17 March 2014
EMA/CHMP/105714/2014 version 4
Procedure Management and Business Support Division

Committee for Medicinal Products for Human Use (CHMP)

Agenda of meeting to be held on 17-20 March 2014

Chair: Tomas Salmonson – Vice-chair: Pierre Demolis

17 March 2014, 13:00 – 19:30, room 3A

18 March 2014, 08:30 – 19:30, room 3A

19 March 2014, 08:30 – 19:30, room 3A

20 March 2014, 08:30 – 15:00, room 3A

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).

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health & safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential and therefore not disclosed. With regards to therapeutic indications listed against products it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. The procedures discussed by the CHMP are on-going and therefore are considered

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confidential. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available. For orphan medicinal products the applicant details are published as this information is already publicly available. Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

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

AGENDA (EMA/CHMP/105714/2014 4) and Annex to CHMP agenda of the CHMP plenary session to be held on 17-20 March 2014	
TIMESCHEDULE EMA/CHMP/131596/2014 version 4) of the CHMP plenary session to be held on 17-20 March 2014	
MINUTES (EMA/CHMP/120991/2014) of the CHMP plenary session held on 17-20 February 2014 and ORGAM meeting held on 10 March 2014	
MINUTES (EMA/CHMP/143039/2014) of the CHMP ORGAM meeting held on 10 March 2014	
PRE-MEETING LIST of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held on 17-20 March 2014	*See March 2014 Minutes (to be published post April 2014 CHMP meeting)*
Draft Agenda of CHMP meeting to be held on 22-25 April 2014 CHMP meeting.	

Table of Contents

1 ORAL EXPLANATIONS

1.1 Pre-authorisation Procedure Oral Explanations

(EMEA/H/C/002085), (tilmanocept), (used in the delineation and localisation of lymph nodes) List of Outstanding Issues adopted in December 2013, October 2013. List of Questions adopted in May 2013.	Oral explanation to be held on Wednesday 19 March 2014 at 9.00.
(EMEA/H/C/002643) (trametinib), (treatment of unresectable or metastatic melanoma with a BRAF V600 mutation) List of Outstanding Issues adopted in November 2013. List of Questions adopted in June 2013.	Oral explanation to be held on Tuesday 18 March at 14.30.

1.2 Re-examination Procedure Oral Explanation

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. Report from SAG Oncology held on 5 March 2014: **For discussion**	Oral explanation to be held on Tuesday 18 March at 17.00. See also 6 Re-examination procedure(New Applications) under Article 9(2) of Regulation no 726/2004

1.3 Post-authorisation Procedure Oral explanation

No items

1.4 Referral Procedures Oral Explanations

No items

2 NEW APPLICATIONS

2.1 Opinions – 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.
(EMEA/H/C/002782) (vedolizumab), (treatment of Ulcerative Colitis and Crohn's Disease) Oral explanation held in January 2014. List of Outstanding Issues adopted in December 2013. List of Questions adopted in July 2013.
(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.
(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.

(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.

(EMEA/H/C/002677) (empagliflozin), (treatment of type II diabetes mellitus)
List of Outstanding Issues adopted in December 2013.
List of Questions adopted in July 2013.

(EMEA/H/C/002777) (simeprevir), (indicated in combination with other medicinal products for the treatment of chronic hepatitis C in adult patients)
List of Outstanding Issues adopted in January 2014.
List of Questions adopted in September 2013.

(EMEA/H/C/002745)
(fluticasone furoate / vilanterol trifenatate), (treatment of asthma)

(EMEA/H/C/003708), Orphan
(siltuximab), Applicant: Janssen-Cilag International NV, (treatment of multicentric Castleman's disease (MCD))
List of Questions adopted in January 2014.

2.2 Day 180 List of outstanding issues – New full applications

(EMEA/H/C/002835) (insulin glargine), (treatment of diabetes mellitus)
List of Questions adopted in October 2013.

(EMEA/H/C/002647)
(insulin degludec / liraglutide), (treatment of type 2 diabetes mellitus)
List of Questions adopted in October 2013.

(EMEA/H/C/002314)
(bazedoxifene / estrogens conjugated), (treatment of oestrogen deficiency and osteoporosis)
List of Questions adopted in November 2012.

(EMEA/H/C/002655) (tacrolimus), (indicated for the prophylaxis of transplant rejection in adult kidney allograft recipients)
List of Questions adopted in September 2013.

(EMEA/H/C/002813) (simoctocog alfa), (treatment and prophylaxis of bleeding (congenital factor VIII deficiency)
List of Questions adopted in October 2013.

(EMEA/H/C/002780) (ospemifene), (treatment of vulvar and vaginal atrophy (VVA))
List of Questions adopted in July 2013.

(EMEA/H/C/002827)
(peginterferon beta-1a), (treatment of relapsing multiple sclerosis)
List of Questions adopted in October 2013.

(EMEA/H/C/002633), Orphan, (tobramycin), Applicant: PARI Pharma GmbH, (treatment of chronic pulmonary infection)
List of Outstanding Issues adopted in October 2013.
List of Questions adopted in February 2013.

(EMEA/H/C/002347) (perflubutane), (ultrasound imaging agent indicated for the detection of coronary artery disease (CAD))
List of Outstanding Issues adopted in November 2013.
List of Questions adopted in February 2013.

2.3 Day 120 List of Questions – New full applications

(EMEA/H/C/002830), Orphan
(mifepristone), Applicant: FGK Representative Service GmbH, (treatment of signs and symptoms of endogenous Cushing's syndrome in adults)

(EMEA/H/C/003729)
(secukinumab), (treatment of plaque psoriasis)

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

(EMEA/H/C/003720)
(faldaprevir), (treatment of chronic genotype-1 hepatitis C virus infection)

(EMEA/H/C/003843) (idelalisib), (treatment of patients with relapsed chronic lymphocytic leukaemia (CLL) and refractory indolent non-Hodgkin lymphoma (iNHL)

(EMEA/H/C/003791), Orphan
(ibrutinib), Applicant: Janssen-Cilag International NV, (treatment of mantle cell lymphoma, chronic lymphocytic leukemia, small lymphocytic lymphoma)

(EMEA/H/C/002807)
(human fibrinogen / human thrombin), (fibrocaps (human plasma-derived fibrinogen and thrombin) is used as an adjunct to haemostasis)

(EMEA/H/C/003771) (nonacog gamma), (treatment of haemophilia B)

(EMEA/H/C/002754)
(dolutegravir / abacavir / lamivudine), (treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age who are antiretroviral treatment-naïve or are infected with HIV without documented or clinically suspected resistance to any of the above-mentioned three antiretroviral agents)

2.4 Update on on-going new applications for Centralised Procedures

(EMEA/H/C/002548), Orphan
(afamelanotide), Applicant: Clinuvel (UK) Limited, (treatment of phototoxicity in adult patients with erythropoietic protoporphyria)
List of Outstanding Issues adopted in March 2013 and January 2014.

- List of Questions to Ad-hoc expert group meeting: **For adoption**

2.5 Products in the Decision Making Phase

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.

- Revised Opinion: **For adoption**
- Revised Assessment Report: **For adoption**

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

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.

Ventavis (EMEA/H/C/000474/X/0043), (iloprost), MAH: Bayer Pharma AG, Rapporteur: Pierre Demolis, PRAC Rapporteur: Evelyne Falip, "To add a new strength: 20 microgram/ml nebuliser solution (in 30 and 168 ampoules package sizes)"
List of Questions adopted in November 2013.

- Similarity Assessment Report: **For adoption**

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

No items

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

Signifor (EMEA/H/C/002052/X/0010), Orphan, (pasireotide), MAH: Novartis Europharm Ltd, Rapporteur: Kristina Dunder, Co-Rapporteur: Joseph Emmerich, PRAC Rapporteur: Qun-Ying Yue, "Line extension application for Signifor to add 20mg, 40mg and 60mg powder and solvent for suspension for injection in the treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative, or who are inadequately controlled on treatment with other somatostatin analogues"

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

No items

4 TYPE II VARIATIONS - Extension of indication procedures

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

Busilvex (EMEA/H/C/000472/II/0019), (busulfan), MAH: Pierre Fabre Médicament, Rapporteur: Arantxa Sancho-Lopez, "Extension of indication for fludarabine followed by Busilvex (FB) as conditioning treatment prior to hematopoietic progenitor cell transplantation (HPCT) in adult patients when such combinations are considered the best available option. Consequently, changes are proposed to sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC and the package leaflet. The MAH also took the opportunity to update the products information in line with QRD template version 9.0."
Request for Supplementary Information adopted in October 2013.

ECALTA (EMEA/H/C/000788/II/0026), (anidulafungin), MAH: Pfizer Limited, Rapporteur: Pieter de Graeff, Co-Rapporteur: Jens Ersbøll, PRAC Rapporteur: Sabine Straus, "Following the CHMP assessment of efficacy and safety data of Ecalta in neutropenic patients with invasive candidiasis and non-neutropenic patients with Cancida deep tissue infection (MEA 014.3), update of sections 4.1, 4.4, 4.8 and 5.1 of the SmPC. The Package Leaflet is updated accordingly. In addition the MAH proposes to take the opportunity of this variation to bring the SmPC in line with the QRD template version 9."	.
Halaven (EMEA/H/C/002084/II/0011), (eribulin), MAH: Eisai Europe Ltd., Rapporteur: Bengt Ljungberg, Co-Rapporteur: Jens Ersbøll, "Extension of the indication of Halaven 0.44 mg/ml solution for injection to earlier lines of metastatic breast cancer following the outcome of a Phase 3 study, Study 301. Changes have been made to SmPC sections 4.1, 4.8, and 5.1. The Package leaflet has been updated accordingly. Furthermore the product information has been updated in line with the latest QRD template version 9." Request for Supplementary Information adopted in December 2013, July 2013.	
Humira (EMEA/H/C/000481/II/0127), (adalimumab), MAH: AbbVie Ltd., Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Melchiorri, "Extension of indication in Enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. Consequently, the MAH proposed the update of sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC. The Package Leaflet was proposed to be updated in accordance."	

Pandemrix (EMEA/H/C/000832/II/0069), (pandemic influenza vaccine (h1n1) (split virion, inactivated, adjuvanted) a/california/7/2009 (h1n1)v like strain (x-179a)), MAH: GlaxoSmithKline Biologicals, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, "Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC to reflect data currently available on H1N1 influenza disease burden, effectiveness and safety of Pandemrix and epidemiology of narcolepsy. The Package Leaflet is updated accordingly. The MAH took also the opportunity to update the list of post-authorisation measures in Annex II"
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."
Stelara (EMEA/H/C/000958/II/0036), (ustekinumab), MAH: Janssen-Cilag International N.V., Rapporteur: Greg Markey, Co-Rapporteur: David Lyons, "Extension of indication to include reduction of the rate of progression of peripheral joint damage as measured by X-ray." Request for Supplementary Information adopted in November 2013.

Tasigna (EMEA/H/C/000798/II/0061), Orphan, (nilotinib), MAH: Novartis Europharm Ltd, Rapporteur: Jens Ersbøll, Co-Rapporteur: Harald Enzmann, PRAC Rapporteur: Doris Stenver, "Extension of indication of Tasigna 200mg hard capsules for the treatment of adult patients with Philadelphia chromosome positive CML in the chronic phase who have not achieved a molecular response greater than or equal to a 4.5-log reduction with imatinib treatment". Consequently, the MAH proposes changes to sections 4.1, 4.2, 4.8 and 5.1 of the SmPC."
Request for Supplementary Information adopted in October 2013.

Tresiba (EMEA/H/C/002498/II/0006), (insulin degludec), MAH: Novo Nordisk A/S, Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue, "The MAH proposed the update of sections 4.2 and 5.1 of the SmPC in order to include guidance for prescribers on the use of Tresiba in combination with GLP-1 receptor agonists. The Package Leaflet was proposed to be updated accordingly.
Furthermore, the MAH proposed this opportunity to bring the PI in line with the latest QRD template version 9 and to include some editorial changes. This variation application contains an updated RMP.
The requested variation proposed amendments to the SmPC, Annex II, Labelling and Package Leaflet."
Request for Supplementary Information adopted in January 2014.

Victoza (EMEA/H/C/001026/II/0023)
MAH: Novo Nordisk A/S, (liraglutide), Rapporteur: Pieter de Graeff, "Proposed updates of the SmPC sections 4.1, 4.2, 4.4, 4.7, 4.8 and 5.1 in order include information on the use of liraglutide in combination with basal insulin. The Package Leaflet is proposed to be updated accordingly."
Request for Supplementary Information adopted in January 2014.

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

No items

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

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. • Report from SAG Oncology held on 5 March 2014: **For discussion**	Oral explanation to be held on Tuesday 18 March at 17.00 See also 1 Oral Explanations

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

No items

8 WITHDRAWAL OF APPLICATION

No items

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

Sofosbuvir (compassionate use) (EMEA/H/K/003891/CU)
Gilead Sciences International Ltd, (hepatitis C virus infection in pre and post liver transplant patients)

- Amendment to the assessment report: **For adoption**

10 PRE-SUBMISSION ISSUES

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

No items

11 POST-AUTHORISATION ISSUES

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

alli (EMEA/H/C/000854)
(orlistat), MAH: Glaxo Group Ltd, Rapporteur: Rafe Suvarna, Co-Rapporteur: Dimitrios Kouvelas, (treatment of overweight and obesity)

Avonex (EMEA/H/C/000102)
(Interferon Beta-1a), MAH: Biogen Idec, Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Johann Lodewijk Hillege

Ad-hoc Influenza Working Group:
EU Strain selection for the Influenza Vaccines for the Season 2014/2015, : **For adoption**

- EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2014/2015: **for adoption**
- Report from the Ad Hoc Influenza working group to the BWP: **for adoption**

Kalydeco (EMEA/H/C/002494/II/0013), Orphan, (ivacaftor), MAH: Vertex Pharmaceuticals (U.K.) Ltd., Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Miguel-Angel Macia, "Update of sections 4.8 and 5.1 of the SmPC to reflect the interim analysis at week 96 of study VX08-770-105, an open-label extension of studies VX08-770-102 and 103."
Request for Supplementary Information adopted in January 2014.

12 REFERRAL PROCEDURES

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

No items

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

Propylene glycol in IV formulations for children under 4 years of age (EMEA/H/A-5(3)/1317)
Rapporteur: Bruno Sepodes, Co-Rapporteurs: Milena Stain, Hubert Leufkens,

Review of the safety of the excipient propylene glycol in IV formulations for short term use in children.

- Opinion: **For adoption**

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

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: **For adoption by written procedure**
- List of expert to ad-hoc meeting: **For adoption**

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

Sandostatin LAR (EMEA/H/A-30/1355)
(Octreotide acetate) Novartis Pharma AG group of companies and associated companies
Rapporteur: Agnes Gyurasics, Co-Rapporteur: Robert James Hemmings,
List of Outstanding Issues adopted in November 2014. List of Questions adopted in May 2013.

- Opinion: **For adoption**

Sandostatin (EMA/H/A-30/1354)
(Octreotide acetate) Novartis Pharma AG Group of companies and associated companies
Rapporteur: Agnes Gyurasics, Co-Rapporteur: Robert James Hemmings,
List of Outstanding Issues adopted in November 2014. List of Questions adopted in May 2013.

- Opinion: **For adoption**

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 2014. List of Questions adopted in June 2013.

- List of Outstanding Issues: **For adoption**

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

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): Omniscan (GE HealthCare) second monthly update and interim analysis report submission as requested by CHMP in November 2013 and assessment report: **For adoption**

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

Estradiol (topical use) (EMEA/H/A-31/1336)
Re-examination Rapporteur: Arantxa Sancho-Lopez, Re-examination Co-Rapporteur: Milena Stain,
Review of the benefit-risk balance of medicinal products containing estradiol for intravaginal

administration and administration on the skin of the vulva due to observed high systemic absorption which may lead to safety issues

- Grounds for re-examination: **For discussion**

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

Ketoprofen formulation for topical use (EMEA/H/A-107/1259)
(Ketum), Rapporteur: Joseph Emmerich, Co-Rapporteur: Radka Montoniová,

- Assessment report of 3-years cumulative analysis of photosensitivity reactions including photo allergy reactions together with a report of the effectiveness of risks minimisation measures (submissions received on 14 November 2013): **For adoption**

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 4-7 March 2014: **For information**

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for March 2014: **For adoption**

Early Notification System:
March 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**

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 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.*

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

15.2 Briefing meetings (Innovation Task Force)

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

15.3 Eligibility to EMA scientific services

No items

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

Update on CHMP opinion under Art. 57 (1)P of Regulation (EC) No 726/2004	
Update on CHMP opinion under Art. 57 (1)P of Regulation (EC) No 726/2004	Call for expression of interest for CHMP and CAT Members to participate in a drafting group.

15.5 Nanomedicines activities

No items

16 SCIENTIFIC ADVICE WORKING PARTY (SAWP)

Report from the SAWP meeting held on 3-5 March 2014. Table of conclusions: **For information**	
Scientific advice letters:	*Disclosure of information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.*

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 March 2014: **For information**	

18 OTHER COMMITTEES

18.1 Committee for Orphan Medicinal Products (COMP)

Press release of the COMP meeting held on11-12 March 2014: **For information**	To be sent in the Post-mail.

18.2 Committee for Herbal Medicinal Products (HMPC)

No items

18.3 Paediatric Committee (PDCO)

PIPs reaching D30 at March 2014 PDCO: **For information**	To be sent in the Post-mail.
Report from the PDCO meeting held on held on 19-21 March 2014: **For information**	

18.4 Committee for Advanced Therapies (CAT)

Table of Decisions of CAT meeting held on 13-14 March 2014: **For information**	

19 INVENTED NAME ISSUES

Table of Decisions of the NRG meeting held on

March 2014: **For adoption**

20 ANY OTHER BUSINESS

Election of BWP Vice Chair	
Infectious Diseases Working Party IDWP Work Programme for 2014: **For adoption**	
Blood Products Working Party BPWP Work Programme for 2014: **For adoption** Request to the CHMP for Member States representation at BPWP	Call for nomination of BPWP members
Feedback from the PCWP and HCPWP joint meeting workshop held on 26 February on regulatory and methodological standards to improve benefit/risk evaluation of medicines: **For information**	
Move to Churchill Place: **For information**	
Q&A on practical implementation of Article 20 Pharmacovigilance Procedure (EMA/796802/2013): **For discussion**	
Updated template for Reader's Guidance document: Addition of field for PRAC's input in relevant procedure: **For adoption**	
Change of procedure for disclosure of invented names of Orphan medicinal products prior to the adoption of CHMP Opinion**: For information**	
Procedure for coordinating GCP inspections as requested by CHMP: **For adoption**	Follow up from February 2014.
Request from the HMPC to the SWP on conclusions of a toxicological assessment of estragole and alkenylbenzenes: **For information**	
Process for regulatory advice on Combination packaging of Medicinal Products: Request for setting up a drafting group to elaborate on "scientific criteria" to determine the "exceptional circumstance" to allow combination pack: **For adoption**	Follow up from March ORGAM meeting
Update on the future EMA product team support for evaluation activities: **For information**	

Drafting group on the asthma guideline

Guideline Rapporteur: Maria Luisa Suarez

Call for expression of interest for CHMP Members to participate at the drafting group to finalise the revision of the Asthma guideline

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)*

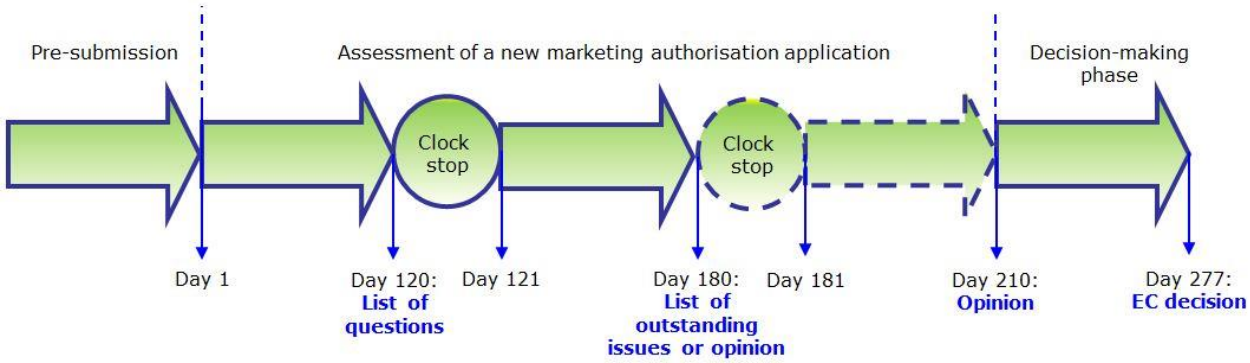
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 2 and 3) or referral procedures (section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