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

London, 25 September 2008
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CHMP Pharmacovigilance Working Party Work Programme 2009

I. Meetings scheduled

Eleven 3-day meetings, each with 38 reimbursed experts:

19 – 21	January	20 – 22	July
16 – 18	February	21 – 23	September
16 – 18	March	19 – 21	October
20 – 22	April	16 – 18	November
26 – 28	May	14 – 16	December
22 – 24	June		

An extraordinary plenary meeting may be scheduled in case of an urgent safety matter, subject to availability of the necessary funds.

Additional specialised experts may be invited to the plenary at the request of the CHMP (to be reimbursed by the EMEA) or a Member State (to be reimbursed by the Member State).

Drafting Groups will be scheduled either for guidance documents or for product-related issues as needed. They are usually organised in the margins of the plenary meetings.

Budget for one pharmacovigilance assessors training over two days is available, and such training will be organised on relevant topics.

II. Product-related issues

	Expected contribution to Scientific Advice	Expected contribution to Protocol Assistance	Expected contribution to product assessment in pre-authorisation phase	Expected contribution to post-authorisation issues
At CHMP's request	3	1	20	80
At Member States' request	-	-	20	80

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

III. CHMP and EC Guidelines

1. Pharmacovigilance-related Guidelines

- **Volume 9A of the Rules Governing Medicinal Products in the European Union – Revisions**

  Finalisation of the revision 2008 following public consultation.

  Further chapters of Volume 9A, in addition to those specified below, may be updated as necessary during the revision 2009, in particular with regard to worksharing between Member States on PSUR assessment and also in follow-up of initiatives taken by the European Commission for the strengthening of the EU pharmacovigilance system, for public consultation.

- **Volume 9A Chapter I.3: Requirements for Risk Management Systems**

  Revision in the light of experience and in line with the Guideline on Safety and Efficacy Follow-up - Risk Management of Advanced Therapy Medicinal Products (EMEA/14995/2008), for public consultation.

- **Volume 9A Chapter II.2.A: Conduct of Pharmacovigilance for Centrally Authorised Products**

  Revision taking into account revised CHMP/PhVWP procedures, for public consultation.

- **Volume 9A Chapter II.2.B: Crisis Management Plan for Centrally Authorised Products**

  Revision taking into account revised CHMP/PhVWP procedures and the EU Incident Management Plan, for public consultation.

- **Conduct of Pharmacovigilance for Vaccines for Pre- and Post-Exposure Prophylaxis Against Infectious Diseases (CHMP/PhVWP/503449/2007)**

  Finalisation of Guideline following public consultation, to be included in Volume 9A.

- **Guidance in relation to lack of efficacy reporting for medicinal products other than vaccines**

  Development of guidance as requested by pharmaceutical industry, for public consultation, to be included in Volume 9A.

- **Guidance in relation to the need for contraception after exposure to medicinal products with teratogenic potential**

  Development of guidance in the light of recent product assessments, for public consultation.

- **Guidelines in relation to public communication of pharmacovigilance information**

  Development of Concept Papers and Guidelines in the context of an overall EMEA communication and transparency strategy, which is currently under development in order to implement the revised Legislation also in the light of ongoing discussions at the level of the Head of Agencies and initiatives taken by the European Commission for the strengthening of the EU pharmacovigilance system.

- **Guidelines in relation to EudraVigilance**

  Contribution to development of guidelines as requested by the EudraVigilance Expert Working Group.

- **Guidance in relation to pharmacovigilance inspections**

  Contribution to development of further guidance in accordance with the Work Programme of the Ad Hoc Pharmacovigilance Inspectors Working Group through their PhVWP Subgroup and discussion at PhVWP plenary level.

- **Standard Operating Procedure for the Review of CPMP Scientific Advice by the CPMP Pharmacovigilance Working Party (CPMP/PhVWP/135/00)**

  Revision with view to Risk Management Plans, if considered necessary in the light of experience gained.

2. Other Guidelines

- **Other CHMP Guidelines**

  Contribution and commenting on Guidelines prepared by other Working Parties as considered necessary by the CHMP.

- **Other EC Guidelines**

  Contribution and commenting on Guidelines as requested by the European Commission. This may include guidance on the safety of excipients.

IV. Guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

- **ICH-E2B(R3): Clinical Safety Data Management – Data Elements for Transmission of Individual Case Safety Reports**

  Contribution to the project to develop ICH-E2B into an international standard (ISO/CEN).

- **ICH-E2F: Development Safety Update Reports (CHMP/ICH/309348/2008)**

  Contribution to finalisation following public consultation.

- **ICH-M1: Medical Dictionary for Drug Regulatory Activities (MedDRA)**

  Contribution to MedDRA maintenance and user guidance documents.

- **ICH-M5: Data Elements and Standards for Drug Dictionaries**

  Contribution to the project to develop ICH-M5 as international standard (ISO/CEN).

- **ICH-M6: Standard Operating Procedures for Maintenance of ICH Terminology Lists**

  Contribution to this ICH Guideline.

V. EU Regulatory Activities

- **Regulatory guidance issued by the EMEA**

  Commenting as requested by EMEA.

- **Guidelines and Standard Operating Procedures issued by the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human**

  Commenting on CMD(h) guidance documents as requested by the CMD(h) through the Joint CMD(h)-PhVWP Working Group and discussion at PhVWP plenary level.

  Development of guidance documents supporting the worksharing between Member States of the assessment of Periodic Safety Update Reports through the Joint PhVWP-CMD(h) Drafting Group on PSUR Assessment Worksharing / PSUR Work Sharing Maintenance Group and discussion at PhVWP plenary level.

- **Legislative proposals and other initiatives taken by the European Commission for the strengthening of the EU pharmacovigilance system**

  Commenting on proposals from the European Commission and contributing to implementing texts from the European Commission as requested.

- **Recommendations and guidelines in relation to the Commission Regulation Concerning the Examination of Variations to the Terms of Marketing Authorisations for Medicinal Products for Human Use and Veterinary Medicinal Products**

  Contribution as requested by the European Commission. Development of timeframes for implementation of safety-related variations and criteria for recall and repackaging following urgent safety restriction and variation procedures for consideration by CHMP and EC.

- **Technical Requirements for Blood and Blood Components (including those used for medicinal products derived from human blood and plasma): Haemovigilance**

  Input from pharmacovigilance experience as requested.

- **Regulation on Products Manufactured by Means of Human Tissue Engineering and Advanced Therapies**

  Input from pharmacovigilance experience as requested.

VI. Activities with External Parties

1. Interested Parties

- Industry:
  - Regular interaction with marketing authorisation holders on product-related safety issues in form of data requests and oral clarifications as necessary.
  - Interaction with industry associations at EU level with regard to Guidelines as necessary.
- Patient organisations:
  - Interaction in accordance with initiatives undertaken by the EMEA in relation to the EMEA Scientific Committees' Working Party with Patients' and Consumers' Organisations.
  - Consultation of wording on adverse reactions and safe use of medicines drafted by the PhVWP for Package Leaflets with the EMEA Scientific Committees' Working Party with Patients' and Consumers' Organisations as safety concerns arise for major classes of medicinal products.
  - Development of improved, possibly harmonised approach to consumer/direct patient reports on adverse reactions in co-operation with the EMEA Scientific Committees' Working Party with Patients' and Consumers' Organisations.
- Healthcare professional organisations:
  - Interaction in accordance with initiatives undertaken by the EMEA in the context of the EMEA Road Map and the EMEA/CHMP Working Group with Healthcare Professionals' Organisations.
- Scientific community:
  - Cooperation with learned societies, academic centres/surveillance networks at EU level as needed with regard to emerging safety issues and Guidelines.
  - Cooperation with the academic centres involved in the EC(FP6)-funded project DRUID – DRiving Under the Influence of Drugs, Alcohol and Medicines.
  - Review of data collected by the European Haemophilia Safety Surveillance System (EUHASS)
- International organisations:
  - Collaboration with the World Health Organization and the Uppsala Monitoring Centre (UMC, the WHO Collaborating Centre for International Drug Monitoring) through a working group for discussion on issues of common interest.

2. Regulatory Authorities Outside the EU

- Contribution to activities preparing future Enlargement of the EU
- Interaction with the US Food and Drug Administration (FDA) for centrally processed/authorised products and products for which a Referral procedure is ongoing (in accordance with the Confidentiality Arrangements concluded between the EU and the FDA).

VII. Organisational Matters

- **Mandate, Objectives and Rules of Procedure for the CHMP Pharmacovigilance Working Party (CHMP/PhVWP/88786/04)**

  Drafting and implementation of documents on improved working practices, document management and communication tools, also regarding the interactions and co-operation CHMP-PhVWP, HMPC-PhVWP, PDCO-PhVWP, CMD(h)-PhVWP and HMA-h-PhVWP.

  This includes internal guidance for assessors on Periodic Safety Update Reports.

- **Tracking system for safety issues and implementation of safety-related regulatory action**

  Further development and maintenance (development initiated in 2006 in accordance with the implementation of the PhVWP Mandate, pilot tool developed in 2007, pilot conducted in 2008, system connection of all Member States by end of 2008 and presentation to HMA in November 2008).

- **Signal management using EudraVigilance**

  Participation in pilot and contribution to development of an EU signal management system using EudraVigilance initiated by EMEA.

- **Worksharing between Member States of the assessment of Periodic Safety Update Reports (PSURs)**

  Operation of system through PSUR Worksharing Maintenance Group.

- **Policies for transparency of pharmacovigilance matters at the level of the PhVWP**

  Development of policies in the context of an overall EMEA communication and transparency strategy, which is currently under development in order to implement the revised Legislation, also in the light of ongoing discussions at the level of the Head of Agencies and initiatives taken by the European Commission for the strengthening of the EU pharmacovigilance system.

- **Responses to requests from members of the public for access to documents held by Competent Authorities or the EMEA**

  Development of resource efficient procedures in accordance with the EMEA Rules for the Implementation of Regulation (EC) No 1049/2001 on Access to EMEA Documents (EMEA/MB/203359/2006 Rev 1) and the EMEA Standard Operating Procedure on Handling of Requests for Access to Documents (SOP/EMEA/0041).

VIII. Methodological Matters

- **Implementation of Risk Management Plans**

  Implementation as initiated in 2006 to be monitored and supported by review & learning project (phase I and II completed in 2007, phase III ongoing) in cooperation between the CHMP, the CMD-h and the PhVWP with view to establishing and maintaining a harmonised approach independent from route of marketing authorisation.

- **Collection of data through post-authorisation safety studies**

  Contribution to the EU Network of Academic Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) as requested by the EMEA.

- **Drug safety research**

  Input, as requested by the European Commission, to project on Important Public Health Issues for Drug Safety Research conducted by DG Research within the Scope for Health Themes in the 7th Framework Programme, which includes the Innovative Medicines Initiative's Strategic Research Agenda (IMI).

- **Interaction with medication error reporting and prevention systems and patient safety initiatives**

  Discussion of 2004 to be continued in relation to prescribing, dispensing and administration errors due to confusion of invented names with view to interaction at the level of Member States concerning medication errors in general and at EU level specifically with the Invented Name Review Group, also in order to contribute to the implementation of Risk Management Plans and EU activities in the field of patient safety. In particular, contribution to the follow-up of the European Commission's public consultation on patient safety conducted in 2008.

- **EU Risk Management Strategy**

  Discussion of issues arising from discussions of the HMA-h, the European Risk Management Strategy Facilitation Group and the EMEA upon their request.

