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

London, 25 September 2008
EMEA/324640/2008

WORK PLAN FOR THE PHARMACOGENOMICS WORKING PARTY (PGWP)

2009

CHAIRPERSON: Dr Eric Abadie

I. Meetings scheduled for 2009

Dates of Plenary meetings:

- 2-3 February 2009
- 6-7 April 2009
- 15-16 July 2009
- 6-7 October
- 7-8 December 2009

II. Product-related issues

Contribution to the scientific advice and protocol assistance provided by the Scientific Advice Working Party of the CHMP, and to CHMP marketing authorisation or post-authorisation procedures on relevant pharmacogenetics and pharmacogenomic aspects, upon request.

Scientific advice/BM Qualification	MAA/Post-Authorisation procedure
5	**2**

III. Briefing meetings with Applicants

- At request of Applicants in conjunction with WP plenary meetings.

Briefing meetings	Joint VGDS/Briefing meetings
8	**4**

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

IV. Reflection Papers and Guidelines

- **Guideline on the use of PG in PK studies (in collaboration with the EWP-PK group)**

Comments	Commentary paper by 1st Q 2009 to be prepared following Workshop with stakeholder on 19 December 2008
Action	*Guideline for Release for consultation 3rd Q 2009*

- **Reflection paper on co-development of PG biomarkers and test platforms**

Comments	*Position on the matter to be clarified on the light of the new qualification process*
Action	*Reflection paper for Release for consultation 3rd Q 2009*

- **Reflection paper on statistical and methodological issues associate with PG biomarkers (in collaboration with the EWP)**

Comments	*Position on the matter to be discussed with stakeholders on the light of the new qualification process*
Action	*Reflection paper for Release for consultation 4th Q 2009*

- **Reflection paper on genomics and personalised medicines**

Comments	*Position on experience (examples and impact on B/R assessment), benefits (new ways to address public health needs and optimise access to medicines) missing links (e.g. genomic epidemiology and phenotype algorithms) etc. To be discussed with stakeholders.*
Action	*Reflection paper for Release for consultation 4th Q 2009*

V. ICH Activities

E 16 : "Genomic Biomarkers Related to Drug Response: Context, Structure and Format of Qualification Submissions"

Comments:	*ICH Step 2 expected by autumn 2009*
Action:	Provide specialised input on to context and claims definition, dossier structure and data format.

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

VI. EU regulatory activities

1. Contribution to legislative activities of the European Commission
2. Exchange and dissemination of new PG information in the EU network.

Action: To be considered according to EMEA/Heads of Agency training plan

VII. Training

- 1 training session for senior assessors 4th Q 2009.

VIII. Activities with external parties

- European Commission (including DG Enterprise, DG Sanco, DG Research): input through the CHMP on initiatives of relevance to Pharmacogenomics.

- EFPIA Efficacy/ PG Working Group: Annual workshop on priority issues and guidelines.

- FDA/CDER: joint briefing meetings on genomic submissions including PG Biomarkers qualification.

- Support to genomic cluster activities within the confidentiality agreements with US FDA, Health Canada and Japanese PMDA.

- Input and support as required to IMI-related initiatives.

- EU Scientific and Ethics Networks: ad hoc sessions to discuss emerging issues, including:

    - European Society of Human Genetics,

    - European Patients Associations and

    - The Working Party of Healthcare Professionals and

    - Other stakeholders as required.

IX. Organisational matters

- Liaison as appropriate with other Working Parties, or Ad-Hoc Expert Groups on pharmacogenomics related matters, and on other matters of relevance to the work of PGWP.