22 July 2014
EMA/CHMP/387601/2014 revision 1
Procedure Management and Business Support Division

Committee for medicinal products for human use (CHMP)

Agenda of meeting to be held on 21-24 July 2014

Chair: Tomas Salmonson – Vice-chair: Pierre Demolis

21 July 2014, 13:00 – 19:30, room 3A

22 July 2014, 08:30 – 19:30, room 3A

23 July 2014, 08:30 – 19:30, room 3A

24 July 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 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.

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For adoption

AGENDA (EMA/657038/2013) and Annex to CHMP agenda of the CHMP plenary session to be held 21-24 July 2014	
TIMESCHEDULE of the CHMP plenary session to be held 21-24 July 2014	
MINUTES Of The CHMP Plenary Session held on 23-26 June 2014 (EMA/CHMP/413428/2014)	
MINUTES of the July 2014 CHMP ORGAM meeting held on 16 July 2014 (EMA/433531/2014)	

For information

MEMBERSHIP ANNOUNCEMENT	The Committee is asked to note that Dr Hrefna Gudmundsdottir was nominated as the Icelandic CHMP alternate member, replacing Dr Reynir Arngrímsson in this role. Dr Christian Schneider was nominated as the Danish CHMP alternate member, replacing Jens Ersbøll in this role as of 1 August 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 21-24 July 2014.	*See July 2014 minutes (to be published post September 2014 CHMP meeting)*
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Harmonisation exercise for EMLA Crème. The review was triggered by the European Commission, due to the need of harmonisation of the Summary of Product Characteristics across Member States. List of Outstanding Issues adopted on 22.05.2014. List of Questions adopted in October 2013. Extension of Timetable adopted in November 2013.

- Opinion: **For adoption**

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Rapporteur: Martina Weise, Co-Rapporteur: Ivana Mikacic,

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- Revised timetable: **For adoption**

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Rapporteur: Martina Weise, Co-Rapporteur: Ivana Mikacic,

- Letter from the MAH dated 15 July 2014 requesting an extension of timeframe to submit responses to the List of Questions adopted in June 2014 **: For information**
- Revised timetable: **For adoption**

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Rapporteur: Kristina Dunder, Co-Rapporteur: Pieter de Graeff,

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List of Outstanding Issues on 22.05.2014. List of Questions adopted in January 2014.

- Opinion: **For adoption**

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

No items

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

No items

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

No items

12.11. Referral under Article 13 Disagreement between Member States on Type II variation– Arbitration procedure initiated by Member State under Article 13 (EC) No 1234/2008)

No items

13. PHARMACOVIGILANCE ISSUES

Summary of recommendations and advice of PRAC meeting held on 7-10 July 2014: **for information**	
List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for July 2014: **for adoption**	
Early Notification System: July 2014 Early Notification System on Envisaged CHMP Recommendations for Regulatory Action (based on Identified Safety Concerns) Accompanied by Communication to the General Public: **for information**	
PRAC outcome on revision of class labelling of antiretrovirals on lactic acidosis, mitochondrial dysfunction and lipodystrophy and letters to be sent to the MAHs: **For adoption** Ziagen, Kivexa, Trizivir, Reyataz, Tybost, Prezista, Stocrin, Sustiva, Atripla, Stribild, Emtriva, Truvada, Eviplera, Fuzeon, Intelence, Telzir, Epivir, Combivir, Kaletra, Celsentri, Viramune, Isentress, Edurant, Norvir, Invirase, Zerit, Viread, Aptivus,	

14. INSPECTIONS

14.1. GMP Inspections

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

14.2. GCP Inspections

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

14.3. Pharmacovigilance Inspections

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

14.4. GLP Inspections

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

15. INNOVATION TASK FORCE

15.1. Minutes of ITF: For information

15.2. Briefing meetings (Innovation Task Force)

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

15.3. Eligibility to EMA scientific services

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

Request from DG SANCO for EMA scientific Opinion under Art. 57 (1)P of Regulation (EC) No 726/2004 • Final report: **For adoption**
Request from EDQM for EMA scientific Opinion under Art. 57 (1)P of Regulation (EC) No 726/2004 • Draft report: **For information**

15.5. Nanomedicines activities

16. SCIENTIFIC ADVICE WORKING PARTY (SAWP)

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

17. SATELLITE GROUPS / OTHER COMMITTEES

17.1. Coordination Group for Mutual Recognition and Decentralised Procedures

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 21-23 July 2014: **For information**	
Cardiovascular WP response to the request from the CMDh on the qualification of flecainide as a drug of narrow therapeutic index (NTI): **For adoption**	
CMDh request to PKWP on acceptability of Mahalanobis test for proof of comparable dissolution (biowaiver) for additional strengths of a bio-batch strength: **For adoption** • Response Assessment Report: **For adoption**	

18. OTHER COMMITTEES

18.1. Committee for Orphan Medicinal Products (COMP)

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

18.2. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 30 June -1 July 2014: **for information**	

18.3. Paediatric Committee (PDCO)

PIPs reaching D30 at July 2014 PDCO: **For information**	To be circulated in the MMD
Report from the PDCO meeting held on 16-18 July 2014: **For information**	
Request from the PDCO for the input regarding the draft Paediatric Investigation Plan for DTaP-containing combination vaccine: **For adoption**	

Response from the CVS Working Party to the PDCO request on (R)-2-[3-({Benzoxazol-2-yl[3-(4-methoxyphenoxy)propyl]amino}methyl)phenoxy]butanoic acid (K-877) (EMEA-001573-PIP01-13): **Adopted by written procedure on 14 July 2014**

18.4. Committee for Advanced Therapies (CAT)

Table of Decisions of CAT meeting held on 17-18 July 2014: **For information**

19. INVENTED NAME ISSUES

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

20. ANY OTHER BUSINESS

Follow up action plan Quality of Opinions
CHMP Work Plan 2015
CHMP visit to 30 Churchill Place on Tuesday 22 July 2014 at 19:15
Discussion on area of expertise of Co-opted Member: Jan Mueller-Berghaus mandate expires in November 2014.
Non-clinical and clinical module of the new Guideline on Influenza vaccines: **For adoption for 6-month consultation**
Election of **QWP** Vice Chairperson: **For adoption**
Election of the Vice-Chairperson of **BMWP**: **For adoption**
Election of the Vice-Chairperson of **IDWP**: **For adoption**
Election of the Vice-Chairperson of **VWP**: **For adoption**
Informal/Workshop Joint CHMP, CAT, COMP to be held in Rome, Italy on 29-30 October 2014 • Draft agenda: **For information**

Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals
Core Membership of SAG Oncology: **For adoption**
SmPC Advisory Group: update on recent Q&As which may affect a number of products
Questions and Answers on Wheat starch containing gluten in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use': **For adoption for 3-month consultation**
Industry Forum on pharmacovigilance: **For information**

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)*

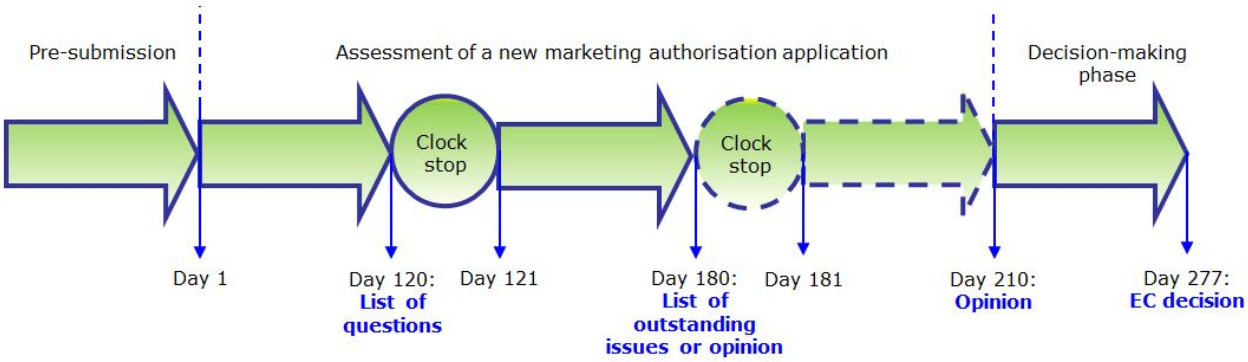
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 2 and 3) or referral procedures (section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