20 March 2014
EMA/CHMP/120991/2014
Procedure Management and Business Support Division

Committee for Medicinal Products for Human Use (CHMP)

Final minutes of the meeting held on 17-20 February 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.

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AGENDA (EMA/CHMP/723655/2014) and Annex to CHMP agenda of the CHMP plenary session to be held 17-20 February 2014: **For adoption**	The agenda and annex were adopted with amendments.
AGENDA of ORGAM meeting to be held within the CHMP plenary session of February 2014: **For adoption**	The agenda was adopted.
TIMESCHEDULE of the CHMP plenary session to be held 17-20 February 2014: **For adoption**	The timeschedule was adopted.
MINUTES (EMA/CHMP/59462/2014) of the CHMP plenary and session held 20-23 January 2014: **For adoption**	The Minutes of the CHMP plenary session held 20–23 January 2014 were adopted.
LIST of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary to be held on 17-20 February 2014: **For information**	*See February 2014 minutes (to be published post March 2014 CHMP meeting)* The pre-meeting list was noted.
CONFLICT OF INTERESTS	In accordance with the Agency's revised policy and procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of meeting (see end of document). All decisions taken at this meeting were made in presence of a quorum of members – i.e. 22 or more members were present in the room.
Draft Agenda of CHMP plenary to be held on 17-20 March 2014 CHMP: **For information**	The draft agenda was noted.

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1 ORAL EXPLANATIONS

1.1 Pre-authorisation Procedure Oral Explanations

(EMEA/H/C/002570), Orphan, (etarfolatide), Applicant: Endocyte Europe, B.V., (indicated for single photon emission computed tomography (SPECT) imaging)
List of Outstanding Issues adopted in November 2013 and January 2014.
List of Questions adopted in March 2013.
An Oral Explanation was held on Tuesday 18 February 2014 at 14.00.

(EMEA/H/C/002773), Orphan, (folic acid), Applicant: Endocyte Europe, B.V., (indicated for the enhancement of etarfolatide single photon emission computed tomography (SPECT) image quality)
List of Outstanding Issues adopted in November 2013 and January 2014.
List of Questions adopted in March 2013.
An Oral Explanation was held on Tuesday 18 February 2014 at 14.00.
See (EMEA/H/C/002570)

(EMEA/H/C/002571), Orphan, (vintafolide), Applicant: Endocyte Europe, B.V., (treatment of platinum resistant ovarian cancer (PROC))
List of Outstanding Issues adopted in November 2013 and January 2014.
List of Questions adopted in March 2013.
An Oral Explanation was held on Tuesday 18 February 2014 at 14.00.
See (EMEA/H/C/002570)

(EMEA/H/C/002782), (vedolizumab), (treatment of Ulcerative Colitis and Crohn's Disease)
List of Outstanding Issues adopted in December 2013.
List of Questions adopted in July 2013.
An Oral Explanation was held on Tuesday 18 February 2014 at 9:00.
The Committee adopted the BWP Report.

1.2 Re-examination procedure oral explanation

No items

1.3 Post-authorisation procedure oral explanation

No items

1.4 Referral procedure oral explanations

Protelos (EMEA/H/C/000560)
(Strontium Ranelate), Les Laboratoires Servier, Rapporteur: Bengt Ljungberg, Co-Rapporteur: Andrea Laslop, (treatment of osteoporosis)
PRAC outcome at January 2014 PRAC meeting. Oral explanation held in January 2014.
The Committee agreed that no Oral Explanation was needed at this time.
See also 12.1 Procedure for Centrally Authorised products under Article 20 Council Regulation (EC) No 726/2004

Osseor (EMEA/H/C/000561)
(Strontium Ranelate), Les Laboratoires Servier, Rapporteur: Bengt Ljungberg, Co-Rapporteur: Andrea Laslop, (treatment of osteoporosis).
PRAC outcome at January 2014 PRAC meeting. Oral explanation held in January 2014.
The Committee agreed that no Oral Explanation was needed at this time.
See also 12.1 Procedure for Centrally Authorised products under Article 20 Council Regulation (EC) No 726/2004

2 NEW APPLICATIONS

2.1 Opinions – New full applications

ANORO (EMEA/H/C/002751), (umeclidinium bromide/vilanterol), Applicant: Glaxo Group Ltd., (treatment of chronic obstructive pulmonary disease (COPD))
New active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted in November 2013, September 2013.
List of Questions adopted in May 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 majority (27 positive out of 29 votes), together with the translation timetable.
Furthermore, the CHMP considered that umeclidinium bromide 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 (Daniela Melchiorri, Concepcion Prieto-Yerro) was appended to the opinion.
The legal status was agreed as medicinal product subject to medical prescription.
The summary of opinion was circulated for information.
Post meeting note: The final assessment report was adopted after the Plenary via written procedure.

Laventair (EMEA/H/C/003754), (umeclidinium bromide/vilanterol), Applicant: Glaxo Group Ltd, Duplicate, Duplicate of ANORO, (treatment of chronic obstructive pulmonary disease (COPD))
New active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted in November 2013, September 2013.
List of Questions adopted in May 2013.
See Anoro

DuoResp Spiromax (EMEA/H/C/002348), (budesonide/formoterol), Applicant: Teva Pharma B.V., (treatment of asthma and COPD)
Hybrid application (Article 10(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted in December 2013.
List of Questions adopted in July 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 medical prescription.
The summary of opinion was circulated for information.

BiResp Spiromax (EMEA/H/C/003890), (budesonide / formoterol), Applicant: Teva Pharma B.V., Duplicate of DuoResp Spiromax, (treatment of asthma and COPD)
Hybrid application (Article 10(3) of Directive No 2001/83/EC) Duplicate of Duoresp Spiromax (EMEA/H/C/002348)
See DuoResp Spiromax

Incruse (EMEA/H/C/002809) (umeclidinium bromide), Applicant: Glaxo Group Ltd, (treatment of symptoms in adult patients with chronic obstructive pulmonary disease (COPD))
New active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted in January 2014.
List of Questions adopted in September 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.
Furthermore, the CHMP considered that umeclidinium bromide is a new active substance, as claimed by the applicant.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The legal status was agreed as medicinal product subject to medical prescription.
The summary of opinion was circulated for information.

HEMANGIOL (EMEA/H/C/002621), (propranolol), Applicant: PIERRE FABRE DERMATOLOGIE, (treatment of proliferating infantile haemangioma)
Known active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted in December 2013.
List of Questions adopted in July 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 paediatric use 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.
This is the second time that the CHMP has granted a positive opinion for a PUMA since their introduction by the Paediatric Regulation, which came into force in 2007.

Pregabalin Pfizer (EMEA/H/C/003880), (pregabalin), Applicant: Pfizer Limited, (neuropathic pain, epilepsy and Generalised Anxiety Disorder)
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.

Ulunar Breezhaler (EMEA/H/C/003875), (indacaterol / glycopyrronium bromide), Applicant: Novartis Europharm Ltd, (bronchodilator treatment to relieve symptoms in adult treatment of chronic obstructive pulmonary disease (COPD))
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.

Vimizim (EMEA/H/C/002779), Orphan, (elosulfase alfa) Applicant: BioMarin Europe Ltd, (treatment of mucopolysaccharidosis type IVA)
New active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted in December 2013.
List of Questions adopted in September 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.
Furthermore, the CHMP considered that elosulfase alfa is a new active substance, as claimed by the applicant.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The legal status was agreed as medicinal product subject to restricted medical prescription.
The summary of opinion was circulated for information.
The Committee adopted the BWP Report.**Vokanamet (EMEA/H/C/002656)**, (canagliflozin/metformin), Applicant: Janssen-Cilag International N.V., (treatment of type 2 diabetes mellitus)
New active substance at the time of submission of the application (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted in December 2013.
List of Questions adopted in July 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 medical prescription.
The summary of opinion was circulated for information.
The Committee discussed the advice from PRAC to include bladder cancer as important potential risk in the RMP. The CHMP did not agree to this and the majority of views expressed were that this would be purely based on extrapolation for a risk that was perceived as uncertain. The CHMP concluded that long term safety data on bladder cancer should be considered as missing information and included in the RMP instead. Based on non-clinical and clinical data in this dossier there is no sign of bladder cancer, however due to the numerical imbalances in bladder cancer found in dapagliflozin studies, bladder cancer should be further investigated post marketing.

2.2 Day 180 List of outstanding issues – New full applications

(EMEA/H/C/003717), (oseltamivir)
1) Treatment of influenza in patients one year of age and older who present with symptoms typical of influenza, when influenza virus is circulating in the community.
2) Treatment of infants less than 1 year of age during a pandemic influenza outbreak.
3) Post-exposure prevention in individuals 1 year of age or older following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.
4) Post-exposure prevention of influenza in infants less than 1 year of age during a pandemic influenza outbreak)
List of Outstanding Issues adopted in December 2013.
List of Questions adopted in September 2013.
The Committee was reminded of the status of this application and its remaining outstanding issues
The Committee adopted a 2nd List of Outstanding Issues with a specific timetable.

(EMEA/H/C/002418), Orphan
(Dexamethasone Acetate), LABORATOIRES CTRS - BOULOGNE BILLANCOURT, (treatment of symptomatic multiple myeloma)
List of Outstanding Issues adopted in September 2013.
List of Questions adopted in May 2013.
The Committee was reminded of the status of this application and its remaining outstanding issues
The Committee adopted a 2nd List of Outstanding Issues with a specific timetable.

2.3 Day 120 List of questions – New full applications

(EMEA/H/C/002825), (dulaglutide), (treatment of adults with type 2 diabetes mellitus)
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/003724), Orphan, (eliglustat), Applicant: Genzyme Europe BV, (treatment of Gaucher disease type 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/002819), (darunavir /cobicistat), (treatment of patients with human immunodeficiency virus (HIV-1) in:
1) antiretroviral therapy (ART) naïve adults.
2) ART-experienced adults with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/ml and CD4+ cell count ≥ 100 cells x 106/l)
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/003687), (naltrexone/bupropion), (indicated for the management of obesity)
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/002569), (nintedanib), (treatment of 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.

2.4 Update on on-going new applications for Centralised Procedures

(EMEA/H/C/003800), Orphan, (ketoconazole), Applicant: Agenzia Industrie Difesa-stabilimento Chimico Farmaceutico Militare, (treatment of Cushing's syndrome)
The CHMP adopted the assessment report of similarity.

(EMEA/H/C/003843), (idelalisib), (treatment of patients with relapsed chronic lymphocytic leukaemia (CLL) and refractory indolent non-Hodgkin lymphoma (iNHL))
The CHMP adopted the assessment report of similarity.

(EMEA/H/C/002593) (Colecalciferol, Strontium Ranelate), (treatment of osteoporosis)
The Committee agreed to the request of the applicant dated 27 January 2014 for an extension of the clock stop for the provision of the responses to the Day 180 List of Outstanding Issues together with a specific timetable.

(EMEA/H/C/002756) (Colecalciferol, Strontium Ranelate), (treatment of osteoporosis)
See (EMEA/H/C/002593)

(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 in March 2013 and January 2014.
Nomination of experts specialised in Erythropoietic Protoporphyria (EPP) to participate in the Ad-hoc expert group meeting to be held in the near future.

2.5 Products in the Decision Making Phase

Tecfidera (EMEA/H/C/002601) (Dimethyl Fumarate), Biogen Idec Ltd., (treatment of multiple sclerosis)
***Post meeting note**: The CHMP adopted the updated EPAR via written procedure after the CHMP Plenary on 24th February 2014.*

3 EXTENSION OF MARKETING AUTHORISATION ACCORDING TO ANNEX I OF REG. 1234/2008

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

Noxafil (EMEA/H/C/000610/X/0028), (posaconazole), MAH: Merck Sharp & Dohme Limited, Rapporteur: Rafe Suvarna, PRAC Rapporteur: Rafe Suvarna, "To add a new pharmaceutical form: gastroresistant tablets 100 mg"
List of Outstanding Issues adopted in December 2013.
List of Questions adopted in July 2013.
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

Imatinib Actavis (EMEA/H/C/002594/X/0003) (imatinib), MAH: Actavis Group PTC ehf, Generic of Glivec, Rapporteur: Reynir Arngrímsson, PRAC Rapporteur: Dolores Montero Corominas, "Line extension to add a new strength, 400mg hard capsule for the extended set of indications already authorised for the reference product Glivec"
List of Questions adopted in November 2013.
The Committee was reminded of the status of this application and its remaining outstanding issues which related to quality aspects.
The Committee adopted a List of Outstanding Issues Questions with specific timetable.

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

Synagis (EMEA/H/C/000257/X/0095), (palivizumab), MAH: AbbVie Ltd., Rapporteur: Jens Heisterberg, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Line Michan, "Introduction of a new pharmaceutical form: 100 mg/ml solution for injection presented in vials containing 0.5 ml and 1 ml."
The Committee discussed the issues identified in this application relating to the quality part, the RMP as well as some pharmacokinetic aspects.
The Committee adopted a List of Questions with specific timetable.
The Committee adopted the BWP Report.

3.4 Update on on-going Extension application according to Annex I of Reg. 1234/2008

Orfadin (EMEA/H/C/000555/X/0041), Orphan MAH: Swedish Orphan Biovitrum International AB, (nitisinone), Rapporteur: Luca Pani, PRAC Rapporteur: Carmela Macchiarulo, "To add an oral suspension 4 mg/ml as additional pharmaceutical form".
The Committee agreed to the request of the applicant dated 14 February 2014 for an extension of the clock stop to respond to the List of Questions adopted in December 2013.

3.5 Extension application according to Annex I of Reg. 1234/2008- Products in the Decision Making Phase

RoActemra (EMEA/H/C/000955/X/0030)
MAH: Roche Registration Ltd, (tocilizumab), Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC Co-Rapporteur: Julia Pallos, Extension application to register a new route of administration "subcutaneous" use, a new pharmaceutical form "solution for injection", a new strength "162 mg" and a new presentation "pre-filled syringe".
Positive Opinion adopted by consensus on 19 December 2013.
Letter from the MAH dated 20 December 2013.
List of Questions to the MAH adopted on 23 January 2014.
The members agreed that this issue which led to the adoption of a List of Questions on 23rd January 2014, was considered resolved. The members were also informed about an issue affecting the pre-filled pen which led to the withdrawal of the pre-filled pen presentation from the extension application.
The Committee adopted a revised positive Opinion by consensus for granting an extension to the Marketing Authorisation for RoActemra 162 mg solution for injection in a pre-filled syringe, together with the CHMP Assessment report and Translation timetable.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

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: Kristina Dunder, 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"
The Committee was reminded of the status of this application and its identified issues, which related mainly to the efficacy data in the paediatric population especially in comparison with the efficacy rates in adults as well as the treatment strategies in children. Furthermore the CHMP discussed the PIP obligations.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Eliquis (EMEA/H/C/002148/II/0014/G), (apixaban), MAH: Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Pieter de Graeff, Co-Rapporteur: Robert James Hemmings, "Grouping of 2 variations including a type II Extension of indication to include treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults and a type IA to add a new pack size of 28 film coated tablets for Eliquis 5mg strength"
The Committee was reminded of the status of this application and its identified issues, which related mainly to pharmacokinetics, efficacy and safety aspects.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Enbrel (EMEA/H/C/000262/II/0167), (etanercept), MAH: Pfizer Limited, Rapporteur: Robert James Hemmings, "Extension of indication for treatment of adults with severe non-radiographic axial spondyloarthritis (nr-AxSpA)"
The Committee was reminded of the status of this application and its identified issues, which related mainly to the SmPC wording in order to bring it in line with other recently approved extensions of indications together with a requirement to provide long-term data, including maintenance of efficacy after treatment withdrawal as well efficacy and safety of retreatment after disease flare.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Eylea (EMEA/H/C/002392/II/0009), (aflibercept), MAH: Bayer Pharma AG, Rapporteur: Pierre Demolis, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Evelyne Falip, "Extension of indication for treatment of adult patients with diabetic macular oedema. Consequential updates were proposed for SmPC sections 4.2, 4.4, 4.8, 5.1 and 5.2. SmPC section 4.8 was furthermore updated to introduce a single table of adverse drug reactions." In addition the MAH has submitted a request for one additional year of Market Exclusivity.
The Committee was reminded of the status of this application and its identified issues which related mainly on the long-term efficacy of Eylea in diabetic macular oedema and whether one year data was considered sufficient to support the extension of indication.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Firazyr (EMEA/H/C/000899/II/0024/G), Orphan, (icatibant), MAH: Shire Orphan Therapies GmbH, Rapporteur: Kristina Dunder, "Update to section 5.1 of the SmPC to include the results of the open-label extension phase of study FAST-3 (HGT-FIR-054). In addition the MAH has taken the opportunity to make minor editorial changes throughout the Package Information."
Request for Supplementary Information adopted in November 2013, March 2013.
The Committee noted the letter from the MAH dated 14 February 2014 informing of the decision to withdraw the type II variation for a new indication for the treatment of ACE-inhibitor induced angioedema from the grouped type II variation, which was part of the grouping.
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 recommendation.

Gilenya (EMEA/H/C/002202/II/0021), (fingolimod), MAH: Novartis Europharm Ltd, Rapporteur: Pierre Demolis, Co-Rapporteur: Bengt Ljungberg, "To modify the indication section 4.1 of Gilenya to extend the patient population from patients with high disease activity despite treatment with a beta-interferon (IFN) to patients with high disease activity despite treatment with a disease modifying therapy (DMT)."
Request for Supplementary Information adopted in October 2013.
The Committee was reminded of the status of this application and its identified issues which related mainly to the wording of the indication in comparison with other available treatment.
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, "Update of SmPC section 4.1 to add a new indication for treatment of adult patients with diabetic macular oedema. Consequential updates were proposed for SmPC sections 4.2, 4.4, 4.8, 5.1 and 5.2. In addition, the MAH proposed to reduce and consolidate the current HCP leaflet, which is provided as tear off section after the PL.
The MAH also used this opportunity to implement QRD version 9.0."
Request for Supplementary Information adopted in October 2013.
The Committee was reminded of the status of this application and its identified issues which related mainly to the benefit/risk of the product.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Pegasys (EMEA/H/C/000395/II/0073), (peginterferon alfa-2a), MAH: Roche Registration Ltd, Rapporteur: Kristina Dunder, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Qun-Ying Yue, "Update of the SmPC to include the use of HCV NS3/4A protease inhibitors for the treatment of HCV genotype 1. Section 4.1 is updated and cross reference to the SmPC's of the HCVNS3/4A protease inhibitors is made throughout the SmPC."
The Committee was reminded of the status of this application and its identified issues which related mainly to the wording of the indication.
The Committee adopted a Request for Supplementary Information with a specific timetable.

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

Stivarga (EMEA/H/C/002573/II/0001) MAH: Bayer Pharma AG, (regorafenib), Rapporteur: Pieter de Graeff, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Sabine Straus, Extension of indication to include treatment of patients with gastrointestinal stromal tumours (GIST) who have been previously treated with 2 tyrosine kinase inhibitors. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC were proposed to be updated. The Package leaflet has been updated accordingly.
Request for Supplementary information adopted in December 2013.
The CHMP agreed to the request by the MAH for a clock stop to respond to the request for supplementary information adopted in December 2013.

Protelos (EMEA/H/C/000560/II/0035) (Strontium Ranelate), Applicant: Les laboratoires Servier, Rapporteur: Kristina Dunder, Co-rapporteur: Andrea Laslop, This type II variation concerns an extension of indication to include treatment of osteoarthritis. Consequently sections 4.1, 4.2, 4.8 and 5.1 of the SmPC have been updated and the Package Leaflet has been updated accordingly.
Request for supplementary information adopted in July 2012 and February 2013.
The CHMP agreed to the request by the applicant for a clock stop for the provision of the responses to the 2nd Request for supplementary information that was adopted in February 2013.

Osseor (EMEA/H/C/000561/II/31) (Strontium Ranelate), Les Laboratoires Servier, Rapporteur: Bengt Ljungberg, Co-Rapporteur: Andrea Laslop, , Quality: Robert Bream, Safety/Efficacy: Daniel Gustafsson, This type II variation concerns an extension of indication to include treatment of osteoarthritis. Consequently sections 4.1, 4.2, 4.8 and 5.1 of the SmPC have been updated and the Package Leaflet has been updated accordingly. Request for supplementary information adopted in July 2012 and February 2013.
See Protelos II/0035

5 ANCILLARY MEDICINAL SUBSTANCES IN MEDICAL DEVICES

5.1 Opinions/ List of outstanding issues / List of Questions

No items

6 RE-EXAMINATION PROCEDURE (NEW APPLICATIONS) UNDER ARTICLE 9(2) OF REGULATION No 726/2004

Reasanz (EMEA/H/C/002817), Applicant: Novartis Europharm Ltd, (serelaxin),
(treatment of acute heart failure)
Negative Opinion adopted in January 2014.
The CHMP noted the letter from the applicant dated 28 January 2014 requesting a re-examination of the opinion adopted in January 2014.
The CHMP appointed a re-examination Rapporteur and a re-examination Co-Rapporteur.
PRAC re-examination Rapporteurs were also appointed.

Translarna (EMEA/H/C/002720), Orphan, Applicant: PTC Therapeutics Limited, (ataluren),
(treatment of Duchenne muscular dystrophy.)
Negative Opinion adopted in January 2014.
The CHMP noted the letter from the applicant dated 28 January 2014 requesting a re-examination of the opinion adopted in January 2014.
The CHMP appointed a re-examination Rapporteur and a re-examination Co-Rapporteur.
PRAC re-examination Rapporteurs were also appointed.

Masiviera (EMEA/H/C/002659), Orphan, (masitinib), Applicant: AB Science, (treatment of non resectable locally advanced or metastatic pancreatic cancer).
Negative Opinion adopted in January 2014.
The CHMP noted the letter from the applicant dated 24 January 2014 requesting a re-examination of the Opinion adopted in January 2014 and consultation of SAG Oncology.
The CHMP appointed a re-examination Rapporteur and a re-examination Co-Rapporteur.
PRAC re-examination Rapporteurs were also appointed.

Masican (EMEA/H/C/002670), Orphan (MASITINIB), Applicant: AB Science, (treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST))
Negative Opinion adopted in November 2013.
The CHMP adopted the list of questions to the SAG-Oncology as well as the list of experts for that SAG meeting.

Nerventra (EMEA/H/C/002546) Applicant: Teva Pharma GmbH, (laquinimod), (treatment of multiple sclerosis)
Negative Opinion adopted in January 2014.
The CHMP noted the letter from the applicant dated 4 February 2014 requesting a re-examination of the Opinion adopted in January 2014 and consultation of SAG.
The CHMP appointed a re-examination Rapporteur and a re-examination Co-Rapporteur.
PRAC re-examination Rapporteurs were also appointed.

7 RE-EXAMINATION PROCEDURE (TYPE II VARIATIONS) UNDER ARTICLE 6(9) OF COMMISSION REGULATION EC NO 1085/2003

No items

8 WITHDRAWAL OF APPLICATION

HEPLISAV (EMEA/H/C/002603)
(Hepatitis B Surface Antigen), Applicant: Dynavax International B.V., (indicated for active immunisation of adults against hepatitis B virus (HBV) infection)
The CHMP noted the letter from the Applicant dated 10 February 2014 informing of the decision to withdraw the marketing authorisation application.
The CHMP noted the withdrawal question-and-answer document.

9 PROCEDURE UNDER ARTICLE 83(1) OF REGULATION (EC) 726/2004 (COMPASSIONATE USE)

Sofosbuvir/Ledipasvir (compassionate use) (H0003892)
Gilead Sciences International Ltd, (treatment of patients with hepatitis C infection that have previously failed on boceprevir or telaprevir based therapy and that are in urgent medical need for effective treatment)
The CHMP adopted an opinion in accordance with Article 83 by consensus together with the CHMP Assessment Report.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

10 PRE-SUBMISSION ISSUES

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

Ketoconazole Lab HRA Pharma (H0003906), Orphan (Ketoconazole), Laboratoire HRA Pharma, (treatment of Cushing's syndrome),
The CHMP agreed to the accelerated assessment request and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

(H0003850) (sofosbuvir/ledipasvir), (treatment of chronic genotype 1 HCV infection in adults),
The CHMP agreed to the accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

(EMEA/H/C/002617) (influenza vaccine (live attenuated, nasal), MedImmune LLC, Rapporteur: Daniel Brasseur, Co-Rapporteur: Karsten Bruins Slot,

11 POST-AUTHORISATION ISSUES

SonoVue (EMEA/H/C/000303/II/0025), (sulphur hexafluoride), MAH: Bracco International B.V., Rapporteur: Pierre Demolis, "Update of section 4.3 of the SmPC to delete the contraindications for use in patients with acute coronary syndrome or clinically unstable ischaemic cardiac disease and to insert these patient populations into section 4.4 Special warnings and precautions for use, with editing of the wording as appropriate. The package leaflet was updated accordingly. Furthermore, the MAH took this opportunity to bring the PI in line with the latest QRD template version 9."
Request for Supplementary Information adopted in December 2013, October 2013.
The Committee was reminded of the status of this application and its identified issues, which related mainly whether the contraindication could be lifted based on the submitted data and it was agreed to seek clarification on recently available data before concluding on the variation.
The Committee adopted a Request for Supplementary Information with a specific timetable.

PSUR procedures (PRAC recommendation for variation) for CHMP opinion in February 2014:
EMEA/H/C/PSUSA/00010007/201307 (PSUSA: PSUR single assessment procedures, referring to CAPs, NAPs products)
CAPS:
Rebetol (EMEA/H/C/000246) (Ribavirin), MAH: Merck Sharp & Dohme Limited, Rapporteur: Joseph Emmerich,
Ribavirin Mylan (EMEA/H/C/001185)
(Ribavirin), MAH: Generics (UK) Limited, Rapporteur: Greg Markey
Ribavirin Teva (EMEA/H/C/001018)
(Ribavirin), MAH: Teva Pharma B.V., Rapporteur: Greg Markey
Ribavirin Teva Pharma BV (EMEA/H/C/001064) (Ribavirin), MAH: Teva Pharma B.V., Rapporteur: Greg Markey

NAPS:
Ribavirin CT -CT Arzneimittel GmbH Ribavirin 200mg capsules JSC Olainfarm
Ribavirin Normon - Laboratorios Normon S.A.
Copegus - Roche registration Limited
Ribavirin NL/H/2303/001/DC – Valeant
Ribavirin Zentiva – Zentiva
PRAC Rapporteur: Isabelle Robine,
The CHMP agreed to the PRAC recommendation on this single PSURs assessment concluding that the benefit/risk remained positive but recommended that a type II variation be submitted to address

appropriate changes in the SmPC such as adding the adverse reactions of tinnitus, hypotension, vasculitis cerebrovascular ischaemia and tongue pigmentation to section 4.8.

Onduarp (EMEA/H/C/002118) (Amlodipine Besilate,Telmisartan), MAH: Boehringer Ingelheim International GmbH, Rapporteur: Harald Enzmann, Co-Rapporteur: Alar Irs, (treatment of essential hypertension), Informed consent application (Article 10c of Directive No 2001/83/EC)
The CHMP noted the letter from the MAH dated 20 December 2013 informing of voluntary withdrawal of Marketing Authorisation for commercial reasons.

Avastin (EMEA/H/C/000582) (bevacizumab), Applicant: Roche Registration Ltd, Rapporteur: Jens Ersbøll, Co-Rapporteur: Ingunn Hagen Westgaard,
Fire III study compared bevacizumab plus FOLFIRI to cetuximab plus FOLFIRI as a frontline treatment for patients with KRAS wild-type metastatic colorectal cancer (mCRC)
The members discussed the observed results from the Fire III study specifically regarding the overall survival and progression free survival data, indicating a disconnection between progression free survival and overall survival.
The CHMP agreed to consult the Oncology Working Party. A letter will be sent to the Oncology Working Party after the plenary.

WS0472
Gardasil-EMEA/H/C/000703/WS0472/0045
Silgard-EMEA/H/C/000732/WS0472/0042
(human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)), MAH: Sanofi Pasteur MSD, SNC, Rapporteur: Kristina Dunder, , "Update of section 4.2 and 5.1 of the Summary of Product Characteristics (SmPC) to include an alternative 2-dose vaccination schedule in children aged from 9 to 13 years. The Package leaflet is updated in accordance. The MAH propose to express the quantity of aluminium salt in milligrams instead of micrograms in order to harmonise with the bivalent HPV vaccines in section 2 of the SmPC, PL and Labelling. In addition the MAH implement version 9.0 of QRD template and took the opportunity to implement minor linguistic changes."
Request for Supplementary Information adopted in December 2013.
The Committee discussed the proposed 2-dose vaccination schedule in comparison with the 3-dose schedule and whether both dosing schemes should be recommended in parallel for 9 – 13 years old individuals. The Committee finally agreed to include both vaccination schedules in the SmPC for this age group.
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.

Sampling and Testing list programme 2015
The CHMP adopted the Sampling and Testing list programme 2015.

12 REFERRAL PROCEDURES

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

Protelos (EMEA/H/C/000560)

(Strontium Ranelate), Les Laboratoires Servier, Rapporteur: Bengt Ljungberg, Co-Rapporteur: Andrea Laslop, (treatment of osteoporosis)

PRAC outcome at January 2014 PRAC meeting. Oral explanation held in January 2014.

The members discussed the proposed SmPC wording and risk minimisation measures.

The Committee agreed that no Oral Explanation was needed at this time.

See also 1.4 Referral procedures Oral Explanations

The CHMP adopted an opinion by majority (22 out of 30 votes) concluding that the benefit-risk balance of strontium ranelate is positive in a restricted target population provided that the proposed measures are successfully implemented.

The Icelandic and Norwegian Members were not in agreement with the CHMP recommendation.

The divergent position (Ivana Mikacic, Daniela Melchiorri, David Lyons, Jan Mazag, Kristina Dunder, Nela Vilceanu, Pierre Demolis, Ondrej Slanar, Reynir Arngrimsson, Ingunn Hagen Westgaard) was appended to the opinion.

The CHMP noted the CHMP public health communication.

The CHMP agreed to the wording of a DHPC letter.

Osseor (EMEA/H/C/000561)

(Strontium Ranelate), Les Laboratoires Servier, Rapporteur: Bengt Ljungberg, Co-Rapporteur: Andrea Laslop, (treatment of osteoporosis).

PRAC outcome at January 2014 PRAC meeting. Oral explanation held in January 2014.

The Committee agreed that no Oral Explanation was needed at this time. See Protelos

See also 1.4 Referral procedure oral explanations

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 the Eur. Pharm. monograph. Triggered by the EMA Executive Director

List of Questions adopted in September 2013.

See also section 12.6 Community Interests - Referral under Article 31

Two parallel reviews of polymyxin-based products are currently on-going, under Article 31 and 5(3) respectively.

The Committee agreed that there was a need for further understanding of colistin and its pro-drug colistimethate sodium (CMS) when it comes to quality aspects.

The CHMP decided to consult the Phamacokinetic Working Party and the Infectious Disease Working Party and adopted Lists of Questions to these Working Parties.

The CHMP adopted a List of Questions to the MAHs with a specific timetable.

CHMP discussion and list of questions to be addressed by the MAHs: February 2014 CHMP; Submission of responses: 28.05.2014; PKWP meeting: Early June (tbc); IDWP meeting: Mid-June (tbc); Assessment reports: 09.07.2014; Comments from CHMP: 14.07.2014; CHMP discussion/CHMP opinion: July 2014 CHMP

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), RMS: FR, CMS: AT, BE, DE, IT, PL, RO, SI ,SK, Procedure number: FR/H/0516/001/DC

The CHMP noted the letter from ANSM dated 3 February 2014 notifying of an official referral under Article 29(4) and its grounds due to disagreement regarding the demonstration of contraceptive effectiveness and treatment compliance.

The CHMP appointed Joseph Emmerich (risk level 3) as Rapporteur and Martina Weise (risk level 2) as Co-Rapporteur. The CHMP decided to consult the BSWP mainly regarding analyses performed using a bootstrap method and adopted List of Questions to the Working Party.

The CHMP adopted a List of Questions to the Applicant with a specific timetable:

Start of procedure: 20.02.2014; Responses to list of questions: 02.05.2014; Restart of the procedure: 27.05.2014; Assessment report: 10.06.2014; Comments from CHMP: 16.06.2014; List of outstanding issues or CHMP opinion: June 2014 CHMP

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

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.

The members were informed about the distinctions in the wording of the national SmPCs of Nasonex, also including differences in the approved indications. The Committee agreed to seek clarification from the MAH.

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

List of outstanding issues or CHMP opinion: February 2014 CHMP; Responses to LoOI: 02.05.2014; Restart of the procedure: 27.05.2014; Joint or Rapporteurs Assessment report(s): 11.06.2014; Comments from CHMP members: 16.06.2014; List of outstanding issues and/or Oral explanation and/or CHMP opinion: June 2014 CHMP

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

Caustinerf arsenical® and Yranicid arsenical® and associated names, paste for dental use (oral formulations) (EMEA/H/A-31/1382)

(lidocaine, ephedrine, arsenic trioxide), SEPTODONT and A.T.O. ZIZINE, Rapporteur: Alar Irs, Co-Rapporteur: Joseph Emmerich

Article 31 triggered by the ANSM for ephedrine hydrochloride, lidocaine and arsenous anhydride containing medicinal products for topical use, based on genotoxicity data.

The Committee noted that the product was only marketed in five EU Member States (France, Italy, Latvia, Lithuania and Estonia) but expressed major concerns regarding the benefit-risk balance of Caustinerf arsenical, Yranicid arsenical and associated names for topical use.

The CHMP adopted a List of Outstanding Issues with a specific timetable:

Responses to LoOIs by MAH(s): 04.03.2014; Restart of the procedure: 26.03.2014; Joint or Rapporteurs Assessment report(s): 10.04.2014; Comments from CHMP: 15.04.2014; List of outstanding issues and/or Oral explanation and/or CHMP opinion: April 2014 CHMP

Gadolinium containing contrast agents, Gd-Cas (EMEA/H/A-31/1097)
Rapporteur: Rafe Suvarna, Co-Rapporteur: Pieter de Graeff,
The CHMP adopted the FUM related to the 3rd annual cumulative safety reviews on nephrogenic systemic fibrosis (NSF): Omniscan (GE HealthCare) first monthly update and interim analysis report submission as requested by CHMP in November 2013 and assessment report.

Methysergide containing products (EMEA/H/A-31/1335)
Rapporteur: Joseph Emmerich, Co-Rapporteur: Rafe Suvarna,
Review of the benefit-risk balance of methysergide containing products due to safety concerns related to fibrotic risks. List of Questions adopted in May 2012. List of Outstanding Issues adopted in December 2012, May 2013, September 2013 and December 2013. SAG meeting held on 5 September 2013.
The CHMP adopted an opinion by consensus recommending restricting the use of methysergide due to concerns that it could cause fibrosis.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The Committee agreed to the wording of DHPC letter and communication plan.
The CHMP agreed to communicate to the NCAs but as currently there are no Methysergide containing products marketed in the European Union, the DHPC letter will not be disseminated at the moment.

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 the European Commission.
List of Questions adopted in September 2013.
See also section 12.2 Requests for CHMP Opinion under Article 5(3)
Two parallel reviews of polymyxin-based products are currently on-going, under Article 31 and 5(3) respectively.
The CHMP decided to consult the PKWP and the IDWP and adopted Lists of Questions to these Working Parties. In addition the CHMP agreed that further clarifications were needed regarding the antimicrobial activity of the individual subcomponents of colistin.
The CHMP adopted a List of Outstanding Issues to the MAHs with a specific timetable.
CHMP discussion and List of Outstanding issues to be addressed by the MAHs: February 2014 CHMP; Submission of responses: 28.05.2014; PKWP meeting: Early June (tbc); IDWP meeting: Mid-June (tbc); Re-start of the procedure: 24.06.2014; Assessment reports: 09.07.2014; Comments from CHMP: 14.07.2014; CHMP discussion/CHMP opinion: July 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)

No items

13 PHARMACOVIGILANCE ISSUES

Summary of recommendations and advice of PRAC meeting held on 3-6 February 2014: The Committee noted the report.
The members noted the Summary of recommendations and advices of the PRAC meeting.
The List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for February 2014 was adopted.

Early Notification System:
February 2014 Early Notification System on Envisaged CHMP Recommendations for Regulatory Action (based on Identified Safety Concerns) Accompanied by Communication to the General Public:
See individual items

14 INSPECTIONS

14.1 GMP Inspections

Request for GMP Inspections: **for adoption**	*Disclosure of information related to GMP inspections will not be published as it undermines the purpose of such inspections.*
Pre-authorisation (Article 8):	

14.2 GCP Inspections

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

14.3 Pharmacovigilance Inspections

Request for Pharmacovigilance Inspections: **For adoption**	*Disclosure of information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections.*
Extension of the target date of the PhV Inspection Reports: **For adoption**	

14.4 GLP Inspections

Request for GLP Inspections: **For adoption**	*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 ITF: For information

Minutes from the 1Q 2014 EU-Innovation Network Teleconference held on 28 January 2014.	The CHMP noted the minutes.
Minutes from the January ITF Plenary held on 24 January 2014.	The CHMP noted the minutes.

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.

ITF Briefing Meeting will be held on 13 March 2014 within/in the margin of CAT: **For information**	The CHMP noted the ITF Briefing Meeting.
ITF Briefing Meeting with for to be held on 15 April 2014 in the margin of CAT: **For information**	The CHMP noted the ITF Briefing Meeting.
ITF Briefing Meeting will be held on 13 March 2014 within/in the margin of CAT: **For information**	The CHMP noted the ITF Briefing Meeting.

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

Update on CHMP opinion under Art. 57 (1)P of	The CHMP noted the document and will further

Regulation (EC) No 726/2004: **For adoption**	discuss in March 2014.
Update on CHMP opinion under Art. 57 (1)P of Regulation (EC) No 726/2004: **For adoption**	The CHMP noted the document and will further discuss in March 2014.

15.5 Nanomedicines activities

No items

16 SCIENTIFIC ADVICE WORKING PARTY (SAWP)

Report from the SAWP meeting held 3-5 February 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 17-19 February 2014: **For information**	The CHMP noted the report.

18 OTHER COMMITTEES

18.1 Committee for Orphan Medicinal Products (COMP)

Press release of the COMP meeting held on 4-5 February 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 27-28 January 2014: **For information**	To be sent in the Post-mail.

18.3 Paediatric Committee (PDCO)

PIPs reaching D30 at February 2014 PDCO: **For information**	To be sent in the Post-mail.
Report from the PDCO meeting held on held on 12-14 February 2014: **For information**	The CHMP noted the report.

18.4 Committee for Advanced Therapies (CAT)

Table of Decisions of CAT meeting held on 13-14 February 2014 **For information**	The CHMP noted the Table of Decision.

19 INVENTED NAME ISSUES

Table of Decisions of the NRG meeting held on 29 January 2014: **For adoption**	The CHMP adopted the Table of Decision.
Table of Decisions of the Teleconference held on 19 February 2014: **For adoption**	The CHMP adopted the Table of Decision.

20 ANY OTHER BUSINESS

Election of CHMP Co-opted member at the February 2014 CHMP meeting	The CHMP elected Robert James Hemmings as Co-opted member for another 3-year term.
Election of BWP Chair	The CHMP elected Sol Ruiz as new BWP chairperson and thanked Jean Hugues Trouvin for all his contributions as previous chair to the BWP.
Calculation of voting quorum and majority vote: **For information**	The CHMP was informed that after clarification un-even numbers related to quorum and majority numbers will be rounded down, leading to a majority at CHMP of 17 votes. The quorum continues to be 22.
Presentation on the Move to Churchill Place: **For information**	The CHMP was informed about the meeting rooms in the new building and the technical equipment to be used.
Multinational assessment teams: **For discussion**	Presentation on the experience gained from a pilot study setting up multinational assessment teams for Co-Rapporteurships in order to broaden European involvement. The pilot which started with a small number of EU member states will now be expanded to all member states. The view was expressed that in future it should be favourable to also include Rapporteurships and post authorisation procedures.
Communication on prevention of medication errors: **For discussion**	The CHMP was informed on a proposal for communicating on measures to prevent medication errors. The CHMP welcomed the proposal for a more transparent and proactive communication on medication errors from the EMA.
Consultation on proposed process improvements as part of 'Review and Reconnect' Programme: :	The CHMP was informed on process design principles in relation to the EMA 'Review and Reconnect' Programme as well as national

For information	competent authorities consultation principles.
Working Parties, Committees, SAGs and DGs	
Safety Working Party (**SWP**) Nomination of Klaudia Hettinger (AT) as additional expert member: **For adoption**	The CHMP agreed to the nomination of Klaudia Hettinger (AT) as additional expert member
Quality Working Party (**QWP**) Q&A on expression/declaration of potency in quantitative and qualitative composition for Vancomycin products (EMA/CHMP/QWP/40776/2014): **For adoption for 3-month public consultation**	Adopted for 3-month public consultation
Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation (EMA/CHMP/CVMP/QWP/40811/2014): **For adoption** Overview of comments received (EMA/774027/2013): **For adoption**	Adopted
Guideline on the use of Near Infrared Spectroscopy (NIRS) by the pharmaceutical industry and the data requirements for new submissions and variations (EMA/CHMP/CVMP/QWP/63700/2014): **For adoption** • Addendum to EMA/CHMP/CVMP/QWP/17760/ 2009 Rev 1: Defining the Scope of an NIRS Procedure (EMA/CHMP/CVMP/QWP/63699/2014): **For adoption** Overview of comments received (EMA/CHMP/CVMP/QWP/63698/2014): **for adoption**	Adopted
Extension of the EMA-FDA Quality-by-Design (QbD) pilot program on parallel assessment of QbD applications: **For adoption**	The CHMP agreed to the Extension of the EMA-FDA Quality-by-Design (QbD) pilot program on parallel assessment of QbD applications for additional two years.
Reflection on the expression of strength: **For discussion**	Adopted
Qualified Person declaration concerning GMP compliance of active substance manufacture and verification of its supply chain Template and guidance document (EMA/CHMP/CVMP/QWP/80360/2014): **For**	Adopted

adoption	
QWP Workshop on Guideline on pharmaceutical development of medicines for paediatric use	The CHMP agreed to the proposed workshop on paediatric formulations to be scheduled in December 2014.
Committees	
CHMP Post-mail CD Rom - February 2014 last CD Rom to be sent: **For information**	The Committee did not agree to stop the post mail CD ROM distribution. Further discussion planned at the March meeting.
Proposal to have a CHMP ORGAM meeting in April 2014: **For discussion**	The Committee agreed to have an ORGAM meeting in April 2014. If only very few topics are identified the ORGAM meeting may be cancelled and topics to be taken at the April Plenary. In the context of this discussion it was highlighted to further discuss the organisation of the Plenary meeting in April which is just after the Easter break.
Opening of MMD to members across the various Committees (CAT/PRAC/PDCO/COMP/CMDh/SAWP): **For information**	The Committee noted that from now on members have access across all MMD folders for the various other scientific Committees (CAT/PRAC/PDCO/COMP/CMDh/SAWP).
Update on Rapporteur payment – fee reductions: **For discussion**	The Committee was updated on Rapporteurs payment. The base of the NCA fee share is being changed from the net amount (reduced fee) to the gross amount (full fee). This change is applicable as of 1 January 2014 (for those procedures validated as of 1 January 2014). In such cases as of January 2014 the EMA will pay the NCA 50% of the full applicable fee. This harmonisation brings in line the last two areas of fee incentives with the already applicable practice of paying the NCA share from the gross amount (i.e. Orphan/SME/Paediatric incentives).
ICH	Andrea Laslop, Martina Weise were nominated.
Call for interest for participation in the ICH Biosimilars Working Group: **For information**	
Biosimilar Medicinal Product Working Party (**BMWP**)	
Concept paper on the revision of the guideline on Immunogenicity Assessment of Biotechnology-derived Therapeutic Proteins (EMA/CHMP/BMWP/275542/2013): **For adoption for 3-month public consultation**	Adopted for 3-months public consultation
Work plan for the Biosimilar Medicinal Products	

Working Party (EMA/CHMP/BMWP/736496/2013): **For adoption**	Adopted Call for expression of interest in becoming BMWP Members. Nominations of experts with expertise including Quality, Non-Clinical, Clinical (both general and also with a focus on interferon alfa, insulin and low molecular weight heparins), Pharmacovigilance, Immunology should be sent to: BMWP.secretariat@ema.europa.eu **by 18 April 2014.**
Biologics Working Party (**BWP**)	
Guideline on the declaration of the quantitative composition/labelling of biological medicinal products that contain modified proteins as active substance (EMA/CHMP/BWP/85290/2012): **For adoption** • Overview of comments (EMA/CHMP/BWP/692937/2013)	Adopted Adopted
Guideline on the use of porcine trypsin used in the manufacture of human biological medicinal products (EMA/CHMP/BWP/814397/2011): **For adoption**	
BWP report on Urine-derived medicinal products: Summary of discussions on viral safety aspects and Warning Statements in the Product Information requested by some Member States (EMEA/CHMP/BWP/657630/2013): **For discussion**	The CHMP noted the BWP report. Further discussion expected at a future CHMP meeting.
Nomination of new BWP member: **For adoption** • Vitalis Briedis (LT)	The Committee agreed to the nomination of Vitalis Briedis as new BWP member.
Vaccines Working Party (**VWP**)	
Vaccines Working Party Work Programme for 2014: **For adoption**	The CHMP adopted the Vaccines Working Party Work Programme 2014.
Nomination of an observer on the VWP: **For adoption** • Nele Berthels (BE)	The CHMP agreed to the nomination of Nele Berthels (BE) as an observer on the VWP.
Blood Products Working Party (**BPWP**)	
Guideline on core SmPC for human fibrinogen products (EMA/CHMP/BPWP/691754/2013): **For adoption for 3 month public consultation**	Adopted for 3-months public consultation

Cardiovascular Working Party	
Draft Reflection paper on the wording of indication for medicinal products for treatment of type 2 diabetes (EMA/50673/2014): **For adoption for 3 months public consultation**	Adopted for 3-months public consultation
Central Nervous System Working Party	
Central Nervous System Working Party Work Programme for 2014: **For adoption**	The CHMP adopted the Central Nervous System Working Party Work Programme for 2014. Call for nomination of CNSWP members (Re)Nomination (together with a CV) of : • assessors with experience and interest in neurology, psychiatry and methodology of clinical trials regarding CNS (specific diagnostic and assessment tools). Optimally, this will include members with knowledge of current clinical guidance and practise. • based on the workplan, additional knowledge in the following fields is desirable: neurodegenerative disorders, neurocognitive disorders, neuromuscular disorders, pain syndromes and psychiatry in children and adolescents Nominations to be sent to CNSWPSecretariat@ema.europa.eu **by 18 April 2014.**
MSWG Comments on the Concept Paper on revision of the Points to Consider on Pharmacokinetics and Pharmacodynamics in the Development of Antibacterial Medicinal Products (CHMP/EWP/2655/99) and conversion to a CHMP guideline: **For information**	Noted
Oncology Working Party (**ONWP**)	
Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia (EMA/68747/2014): **For adoption** • Overview of comments	Adopted
Oncology Working Party Work Programme for 2014 (EMA/711415/2013): **For adoption**	The CHMP adopted the Oncology Working Party Work Programme for 2014.
Nomination of Olga Kholmanskikh (BE) as a new	The CHMP agreed to the nomination of Olga

observer: **For adoption**	Kholmanskikh (BE) as a new observer.
Pharmacokinetics Working Party (**PKWP**) Guideline on the evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function: **For adoption for 6-month public consultation**	Adopted for 6-month public consultation
Question from PDCO concerning bioavailability/bioequivalence demonstration for BCS II and IV compounds: Final response: **For adoption**	The final response to the question raised by PDCO regarding bioavailability/bioequivalence demonstration for BCS II and IV compounds was adopted by the Committee.
Biostatistics Working Party (**BSWP**) Biostatistics Working Party Work Programme for 2014 (EMA/CHMP/469174/2013): **For adoption**	The CHMP adopted the Biostatistics Working Party Work Programme for 2014. Call for expression of interest in becoming BSWP Members. Nominations of professionally qualified medical statisticians within the European regulatory network should be sent to Biostatistics@ema.europa.eu by 18 April 2014**.**
Gastroenterology Drafting Group**(GDG)** Guideline on the evaluation of Medicinal Products for the treatment of Chronic Constipation: **For adoption for 6-month public consultation**	Adopted for 6-month public consultation
Radiopharmaceutical Drafting Group **(RDG)** Radiopharmaceutical Drafting Group Work Programme 2014: **For adoption**	Adopted
SmPC Advisory Group : 3-year activity report and SmPC Guideline Checklist: **For information**	The CHMP noted the report form the 3-year activity of the SmPC Advisory group and adopted the SmPC Guideline Checklist. *Post-meeting note: The CHMP noted the nomination of a new SmPC Advisory Group from the MEB: Nanneke Hendricks.*
Activity Report of the Modelling & Simulation Working Group (MSWG): **For discussion** Proposal to transition to a Working Party: **For discussion** Modelling & Simulation Working Group Work Programme for 2014: **For adoption**	The CHMP welcomed the proposal to change the Working Group into a Working Party but highlighted that this needed to be endorsed by EMA. The CHMP adopted the Modelling & Simulation Working Group Work Programme for 2014.

21 **List of participants:** *including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 17-20 February 2014 meeting.*

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 Mikačić	Croatia	Full involvement	
Ondřej Slanař	Czech Republic	No participation in discussions, final deliberations and voting on:	HEPLISAV (EMEA/H/C/002603) (hepatitis b surface antigen)
			(EMEA/H/C/002819) (darunavir/cobicistat)
			(EMEA/H/C/002656) (canagliflozin /metformin)
			(EMEA/H/C/002825) (dulaglutide)
			(EMEA/H/C/000308) (Insulin Aspart)
		No participation in final deliberations and voting on:	(EMEA/H/C/002751) (umeclidinium bromide/vilanterol)
			(EMEA/H/C/003754) (umeclidinium bromide/vilanterol)
			(EMEA/H/C/002348) (budesonide/ formoterol)
			(EMEA/H/C/003890) (budesonide/formoterol)
			(EMEA/H/C/002809) (umeclidinium bromide), (indacaterol/glycopyrronium bromide)
			Noxafil (EMEA/H/C/000610/X/0033) (posaconazole)
			Ketoprofen formulation for topical use (EMEA/H/A-107/1259)
Jens Heisterberg	Denmark	Full involvement	
Alar Irs	Estonia	Full involvement	
Outi Mäki-Ikola	Finland	No participation in final deliberations and voting on:	(previously Serelaxin) (EMEA/H/C/002817)
			Enbrel (EMEA/H/C/000262/II/0167) (etanercept)
Pierre Demolis	France	Full involvement	
Harald Enzmann	Germany	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
Agnes Gyurasics	Hungary	Full involvement	
David Lyons	Ireland	Full involvement	
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	
Dunder Kristina	Sweden	Full involvement	
Greg Markey	United Kingdom	Full involvement	
Tomas Salmonson	Sweden	Full involvement	
Robert James Hemmings	United Kingdom	Full involvement	
Hubert Leufkens	Netherlands	Full involvement	
Jan Mueller-Berghaus	Germany	Full involvement	
Robert Jean-Louis	Luxembourg	Full involvement	
Sol Ruiz	Spain	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
Milena Stain	Austria	Full involvement	
Bart Van der Schueren	Belgium	Full involvement	
Radka Montoniová	Czech Republic	Full involvement	
Jens Ersbøll	Denmark	Full involvement	
Joseph Emmerich	France	No participation in final deliberations and voting on:	Eliquis (EMEA/H/C/002148/II/0014/G) (apixaban)
Martina Weise	Germany	Full involvement	
Reynir Arngrímsson	Iceland	Full involvement	
Patrick Salmon	Ireland	Full involvement	
Daniela Melchiorri	Italy	Full involvement	
Natalja Karpova	Latvia	Full involvement	
Johann Lodewijk Hillege	Netherlands	Full involvement	
Ingunn Hagen Westgaard	Norway	Full involvement	
Dinah Duarte	Portugal	Full involvement	
Jana Klimasová	Slovakia	Full involvement	
Arantxa Sancho-Lopez	Spain	Full involvement	
Bengt Ljungberg	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	(via phone)	Tecfidera (Dimethyl Fumarate)

CHMP Expert	*Country*	*Outcome restriction following evaluation of e-DoI for the meeting*	*Topics on the current Committee Agenda for which restriction applies* *Product/* *substance*
* Experts were only evaluated against the product they have been invited to talk about.			
Christophe Focke	Belgium	Full involvement	
Anne Hasle Buur	Denmark	Full involvement	
Ljiljana Milosevic-Kapetanovic	France	Full involvement	
Sylvain Gueho	France	Full involvement	
Nessryne Sater	France	Full involvement	
Marie-Caroline Pesquidous	France	Full involvement	
Sabine Mayrhofer	Germany	Full involvement	
Ralf Meyer	Germany	Full involvement	
Karl Broich	Germany	Full involvement	
Ana Alonso Gutierrez	Spain	Full involvement	
Filip Josephson	Sweden	Full involvement	
Bertil Jonsson	Sweden	Full involvement	
Annika Folin	Sweden	Full involvement	
David Silverman	United Kingdom	Full involvement	
Terry Shepard	United Kingdom	Full involvement	
Emmanouil Zouridakis	United Kingdom	Full involvement	
Elisabeth Baker	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 restriction applies* *Product/* *substance*
*Experts were only evaluated against the product they have been invited to talk about.			
Christian Schneider	Denmark	Full involvement	
Jean-Hugues Trouvin	France	Full involvement	
Elmer Schabel	Germany	Full involvement	
Beate Ziegeler	Germany	Full involvement	
Norbert Benda	Germany	Full involvement	
Jochen Zünkler	Germany	Full involvement	
Andreas Brandt	Germany	Full involvement	
Michael Pfleiderer	Germany	Full involvement	
Ulrike Hermes	Germany	Full involvement	
Frauke Naumann-Winter	Germany	Full involvement	
Tania Meier	Germany	Full involvement	
Valerie Straßmann	Germany	Full involvement	
Dirk Mentzer	Germany	Full involvement	
Sara Galluzzo	Italy	Full involvement	
Menno van der Elst	Netherlands	Full involvement	
Nancy Breekveldt-Postma	Netherlands	Full involvement	
Alfredo Garcia	Spain	Full involvement	
Monica Edholm	Sweden	Full involvement	
Krystyna Fielden	United Kingdom	Full involvement	
Kathryn Ord	United Kingdom	Full involvement	
David Wright	United Kingdom	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)*

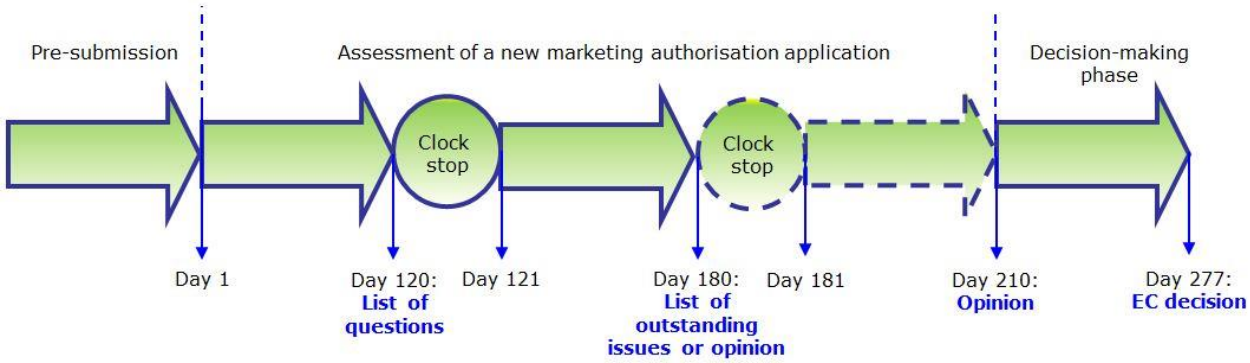
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 2 and 3) or referral procedures (section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