European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 25 September 2008
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WORKPLAN FOR THE EFFICACY WORKING PARTY (EWP)

2009-2010

CHAIRPERSON: Dr. Barbara van Zwieten-Boot

I. MEETINGS SCHEDULED FOR 2009

- 12-13 January 2009
- 30-31 March 2009
- 8-9 June 2009
- 28-29 September 2009

MEETINGS SCHEDULED FOR 2010 (tentative dates)

- 11-12 January 2010
- 6-7 April 2010
- 5-6 July 2010
- 4-5 October 2010

II. **Product related issues** (such as support to Marketing Authorisation Assessment, Post-marketing Data Evaluation, Scientific Advice, and Protocol Assistance).

The following table provides the expected number per year of contribution (number of involvement in dossier) for Scientific Advice, Protocol Assistance, Product Assessment and Post-Authorisation issue (pharmacovigilance issue related to a product or a class of product).

	Expected contribution in Scientific Advice	Expected contribution in Protocol Assistance	Expected contribution in Product Assessment	Expected contribution in post-authorisation issue
Efficacy Working Party contribution per year	10	5	10	2

III. CHMP Guidelines

CHMP Guidelines in development or under revision are presented below by therapeutic area. In addition to the Guidelines listed in the sections below in agreement with the Procedure for European Union Guidelines and related documents within the Pharmaceutical Legislative Framework (EMEA/P/24143/2004), guidance documents will be considered for revision after 5 years.

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1. Alimentary tract and metabolism

Guidelines under preparation:

Guideline on Gastroparesis and Gastroesophageal Reflux Disease (GERD).

Action: To be considered in 2009.

Guidelines under revision:

Guideline on Clinical Investigation of Medicinal Products in the Treatment of Diabetes Mellitus (CPMP/EWP/1080/00).

Action: Concept paper adopted in May 2008 (EMEA/CHMP/EWP/176348/2008). Draft Guideline to be released for consultation in 1Q 2009.

Guideline on Clinical Investigation of Medicinal Products for Hormone Replacement Therapy of Oestrogen Deficiency Symptoms in Postmenopausal Women (EMEA/CHMP/021/97 Rev. 1).

Action: Revision to be considered in 2009.

2. Anti-infectives for systemic use

Guidelines under preparation:

Addendum to the Note for Guidance on Evaluation of Medicinal Products Indicated for the Treatment of Bacterial Infections (CPMP/EWP/558/95 Rev 1) to Specifically Address the Clinical Development of New Agents to Treat Disease Due to Mycobacterium Tuberculosis (EMEA/CHMP/EWP/14377/2008).

Action: Addendum released for consultation in April 2008. Finalisation expected in 1Q/2Q 2009.

Guideline on the Clinical Evaluation of Direct Acting Antiviral Agents Intended for Treatment of Chronic Hepatitis C (CHMP/EWP/30039/2008).

Action: Draft guideline released for consultation in April 2008. Finalisation expected in 1Q/2Q 2009.

Guidelines under revision

Points to Consider on the Clinical Evaluation of New Agents for Invasive Fungal Infections (CPMP/EWP/1343/01).

Action: Concept Paper adopted in January 2008 (EMEA/CHMP/EWP/12025/2008). Draft guideline expected to be released for consultation in 4Q 2008. Finalisation expected in 2009.

Guideline on the Clinical Development of Medicinal Products for Treatment of HIV Infection (CPMP/EWP/633/02 Rev. 1).

Action: Draft guideline released for consultation in October 2007. Finalisation is expected in 4Q 2008/1Q 2009.

Guideline on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections (CPMP/EWP/558/95 Rev 2).

Action: Concept paper expected in 4Q 2008/1Q 2009.

3. Cancer and immunomodulating agents

Guidelines under preparation:

Annex to the Guideline on the evaluation of Anticancer Medicinal Products in Man (CPMP/EWP/205/95 Rev. 3) on Haematology Malignancies.

Action: Concept Paper adopted in January 2008 (EMEA/CHMP/EWP/20808/2008). Annex expected to be released for consultation in 4Q 2008. Finalisation expected in 2009.

Guideline on Lupus and Lupus Nephritis.

Action: To be considered in 2009.

4. Cardio-vascular

Guidelines under preparation:

Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Pulmonary Hypertension.

Action: Concept paper adopted in January 2008 (CHMP/EWP/566954/2007). Draft guideline expected to be released for consultation in 4Q 2008/1Q 2009.

Reflection Paper on the Need for Outcome Studies.

Action: To be considered in 2009.

Guidelines under revision:

Guideline on Clinical Investigation of Medicinal Products in the Treatment of Hypertension (CPMP/EWP/238/95 Rev. 2).

Action: Concept paper on the need for regulatory guidance for first-line indication of fixed combination products in the treatment of hypertension adopted in October 2006 (CHMP/EWP/426093/2006). Draft guideline to be released for consultation in 1Q 2009.

Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (CPMP/EWP/3020/03).

Action: Concept paper adopted in May 2008 (EMEA/CHMP/EWP/255210/2008). Draft guideline to be released for consultation in 4Q 2008/1Q 2009.

Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Peripheral Arterial Occlusive Disease (CPMP/EWP/714/98 Rev.1).

Action: Revision to be considered in 2009.

Paediatric sections under revision:

Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Hypertension (CPMP/EWP/238/95 Rev. 2).

Action: Concept paper on the need of a paediatric addendum expected in 4Q 2008. Draft guideline expected in 2009.

Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (CPMP/EWP/3020/03).

Action: Concept paper on the need of a paediatric addendum expected in 1Q 2009.

5. Dermatology

No guidelines under preparation/revision.

6. Musculo-skeletal system

Guidelines under preparation:

Guideline on the Clinical Investigation of Medicinal Products for Treatment of Ankylosing Spondylitis (CPMP/EWP/4891/03).
Action: Draft guideline released for external consultation in June 2005. Finalisation expected in 4Q 2008/1Q 2009.

Guidelines under revision:

Points to Consider on Clinical Investigation of Medicinal Products for the Treatment of Osteoarthritis (CPMP/EWP/784/97).
Action: Concept paper adopted in April 2008 (EMEA/CHMP/EWP/141412/2008). Draft guideline expected to be released for consultation in 4Q 2008/1Q 2009.

Guideline on the Evaluation of Medicinal Products in the treatment of Primary Osteoporosis (CPMP/EWP/552/95 Rev. 2).
Action: Addendum on Secondary Disease to be considered in 2009.

7. Nervous system

Guidelines under preparation:

Guideline on the Development of New Products for the Treatment of Nicotine Dependence (CHMP/EWP/369963/05).
Action: Draft guideline released for consultation in July 2007. Finalisation expected in 1Q 2009.

Guideline on the Development of New Products for the Treatment of Alcohol Dependence.
Action: Concept paper on the Development of a Guideline on the Development of New Products for the Treatment of Tobacco and Alcohol Dependence adopted in Nov 2005 (EMEA/CHMP/EWP/369963/2005). Draft guideline to be released for consultation in 1Q/2Q 2009.

Guideline on the treatment of Attentional Deficit Hyperactivity Disorder (ADHD).
Action: Concept paper adopted in Jan 2008 (CHMP/EWP/20119/08). Draft guideline expected to be released for consultation in 1Q 2009.

Guideline on Premenstrual Dysphoric Disorders.

Action: Concept paper expected in 1Q 2009.

Guidelines under revision:

Guideline on Clinical Investigation of Hypnotic Medicinal Products (3CC27 a).
Action: Concept paper adopted in October 2007 (EMEA/CHMP/EWP/310566/2007). Draft guideline expected to be released for consultation in 1Q 2009.

Note of Guidance on Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders (CPMP/EWP/566/98 Rev. 1).

Action: Concept paper adopted in October 2007 (EMEA/CHMP/EWP/453780/2007). Draft guideline expected to be released for consultation in 4Q 2008/1Q 2009.

Points to Consider on Clinical Investigation of Medicinal Products for the Treatment of Amyotrophic Lateral Sclerosis (CPMP/EWP/565/98).

Action: Revision to be considered in 2009.

8. Pharmacokinetic

Guidelines under revision:

Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1).

Action: Draft guideline released for consultation in July 2008. Finalisation expected in 2Q/3Q 2009.

Note for Guidance on the Investigation of Drug Interactions (CPMP/EWP/560/95).

Action: Concept paper adopted in July 2008 (EMEA/CHMP/EWP/297931/2008). Draft guideline expected to be released for consultation in 1Q 2009

9. Respiratory

Guidelines under preparation:

Guideline on the clinical development of medicinal products for Cystic Fibrosis (CHMP/EWP/9147/2008).

Action: Guideline released for consultation in May 2008. Finalisation expected in 2Q/3Q 2009.

Guidelines under revision:

Guideline on the Requirements for Clinical Documentation for Orally inhaled products (OIP) (CPMP/EWP/4151/00 Rev. 1).

Action: Draft guideline released for consultation in October 2007. Draft appendix on children released for consultation in March 2008 (EMEA/CHMP/EWP/48501/2008). Finalisation expected in 1Q 2009.

Guideline on Clinical Investigation of Medicinal Products in the Treatment of Asthma (CPMP/EWP/2922/01).

Action: Revision to be considered in 2009.

Guideline on Clinical Investigation of Medicinal Products in the Chronic Treatment of Patients with Chronic Obstructive Pulmonary Disease (COPD) (CPMP/EWP/562/98).

Action: Revision to be considered in 2009.

10. General guidelines

Guidelines under preparation:

Harmonisation and Update of the Clinical Aspects in the Authorised Conditions of Use for Radiopharmaceuticals and other Diagnostic Medicinal Products.

Action: Concept paper adopted in April 2008 (CHMP/EWP/12052/20080). Draft core SPCs expected to be released for consultation in 2009.

Annex to the Guideline on Conditional Marketing Authorisation (EMEA/509951/2006) on Methodological Considerations.

Action: Draft annex expected to be released for consultation in 1Q 2009.

Guideline on Extrapolation Results in Clinical Studies to the EU-Population.

Action: Concept paper adopted in January 2007 (CHMP/EWP/7799/2007). Draft guideline expected to be released for consultation in 1Q 2009.

Guidelines under revision:

Guideline on the Evaluation of Diagnostic Agents (CPMP/EWP/1119/98 Rev. 1).

Action: Draft guideline released for consultation in June 2008. Finalisation expected in 2Q/3Q 2009.

Appendix 1 to the Guideline on Diagnostics on Imaging (EMEA/CHMP/EWP/321180/2008).

Action: Draft appendix released for consultation in June 2008. Finalisation expected in 2Q/3Q 2009.

Guideline on Fixed-Combination Medicinal Products (CHMP/EWP/240/95 Rev.1).

Action: Draft guideline released for consultation in February 2008. Finalisation expected 4Q 2008/1Q 2009

Points to Consider on Missing Data (CPMP/EWP/1776/99).

Action: Concept paper adopted in December 2007 (EMEA/CHMP/EWP/439980/2007). Draft guideline expected to be released for consultation in 1Q 2009.

11. Interaction with other working parties:

Multidisciplinary Guidelines:

Concept Paper on Pegylated and Liposomal Formulations. Working parties involved: EWP-PK (leading), QWP, BMWP.

Action: Concept paper expected in 4Q 2008. Draft guideline expected to be released for consultation in 2009.

Concept Paper on Analytical Validation of Bioequivalence studies. Workings parties involved: Inspections team (leading), EWP-PK, QWP.

Action: Concept paper expected in 4Q 2008. Draft guideline expected to be released for consultation in 2009.

Guideline on Similar Medicinal Products containing Recombinant Interferon Alpha (EMEA/CHMP/BMWP/102046/2006). Workings parties involved BMWP (leading), EWP.

Action: Draft guideline released for consultation in October 2007. Final guideline expected in 1Q 2009.

Annex to the Guideline on Biosimilar Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance – Non-clinical and Clinical Issues: Guidance on Biosimilar Medicinal Products containing Recombinant Erythropoietins (EMEA/CHMP/BMWP/94526/2005 Corr.).

Action: Concept Paper adopted July 2008 (EMEA/CHMP/BMWP/170734/2008). Draft guideline expected to be released for consultation in 4Q 2008. Finalisation expected in 2009.

Guideline on Similar Biological Medicinal Products containing Low Molecular Weight Heparins- (non) clinical and clinical issues (EMEA/CHMP/BMWP/118264/2007).

Action: Guideline released for consultation in April 2008. Final version expected 4Q 2008/1Q 2009.

Reflection paper on statistical and methodological issues associated with PG biomarkers. Working parties involved: PGWP (leading), EWP.

Action: Reflection paper expected 4Q 2009.

Guideline on the Use of Pharmacogenomics in PK Studies: PGWP (leading), EWP-PK.

Action: Reflection paper adopted in May 2007 (EMEA/128517/2006). Revision/Need for a guideline to be considered in 2009.

Other actions:

- Support to new framework for Scientific Advice and Protocol Assistance.

- Support to scientific queries coming from CMDh and PDCO.

- Input in Guidelines of other Working Parties upon their request.

II. ICH Guidelines and activities

- ICH E7

Action: EWP CNS Drafting Group involvement.

The working party shall contribute to applicable ICH guidelines under development that are identified after adoption of this work plan.

III. EU Regulatory Activities

- Activities related to implementation of legislation: Regulation (EC) 726/2004 and Directive 2001/83/EC, as amended.
- Cooperation with other bodies in the EU to maintain consistency in Scientific Opinions.

IV. Activities with external parties

1. Drug Regulatory Authorities Outside the EU

- Liaison with FDA or other Agencies

2. Meeting with Interested Parties

- Workshop/meeting with learned Societies to be considered once a year, in addition to improvement of written communication to favour Learned Societies' input in draft EWP guidance.
- Meeting with EFPIA and/or other Pharmaceutical Industry Representative once a year, upon request.
- Meeting with Patients' organisations related to the guidelines under preparation.

V. Organisational matters

1. List of adopted organisational documents

- EWP work plan.

2. List of proposed scientific guidelines for the next work programme/work plan

Need for a guideline on thrombocytopenia to be considered in 2010.

3. Training of assessors

1. Risk-Benefit assessment.
2. Revised bioequivalence guideline.

4. Workshops

Antibiotics/Revision of the Guideline on Bacterial Infections.