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 members noted the letter of recommendation dated 22 July 2014.The summary of opinion was circulated for information.

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

(EMEA/H/C/003969), (aclidinium / formoterol fumarate dihydrate), (maintenance bronchodilator treatment for airflow obstruction and relief of symptoms in adult patients with chronic obstructive pulmonary disease (COPD)), List of Questions adopted on 20.03.2014. 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.

(EMEA/H/C/003724), Orphan, (eliglustat), Applicant: Genzyme Europe BV, (treatment of Gaucher disease type 1) List of Questions adopted on 20.02.2014. 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.

(EMEA/H/C/003745), (aclidinium / formoterol fumarate dihydrate), (maintenance bronchodilator treatment for airflow obstruction and relief of symptoms in adult patients with chronic obstructive pulmonary disease (COPD)), List of Questions adopted on 20.03.2014. 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.

(EMEA/H/C/003687), (naltrexone / bupropion), (indicated for the management of obesity)
List of Questions adopted on 20.02.2014. The Committee was reminded of the status of this application and its remaining outstanding issues. The Committee adopted a List of Outstanding Issues. The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the List of Outstanding Issues with a specific timetable.

(EMEA/H/C/003771), (nonacog gamma), (treatment of haemophilia B)
List of Questions adopted on 20.03.2014. The Committee was reminded of the status of this application and its remaining outstanding issues. As there are issues for other recombinant FIX products on the market or in development, a statement should be included in the core SmPC for FIX products. The Committee adopted a List of Outstanding Issues with a specific timetable. The CHMP agreed to ask the Blood Product Working Party to revise the core SmPC for FIX products accordingly. The BWP report was adopted.

(EMEA/H/C/002780), (ospemifene), (treatment of vulvar and vaginal atrophy (VVA))
List of Outstanding Issues adopted on 20.03.2014. List of Questions adopted on 25.07.2013. The Committee was reminded of the status of this application and its remaining outstanding issues. The Committee adopted a List of Outstanding Issues. The CHMP agreed to the request by the applicant for an extension to clock stop to respond to the List of Outstanding issues with a specific timetable.

(EMEA/H/C/002569), (nintedanib), (treatment of non-small cell lung cancer (NSCLC))
List of Questions adopted on 20.02.2014. 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.

2.3. Day 120 List of questions – New full applications

(EMEA/H/C/003951), (budesonide / formoterol), (treatment of asthma and treatment of patients with severe COPD), 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/003952), (budesonide / formoterol), (treatment of asthma and treatment of patients with severe COPD), 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/003953), (budesonide / formoterol), (treatment of asthma)
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/004000), (duloxetine), (treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalised anxiety disorder), 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/003776), (ferric citrate coordination complex), (treatment of hyperphosphataemia), The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions.

(EMEA/H/C/003852), (human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)), (treatment of HPV diseases), 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 BWP report was adopted.

(EMEA/H/C/003759), (guanfacine), (treatment of Attention Deficit Hyperactivity Disorder (ADHD)) 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/003823), (lamivudine / raltegravir), (treatment of human immunodeficiency virus (HIV-1)), 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/003819), (ceritinib), (treatment of adult patients with previously treated anaplastic lymphoma, treatment of anaplastic lymphomakinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC)), 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/003850), (sofosbuvir / ledipasvir), (treatment of chronic hepatitis C)
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/003737), (voriconazole), (treatment of fungal infections)
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/002801), Orphan, ATMP, (allogeneic t cells genetically modified to express suicide gene), Applicant: MolMed SpA, (treatment in haploidentical haematopoietic stem cell transplantation), The Committee discussed the issues identified in this application. The Committee agreed on the recommendation and scientific discussion as adopted by CAT, together with the updated List of Questions. The BWP report was adopted.

2.4. Update on on-going new applications for Centralised Procedures

(EMEA/H/C/002788), Orphan, (tolvaptan), Applicant: Otsuka Pharmaceutical Europe Ltd, (treatment of autosomal dominant polycystic kidney disease (ADPKD)), List of Questions adopted on 25.04.2014. The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the Day 120 List of Questions adopted in April 2014.

(EMEA/H/C/002749), (lutetium, isotope of mass 177), (used only for the radiolabelling of carrier molecules), The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the Day 120 List of Questions adopted in June 2014.

(EMEA/H/C/003821), Orphan, (nintedanib), Applicant: Boehringer Ingelheim International GmbH, (treatment of Idiopathic Pulmonary Fibrosis (IPF)), The CHMP adopted the CHMP similarity assessment report.

(EMEA/H/C/002548), Orphan, (afamelanotide), Applicant: Clinuvel (UK) Limited, (treatment of phototoxicity in adult patients with erythropoietic protoporphyria (EPP)). List of Outstanding Issues adopted on 23 March 2013. List of Questions adopted on 19 July 2012. The CHMP noted the Minutes and answers from the CHMP ad-hoc expert group meeting for afamelanotide. The CHMP discussed the areas of specific interest to receive the views from the patient experts on. They will be adopted via written procedure after the Plenary.

2.5. Products in the Decision Making Phase

Masican (EMEA/H/C/002670), Orphan (Masitinib Mesylate), Applicant: AB Science, New active substance (Article 8(3) of Directive No 2001/83/EC). The CHMP was informed about communication from the applicant on the EPAR wording as well as the published CHMP minutes. The CHMP has been aware of A.B. Science that the program of masitinib in non-oncology indications is on-going in Europe. The CHMP agreed that no amendments of the Minutes and EPAR were needed but that the procedures should be explained to the applicant.

3. Extension of marketing authorisation according to Annex I of Reg. 1234/2008-Line extension procedures

3.1. Extension of marketing authorisation according to Annex I of Reg. 1234/2008; Opinions

Humalog (EMEA/H/C/000088/X/0125), (insulin lispro), MAH: Eli Lilly Nederland B.V., Rapporteur: Robert James Hemmings, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Julie Williams, “to add a new strength (200 U/ml KwikPen presentation)”. List of Questions adopted on 25.04.2014. The Committee confirmed that all issues previously identified in this application had been addressed. The Committee adopted a positive opinion by consensus, together with the CHMP assessment report and Translation timetable. The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

Jakavi (EMEA/H/C/002464/X/0013), Orphan, (ruxolitinib), MAH: Novartis Europharm Ltd, Rapporteur: Filip Josephson, "to add a new strength 10 mg tablet". The Committee confirmed that no issues have been identified in this application. The Committee adopted a positive opinion by consensus, together with the CHMP assessment report and Translation timetable. The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

Liprolog (EMEA/H/C/000393/X/0092), (insulin lispro), MAH: Eli Lilly Nederland B.V., Informed Consent of Humalog, Rapporteur: Robert James Hemmings, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Julie Williams, "to add a new strength (200 U/ml KwikPen presentation)"
List of Questions adopted on 25.04.2014. The Committee confirmed that all issues previously identified in this application had been addressed. The Committee adopted a positive opinion by consensus, together with the CHMP assessment report and Translation timetable. The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

Noxafil (EMEA/H/C/000610/X/0033), (posaconazole), MAH: Merck Sharp & Dohme Limited, Rapporteur: Rafe Suvarna, PRAC Rapporteur: Julie Williams, "Line extension to Noxafil 300 mg (18mg/ml) concentrate for solution for infusion". List of Outstanding Issues adopted on 22.05.2014. 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 by consensus, together with the CHMP assessment report and Translation timetable. The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

Zoledronic acid Teva (EMEA/H/C/002439/X/0008), (zoledronic acid), MAH: Teva Pharma B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "Line extension to include a new pharmaceutical form, solution for infusion. The new pharmaceutical form has three new presentations."
List of Questions adopted on 25.04.2014. The Committee confirmed that all issues previously identified in this application had been addressed. The Committee adopted a positive opinion by consensus, together with the CHMP assessment report and Translation timetable. The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

3.2. Extension of marketing authorisation according to Annex I of Reg. 1234/2008; Day 180 List of outstanding issues

Signifor (EMEA/H/C/002052/X/0010), Orphan, (pasireotide), MAH: Novartis Europharm Ltd, Rapporteur: Kristina Dunder, Co-Rapporteur: Joseph Emmerich, PRAC Rapporteur: Qun-Ying Yue, "Line extension application for Signifor to add 20mg, 40mg and 60mg powder and solvent for suspension for injection in the treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative, or who are inadequately controlled on treatment with other somatostatin analogues."
List of Questions adopted on 20.03.2014. The Committee was reminded of the status of this application and its remaining outstanding issues, which mainly focused on the quality part (dissolution testing) and the wording of the indication. The Committee adopted a List of Outstanding Issues with a specific timetable.

3.3. Extension of marketing authorisation according to Annex I of Reg. 1234/2008; Day 120 List of Questions

Orfadin (EMEA/H/C/000555/X/0042), Orphan, (nitisinone), MAH: Swedish Orphan Biovitrum International AB, Rapporteur: Luca Pani, "To add a new strength 20 mg capsule, hard." The Committee discussed the issues identified in this application. The members considered that further clarification was required for some quality issues as well as the SmPC wording. The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions.

Revlimid (EMEA/H/C/000717/X/0073/G), Orphan, (lenalidomide), MAH: Celgene Europe Limited, Rapporteur: Pierre Demolis, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Isabelle Robine, "A type II variation (C.I.6) to add the following indication: "Revlimid is indicated for the continuous treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant." A line extension application to add the following strength: 20 mg (21 capsules pack). The Committee discussed the issues identified in this application. The members agreed that further clarification was required on the efficacy and safety of the drug regimens. 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 Reg. 1234/2008

No items

4. Type II variations - Extension of indication procedures

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

Baraclude (EMEA/H/C/000623/II/0041), (entecavir), MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson, Co-Rapporteur: Pierre Demolis, PRAC Rapporteur: Qun-Ying Yue, "Extension of indication to include treatment of chronic HBV infection in paediatric patients from 2 to <18 years of age with compensated liver disease and evidence of active viral replication and persistently elevated serum ALT levels". Request for Supplementary Information adopted on 20.02.2014. 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.

Busilvex (EMEA/H/C/000472/II/0019), (busulfan), MAH: Pierre Fabre Médicament, Rapporteur: Arantxa Sancho-Lopez, "Extension of indication for Busilvex following fludarabine (FB) as conditioning treatment prior to haematopoietic progenitor cell transplantation (HPCT) in adult patients who are candidates for a reduced-intensity conditioning (RIC) regimen. Consequently, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC and the package leaflet are updated. The MAH also took the opportunity to update the product information in line with QRD template version 9.0." Request for Supplementary

Information adopted on 20.03.2014, 24.10.2013. See also 1.3 Post-authorisation Procedure Oral explanations. An Oral explanation was held on Tuesday 22 July 2014 at 9.00. The company addressed the outstanding issues identified by the CHMP, mainly on the benefit/risk in the proposed indication. The efficacy and the safety data were summarised as well as a literature analysis presented to support the combination of busulfan and fludarabine in the Myeloablative Controlled regimens (MAC) as well as the RIC setting. After the oral explanation the members further discussed the available data in the two presented settings. The Committee confirmed that all issues previously identified in this application for the RIC setting had been resolved. The Committee adopted a positive opinion by consensus for RIC together with the CHMP assessment report and translation timetable. The members noted the letter of recommendations dated 23 July 2014. The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations. The summary of opinion was circulated for information.

ECALTA (EMEA/H/C/000788/II/0026), (anidulafungin), MAH: Pfizer Limited, Rapporteur: Pieter de Graeff, Co-Rapporteur: Jens Ersbøll, PRAC Rapporteur: Sabine Straus, "Following the CHMP assessment of efficacy and safety data of Ecalta in neutropenic patients with invasive candidiasis and non-neutropenic patients with Cancida spp. deep tissue infection (MEA 014.3), extension of indication to include neutropenic patient for Ecalta. As a consequence, update of sections 4.1, 4.4, 4.8 and 5.1 of the SmPC in order to add a warning, update the safety information and reflect additional data in neutropenic patients. The Package Leaflet is updated in accordance. Furthermore, the Product Information is being brought in line with the latest QRD template version 9." 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 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.

Humira (EMEA/H/C/000481/II/0127), (adalimumab), MAH: AbbVie Ltd., Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Melchiorri, "Extension of indication in Enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. Consequently, the MAH proposed the update of sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC. The Package Leaflet was proposed to be updated in accordance." Request for Supplementary Information adopted on 20.03.2014. 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.

InductOs (EMEA/H/C/000408/II/0071), (dibotermin alfa), MAH: Medtronic BioPharma B.V., Rapporteur: Pieter de Graeff, Co-Rapporteur: Janne Komi, PRAC Rapporteur: Menno van der Elst, "Extension of indication to broaden the use of Inductos in interbody lumbar spine fusion." The Committee discussed the issues identified in this application, mainly relating the clinical efficacy and safety data for the proposed subgroups. The Committee adopted a Request for Supplementary Information with a specific timetable.

Ozurdex (EMEA/H/C/001140/II/0015), (dexamethasone), MAH: Allergan Pharmaceuticals Ireland, Rapporteur: Greg Markey, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Julie Williams, "Extension of Indication to include in SmPC section 4.1 a new indication for the treatment of adult patients with visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.
As a consequence, update of section 4.2, 4.3, 4.4, 4.8, 5.1 and 5.2 of the SmPC to provide posology recommendations, update the safety information and provide relevant clinical data on the pharmacodynamic and pharmacokinetic properties. The package leaflet (PL) was updated accordingly. In addition, the HCP leaflet which is provided as tear off section at the end of the PL was reduced to safety information only. In addition, the MAH took the opportunity to update the list of local representatives for Austria in the Package Leaflet. Furthermore, the product information (PI) was updated to include information on the reporting of suspected adverse reactions in line with the latest QRD template version 9.0. In addition, editorial changes were made throughout the PI including Annex II. Amendments were also made to increase the clarity of the safety information." Request for Supplementary Information adopted on 26.06.2014, 20.02.2014, 24.10.2013. The CHMP discussed the benefit/risk balance of the proposed restricted indication. The Committee continued to discuss the wording of the indication. 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.

RoActemra (EMEA/H/C/000955/II/0032), (tocilizumab), MAH: Roche Registration Ltd, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of Indication to include treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC and the Package Leaflet are updated. In addition, minor editorial changes are implemented in the SmPC, Annex II and PL." Request for Supplementary Information adopted on 25.04.2014, 21.11.2013. 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.

Soliris (EMEA/H/C/000791/II/0066), Orphan, (eculizumab), MAH: Alexion Europe SAS, Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Pierre Demolis, "Update of sections 4.1 and 5.1 of the SmPC with an extension of the indication in patients with Paroxysmal nocturnal haemoglobinuria (PNH) regardless of their history of transfusion. The PL has been updated accordingly. In addition, some minor corrections are proposed in Section 5.1 of the SmPC and in the PL." The Committee discussed the issues identified in this application, mainly relating the clinical efficacy data for the proposed indication. The Committee adopted a Request for Supplementary Information with a specific timetable.

Tracleer (EMEA/H/C/000401/II/0066), (bosentan), MAH: Actelion Registration Ltd., Rapporteur: Pierre Demolis, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Evelyne Falip, "Extension of Indication to include treatment of symptomatic pulmonary arterial hypertension in paediatric patients aged from 3 months to 18 years. The SmPC has been updated in order to include the data generated in studies conducted according to the agreed Paediatric Investigational Plan for bosentan

(EMEA-000425-PIP02-10-M04). As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC have been updated. The Package Leaflet has been updated accordingly. In addition, taking into account the new data in the paediatric population, an updated version of the RMP (version 5) has been provided." The Committee discussed the issues identified in this application, mainly concerning the clinical data with specific focus on the pharmacokinetic profile and whether bridging to the adult population was considered acceptable. The Committee adopted a Request for Supplementary Information with a specific timetable.

Xagrid (EMEA/H/C/000480/II/0059), Orphan, (anagrelide), MAH: Shire Pharmaceutical Contracts Ltd., Rapporteur: Pierre Demolis, Co-Rapporteur: Daniel Brasseur, "The MAH proposed a variation to update the indication for use in paediatric patients aged 6 to 17 years. The proposed updates to the SmPC and PL include sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2. The PL is proposed to be updated accordingly. The MAH also took the opportunity to update the list of local representatives." Request for Supplementary Information adopted on 22.05.2014. The Committee discussed the issues identified in this application, mainly relating to the starting dose in children and adolescents. The Committee adopted a Request for Supplementary Information with a specific timetable.

XGEVA (EMEA/H/C/002173/II/0016), (denosumab), MAH: Amgen Europe B.V., Rapporteur: Kristina Dunder, Co-Rapporteur: Jan Mueller-Berghaus, "The MAH has applied for an Extension of indication to add treatment of giant cell tumour of bone in adults or skeletally mature adolescents. As a consequence, it is proposed to update sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and to update the Package Leaflet accordingly." Request for Supplementary Information adopted on 22.05.2014, 19.09.2013, 21.03.2013. 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.

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 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, mainly requesting clarification on efficacy and safety data aspects. The Committee adopted a Request for Supplementary Information with a specific timetable.

4.2. Update on on-going Type II variation - Extension of indications

No items

5. Ancillary medicinal substances in medical devices

5.1. Opinions / Day 180 List of outstanding issues / Day 120 List of Questions

No items

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 6(9) of Commission Regulation EC No 1085/2003

Avastin (EMEA/H/C/000582/II/0059), (bevacizumab), MAH: Roche Registration Ltd, Re-examination Rapporteur: Robert Hemmings, Re-examination Co-Rapporteur: George Aislaitner, Re-examination PRAC Rapporteur: Julie Williams, "Update of section 4.1 of the SmPC in order to extend the indication of Avastin in combination with radiotherapy and temozolomide for the treatment of adult patients with newly diagnosed glioblastoma." Opinion adopted on 22.05.2014. The CHMP noted the re-examination timetable.

8. Withdrawal of Application

Neofordex (EMEA/H/C/002418), Orphan (dexamethasone acetate), Applicant: Laboratoires Ctrs - Boulogne Billancourt, (treatment of symptomatic multiple myeloma). The CHMP noted the letter from the applicant informing of the decision to withdraw the marketing authorisation application. The question-and-answer document was noted.

Imagify (EMEA/H/C/002347), (perflubutane), MAH: Acusphere Ltd, (ultrasound imaging agent indicated for the detection of coronary artery disease (CAD)). Oral explanation in May 2014. List of Outstanding Issues adopted on 22.05.2014, 20.03.2014, 21.11.2013. List of Questions adopted on 21.02.2013. The CHMP noted the SAG report. Several experts considered sensitivity and specificity as more appropriate primary outcomes than accuracy. Some recommendations concerning the standard of truth (gold standard) were made. The experts did not consider the variability of echocardiography and SPECT readings as unusual. The SAG concluded that the use of stress echocardiography with a contrast agent improves image quality compared to stress echo alone. However the size of additional sensitivity could not be estimated as no direct comparison data was available. The SAG remained uncertain regarding the level of risk associated with the product. The experts made some recommendation concerning the most appropriate patient population. The members discussed the lack of data on sensitivity and specificity. Furthermore concern was expressed on some potential safety issues. An oral explanation was held on Monday 21 July 2014 at 17.15 pm. The oral explanation focused on the clinical benefit and the positioning of the product and outlined efficacy and safety data. Furthermore they

presented the diagnostic benefit versus non-contrast. The CHMP noted that the applicant withdrew the application. See also section I Oral Explanation

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

No items

10. Pre-submission issues

(H0003766)
(evolocumab), (hyperlipidaemia and mixed dyslipidaemia, homozygous familial hypercholesterolaemia). The CHMP did not agree to the accelerated assessment request and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

(H0003727), Orphan
(lenvatinib), Applicant: Eisai Ltd, (treatment of radioiodine refractory differentiated thyroid cancer in adults). The CHMP agreed to the accelerated assessment request and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

(H0003985)
(nivolumab), (treatment of advanced (unresectable or metastatic) melanoma). The CHMP agreed to the accelerated assessment request and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

11. Post-authorisation issues

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". Request for Supplementary Information adopted on 26.06.2014, 20.03.2014. See also 1.3 Post-authorisation Procedure Oral explanations. The members were reminded of previous discussions and the remaining issues. An Oral explanation was held on Tuesday 22 July 2014 at 14.00. The MAH outlined the risk minimisation activities and presented some technical aspects of the spray configuration. The Committee adopted a Request for Supplementary Information with a specific timetable.

VELCADE (EMEA/H/C/000539) (bortezomib), MAH: Janssen-Cilag International N.V., Rapporteur: Daniela Melchiorri, Co-Rapporteur: Outi Mäki-Ikola, (treatment of multiple myeloma), Complete application (stand-alone) - Council Directive 81/851/EEC. The CHMP noted the DHPC and communication plan agreed via written procedure.

Doribax (EMEA/H/C/000891) (Doripenem Monohydrate), MAH: Janssen-Cilag International N.V., Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs, (treatment of nosocomial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections), New active substance (Article 8(3) of Directive No 2001/83/EC). The CHMP noted the letter by the MAH notifying of voluntary withdrawal of the marketing authorisation.

Vistide (**EMEA/H/C/000121)** (Cidofovir), MAH: Gilead Sciences International Ltd, Rapporteur: Bruno Sepodes, Co-Rapporteur: Rafe Suvarna, (treatment of CMV retinitis in patients with AIDS), Complete application (stand-alone) - Council Directive 81/851/EEC). The CHMP noted the letter by the MAH notifying of voluntary withdrawal of the marketing authorisation.

Rienso (EMEA/H/C/002215/PSUV/014) (Ferumoxytol), MAH: Takeda Pharma A/S, Rapporeur: Harald Enzmann, Co-Rapporteur: Romaldas Mačiulaitis, New active substance (Article 8(3) of Directive No 2001/83/EC). The members were updated on fatal cases of hypersensitivity reactions reported with Rienso mainly from the US. The CHMP discussed the PRAC recommendation to amend the product information as well as the conditions to the marketing authorisation, which had been adopted by PRAC by majority during their July 2014 meeting. The CHMP adopted a positive opinion by majority (19 positive out of 33 votes), including additional minor changes to the product information.
The divergent position (Agnes Gyurasics, Bruno Sepodes, Concepcion Prieto Yerro, Daniel Brasseur, Dimitrios Kouvelas, Harald Enzmann, Ivana Mikacic, Jan Mueller-Berghaus, Jean-Louis Robert, Nela Vilceanu, Pierre Demolis, Piotr Fiedor, Stansilav Primozic, Sol Ruiz) was appended to the opinion.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The Committee agreed to the wording of DHPC letter and communication plan.

Simulect (EMEA/H/C/000207/II/0078), (basiliximab), MAH: Novartis Europharm Ltd, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, “Update of section 4.4 of the SmPC in order to add a warning on the fact that the efficacy and safety of Simulect for the prophylaxis of acute rejection in recipients of solid organ allografts other than renal have not been demonstrated.” The CHMP agreed to the PRAC advice. The Committee agreed to the wording of DHPC letter and communication plan.

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”. The members discussed the data from the phase II clinical trial which had been stopped prematurely following an interim analysis. In addition the Committee assessed the relevance of the information from the trial on the approved monotherapy indication of Giotrif, considering potential off label use of the product, and agreed that at this time no SmPC changes were warranted in the licensed indication. The Committee adopted a Request for Supplementary Information with a specific timetable.

MACI (EMEA/H/C/002522) (Matrix Applied Characterised Autologous Cultured Chondrocytes), MAH: Genzyme Europe BV, Rapporteur: Elaine French, Co-Rapporteur: Johannes H. Ovelgönne, CHMP Co-ordinators: Greg Markey and Johann Lodewijk Hillege, (repair of symptomatic cartilage defects of the

knee), New active substance (Article 8(3) of Directive No 2001/83/EC). The CHMP was updated on the marketing authorisation status and the biopsies. The members were informed that 45 biopsies have been taken. 33 of those patients have responded whether they want to continue with the treatment or not. Once the EMA will be notified of the closure of manufacturing facility, the marketing authorisation should be suspended with the condition to register a new manufacturing site or the lifting of the MA to be considered. Furthermore the MAH should ensure storage of the remaining biopsies.

InductOs (EMEA/H/C/000408) (Dibotermin Alfa), MAH: Medtronic BioPharma B.V., Rapporteur: Pieter de Graeff, Co-Rapporteur: Janne Komi, (treatment of anterior lumbar spine fusion and tibia fractures), Complete application (stand-alone) - Council Directive 81/851/EEC. The CHMP discussed the new information.

Pandemrix (EMEA/H/C/000832) (Split Influenza Virus, Inactivated, Containing Antigen: A/California/7/2009 (H1n1)V Like Strain (X-179a) (Produced In Eggs)), MAH: GlaxoSmithKline Biologicals, Rapporteur: Rafe Suvarna, Co-Rapporteur: Johann Lodewijk Hillege, (prophylaxis of influenza), New active substance (Article 8(3) of Directive No 2001/83/EC). The members noted the letters from the MAH dated 14 and 15 July 2014 regarding expiry of the Marketing Authorisation and the reproducibility of the ELISPOT assay.

Tritanrix HB (EMEA/H/W/003838) and Tritanrix HB + Hib (Bordetella Pertussis (Inactivated), Diphtheria Toxoid, Hepatitis B Surface Antigen, Tetanus Toxoid), MAH: GlaxoSmithKline Biologicals S.A., (indicated for active immunisation against diphtheria, tetanus, pertussis and hepatitis B; indicated for active immunisation against diphtheria, tetanus, pertussis and hepatitis B (HBV)), Article 58 of Regulation (EC) No 726/2004. The CHMP noted the letter from the MAH informing on the discontinuation of Tritanrix HB and Tritanrix HB + Hib production.

Opgenra (EMEA/H/C/000819) (Eptotermin Alfa), MAH: Olympus Biotech International Limited, Rapporteur: Janne Komi, Co-Rapporteur: Patrick Salmon, (treatment of spondylolisthesis), Known active substance (Article 8(3) of Directive No 2001/83/EC). The Committee noted the Letter from the MAH informing of their decision to permanently cease marketing Opgenra and Osigraft on 31 July for commercial reasons and not related to the quality, safety and efficacy of the product.
See Osigraft.

Osigraft (EMEA/H/C/000293) (Eptotermin Alfa), MAH: Olympus Biotech International Limited, Rapporteur: Janne Komi, Co-Rapporteur: Patrick Salmon, (treatment of nonunion of tibia), Complete application (stand-alone) - Council Directive 81/851/EEC
The Committee noted the Letter from the MAH informing of their decision to permanently cease marketing Opgenra and Osigraft on 31 July for commercial reasons and not related to the quality, safety and efficacy of the product.
See Opgenra.

12. Referral Procedures

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

No items

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), Rapporteur: Robert Hemmings, Co-Rapporteur: Martina Weise,
Review of the module 3 (quality) and European Pharmacopeia monograph triggered by the EMA Executive Director. The Committee discussed the outstanding issues relating to the potency of colistimethate sodium as well as the stability of this substance. The CHMP adopted a List of Outstanding Issues to the MAHs with a specific timetable. CHMP discussion/CHMP list of outstanding issues: July 2014 CHMP; Responses to list of outstanding issues by MAHs: 01.09.2014; Assessment reports: 08.10.2014; Comments from CHMP: 13.10.2014; CHMP discussion/CHMP opinion: October 2014 CHMP
The CHMP adopted the PKWP report on the adequacy of the PK data submitted by the MAH in the context of the on-going procedure (including a consultation of the MSWG (Modelling and Simulation Working Group)) and the IDWP report on the proposed revisions of the SmPC for polymyxin-based products.
See also section 12.6 Community Interests - Referral under Article 31.

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 2001/83/EC

No items

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

EMLA Cream (EMEA/H/A-30/1388) (lidocaine / prilocaine), Astra Zeneca group of companies and associated companies, Rapporteur: Martina Weise, Co-Rapporteur: Greg Markey,
Harmonisation exercise for EMLA Cream. The review was triggered by Germany, due to the need of harmonisation of the Summary of Product Characteristics across Member States. List of Questions adopted in October 2013. Extension of Timetable adopted in November 2013. List of Outstanding Issues adopted on 22.05.2014. The Committee was reminded of the status of this application and its remaining outstanding issues, mainly relating to SmPC wording. The CHMP adopted a List of Outstanding Issues to the MAH with a specific timetable.

2nd List of outstanding issues: 24.07.2014; Responses to list of outstanding issues: 20.08.2014; Restart of the procedure: 26.08.2014; Assessment report: 10.09.2014; Comments from CHMP: 15.09.2014; Oral explanation / CHMP Opinion: September 2014 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 November 2013. The Committee was reminded of the status of this application and its remaining outstanding issues, mainly relating to SmPC wording.The CHMP adopted a List of Outstanding Issues to the MAH with a specific timetable.

Second list of outstanding issues: 24.07.2014; Responses to second list of outstanding issues: 01.09.2014; Restart of the procedure: 23.09.2014; Assessment report: 08.10.2014; Comments from CHMP: 13.10.2014; CHMP Opinion: October 2014 CHMP

Call for comments on the draft list of products for SmPC harmonisation for 2014

Durogesic (fentanyl), Janssen-Cilag
Innohep (tinazaparin sodium), Leo Laboratories Limited/
Etopophos / Vepesid (etoposide), Bristol-Myers Squibb Holdings Limited.
The CHMP discussed the draft list for SmPC harmonisation as prepared by the CMDh to be released for public consultation. The CHMP agreed to the consultation. The CHMP requested to be involved in the finalisation of the list after public consultation. The members noted the de-briefing note from CMDh.

Haldol and associated names (EMEA/H/A-30/1393) (haloperidol), Janssen-Cilag Group of companies and associated companies
Rapporteur: Martina Weise, Co-Rapporteur: Ivana Mikacic, The CHMP agreed to the request by the MAH for an additional extension to the clock stop to respond to the List of Questions adopted in June 2014 with a specific timetable.

Responses to list of questions: 05.01.2015; Restart of the procedure: 27.01.2015; Assessment report: 11.02.2015; Comments from CHMP: 16.02.2015; List of outstanding issues or CHMP opinion: February 2015 CHMP

Haldol decanoate and associated names (EMEA/H/A-30/1405) (haloperidol) Janssen-Cilag Group of companies and associated companies
Rapporteur: Martina Weise, Co-Rapporteur: Ivana Mikacic, The CHMP agreed to the request by the MAH for an additional extension to the clock stop to respond to the List of Questions adopted in June 2014 with a specific timetable.

Responses to list of questions: 05.01.2015; Restart of the procedure: 27.01.2015; Assessment report: 11.02.2015; Comments from CHMP: 16.02.2015; List of outstanding issues or CHMP opinion: February 2015 CHMP

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

Emergency contraceptives (EMEA/H/A-31/1391)
NAPs: emergency contraceptive medicinal products containing levonorgestrel or ulipristal, CAP: ellaOne (ulipristal acetate), MAH: Laboratoire HRA Pharma SA, Rapporteur: Kristina Dunder, Co-Rapporteur: Pieter de Graeff, Influence of body weight and Body mass index (BMI) of women on the efficacy of the emergency contraceptives. List of Outstanding Issues on 22.05.2014. List of Questions adopted in January 2014. The Committee was reminded of the status of this application. The members discussed the SmPC wording and whether further information on the pharmacodynamic effect was required. The CHMP agreed that all outstanding issues were considered resolved. 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.

Gadolinium containing contrast agents, Gd-Cas (EMEA/H/A-31/1097)
Rapporteur: Rafe Suvarna, Co-Rapporteur: Pieter de Graeff, 4th annual cumulative safety reviews on NSF

The CHMP adopted the timetable for assessment of the 4th annual cumulative review submissions. Start: 27.07.2014; Preliminary Assessment Report: 10.09.2014; Comments: 16.09.2014; Final Assessment Report: 18.09.2014; Opinion: CHMP September 2014

Polymyxin-based products (EMEA/H/A-31/1383) (colistin, colistimethate), Rapporteur: Robert Hemmings, Co-Rapporteur: Joseph Emmerich,
Full benefit-risk review and update and harmonisation of the product information triggered by European Commission. The Committee discussed the outstanding issues relating to the potency of colistimethate sodium as well as the stability of this substance. The CHMP adopted a second List of Outstanding Issues to the MAH with a specific timetable. CHMP discussion/CHMP list of outstanding issues: July 2014 CHMP; Responses to list of outstanding issues by MAHs: 01.09.2014; Assessment reports: 08.10.2014; Comments from CHMP: 13.10.2014; CHMP discussion/CHMP opinion: October 2014 CHMP

The CHMP adopted the PKWP report on the adequacy of the PK data submitted by the MAH in the context of the on-going procedure (including a consultation of the MSWG (Modelling and Simulation Working Group)) and the IDWP report on the proposed revisions of the SmPC for polymyxin-based products. See also section 12.2 Requests for CHMP opinion under Article 5(3).

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)

No items

13. Pharmacovigilance issues

Summary of recommendations and advice of PRAC meeting held on 7-10 July 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 July 2014: **for adoption**	The EURD list was adopted.
Early Notification System: July 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
PRAC outcome on revision of class labelling of antiretrovirals on lactic acidosis, mitochondrial dysfunction and lipodystrophy and letters to be sent to the MAHs: **For adoption** Ziagen, Kivexa, Trizivir, Reyataz, , Prezista, Stocrin, Sustiva, Atripla, Stribild, Emtriva, Truvada, Eviplera, , Intelence, Telzir, Epivir/Lamivudine ViiV, Combivir, Kaletra/Aluvia, , Viramune, , Edurant, Norvir, Invirase, Zerit, Viread, Aptivus,	The CHMP agreed to the PRAC outcome on revision of class labelling of antiretrovirals on lactic acidosis, mitochondrial dysfunction and lipodystrophy and letters to be sent to the MAHs.

14. Inspections

14.1. GMP Inspections

Request for GMP Inspections: **for adoption**	*Disclosure of information relating to GMP inspections will not be published as undermining the purpose of such inspections.*

14.2. GCP Inspections

Request for GCP Inspections: **for adoption**	*Disclosure of information relating to GCP inspections will not be published as undermining the purpose of such inspections.*

14.3. Pharmacovigilance Inspections

	Disclosure of information relating to Pharmacovigilance inspections will not be published as undermining the purpose of such inspections.

14.4. GLP Inspections

Request for GLP Inspections: **for adoption**	*Disclosure of information relating to GLP inspections will not be published as undermining the purpose of such inspections.*

15. Innovation Task Force

15.1. Minutes of ITF: For information

15.2. Briefing meetings (Innovation Task Force)

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

15.3. Eligibility to EMA scientific services

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

Request from DG SANCO for EMA scientific Opinion under Art. 57 (1)P of Regulation (EC) No 726/2004 • Final report: **For adoption**	The CHMP adopted the opinion.
Request from EDQM for EMA scientific Opinion under Art. 57 (1)P of Regulation (EC) No 726/2004 • Draft report: **For information**	Postponed to September 2014.

15.5. Nanomedicines activities

16. Scientific Advice Working Party (SAWP)

Report from the SAWP meeting held on 7-10 July 2014. Table of conclusions: **for information**	The CHMP noted the report.
Scientific advice letters:	*Disclosure of information relating to scientific advice letters cannot be released at present time as deemed containing commercially confidential information.*

17. Satellite Groups / Other Committees

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 21-23 July 2014: **For information**	The CHMP noted the report.
Cardiovascular WP response to the request from the CMDh on the qualification of flecainide as a drug of narrow therapeutic index (NTI): **For adoption**	The CHMP adopted the response to CMDh, concluding that the confidence intervals for demonstration of bioequivalence for oral IR formulations containing flecainide should not be narrowed i.e. the standard acceptance range (80.00-125.00) should be applied.

CMDh request to PKWP on acceptability of Mahalanobis test for proof of comparable dissolution (biowaiver) for additional strengths of a bio-batch strength. • Response assessment report: **For adoption**	Postponed to September 2014.

18. Other Committees

18.1. Committee for Orphan Medicinal Products (COMP)

Press release of the COMP meeting held on 21-23: **for information**	To be sent in the Post-mail.

18.2. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 30 June -1 July 2014: **for information**	The CHMP noted the report.

18.3. Paediatric Committee (PDCO)

PIPs reaching D30 at July 2014 PDCO: **For information**	To be circulated in the MMD
Report from the PDCO meeting held on 16-18 July 2014: **For information**	The CHMP noted the report.
Request from the PDCO for the input regarding the draft Paediatric Investigation Plan for DTaP-containing combination vaccine: **For adoption**	The CHMP adopted the response.
Response from the CVS Working Party to the PDCO request on (R)-2-[3-({Benzoxazol-2-yl[3-(4-methoxyphenoxy)propyl]amino}methyl)phenoxy]butanoic acid (K-877) (EMEA-001573-PIP01-13): **Adopted by written procedure on 14 July 2014**	The CHMP noted the response which was adopted via written procedure on 14 July 2014.

18.4. Committee for Advanced Therapies (CAT)

Table of Decisions of CAT meeting held on 17-18 July 2014: **For information**	The CHMP noted the Table of Decision.

19. Invented name issues

Table of Decisions of the NRG meeting held on 2 July 2014: **For adoption**	Adopted.

20. Any Other Business

Follow up action plan Quality of Opinions	The members agreed on a workshop to be scheduled end of 2014/beginning of 2015 to train a limited number of national experts. Those experts would then update assessors at their NCA. A future role out of such training as webinar should be considered.
CHMP Work Plan 2015	The CHMP agreed on the proposed topics for the CHMP Work plan 2015.
CHMP visit to 30 Churchill Place on Tuesday 22 July 2014 at 19:15	The CHMP members were shown the new EMA building at 30 Churchill Place. They visited the meeting rooms as well as the delegates' area and shared areas. The next CHMP Plenary in September 2014 will be held in the new building.
Discussion on area of expertise of Co-opted Member: Jan Mueller –Berghaus mandate expires in November 2014.	The members noted the current expertise of the CHMP. Proposals for additional expertise in expectation of the mandate expiry of the co-opted member Jan Mueller-Berghaus should be sent. The agreement on the additional expertise is scheduled for the September CHMP Plenary.
Non-clinical and clinical module of the new Guideline on Influenza vaccines: **For adoption for 6-month consultation**	Adopted for 6-month public consultation
Election of **QWP** Vice Chairperson	The CHMP elected Keith Pugh as new QWP Vice Chairperson.
Election of the Vice-Chairperson of **BMWP**	The CHMP elected Martina Weise as new BMWP Vice Chairperson.
Election of the Vice-Chairperson of **IDWP**	The CHMP elected Maria Fernandez-Cortizo as new IDWP Vice Chairperson.
Election of the Vice-Chairperson of **VWP**	The CHMP elected Daniel Brasseur as new VWP Vice Chairperson.
Informal/Workshop Joint CHMP, CAT, COMP to be held in Rome, Italy on 29-30 October 2014 • Draft agenda: **For information**	The CHMP noted the draft agenda of the Informal/Workshop Joint CHMP, CAT, COMP.

Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals	The CHMP adopted the answers for public consultation until end of September 2014
Core Membership of SAG Oncology: **For adoption**	The CHMP adopted the Core Membership of SAG Oncology.
SmPC Advisory Group: update on recent Q&As which may affect a number of products	The CHMP noted the updated Q&A.
Questions and Answers on Wheat starch containing gluten in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use': **For adoption for 3-month consultation**	The CHMP adopted the Q&A for 3-month public consultation.
Industry Forum on pharmacovigilance: **For information**	The members were informed about the industry forum on pharmacovigilance and were asked for nominations to this forum. The first meeting is planned for the 16h of September 2014. Tomas Salmonson agreed to participate.
Concept Paper on good genomics practices: **For adoption**	The CHMP adopted the Concept Paper on good genomics practices.
Nomination of new BWP member: Erika Szabo (HU): **For agreement**	The CHMP endorsed Erika Szabo as new Hungarian BWP member.
IMI Protect study	The members were made aware of the project and the stakeholders involved in the IMI Protect project.
Request by PDCO for PKWP liaison	The CHMP advised the PDCO to interact with the PKWP chair for any issue.
Type II template and rolling timetable for type II variations: **for information**	The CHMP was updated on the new template for type II variations. The template will start being phased in from July 2014. Furthermore the members were informed about the new rolling timetables for type II variations, which are of the same duration as the standard ones but which will start every week. At the time of conclusion, draft opinion documents will be circulated to all committee members towards adoption of an opinion by the Committee via written procedure.

21. List of participants: including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 21-24 July 2014 meeting.

CHMP Chair	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction 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 restriction applies Product / substance
Andrea Laslop	Austria	Full involvement	
Daniel Brasseur	Belgium	Full involvement	
Mila Vlaskovska	Bulgaria	Full involvement	
Ivana Mikacic	Croatia	No participation in final deliberations and voting	Doribax (EMEA/H/C/000891) (doripenem monohydrate)
Panayiotis Triantafyllis	Cyprus	Full involvement	
Ondřej Slanař	Czech Republic	Full involvement	(H0003766)
			Emergency contraceptives (EMEA/H/A-31/1391)
			(EMEA/H/C/003850)
			(EMEA/H/C/003823)
			(EMEA/H/C/004000)
			(EMEA/H/C/002647)
		No participation in final deliberations and voting	(EMEA/H/C/003969)
			(EMEA/H/C/003745)
			(EMEA/H/C/003951)
			(EMEA/H/C/003952)
			(EMEA/H/C/003737)
			ECALTA (EMEA/H/C/000788/II/0026)
Jens Heisterberg	Denmark	Full involvement	
Alar Irs	Estonia	Full involvement	
Outi Mäki-Ikola	Finland	No participation in final deliberations and voting	(EMEA/H/C/000481/II/0127), (adalimumab)
			(EMEA/H/C/002173/II/0016), (denosumab)
			(EMEA/H/C/003776), (ferric citrate coordination complex)
			(H0003766)
			Rienso (EMEA/H/C/002215/PSUV/014)
Pierre Demolis	France	Full involvement	
Harald Enzmann	Germany	Full involvement	
Dimitrios Kouvelas	Greece	Full involvement	
Agnes Gyurasics	Hungary	Full involvement	
Kolbeinn Gudmundsson	Iceland	Full involvement	
David Lyons	Ireland	Full involvement	
Romaldas Mačiulaitis	Lithuania	Full involvement	

CHMP Member	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product / substance
Jacqueline Genoux-Hames	Luxembourg	Full involvement	
John Joseph Borg	Malta	Full involvement	
Pieter de Graeff	Netherlands	Full involvement	
Piotr Fiedor	Poland	Full involvement	
Bruno Sepodes	Portugal	Full involvement	
Nela Vilceanu	Romania	Full involvement	
Jan Mazag	Slovakia	Full involvement	
Stanislav Primožič	Slovenia	Full involvement	
Concepcion Prieto Yerro	Spain	Full involvement	
Kristina Dunder	Sweden	Full involvement	
Greg Markey	United Kingdom	Full involvement	
Jean-Louis Robert	Co-opted	Full involvement	
Robert James Hemmings	Co-opted	Full involvement	
Sol Ruiz	Co-opted	Full involvement	
Jan Mueller-Berghaus	Co-opted	Full involvement	
Hubert Leufkens	Co-opted	Full involvement	

CHMP Alternate	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product / substance
Bart Van der Schueren	Belgium	Full involvement	
Ana Dugonjić	CROATIA	Full involvement	
Radka Montoniová	Czech Republic	Full involvement	
Jens Ersbøll	Denmark	Full involvement	
Kersti Oselin	Estonia	Full involvement	
Joseph Emmerich	France	No participation in final deliberations and voting	EMLA Cream (EMEA/H/A-30/1388) Plendil (EMA/H/A-30/1385)
Martina Weise	Germany	Full involvement	
Melinda Sobor	Hungary	Full involvement	
Patrick Salmon	Ireland	Full involvement	
Daniela Melchiorri	Italy	Full involvement	Replacing CHMP member
Natalja Karpova	Latvia	Full involvement	Replacing CHMP member
Johann Lodewijk Hillege	Netherlands	Full involvement	
Ingunn Hagen Westgaard	Norway	No participation in final deliberations and voting	Replacing CHMP member Xtandi (EMEA/H/C/002639/II/0008) (enzalutamide)
Dinah Duarte	Portugal	Full involvement	
Jana Klimasová	Slovakia	Full involvement	
Arantxa Sancho-Lopez	Spain	Full involvement	
Filip Josephson	Sweden	Full involvement	
Rafe Suvarna	United Kingdom	Full involvement	

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	
	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.			
Jorge Camarero Jiménez	Spain	Full involvement	
Sabine Mayrhofer	Germany	Full involvement	
Dahlia Saccal Diab	France	Full involvement	
Isabelle Yoldjian	France	Full involvement	
Kristina Bech Jensen	Denmark	Full involvement	
Valerie Lescrainier	Belgium	Full involvement	
Ljiljana Milosevic-Kapetanovic	France	Full involvement	
Sophie Negellen	France	Full involvement	
Anne Driheme	France	Full involvement	
Martin Dalle	France	Full involvement	
David Silverman	United Kingdom	Full involvement	
Nicole Assmann	United Kingdom	Full involvement	
Vikas Jaitely	United Kingdom	Full involvement	

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.			
Tamar Wohlfarth	Netherlands	Full involvement	
Leon Bongers	Netherlands	Full involvement	
Leon van Aerts	Netherlands	Full involvement	
Berendina Maria van den Hoorn	Netherlands	Full involvement	
Karolina Kwiatek	Netherlands	Full involvement	
Rob van Ojen	Netherlands	Full involvement	
Lies (Elizabeth) Van Vlijmen	Netherlands	Full involvement	
Anna Maria Gerdina Pasmooij	Netherlands	Full involvement	
Nicole Visser	Netherlands	Full involvement	
Michael Pfleiderer	Germany	Full involvement	
Anneliese Hilger	Germany	Full involvement	
Clemens Mittmann	Germany	Full involvement	
Vera Luetgendorf	Germany	Full involvement	
Antonio Gomez-Outes	Spain	Full involvement	
Alfredo García-Arieta	Spain	Full involvement	
Maarten Simoons	EMA	Full involvement	
Massimo Cirillo	Italy	Full involvement	
Mair Powell	United Kingdom	Full involvement	
Frank Holtkamp	Netherlands	Full involvement	
Bertil Jonsson	Sweden	Full involvement	

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)*

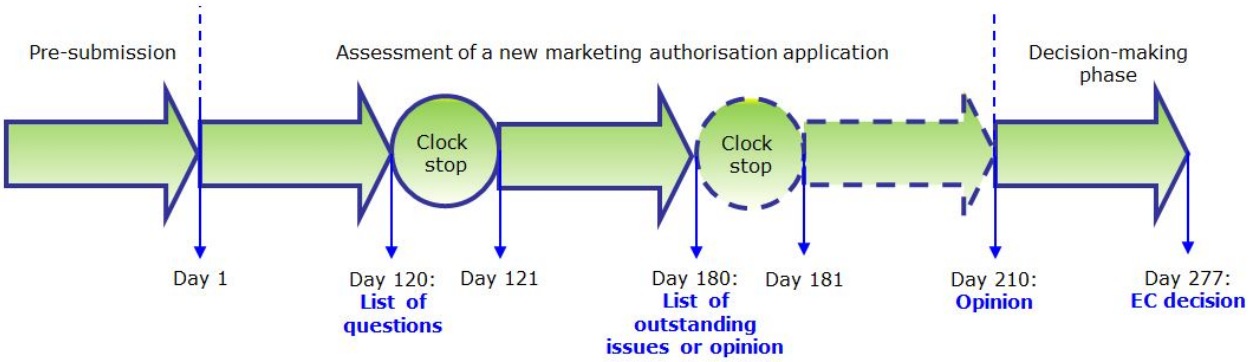
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 2 and 3) or referral procedures (section 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 a 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 a 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.