26 June 2014
EMA/CHMP/329259/2014
Procedure Management and Business Support Division

Committee for medicinal products for human use (CHMP)

Final Minutes of meeting held on 19 – 22 May 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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For adoption

AGENDA (EMA/CHMP/252366/2014) and Annex to CHMP agenda of the CHMP plenary session to be held 19-22 May 2014	The agenda and annex were adopted with amendments.
TIMESCHEDULE of the CHMP plenary session to be held 19-22 May 2014	The timeschedule was adopted.
MINUTES of the CHMP plenary session held 22-25 April 2014 (EMA/CHMP/240831/2014)	The Minutes of the CHMP plenary session held 22-25 April 2014 were adopted.
MINUTES of the May 2014 CHMP ORGAM meeting held on 12 May 2014 (EMA/CHMP/287131/2014)	The Minutes of the May 2014 CHMP ORGAM meeting held on 12 May 2014 were adopted together with all decisions taken at that meeting.
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 19-22 May 2014.	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 meeting to be held on 23-26 June 2014 CHMP meeting: **for information**	The draft agenda was noted.

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1. ORAL EXPLANATIONS

1.1. Pre-authorisation Procedure Oral Explanations

(EMEA/H/C/002347), (perflubutane), (ultrasound imaging agent indicated for the detection of coronary artery disease (CAD))
List of Outstanding Issues adopted on 20.03.2014, 21.11.2013. List of Questions adopted on 21.02.2013.
An Oral explanation was held on Wednesday 21 May 2014 at 14.00.
See also section 2.2. List of Outstanding Issues – new applications

VANTOBRA (EMEA/H/C/002633), Orphan, (tobramycin), Applicant: PARI Pharma GmbH, (treatment of chronic pulmonary infection)
Hybrid application (Article 10(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 24.10.2013. List of Questions adopted on 21.02.2013.
An Oral explanation was held on Wednesday 21 May 2014 at 9.00.
See also section 2.1 Opinions – new applications

1.2. Re-examination Procedure Oral Explanation

Masiviera (EMEA/H/C/002659), Orphan, (masitinib), Applicant: AB Science, (treatment of non resectable locally advanced or metastatic pancreatic cancer)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted on 23.01.2014. List of Outstanding Issues adopted on 19.09.2013. List of Questions adopted on 17.01.2013.
An Oral explanation was held on Wednesday 21 May 2014 at 11.00.
See also 6 Re-examination procedure (new applications) under Article 9(2) of Regulation No 726/2004

Nerventra (EMEA/H/C/002546), (laquinimod), Applicant: Teva Pharma GmbH, (treatment of multiple sclerosis)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted on 23.01.2014. List of Outstanding Issues adopted on 21.11.2013, 25.07.2013. List of Questions adopted on 15.11.2012.
An Oral explanation was held on Monday 19 May 2014 at 15.00.
See also 6 Re-examination procedure (new applications) under Article 9(2) of Regulation No 726/2004

Reasanz (EMEA/H/C/002817), (serelaxin), Applicant: Novartis Europharm Ltd, (treatment of acute heart failure)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted in January 2014.
An Oral explanation was held on Tuesday 20 May 2014 at 15.00.
See also 6 Re-examination procedure (new applications) under Article 9(2) of Regulation No 726/2004

Translarna (EMEA/H/C/002720), Orphan, (ataluren), Applicant: PTC Therapeutics Limited, (treatment of Duchenne muscular dystrophy.)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted on 23.01.2014. List of Outstanding Issues adopted on 19.09.2013. List of Questions adopted on 21.03.2013.
An Oral explanation was held on Tuesday 20 May 2014 at 11.00.
A second Oral explanation was held on Wednesday 21 May 2014 at 08:30.
See also 6 Re-examination procedure (new applications) under Article 9(2) of Regulation No 726/2004

1.3. Post-authorisation Procedure Oral explanation

Avastin (EMEA/H/C/000582/II/0059), (bevacizumab), MAH: Roche Registration Ltd, Rapporteur: Jens Ersbøll, Co-Rapporteur: Ingunn Hagen Westgaard, PRAC Rapporteur: Doris Stenver, "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. Related changes were proposed to SmPC sections 4.2, 4.5, 4.8 and 5.1. The Package Leaflet was proposed to be updated accordingly. Furthermore, the MAH took the opportunity to make some editorial changes in the SmPC and the PL."
Request for Supplementary Information adopted on 21.11.2013, 27.06.2013.
An Oral explanation was held on Monday 19 May 2014 at 17.45.
See also 4.1 Type II variations - Extension of indication procedures; Opinion

1.4. Referral Oral Explanations

Dexamed 5 mg Tablets (EMEA/H/A-29/1375) (dexamfetamine sulphate film coated tablets), Kohne Pharma GmbH, Rapporteur: Greg Markey, Co-Rapporteur: Johann Lodewijk Hillege, Article 29(4) procedure triggered by the Netherlands on the following grounds: enhanced risk for dependence and abuse potential of this product compared to other treatment options in ADHD and lack of convincing evidence for the efficacy in a second line setting – film coated tablets.
List of Outstanding Issues adopted in March 2014 by written procedure.
An Oral explanation was held on Tuesday 20 May 2014 at 9.00.
See also 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

2. NEW APPLICATIONS

2.1. Opinions – New full applications

Envarsus (EMEA/H/C/002655), (tacrolimus), Applicant: Chiesi Farmaceutici S.p.A., (indicated for the prophylaxis of transplant rejection in adult kidney allograft recipients.)
Hybrid application (Article 10(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 20.03.2014. List of Questions adopted on 19.09.2013.
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.

Gazyvaro (EMEA/H/C/002799), Orphan, (obinutuzumab), Applicant: Roche Registration Ltd, (Treatment of chronic lymphocytic leukaemia)
New active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 25.04.2014. List of Questions adopted on 19.09.2013.
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 obinutuzumab 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.
The Committee adopted the BWP report.

NUWIQ (EMEA/H/C/002813), (simoctocog alfa), Applicant: Octapharma AB, (treatment and prophylaxis of bleeding (congenital factor VIII deficiency))
New active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted in March 2014. List of Questions adopted in October 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 simoctocog 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 CHMP noted the Letter of recommendations dated 14.05.2014.
The summary of opinion was circulated for information.
The Committee adopted the BWP report.

Plegridy (EMEA/H/C/002827), (peginterferon beta-1a), Applicant: Biogen Idec Ltd, (treatment of relapsing multiple sclerosis)
New active substance (Article 8(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 20.03.2014. List of Questions adopted on 24.10.2013.
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 peginterferon beta-1a 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.

SIMBRINZA (EMEA/H/C/003698), (brinzolamide / brimonidine tartrate), Applicant: Alcon Laboratories (UK) Ltd, (Treatment of open-angle glaucoma or ocular hypertension.)
Fixed combination application (Article 10b of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 25.04.2014. List of Questions adopted on 21.11.2013.
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.

VANTOBRA (EMEA/H/C/002633), Orphan, (tobramycin), Applicant: PARI Pharma GmbH, (treatment of chronic pulmonary infection)
Hybrid application (Article 10(3) of Directive No 2001/83/EC)
List of Outstanding Issues adopted on 24.10.2013. List of Questions adopted on 21.02.2013.
See also section I Oral explanations
An Oral explanation was held on Wednesday 21 May 2014 at 9.00, focusing on the bridging to the reference product as well as substantiating the patient subgroup population.
After the Oral explanation the Committee discussed the available data and legal framework.
The final positive opinion was adopted after the Plenary by consensus via written procedure on 02.06.2014 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.

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

(EMEA/H/C/002806), (busulfan), (conditioning prior to conventional haematopoietic progenitor cell transplantation (HPCT))
List of Questions adopted on 19.12.2013.
The Committee was reminded of the status of this application and its remaining outstanding issues.
The Committee adopted a List of Outstanding Issues with a specific timetable.

(EMEA/H/C/002637) (balugrastim), (treatment of chemotherapy-induced neutropenia)
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 List of Outstanding Issues with a specific timetable.
The Committee adopted the BWP report.

(EMEA/H/C/002347), (perflubutane), (ultrasound imaging agent indicated for the detection of coronary artery disease (CAD))
List of Outstanding Issues adopted on 20.03.2014, 21.11.2013. List of Questions adopted on 21.02.2013. See also section I. Oral explanation
An Oral explanation was held on Wednesday 21 May 2014 at 14.00.
The CHMP agreed to obtain further advice from a SAG and adopted a 3rd List of Outstanding Issues with a specific timetable.
The CHMP adopted a List of Questions to the SAG.

(EMEA/H/C/003702), (phenylephrine hydrochloride / ketorolac trometamol), (maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement (ILR) in adults. replacement (ILR).)
List of Questions adopted on 23.01.2014.
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/002705), (mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches), (is indicated for the control of serum phosphorus levels in patients with end-stage renal disease (ESRD))
List of Outstanding Issues adopted on 24.10.2013. List of Questions adopted on 30.05.2013.
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/003728), (netupitant / palonosetron), (prevention of acute and delayed Chemotherapy-Induced Nausea and Vomiting induced by highly emetogenic chemotherapy and moderately emetogenic chemotherapy)
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/003780) (liraglutide), (treatment 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.
The Committee adopted the BWP report.

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

(EMEA/H/C/002739), ((substance to be reviewed) human alpha1-proteinase inhibitor), (treatment to slow the underlying destruction of lung tissue)
List of Questions adopted on 25.04.2014.
The Committee agreed to the request from the applicant for an additional extension of clock stop to respond to the Day 120 List of Questions.

2.5. Products in the Decision Making Phase

No items

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

Ventavis (EMEA/H/C/000474/X/0043), (iloprost), MAH: Bayer Pharma AG, Rapporteur: Pierre Demolis, PRAC Rapporteur: Evelyne Falip, "To add a new strength: the 20 microgram/ml nebuliser solution (in 30 and 168 ampoules package sizes)"
List of Outstanding Issues adopted in March 2014. List of Questions adopted in November 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.
The CHMP adopted the updated similarity assessment report for Ventavis 20 µg/ml.

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

Noxafil (EMEA/H/C/000610/X/0033), (posaconazole), MAH: Merck Sharp & Dohme Limited, Rapporteur: Rafe Suvarna, PRAC Rapporteur: Julie Williams, "Line extension to Noxafil 18mg/ml concentrate for solution for infusion"
List of Questions adopted on 23.01.2014.
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.

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

No items

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

Simponi (EMEA/H/C/000992/X/0047), (golimumab), MAH: Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga "to add new strength, pharmaceutical form and new route of administration 12.5 mg/ml solution for infusion"
List of Questions adopted in October 2013.
The CHMP noted the letter from the MAH dated 12 May 2014 informing of its decision to withdraw the line extension application.

4. TYPE II VARIATIONS - Extension of indication procedures

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

Arzerra (EMEA/H/C/001131/II/0023), Orphan, (ofatumumab), MAH: Glaxo Group Ltd, Rapporteur: Jens Ersbøll, Co-Rapporteur: Ingunn Hagen Westgaard, PRAC Rapporteur: Doris Stenver, "Extension of Indication to include in previously untreated chronic lymphocytic leukaemia (CLL) patients, the treatment in combination with chlorambucil or bendamustine of patients with CLL who have not received prior therapy and who are not eligible for fludarabine-based therapy. The Package Leaflet is updated accordingly."
Request for Supplementary Information adopted on 23.01.2014.
Requested 1-year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)
The CHMP adopted a negative opinion by consensus on the additional 1-year market protection, in light of other existing therapies.
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 recommendation.
The summary of opinion was circulated for information.

Avastin (EMEA/H/C/000582/II/0059), (bevacizumab), MAH: Roche Registration Ltd, Rapporteur: Jens Ersbøll, Co-Rapporteur: Ingunn Hagen Westgaard, PRAC Rapporteur: Doris Stenver, "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. The Package Leaflet was proposed to be updated accordingly".
Request for Supplementary Information adopted on 21.11.2013, 27.06.2013.
See also 1.4 Post-authorisation Procedure Oral Explanation
The CHMP noted the report from the SAG Oncology held in January 2014. The experts highlighted issues with the clinical endpoints and possible bias. The SAG recommended that the RTOG0825 study should be further assessed by the CHMP outlining that only limited data on this study was available. The experts did not express major concern on the possible impact of first line treatment with bevacizumab on the efficacy of subsequent post-progression therapy. Although the safety profile of the drug did not raise major concern, it was not considered acceptable in light with the presented efficacy.

An Oral explanation was held on Monday 19 May 2014 at 17.45.
After the Oral explanation the Committee discussed the available data, especially on the efficacy and uncertainties with the clinical trial conduct.
The CHMP adopted a final negative opinion by majority (21 negative out of 31 votes) together with the CHMP assessment report.
The divergent position was appended to the opinion.

Avastin (EMEA/H/C/000582/II/0063), (bevacizumab), MAH: Roche Registration Ltd, Rapporteur: Jens Ersbøll, Co-Rapporteur: Ingunn Hagen Westgaard, PRAC Rapporteur: Doris Stenver, "Extension of indication to include the use of Avastin in combination with chemotherapy (paclitaxel, topotecan or pegylated liposomal doxorubicin) in patients with recurrent, platinum-resistant epithelial ovarian, primary peritoneal, or fallopian tube carcinoma based on the results of study MO22224 (AURELIA)."
Request for Supplementary Information adopted on 19.12.2013.
The Committee discussed the issues identified in this application, mainly concerning the efficacy and safety of the product as well as proposed SmPC changes.
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, "The MAH proposed the update of SmPC section 4.1 to add a new indication for treatment of adult patients with diabetic macular oedema. The Package Leaflet was proposed to be updated accordingly."
Request for Supplementary Information adopted on 20.02.2014.
Requested 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 related to the optimal long-term posology and the need to collect additional post marketing data in this respect.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Halaven (EMEA/H/C/002084/II/0011), (eribulin), MAH: Eisai Europe Ltd., Rapporteur: Filip Josephson, Co-Rapporteur: Jens Ersbøll, "Extension of Indication to include the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. The Package Leaflet is updated accordingly."
Request for Supplementary Information adopted on 20.03.2014, 19.12.2013, 25.07.2013.
The members noted that the applicant withdrew the request to exclude patients with HER2-positive disease from 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 recommendation.
The summary of opinion was circulated for information.

Prezista (EMEA/H/C/000707/II/0064), (darunavir), MAH: Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Sabine Straus, "Update of the SmPC with an extension of indication in treatment naïve children aged 3 to 12 years and changes in the posology of the treatment experienced children aged 3 to 12 years with no DRV RAMs based on the data from a 2 week qd substudy of the Phase 2 study TMC114 C228 and results from model-based pharmacokinetic simulations. The Package Leaflet is proposed to be updated accordingly."

The Committee discussed the issues identified in this application which related mainly to requesting additional pharmacokinetics clarifications and the need for an updated RMP.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Stivarga (EMEA/H/C/002573/II/0001), (regorafenib), MAH: Bayer Pharma AG, 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. The Package Leaflet is proposed to be updated accordingly."
Request for Supplementary Information adopted on 19.12.2013.
Requested 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, focusing on clarifications required for some clinical efficacy aspects including the biomarker analyses as well as non-clinical and RMP issues.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Sustiva (EMEA/H/C/000249/II/0126/G), (efavirenz), MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Margarida Guimarães, "Grouped variation consisting of two consequential variations. A type II variation to extend the therapeutic indication to include children 3 months of age to less than 3 year of age and weighing at least 3.5kg. A type IB, consequential to this update, to remove the Oral Solution pharmaceutical form for Sustiva (efavirenz) and as such upgrade the already approved "capsule sprinkle" dosing method as primary means of dosing for young patients and those that cannot swallow capsules and/or tablets"
The Committee discussed the issues identified in this application which related to non-clinical and a number of pharmacokinetics aspects. In addition, safety clarifications were requested regarding the possibility that long term exposure to efavirenz in children might impact CNS development and further comparative safety analysis of the use of the 3 different pharmaceutical forms.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Vfend (EMEA/H/C/000387/II/0097), (voriconazole), MAH: Pfizer Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Pierre Demolis, PRAC Rapporteur: Sabine Straus, "Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the Vfend SmPC to include information pertaining to the proposed new indication in prophylaxis of invasive fungal infections in high risk hematopoietic stem cell transplant recipients. The Package Leaflet is updated accordingly."
Request for Supplementary Information adopted on 25.04.2014, 24.10.2013.
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 recommendation.
The summary of opinion was circulated for information.

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 PL is proposed to be updated accordingly."
The CHMP noted the background information from the PDCO coordinator on the PIP, proposing an extrapolation study.

The Committee discussed the issues identified in this application mainly relating to further justifications required for the recommended starting dose in children and adolescents. The Committee also noted that a RMP in the general use would be required as so far none was available.
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. The Package Leaflet is proposed to be updated accordingly."
Request for Supplementary Information adopted on 19.09.2013, 21.03.2013.
The Committee discussed the issues identified in this application which related to several aspects of the clinical efficacy and 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

No items

5. ANCILLARY MEDICINAL SUBSTANCES IN MEDICAL DEVICES

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

Floseal Hemostatic Matrix (Floseal VH S/D) (EMEA/H/D/000956/X/0016), (human thrombin), "Addition of a new strength/concentration: 5000 IU Thrombin/vial (500 IU Thrombin/mL)."
The Committee discussed the issues identified in this application.
The Committee adopted the CHMP recommendation and scientific discussion together with the List of Questions

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

Masiviera (EMEA/H/C/002659), Orphan, (masitinib), Applicant: AB Science, (treatment of non resectable locally advanced or metastatic pancreatic cancer)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted on 23.01.2014. List of Outstanding Issues adopted on 19.09.2013. List of Questions adopted on 17.01.2013.
See also 1.2 Re-examination Procedure Oral Explanation
The CHMP noted the report from the SAG Oncology held on 7 May 2014. The experts considered the efficacy data not convincing due to methodological and pathophysiological/biological issues. The SAG concluded that the efficacy has not been sufficiently demonstrated. Although the experts did not have major concern on the toxicity profile, the safety was considered unacceptable in light of the presented efficacy. Overall the SAG agreed with the CHMP grounds for negative opinion and made minor recommendations for amendment.
An Oral explanation was held on Wednesday 21 May 2014 at 11.00 mainly focusing on clarifying the CHMP perception on the poor efficacy of this product.
The Committee was also made aware of the decision of the French authority to suspend all clinical trials outside cancer indication due to concerns over patient's safety.

The CHMP adopted a negative opinion by consensus confirming the negative opinion adopted in January 2014, together with the assessment report.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The refusal question-and-answer document was circulated for information.

Nerventra (EMEA/H/C/002546), (laquinimod), Applicant: Teva Pharma GmbH, (treatment of multiple sclerosis)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted on 23.01.2014. List of Outstanding Issues adopted on 21.11.2013, 25.07.2013. List of Questions adopted on 15.11.2012.
See 1.2 Re-examination Procedure Oral Explanation
The CHMP noted the report from the SAG Neurology meeting held on 8 May 2014 as well as the report from the SWP and the PRAC advice. Overall, the SWP and PRAC maintain their initial views regarding the concerns over the non-clinical findings (carcinogenicity, teratogenicity) and the proposed risk minimisation measures and pharmacovigilance activities, respectively. The SAG advised that the risks seen in animal studies could have been acceptable if a clear benefit was seen in clinical studies, although a strict pregnancy prevention scheme would have been required. The SAG also considered that according to the available data there was no sub-group of patients that stood out on the basis of the observed efficacy. The drug did not seem to perform differently according to baseline EDSS or other characteristics of the relapsing remitting multiple sclerosis (RRMS) population.
An Oral explanation was held on Monday 19 May 2014 at 15.00. Of note, the limited RRMS population as proposed as revised indication within the re-examination package was finally not pursued by the applicant in their latest SmPC proposal.
After the Oral explanation the members discussed the available efficacy and safety data for the broad RRMS indication and potential restrictions in the wording of the indication to address the teratogenicity risk. The CHMP noted that the effect of the medicine in preventing relapses was modest, and though its effect in slowing the worsening of disability was encouraging it still needed to be confirmed. Therefore the Committee concluded that the benefits of Nerventra at the dose studied were not sufficient to outweigh the potential risks in patients with relapsing remitting multiple sclerosis and maintained its recommendation that the medicine be refused marketing authorisation.
The CHMP adopted a negative opinion by consensus confirming the negative opinion adopted in January 2014, together with the CHMP assessment report.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The refusal question-and-answer document was circulated for information.
The SWP report was adopted.

Reasanz (EMEA/H/C/002817), (serelaxin), Applicant: Novartis Europharm Ltd, (treatment of acute heart failure)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted in January 2014.
See 1.2 Re-examination Procedure Oral Explanation
The CHMP noted the report from the SAG CVS held on 12 May 2014 which was consistent with the previous view of the SAG despite a slightly different composition of members.
An Oral explanation was held on Tuesday 20 May 2014 at 15.00, mainly focusing on the worsening of effect and the selectivity.
The Committee adopted a negative opinion by majority (25 negative out of 32 votes), together with the assessment report.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The divergent position (David Lyons, John Joseph Borg, Jens Heisterberg, Nela Vilceanu, Kristina Dunder, Mila Vlaskovska, Dimitrios Kouvelas) was appended to the opinion.
The refusal question-and-answer document was circulated for information.

Translarna (EMEA/H/C/002720), Orphan, (ataluren), Applicant: PTC Therapeutics Limited, (treatment of Duchenne muscular dystrophy.)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted on 23.01.2014. List of Outstanding Issues adopted on 19.09.2013. List of Questions adopted on 21.03.2013.
See 1.2 Re-examination Procedure Oral Explanation
An Oral explanation was held on Tuesday 20 May 2014 at 11.00.
The applicant presented data in order to substantiate the efficacy for a conditional approval, including justifying the bell-shaped dose-response curve.
After the Oral explanation the members discussed the available efficacy data with specific emphasis on the dose-response curve. The members agreed that the data was limited, but discussed whether a conditional approval could be considered with further data to be generated after approval. The members were reminded of possible regulatory action in case further data from on-going clinical trials were negative.
The members discussed whether the indication pursued by the Applicant, i.e. treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 5 years and older, should be restricted to patients in the decline phase of ambulation. The CHMP concluded that such restriction would not be warranted in line with the available data. The CHMP was made aware of a recent publication: Eitan Kerem et al. Ataluren for the treatment of nonsense-mutation cystic fibrosis: a randomised, double-blind, placebo-controlled phase 3 trial, Lancet, published online on 16 May 2014. In this publication some safety issues were raised, although in a different indication.
In order to ensure that the publication did not include any new data which had not been assessed the CHMP agreed on a 2nd Oral Explanation.
A second Oral explanation was held on Wednesday 21 May 2014 at 08:30. After the second oral explanation the Committee discussed the safety profile of the drug considering the concomitant administration of systemic nephrotoxic drugs (in particular aminoglycosides) in the study and concluded that the safety profile of ataluren could be considered acceptable.
The Committee adopted a positive Opinion recommending the granting of a conditional marketing authorisation by majority (20 positive out of 32 votes), together with the CHMP assessment report and translation timetable.
The Icelandic and Norwegian Members were not in agreement with the CHMP recommendation.
The divergent position (Karsten Bruins Slot, Greg Markey, Pieter de Graeff, Alar Irs, Sol Ruiz, Concepcion Prieto Yerro, Ondrej Slanar, Nela Vilceanu, Robert Hemmings, Daniel Brasseur, Romaldas Maciulaitis, Dinah Duarte, Reynir Arngrimsson, David Lyons) was appended to the opinion.
The legal status was agreed as medicinal product subject to restricted medical prescription.
The members noted the letter of recommendation dated 21.05.2014.
The summary of opinion and the updated question-and-answer document were circulated for information.

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

No items

8. WITHDRAWAL OF APPLICATION

Vynfinit (EMEA/H/C/002571), Orphan, (vintafolide), Applicant: Endocyte Europe, B.V., (treatment of platinum resistant ovarian cancer (PROC))
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted in March 2014.
See Neocepri, Folcepri
The CHMP noted the letter from the applicant informing of the decision to withdraw the marketing Authorisation Application.
Furthermore the CHMP noted the letter from the EC requesting a revision of the opinion, in view of the preliminary data on an on-going confirmatory study that became available and led to the termination of the study. The members noted that a response letter will be sent.

Folcepri (EMEA/H/C/002570), Orphan, (etarfolatide), Applicant: Endocyte Europe, B.V., (indicated for single photon emission computed tomography (SPECT) imaging)
New active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted in March 2014.
See Vynfinit

Neocepri (EMEA/H/C/002773), Orphan, (folic acid), Applicant: Endocyte Europe, B.V., (indicated for the enhancement of Folcepri single photon emission computed tomography (SPECT) image quality)
Known active substance (Article 8(3) of Directive No 2001/83/EC)
Opinion adopted in March 2014.
See Vynfinit

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

No items

10. PRE-SUBMISSION ISSUES

(H0003870), Orphan (Tasielteon), (Non-24-Hour Disorder (Non-24) in the totally blind)
The CHMP did not agree to the accelerated assessment request and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

11. POST-AUTHORISATION ISSUES

Protelos (EMEA/H/C/000560/II/0035) (Strontium Ranelate), Applicant: Les laboratoires Servier, Rapporteur: Kristina Dunder, Co-rapporteur: Andrea Laslop, Extension of indication to include treatment of osteoarthritis. Request for supplementary information adopted in July 2012 and February 2013.
See Osseor II/31
The CHMP noted the letter from the MAH dated 21 March 2014 informing of the decision to withdraw the application.

Osseor (EMEA/H/C/000561/II/31) (Strontium Ranelate), Les Laboratoires Servier, Rapporteur: Kristina Dunder, Co-Rapporteur: Andrea Laslop, Extension of indication to include treatment of osteoarthritis. Request for supplementary information adopted in July 2012 and February 2013.
See Protelos II/35
The CHMP noted the letter from the MAH dated 21 March 2014 informing of the decision to withdraw the application.

Hirobriz Breezhaler (EMEA/H/C/001211/R/0030), (indacaterol), MAH: Novartis Europharm Ltd, Duplicate, Duplicate of Onbrez Breezhaler, Oslif Breezhaler, Rapporteur: Jens Heisterberg, Co-Rapporteur: David Lyons, PRAC Rapporteur: Line Michan
Renewal procedure
The Committee discussed the issues identified in this application, regarding the labelling of the dose.
The CHMP agreed to change the expression of dose to “delivered dose”.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Onbrez Breezhaler (EMEA/H/C/001114/R/0029), (indacaterol), MAH: Novartis Europharm Ltd, Rapporteur: Jens Heisterberg, Co-Rapporteur: David Lyons, PRAC Rapporteur: Line Michan,
Renewal procedure
The Committee discussed the issues identified in this application, regarding the labelling of the dose.
The CHMP agreed to change the expression of dose to “delivered dose”.
The Committee adopted a Request for Supplementary Information with a specific timetable.

Oslif Breezhaler (EMEA/H/C/001210/R/0029), (indacaterol), MAH: Novartis Europharm Ltd, Duplicate, Duplicate of Onbrez Breezhaler, Rapporteur: Jens Heisterberg, Co-Rapporteur: David Lyons, PRAC Rapporteur: Line Michan
Renewal procedure
The Committee discussed the issues identified in this application, regarding the labelling of the dose.
The CHMP agreed to change the expression of dose to “delivered dose”.
The Committee adopted a Request for Supplementary Information with a specific timetable.

WS0558
Januvia-EMEA/H/C/000722/WS0558/0041
Ristaben-EMEA/H/C/001234/WS0558/0031
TESAVEL-EMEA/H/C/000910/WS0558/0041
Xelevia-EMEA/H/C/000762/WS0558/0045
(sitagliptin), MAH: Merck Sharp & Dohme Limited, Rapporteur: Pieter de Graeff, “Proposal to update section 5.1 of the SmPC with the results of study PN260 which examined the insulin-sparing effect of sitagliptin 100 mg once-daily compared with placebo over 24 weeks in participants with type 2 diabetes mellitus who have inadequate glycaemic control on insulin alone or in combination with metformin.”
The Committee discussed the proposed major objection but agreed that it would be appropriate in this case to add the proposed information in section 5.1 of the SmPC. Thus, there was no longer any need for an RSI and the Committee adopted a positive opinion for WS0558.
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.

WS0559
Efficib-EMEA/H/C/000896/WS0559/0060
Janumet-EMEA/H/C/000861/WS0559/0059
Ristfor-EMEA/H/C/001235/WS0559/0045
Velmetia-EMEA/H/C/000862/WS0559/0063
(sitagliptin / metformin hydrochloride), MAH: Merck Sharp & Dohme Limited, Rapporteur: Pieter de Graeff, "Proposal to update section 5.1 of the SmPC with the results of study PN260 which examined the insulin-sparing effect of sitagliptin 100 mg once-daily compared with placebo over 24 weeks in participants with type 2 diabetes mellitus who have inadequate glycaemic control on insulin alone or in combination with metformin."

The Committee discussed the proposed major objection but agreed that it would be appropriate in this case to add the proposed information in section 5.1 of the SmPC. Thus, there was no longer any need for an RSI and the Committee adopted a positive opinion for WS0559.
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.

Avastin (EMEA/H/C/000582) (BEVACIZUMAB), Applicant: Roche Registration Ltd, Rapporteur: Jens Ersbøll, Co-Rapporteur: Ingunn Hagen Westgaard
Follow up from March 2014. 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 Committee agreed to the advice from the Oncology Working Party to further elaborate on discrepancies between PFS and OS but recommended to only focus on colorectal cancer.
The CHMP adopted a list of questions to the MAH.

12. REFERRAL PROCEDURES

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

Procoralan (EMEA/H/C/000597)
Corlentor (EMEA/H/C/000598)
Procedure number: **EMEA/H/A20/1404/C/000597-598/0031-0032**
(Ivabradine Hydrochloride), MAH: Les Laboratoires Servier, Rapporteur: Pieter de Graeff, Co-Rapporteur: Janne Komi,
Article 20 procedure triggered by the EC to assess how the results of the SIGNIFY study, which showed a statistically significant increase in a composite endpoint of cardiovascular death and non-fatal MI, impact on the benefit-risk balance of Corlentor and Procoralan.
The CHMP was informed about the start of procedure of this Article 20 referral at the PRAC.

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
See also section 12.6 Community Interests - Referral under Article 31
The CHMP agreed that the PKWP should consult the MSWG (Modelling and simulation working group) on the adequacy of the PK data submitted by the MAH in the context of the on-going procedure.
The CHMP adopted a revised timetable to reflect the dates for the consultation of the PKWP and the IDWP: Submission of responses: 28.05.2014; PKWP consultation: 10.06.2014; IDWP meeting: 12-13.06.2014; 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 2001/83/EC

Dexamed 5 mg Tablets (EMEA/H/A-29/1375) (Dexamfetamine Sulphate film coated tablets), Kohne Pharma GmbH, Rapporteur: Greg Markey, Co-Rapporteur: Johann Lodewijk Hillege,
Article 29(4) procedure triggered by the Netherlands on the following grounds: enhanced risk for dependence and abuse potential of this product compared to other treatment options in ADHD and lack of convincing evidence for the efficacy in a second line setting – film coated tablets.
List of Outstanding Issues adopted in March 2014 by written procedure.
See also 1.4 Referral Oral explanations

The CHMP noted the report from the SAG Psychiatry meeting held on 12 May 2014. The experts considered the risk of dependence in patients treated with Dexamfetamine to be low. The proposed risk minimisation measures were thought to be sufficient. Although some safety issues were identified with long-term use, no major concern was raised. The experts saw a value of Dexamed as additional treatment option of ADHD. The SAG recommended treatment initiation and monitoring by a specialist.
An Oral explanation was held on Tuesday 20 May 2014 at 9.00 mainly focusing on addressing CHMP concerns regarding the risk of dependence amongst children and the abuse potential of such product.
The Committee confirmed that all issues previously identified in this application had been addressed.
The Committee concluded that the objections raised by the Netherlands should not prevent the granting of the marketing authorisation.
The Committee adopted an Opinion recommending the granting of a 2nd line indication by majority (28 positive out of 32 votes), together with the CHMP assessment report.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
The divergent position (Daniel Brasseur, Nela Vilceanu, Pierre Demolis, Pieter de Graeff) was appended to the opinion.
The question-and-answer document was circulated for information.

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

EMLA Crème (EMEA/H/A-30/1388) (lidocaine / prilocaine), Astra Zeneca group of companies and associated companies, Rapporteur: Martina Weise, Co-Rapporteur: Greg Markey,
List of Questions adopted in October 2013, Extension of Timetable 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 together with a specific timetable.
List of outstanding issues: 22.05.2014; Responses to list of outstanding issues: 13.06.2014; Restart of the procedure: 24.06.2014; Assessment report: 09.07.2014; Comments from CHMP 14.07.2014; Oral explanation / CHMP Opinion: July 2014 CHMP

Seroquel IR&XR (EMA/H/A-30/1362) (quetiapine), Astra Zeneca, Rapporteur: Hans Hillege, Co-Rapporteur: Melinda Sobor,
List of Outstanding Issues adopted in November 2013 and March 2014. List of Questions adopted in June 2013.
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 question-and-answer document was circulated for information.

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 and 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 Questions adopted in January 2014.
The CHMP discussed the available data and which further supportive information could be generated by additional studies or analysis.
The CHMP adopted a List of Outstanding Issues together with a specific timetable.
Submission of responses: 16.06.2014; Re-start of the procedure: 23.06.2014; Rapporteur/co-rapporteur assessment reports circulated to CHMP: 15.07.2014; Comments: 17.07.2014
List of outstanding issues / Oral explanation / CHMP opinion: July 2014 CHMP

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

RAS-acting agents (EMEA/H/A-31/1370) Overall CHMP Rapporteur: Daniela Melchiorri, Overall PRAC Rapporteur: Carmela Macchiarulo (IT), PRAC Co-Rapporteurs: Margarida Guimarães (PT), Valerie Strassmann (DE), Tatiana Magálová (SK), Dolores Montero Corominas (ES), Almath Spooner (IE), Menno van der Elst (NL), Julie Williams (UK), Qun-Ying Yue (SE)
Review of the benefit-risk of dual blockade of the renin angiotensin system through concomitant use of ARBs, ACE-inhibitors or aliskiren-containing medicines following the notification by Italy of a referral under Article 31 of Directive 2001/83/EC based on pharmacovigilance data
The CHMP noted the PRAC conclusion that the benefit-risk balance of the RAS-acting agents remains favourable, provided that their product information is revised to reflect the concerns associated with dual RAS blockade therapy.
Based on the PRAC recommendation, the CHMP adopted an opinion by consensus recommending that the marketing authorisations for RAS-acting agents should be varied.
The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

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.
See also section 12.2 Requests for CHMP Opinion under Article 5(3)
The CHMP agreed that the PKWP should consult the MSWG (Modelling and simulation working group) on the adequacy of the PK data submitted by the MAH in the context of the on-going procedure.
The CHMP adopted a revised timetable to reflect the dates for the consultation of the PKWP and the IDWP: Submission of responses: 28.05.2014; PKWP consultation: 10.06.2014; IDWP meeting: 12-13.06.2014; 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)

Oxynal 10mg/5mg, 20mg/10mg

Targin 10mg/5mg, 20mg/10mg, 40mg/20mg, 5mg/2.5mg
(EMEA/A-13/1402)
(oxycodone/naloxone), Mundipharma GmbH, Mutual Recognition Procedure number: DE/H/XXXX/WS/044.
Article 13 procedure triggered by Germany on the following grounds: the benefit risk balance for the claimed indication is considered negative as the available clinical data, the proposed product information and the proposed risk minimisation measures are insufficient to assure that the risks of iatrogenic drug dependence and drug prescription abuse outweigh the benefits.
The CHMP noted the Letter from BfArM in Germany dated 2 May 2014 notifying of an official referral under Article 13.
The CHMP appointed Martina Weise as Rapporteur and Johann Lodewijk Hillege as Co-Rapporteur.
The Committee adopted a List of Questions together with a specific timetable.
Notification: 02.05.2014; Start of the procedure (CHMP): 22.05.2014; List of questions to be addressed to the MAH: 22.05.2014; Responses to list of questions by MAH: 01.09.2014; Re-start of the procedure: 23.09.2014; Rapporteur/co-rapporteur assessment reports circulated to CHMP: 08.10.2014 Comments from CHMP: 13.10.2014; List of outstanding issues or CHMP opinion: October 2014 CHMP

13. PHARMACOVIGILANCE ISSUES

Summary of recommendations and advice of PRAC meeting held on 5-8 May 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 May 2014: **for adoption**	The EURD list was adopted.
Early Notification System: May 2014 Early Notification System on Envisaged CHMP Recommendations for Regulatory Action (based on Identified Safety Concerns) Accompanied by Communication to the General Public: **for information**	See individual items

14. INSPECTIONS

14.1. GMP Inspections

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.*

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

Minutes from the 2Q 2014 EU-Innovation Network Teleconference held on 12 May 2014: **For information** Minutes from the March ITF Plenary held on 21 March 2014: **For information**	The Minutes were noted by the CHMP.

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 Report. Briefing Meeting held on 13 March 2014 within the margin of CAT: **For information**	The Meeting Report was noted by the CHMP.
ITF Briefing held on 19 May 2014 within/in the margin of CAT**: For information**	The Meeting Report was noted by the CHMP.

15.3. Eligibility to EMA scientific services

No items

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

Request from DG Sanco for EMA scientific Opinion under Article 57 (1)P of Regulation No 726/2004**.** • CHMP Coordinator: **To be appointed**	The CHMP adopted the Request from DG Sanco for EMA scientific Opinion under Article 57 (1)P of Regulation No 726/2004**.** A CHMP coordinator was appointed.

15.5. Nanomedicines activities

No items

16. SCIENTIFIC ADVICE WORKING PARTY (SAWP)

Report from the SAWP meeting held on 05-07 (08) May 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 19-21 May 2014: **for information**	The CHMP noted the report.
Letter from CMD(h) to QWP on dissolution specifications for Levothyroxine Vale tablets (NL/H/2700/001-011/DC): **For information** • Consultation of QWP: **For adoption** • QWP response to CMDh on Levothyroxine Vale tablets (NL/H/2700/001-011/DC)	The CHMP noted the letter from the CMDh and having agreed to the consultation of the QWP, the Committee adopted the QWP response.
Letter from CMD(h) to CHMP regarding guidance on comparison of quality attributes: **For information**	The CHMP noted the letter from the CMDh.

18. OTHER COMMITTEES

Committee for Orphan Medicinal Products (COMP)

Press release of the COMP meeting held on 13-14 May 2014: **for information**	To be sent in the Post-mail.

Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 5-6 May 2014: **for information**	To be sent in the Post-mail.

Paediatric Committee (PDCO)

PIPs reaching D30 at May 2014 PDCO: **for information**	To be sent in the Post-mail.
Report from the PDCO meeting held on 21-23 May 2014: **for information**	The CHMP noted the report.

Committee for Advanced Therapies (CAT)

Table of Decisions of CAT meeting held on 15-16 May 2014: **for information**	The CHMP noted the Table of Decision.

19. INVENTED NAME ISSUES

• Invented name issue	Report on the outcome of the drafting group. The clinical risk related to use of the different salts was considered to be very low. The use of invented names was not considered necessary and it was agreed to use the INNMs (salt forms) combined with the MAH option.

20. ANY OTHER BUSINESS

Procedural Advice on the CHMP, CAT & PRAC (Co-) Rapporteur appointment: **For discussion**	Postponed to June 2014.
BPWP composition: **For adoption**	The CHMP adopted the composition of the BPWP.
Composition of temporary Working Party: **For adoption** • Biosimilar Medicinal Products Working Party • Infectious Diseases Working Party • Rheumatology-Immunology Working Party • Vaccines Working Party • Central Nervous System Working Party Work • Cardiovascular Working Party • Pharmacogonomics Working Party Work • Pharmacokinetics Working Party Work • Oncology Working Party • Biostatistics Working Party Work	The CHMP adopted the compositions of the temporary working parties. Further to the adoption of the composition of the temporary working parties an additional expert for the Oncology Working Party was agreed (for paediatric aspects). For the Biostatistics Working Party further to the composition of members presented, the CHMP noted the nomination of an observer.
Composition of Drafting Groups: **For adoption** • Radiopharmaceutical Drafting Group • Gastroenterology Drafting Group	The CHMP adopted the compositions of the drafting groups. For the Gastroenterology Drafting Group further to the composition of members presented, the CHMP noted the nomination of an observer.

Q&A on excipients Gluten (EMA/CHMP/704219/2013): **For adoption for 3-month public consultation**	Postponed to June 2014.
Q&A on Benzalkonium chloride (EMA/CHMP/495737/2013): **For adoption for 3-month public consultation**	Adopted for 3-month public consultation.
Reflection Paper on the use of Patient Reported Outcome (PRO) measures in oncology studies" following comments from the GCG: **For adoption** • Overview of comments from the Guidelines Consistency Group: **For information**	The Reflection Paper was presented and was adopted for 6-month public consultation.
Follow-up discussion on changes regarding the processing of type II variations, introduction to rolling timetable, and changes to the AR template CHMP Sponsors: Pieter De Graeff, Jan Mueller Berghaus and Outi Mäki-Ikola •	Initial discussion regarding the proposed changes for processing some type II variations. The Committee discussed the potential introduction of rolling timetables for "simple" type II variations and subsequent changes to the assessment report template. It was agreed that members should sent their comments. Further discussion will take place at the June CHMP meeting.
Follow up discussion on principles for RMP revised process: **For discussion**	Overall the CHMP was positive towards the proposal. Comments were raised how this new procedure would impact abridged applications due to concerns of potential increased workload for CHMP. Comments were also raised regarding future templates and responsibilities to fill the various sections. It was clarified that the templates were under revision and further discussion will be needed. Finally, a number of clarifications were provided on the responsibility of the CHMP (Co-) Rapporteurs. It was confirmed that the CHMP Rapporteur assesses the Q, S, E aspects of the MAA, as well as the safety specifications part of the RMP while the CHMP Co-Rapporteur assesses the Q, S, E aspects of the MAA, raising only high level issues on the safety specifications part of the RMP. The revised principles will now be discussed at HMA prior to further discussion at the MB on 12th June 2014.

Mandate of new Ethics Advisory Group (EAG) CHMP sponsors to be appointed to revise the mandate: **For discussion**	The proposed Ethics Advisory Group (EAG) should be an ad-hoc EMA inter-committee advisory group, with a structure similar to a SAG. The main role of the EAG should be to deliver answers, on a consultative basis, to specific questions addressed to them in relation to ethical aspects of clinical trials, in the context of their evaluation for marketing authorisation, and assist the CHMP and/or the other Committees in preparing their opinion.
EMA Guidelines Consistency Group (GCG)updated mandate (EXT/268347/2014): **For adoption** • Appointment of GCG Chair: **For adoption**	The CHMP appointed Barbara van Zwieten-Boot as GCG Chair and adopted the revised mandate for this group.
Guideline on the acceptability of names for human medicinal products processed through the centralised procedure – Revision 6 (EMA/219064/2014): **For adoption**	Follow up from the May 2014 ORGAM meeting. The CHMP adopted the Guideline.

21. **List of participants:** *including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 19-22 May 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*
Daniel Brasseur	Belgium	Full involvement	
Mila Vlaskovska	Bulgaria	Full involvement	
Panayiotis Triantafyllis	Cyprus	Full involvement	
Ondřej Slanař	Czech Republic	No participation in discussions, final deliberations and voting on:	WS0558 Januvia-EMEA/H/C/000722/WS0558/0041 Ristaben-EMEA/H/C/001234/WS0558/0031 TESAVEL-EMEA/H/C/000910/WS0558/0041 Xelevia-EMEA/H/C/000762/WS0558/0045 (sitagliptin)
			WS0559 Efficib-EMEA/H/C/000896/WS0559/0060 Janumet-EMEA/H/C/000861/WS0559/0059 Ristfor-EMEA/H/C/001235/WS0559/0045 Velmetia-EMEA/H/C/000862/WS0559/0063 (sitagliptin / metformin hydrochloride)
			Prezista (EMEA/H/C/000707/II/0064), (darunavir)
			Sustiva (EMEA/H/C/000249/II/0126/G), (efavirenz)
			(EMEA/H/C/003698), (brinzolamide / brimonidine tartrate)
			Seroquel IR&XR (EMA/H/A-30/1362) (quetiapine)
			RAS-acting agents (EMEA/H/A-31/1370)
			Oxynal 10mg/5mg, 20mg/10mg Targin 10mg/5mg, 20mg/10mg, 40mg/20mg, 5mg/2.5mg (EMEA/A-13/1402) (oxycodone/naloxone)
		No participation in final	Vfend (EMEA/H/C/000387/II/0097), (voriconazole)

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
		deliberations and voting on:	Noxafil (EMEA/H/C/000610/X/0033), (posaconazole)
			Hirobriz Breezhaler (EMEA/H/C/001211/R/0030), (indacaterol)
			Onbrez Breezhaler (EMEA/H/C/001114/R/0029), (indacaterol)
			Oslif Breezhaler (EMEA/H/C/001210/R/0029), (indacaterol)
Jens Heisterberg	Denmark	No participation in final deliberations and voting on:	Seroquel IR&XR (EMA/H/A-30/1362) (quetiapine)
Alar Irs	Estonia	Full involvement	
Outi Mäki-Ikola	Finland	No participation in final deliberations and voting on:	(EMEA/H/C/002705), (mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches)
			Xgeva(EMEA/H/C/002173/II/0016 (denosumab)
			Reasanz (EMEA/H/C/002817) (Serelaxin)
			Rienso (EMEA/H/C/002215/II/0008), (ferumoxytol)
			Procoralan (EMEA/H/C/000597)
			Corlentor (EMEA/H/C/000598)
Pierre Demolis	France	Full involvement	
Harald Enzmann	Germany	Full involvement	
Dimitrios Kouvelas	Greece	Full involvement	
Agnes Gyurasics	Hungary	Full involvement	
David Lyons	Ireland	Full involvement	
Juris Pokrotnieks	Latvia	No participation in discussions, final deliberations and voting on:	Rienso (EMEA/H/C/002215/II/0008), (ferumoxytol)
			Simponi (EMEA/H/C/000992/X/0047), (golimumab)
Romaldas Mačiulaitis	Lithuania	Full involvement	
Jacqueline Genoux-Hames	Luxembourg	Full involvement	
John Joseph Borg	Malta	Full involvement	
Pieter de Graeff	Netherlands	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
Karsten Bruins Slot	Norway	Full involvement	
Piotr Fiedor	Poland	Full involvement	
Bruno Sepodes	Portugal	Full involvement	*Only connecting via TC on Sustiva*
Nela Vilceanu	Romania	Full involvement	
Stanislav Primožič	Slovenia	Full involvement	
Concepcion Prieto Yerro	Spain	Full involvement	
Kristina Dunder	Sweden	Full involvement	
Greg Markey	United Kingdom	Full involvement	
Robert James Hemmings	Co-opted	Full involvement	
Sol Ruiz	Co-opted	Full involvement	
Jean-Louis Robert	Co-opted	Full involvement	
Jan Mueller-Berghaus	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
Milena Stain	Austria	Full involvement	*Replacing CHMP member*
Bart Van der Schueren	Belgium	Full involvement	
Ana Dugonjić	Croatia	Full involvement	*Replacing CHMP member*
Jens Ersbøll	Denmark	Full involvement	
Janne Komi	Finland	Full involvement	
Joseph Emmerich	France	Full involvement	
Martina Weise	Germany	Full involvement	
Reynir Arngrímsson	Iceland	Full involvement	*Replacing CHMP member*
Patrick Salmon	Ireland	Full involvement	
Daniela Melchiorri	Italy	Full involvement	*Replacing CHMP member*
Johann Lodewijk Hillege	Netherlands	Full involvement	
Ingunn Hagen Westgaard	Norway	Full involvement	
Dinah Duarte	Portugal	Full involvement	*Replacing CHMP member*
Jana Klimasová	Slovakia	Full involvement	*Replacing CHMP member*
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	

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.			
Valerie Leschrainier	Belgium	Full involvement	
Jelena Biruš	Croatia	Full involvement	
Mette Madsen	Denmark	Full involvement	
Ljiljana Milosevic-Kapetanovic	France	Full involvement	
Gaelle Guyader	France	Full involvement	
Camille Schurtz	France	Full involvement	
Philippe Lechat	France	Full involvement	
Anne Driheme	France	Full involvement	
Sabine Mayrhofer	Germany	Full involvement	
Christoph Unkrig	Germany	Full involvement	
Anja Schiel	Norway	Full involvement	
Ana Alonso Gutierrez	Spain	Full involvement	
Jorge Camarero Jiménez	Spain	Full involvement	
Bengt Ljungberg	Sweden	Full involvement	
Gary Peters	United Kingdom	Full involvement	
Abidali Fazal	United Kingdom	Full involvement	
Nicola Parkinson	United Kingdom	Full involvement	
Marie-Christine Bielsky	United Kingdom	Full involvement	
Sabine Lenton	United Kingdom	Full involvement	
Parvinder Singh Phul	United Kingdom	Full involvement	
Zoran Simic	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.			
Serge Bakchine	France	Full involvement	
Clemens Mittmann	Germany	Full involvement	
Gabriele Schlosser	Germany	Full involvement	
Henning Brohmann	Germany	Full involvement	
Andreas Brandt	Germany	Full involvement	
Marcus Savsek	Germany	Full involvement	
Elmer Schabel	Germany	Full involvement	
Jan Willem van der Laan	Netherlands	Full involvement	
Patrick Vrijlandt	Netherlands	Full involvement	
Jan Schellens	Netherlands	Full involvement	
Anna Maria Gerdina Pasmooij	Netherlands	Full involvement	
Lies van Vlijmen	Netherlands	Full involvement	
Violeta Stoyanova-Beninska	Netherlands	Full involvement	
Leon Bongers	Netherlands	Full involvement	
Inger Mulder-van Dam	Netherlands	Full involvement	
Janneke van Leeuwen	Netherlands	Full involvement	
Luis Caldeira	Portugal	Full involvement	
Maria do Rosário Lobato	Portugal	Full involvement	
Maria Concepcion Payares	Spain	Full involvement	
Johan Franck	Sweden	Full involvement	
Daniel O'Connor	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)*

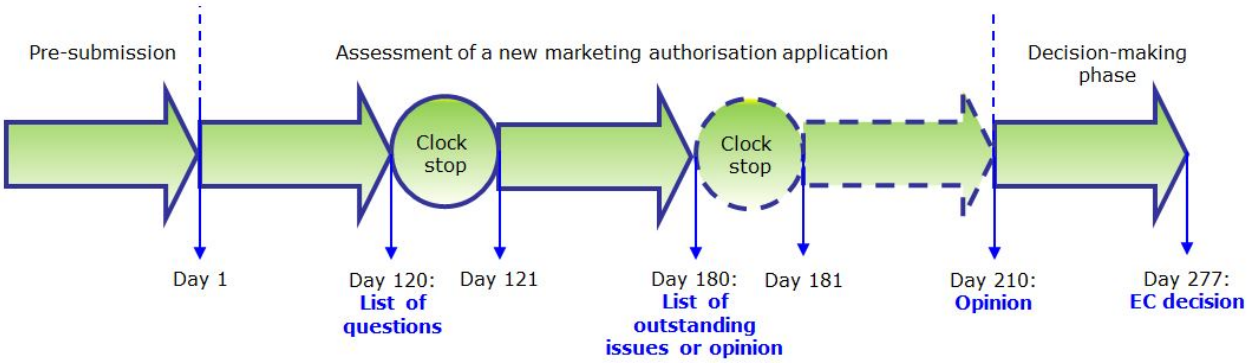
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 2 and 3) or referral procedures (section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