European Medicines Agency

London, 17 December 2009
EMA/CHMP/EWP/248088/2009 Rev. 1

WORK PLAN FOR THE EFFICACY WORKING PARTY (EWP) 2010

CHAIRPERSON: Barbara van Zwieten-Boot

1. MEETINGS SCHEDULED FOR 2010

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

MEETINGS SCHEDULED FOR 2011 (tentative dates)

- 10- 11 January 2011
- 4 - 5 April 2011
- 11 - 12 July 2011
- 10 - 11 October 2011

2. PRODUCT RELATED ISSUES

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

3. 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.

1. Alimentary tract and metabolism

Guidelines under preparation:

Guideline on Gastroesophageal Reflux Disease (GERD)

Action: Finalisation expected in 2010.
Comments: Draft guideline adopted by CHMP in December 2009.

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Guidelines under revision:

Guideline on Clinical Investigation of Medicinal Products in the Treatment of Diabetes Mellitus (CPMP/EWP/1080/00)
Action: Draft guideline expected to be released for consultation in 1Q 2010.
Comments: Concept paper adopted in May 2008.

2. Renal

Guidelines under preparation:

Guideline on Renal Insufficiency.

Action: To be considered in 2010.

3. Anti-infectives for systemic use

Guidelines under revision

Points to Consider on the Clinical Evaluation of New Agents for Invasive Fungal Infections (CPMP/EWP/1343/01)
Action: Finalisation expected in 2010.
Comments: Draft guideline released for consultation in May 2009.

Guideline on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections (CPMP/EWP/558/95 Rev 2)
Action: Draft guideline expected to be released for consultation in 1Q 2010.
Comments: Concept paper adopted in February 2009.

Addendum to the Note for Guidance on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections CPMP/EWP/558/95 Rev 2 to Specifically Address the Clinical Development of New Agents to Treat Disease Due to Mycobacterium Tuberculosis (EMEA/CHMP/EWP/14377/2008)
Action: Final addendum expected to be released for consultation in 1Q-2Q 2010.
Comments: Draft guideline released for consultation in April 2008.

4. Cancer and immunomodulating agents

Guidelines under preparation:

Appendix 2 to the Guideline on the evaluation of Anticancer Medicinal Products in Man (CPMP/EWP/205/95 Rev. 3) on Haematological Malignancies (EMEA/CHMP/EWP/520088/2008)
Action: Final appendix expected in 1Q 2010.
Comments: Draft appendix released for consultation in November 2008.

Guideline on Lupus and Lupus Nephritis
Action: Draft guideline expected to be released for consultation in 2010.
Comments: Concept paper adopted in November 2009.

Guidelines under revision

Note for guidance on evaluation of anticancer medicinal products in man Addendum on Paediatric Oncology (CPMP/EWP/569/02)
Action: To be considered in 2010.

5. Cardio-vascular

Guidelines under preparation:

Addendum to the Note for Guidance on Antiarrhythmics (CPMP/EWP/237/95) on Atrial Fibrillation (EMEA/CHMP/EWP/352438/2008)
Action: Finalisation expected in 1Q 2010.
Comments: Draft guideline released for consultation in July 2008.

Guideline on the Prevention of Thromboembolic events in Atrial Fibrillation.
Action: To be considered in 2010.

Guidelines under revision:

Guideline on Clinical Investigation of Medicinal Products in the Treatment of Hypertension (CPMP/EWP/238/95 Rev. 3)
Action: Finalisation expected in 2010.
Comments: Draft guideline released for consultation in January 2009.

Guidelines on Clinical Investigation of Medicinal Products in the Treatment of Hypertension (CPMP/EWP/238/95 Rev. 3) and of the Guideline on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (CPMP/EWP/3020/03): Need for Outcome Studies Basis on Safety Data at the Time of MAA.
Action: Draft guidelines expected to be released for consultation in 2010.
Comments: Concept paper released in July 2009.

Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (CPMP/EWP/3020/03): Revision on imaging surrogate endpoints.
Action: Draft guideline expected to be released for consultation in 1Q 2010.
Comments: Concept paper adopted in May 2008.

Addendum on Acute Cardiac Failure of the Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Cardiac Failure CPMP/EWP/235/95, Rev 1 (CPMP/EWP/2986/03)
Action: Concept paper expected in 1Q 2010. Draft addendum expected to be released for consultation in 2010.

Paediatric sections under revision:

Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Hypertension (CPMP/EWP/238/95 Rev. 3)
Action: Draft paediatric addendum expected to be released for consultation in 2010.
Comments: Concept paper adopted in December 2008.

Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (CPMP/EWP/3020/03)
Action: Draft paediatric addendum expected to be released for consultation in 2010.
Comments: Concept paper adopted in January 2009.

Paediatric Addendum to the Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Pulmonary Hypertension

Action: Draft paediatric addendum expected to be released for consultation in 1Q/2Q 2010.
Comments: Concept paper adopted in January 2009.

6. Dermatology

None

7. Musculo-skeletal system

Guidelines under revision:

Guideline on Clinical Investigation of Medicinal Products used in the Treatment of Osteoarthritis (CPMP/EWP/784/97 Rev. 1)
Action: Finalisation expected in 2010.
Comments: Draft guideline released for consultation in April 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 2010.

Points to Consider on the Clinical Investigation of Medicinal Products other than NSAIDs in Rheumatoid Arthritis (CPMP/EWP/556/95)
Action: Revision to be considered in 2010.

Guidelines under revision:

Guideline on Clinical Investigation of Medicinal Products for the Treatment of Juvenile Idiopathic Arthritis (CPMP/EWP/422/04).
Action: Revision to be considered in 2010.

8. Nervous system

Guidelines under preparation:

Guideline on the Development of Medicinal Products for the Treatment of Alcohol Dependence (EMEA/CHMP/EWP/20097/2008)
Action: Finalisation expected in 2010.
Comments: Draft guideline released for consultation in January 2009.

Guideline on the clinical Investigation of Medical Products for the Treatment of Attentional Deficit Hyperactivity Disorder (ADHD) (EMEA/CHMP/EWP/431734/2008)
Action: Finalisation expected in 2010.
Comments: Draft guideline released for consultation in December 2008.

Guideline on the Treatment of Premenstrual Dysphoric Disorders (PMDD).

Action: Draft guideline expected in 1Q/2Q 2010.
Comments: Concept paper adopted in February 2009.

Guidelines under revision:

Guideline on Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders (CPMP/EWP/566/98 Rev. 2)
Action: Finalisation expected in 2010.
Comments: Draft guideline released for consultation in January 2009.

Guideline on Medicinal Products for the Treatment of Insomnia (EMEA/16274/2009).

Action: Finalisation expected in 2010.

Comments: Draft guideline released for consultation in October 2009.

Note for guidance on the Clinical Investigation of Medicinal Products in the Treatment of Schizophrenia (CPMP/EWP/559/95)

Action: Concept paper on the need for revision expected in 1Q 2010. Draft guideline expected to be released for consultation in 2010.

Note for Guidance on the Clinical Investigation of Medicinal Products in the Treatment of Depression (CHMP/EWP/518/97 Rev. 1).

Action: Draft guideline expected to be released for consultation in 2010.

Comments: Concept paper on the need for revision with regard to treatment of resistant depression released in September 2009.

9. Pharmacokinetic

Guidelines under revision:

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

Action: Finalisation expected in 2010.

Comments: Draft guideline released for consultation in July 2008.

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

Action: Draft guideline expected to be released for consultation in 2010.

Comments: Concept paper adopted in July 2008.

Note for guidance on Modified Release Oral and Transdermal Dosage Forms: Section II (Pharmacokinetic and Clinical Evaluation) (CPMP/EWP/280/96)

Action: Revision to be considered in 2010.

10. Respiratory

Guidelines under revision:

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

Action: Draft guideline expected to be released for consultation in 2010.

Comments: Concept paper adopted in October 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: Draft guideline expected to be released for consultation in 2010.

Comments: Concept paper adopted in February 2009.

11. Genito-urinary system and sex hormones

Guidelines under revision:

Note for Guidance on the Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinency in Women (CPMP/EWP/18/01)
Action: Revision to be considered in 2010.

12. 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 (EMEA/CHMP/EWP/12052/2008)
Action: Draft core SPCs expected to be released for consultation in 2010.
Comments: Concept paper adopted in April 2008.

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 2010.

Reflection Paper on the Bioequivalence Criteria for Narrow Therapeutic Index Drugs
Action: To be considered in 2010.

Guideline on the Use of Subgroup Analyses in Confirmatory Clinical Trials
Action: To be considered in 2010.

Guideline on Thrombocytopenia.
Action: Concept Paper expected in 2Q/3Q 2010.

Guidelines under revision:

Guideline on Missing Data (CPMP/EWP/1776/99 Rev. 1)

Action: Finalisation expected in 2010.
Comments: Draft guideline released for consultation in April 2009.

11. Interaction with other working parties:

Multidisciplinary Guidelines:

Reflexion Paper on Pegylated and Liposomal Formulations. Working parties involved: EWP-PK (leading), QWP, BMWP
Action: Concept Paper expected in 2010.

Guideline on the Validation of Analytical Methods. Workings parties involved: EWP-PK, inspections team, QWP.
Action: Finalisation expected in 2010.
Comments: Draft guideline released for consultation in November 2009.

Reflection Paper on Statistical and Methodological Issues Associated with PG biomarkers. Working parties involved: PGWP (leading), EWP.
Action: Reflexion paper expected to be released for consultation in 2010.

Guideline on the Use of Pharmacogenomic Methodologies in the Pharmacokinetic Evaluation of Medicinal Products. Working parties involved: PGWP (leading), EWP-PK.
Action: Finalisation expected in 2010.

Comments: Concept paper adopted in April 2009.

4. OTHER ACTIONS

Support to *ad hoc* scientific queries requested by:

- Scientific committees CHMP, HMPC, CMD(h), COMP, PDCO and CAT.
- CHMP Working Parties.

Note: Expected workload not measurable in advance.

5. ICH GUIDELINES AND ACTIVITIES

Note For Guidance On Studies In Support Of Special Populations: Geriatrics (CPMP/ICH/379/95; 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.

6. EU REGULATORY ACTIVITIES

Activities related to the implementation of the current variation legislation: Commission Regulation (EC) No 1234/2008.

7. ACTIVITIES WITH EXTERNAL PARTIES

Drug Regulatory Authorities outside the EU

- Liaison with FDA or other Agencies

Meeting with Interested Parties

- Meeting with Learned Societies related to the guidelines under preparation, upon request.
- Meeting with Patients' Organisations related to the guidelines under preparation, upon request.
- Meeting with EFPIA and/or other Pharmaceutical Industry Representatives once a year, upon request.

8. ORGANISATIONAL MATTERS

EWP drafting groups will have regular discussions via teleconference and/or virtual meetings. If necessary drafting groups will meet at the EMEA (expected: 4-5 PK drafting group meetings, 2 CVS drafting group meetings, 2 CNS drafting group meetings and 1 anti-infective drafting group meeting).

Training of assessors

- 1 training session for senior assessors on the Bioequivalence guideline.

Workshops

- 1 workshop with stakeholders.