07 November 2011
EMA/CHMP/PhVWP/652319/2011 FINAL

Work plan for the European Medicines Agency CHMP Pharmacovigilance Working Party (PhVWP) 2012

Chairperson:

June M Raine

Status

November 2011: Final

1. Meetings scheduled for 2012

Plenary meetings of the PhVWP are planned until July 2012 inclusive; following the plenary meeting of the 16-18 July 2012 the PhVWP will no longer exists given the constitution of the Pharmacovigilance Risk Assessment Committee (PRAC) under the new pharmacovigilance legislation hence the following seven three-day meetings are scheduled, each with 41 reimbursed experts:

- 16 - 18 January 2012
- 13 - 15 February 2012
- 12 - 14 March 2012
- 16 - 18 April 2012
- 21 - 23 May 2012
- 18 - 20 June 2012
- 16 - 18 July 2012

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 or EMA (to be reimbursed by the EMA) 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. Any drafting group should have a mandate, timelines and deliverables agreed at the plenary PhVWP to which the drafting groups

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44(0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

report. Additional Drafting Groups may be constituted in the preparation of the Good Vigilance Practice guidelines.

2. Product-related issues

The PhVWP provides support to the CHMP by peer reviewing, in accordance with a set timeframe, the report(s) prepared by the specialised expert(s) appointed by the CHMP to reply to the questions raised by the CHMP on safety issues. The PhVWP also provides recommendations to the Member States at their request on nationally authorised products.

Action: Expected reports and/or contributions in 2012:

	On product assessment in pre-authorisation phase	**Post-authorisation issues (reports, issues for finalisation)**	**DHPCs**
At CHMP's request	3	50	25
At Member States' request	-	25	5

Action: a standing Drafting Group dedicated to the review of Dear Healthcare Professional Communications (DHPCs) has met regularly in the margins on the PhVWP for the whole of 2011. The group was also involved in the review of other documents intended for communication such as Press Releases and Q&A as requested by the CHMP or by the MSs. The DG will continue its work from January until July 2012.

Action: on safety issues relating to nationally authorised products, the PhVWP publishes the outcome of its discussions and recommendations in the PhVWP Monthly Report according to the agreed policy. The PhVWP will continue this activity in 2012.

3. CHMP and EC Guidelines

3.1. Pharmacovigilance-related Guidelines

Good Vigilance Practice guidelines and implementation and detailed guidance in accordance with new legislation strengthening pharmacovigilance in the EU

Comments: Most of the provisions of Regulation (EU) No 1235/2010 and Directive 2010/84/EU will be implemented 18 months following their publication in the Official Journal of the EU on 31 December 2010 (i.e. 2 July 2012 and 21 July 2012 respectively).

Deliverables of Project Planning for the Implementation of the New Legislation on Pharmacovigilance (Project 00305) are discussed at the respective EMA/Member States Project Teams established as per the Governance structure agreed by the EU Network. Final agreement is sought at European Risk Management Strategy – Facilitation Group (ERMS-FG) level. Involvement of PhVWP is understood as necessary prior to final agreement by the ERMS-FG and consultation on all Good Vigilance Practice Guideline modules is foreseen.

Action: Contribution to development of the modules of the Good Vigilance Practice guidelines

prior to public consultation and prior to adoption will be the main focus in 2012.

Other guidelines in relation to pharmacovigilance inspections

Action: Contribution to development of further guidance in accordance with the Work Programme of the Pharmacovigilance Inspectors Working Group (PhVIWG) through their PhVWP Subgroup building on the progress achieved in 2011.

Comments: Contribution to development of guidelines as discussed in the PhVIWG.

Other guidelines in relation to EudraVigilance

Action: Contribution to development of guidelines as requested by the EudraVigilance Expert Working Group (EV-EWG).

Other guidelines on pharmacogenomics and pharmacovigilance

Action: If resources allow, development of an overarching guidance encompassing various aspects of pharmacogenomics in pharmacovigilance concluding the work and the discussions that took place in 2011. This guidance will be considered for inclusion in the Good Vigilance Practice guideline.

3.2. Other CHMP Guidelines and EC Guidelines

Action: Contribution and commenting on Guidelines prepared by other Working Parties as considered necessary by the CHMP. See also 6.1.

Action: Contribution and commenting on Guidelines as requested by the European Commission.

3.3. Guidelines and Standard Operating Procedures issued by the Co-ordination Group for Mutual Recognition and Decentralised Procedures Human (CMDh) or developed jointly by the CMDh and the PhVWP

Action: Commenting on CMDh guidance documents as requested by the CMDh through the Joint CMDh-PhVWP Working Group and discussion at PhVWP plenary level.

4. 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 / IS ICSR: International Standard: Health informatics – Pharmacovigilance – Individual Case Safety Report

Action: Contribution to the development of ICH-E2B into an international standard (ISO/CEN) and contribution to the ICH implementation guide. 2011 will see the finalisation of Step 3 and Step 4 will be achieved in 2012.

ICH-E2C(R2): Clinical Safety Data Management – Periodic Safety Update Reports (PSURs)

Action: Contribution to the revision of the current ICH-E2C Guideline.

Comments: It is planned to have Step 3 (regional regulatory consultation) initiated beginning of 2012; Step 4 is expected to be completed by Q4 2012.

ICH-E2F: Development Safety Update Report (DSUR)

Action: Contribution to the implementation of the Guideline (step 4) in the EU.

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

Action: Contribution to MedDRA maintenance and user guidance documents as requested by the EC throughout 2012.

Action: The PhVWP will provide a representative to support the work of the MedDRA Points-to-Consider Working Group in 2012.

ICH-M5: Data Elements and Standards for Drug Dictionaries / IS IDMP: International Standard: Health informatics – Identification of Medicinal Products

Action: Contribution to the implementation in the EU of the Guideline (step 4) ICH-M5 as international standard (ISO/CEN); finalisation of Step 3 and Step 4 is planned for 2012.

5. EU Regulatory Activities

5.1. Regulatory guidance issued by the EMA

Action: Commenting as requested by EMA.

5.2. EU Risk Management Strategy

Action: Discussion of issues arising from the HMAh, the European Risk Management Strategy (ERMS) Facilitation Group and the EMA upon their request.

6. Activities with External Parties

6.1. Other Working Parties/Working Groups of the CHMP, other Committees of the EMA

Biologics Working Party (BWP)

Action: The PhVWP will discuss safety related aspects and provide input in the wording to be included in Core SmPC specific to a substance or range of substances, as requested by the BWP/CHMP.

Biosimilar Medicinal Products Working Party (BMWP)

Action: The PhVWP discussed in 2010 the challenges of pharmacovigilance for biosimilars. The PhVWP will seek further interaction with the BMWP to progress these discussions and to progress on the discussion that took place in 2011. Any principles for guidance

will be considered for inclusion in the Good Vigilance Practice guideline. See also 3.1.

Blood Product Working Party (BPWP)

Action: The PhVWP will discuss safety related aspects and provide input in the wording to be included in Core SmPC specific to a substance or a range of substances, as requested by the BPWP/CHMP.

Committee on Herbal Medicinal Products (HMPC)

Action: The PhVWP informs the HMPC of discussions on herbal medicinal products which take place at the PhVWP and their outcome. The HMPC and the PhVWP will continue exchanging information when a safety issue concerns an herbal medicinal product.

Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)

Action: The PhVWP/CMDh will continue their interaction meeting bimonthly for discussion of the implementation of the PhVWP recommendations in the joint PhVWP/CMDh working Group. The group will also discuss other topics of mutual interest as regards as safety of medicines authorised trough the mutual recognition or decentralised procedure. See also 3.3.

Healthcare Professionals Working Group (HCPWG)

Action: See also below "Healthcare professional organisations". The HCPWG will be asked to input in the design of risk minimisation measures for particular products and giving its views on the effectiveness of risk minimisation measures already in place. Healthcare professionals feed-back on the awareness of DHPCs on particular safety issues will also be explored.

Action: The PhVWP will be involved in the consultation of the Framework for Interaction between the EMA and Healthcare Professionals.

EudraVigilance Expert Working Group (EV-EWG)

Action: The PhVWP will continue to support and will contribute to the development of the EudraVigilance Data-warehouse and Analysis System (EVDAS) project.

Action: A representative of the PhVWP will provide updates and support in the identification of areas of common interest for interaction.

Geriatric Experts Working Group

Action: The PhVWP began discussion in 2010 on how to contribute to the implementation of the EMA geriatric medicines strategy. The PhVWP will continue the discussion in 2011 and will liaise further with the Geriatric Experts Working Group for issues related to pharmacovigilance in the geriatric population.

Patients and Consumers Working Party (PCWP)

Action: The PhVWP will continue in its interaction with the PCWP. The PhVWP will ask the input of the PCWP on proposed wording revision for PLs for Centrally Authorised Products (CAPs, upon request of the CHMP), nationally authorised products (e.g. therapeutic class review) and products authorised by the Mutual Recognition Procedure (MRP - in the context of PhVWP/CMDh collaboration).
The PCWP will also be involved in giving feed-back on the feasibility related aspects of some risk minimisation measures and on the clarity of communication directed to patients. See also below "Patient organisations"

Action: A representative of the PhVWP will participate in the meeting of the PCWP in 2012 to discuss aspects related to the interaction and feed-back on the outcome of the consultation performed.

Paediatric Committee (PDCO)

Action: The PhVWP will continue its interaction with the PDCO exchanging information on discussed safety issues of common interest. In particular the PhVWP will recommend highlighting safety issues that will be considered in the Risk Management Plans which could be important in the paediatric population.

Action: Outcome measures to evaluate the effectiveness of the interaction PhVWP/PDCO will be discussed by the PhVWP before the end of its activity with a view to plan appropriate interaction between the PRAC and the PDCO in the future.

Pharmacogenomics Working Party (PgWP)

Action: The PhVWP will continue in its interaction and exchange of expert opinion with the PgWP on relevant pharmacogenetic and pharmacogenomic aspects for product-related issues including nationally authorised products.

Comments: The PhVWP initiated co-operation with the PgWP in 2010 with a representative attending the meetings of the PgWP and providing feedback to the PhVWP. The interaction included discussions on some product-related issues.

Pharmacovigilance Inspectors Working Group (PhVIWG)

Action: The PhVWP will provide input to the risk-based programme for routine pharmacovigilance inspections of MAHs connected with human centrally authorised products for the years 2012 to 2014 submitted to the PhVWP for periodic revision in 2012.
The PhVWP will continue to address inspection related pharmacovigilance issues and pharmacovigilance inspection follow up in conjunction with the PhVIWG.
The PhVWP will contribute to the development of procedures for pharmacovigilance inspection and related topics and their updates by the PhVIWG.

6.2. Parties within the EU

Other EU agencies

Action: Co-operation with the ECDC, EMCDDA and EFSA as necessary.

Industry

Action: Interaction with marketing authorisation holders on product-related safety issues in form of data requests and oral clarifications as necessary.

Action: Interaction with industry associations at EU level with regard to guidelines as necessary.

Patient organisations

Action: Interaction in accordance with initiatives undertaken by the EMA in relation to the EMA Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP), see also above "PCWP".

Comments: Two observers from patient organisations participate in the meetings of the PhVWP since May 2010 as agreed by the EMA Management Board in 2009. Participation will continue in 2012.

Healthcare professional organisations

Action: Interaction in accordance with initiatives undertaken by the EMA in the context of the EMA Road Map and the EMA/CHMP Working Group with Healthcare Professionals' Organisations (HCPWG).

Scientific community

Action: Contact and subsequent follow-up of drug safety research projects funded through the European Commission under the Health Area of the VII Framework Programme.

The PhVWP will invite the leaders of several projects of the Framework Programme (such as SOS Safety Of non-Steroidal anti-inflammatory drugs, ARITMO arrhythmic potential of drugs) in the field of drug safety research to provide updates of their research activities and discuss any findings with regulatory implications.

Action: The PhVWP will continue the review of data collected by the EC-funded project European Haemophilia Safety Surveillance System (EUHASS).

Comments: The Data Collection on Adverse events of Anti-HIV Drugs (D:A:D) is a prospective multi-cohort study of HIV-infected persons under active follow up. The study is supervised by a Steering Committee with representation from each cohort, EMA, patient community and industry.

Action: The data collection for D:A:D takes place at least every eight months. The PhVWP provides advice to the CHMP on the review of the data and liaises with representatives nominated to participate to the Oversight Committee for the evaluation of metabolic complications of HAART (Highly Active Antiretroviral Therapy).

Action: Co-operation with learned societies, academic centres/surveillance networks at EU level as needed with regard to emerging safety issues and guidelines.

ENCePP

Action: A representative of the PhVWP is a member of the Steering Group of the ENCePP.

The PhVWP will input in the ENCePP documents as requested.

6.3. Parties outside the EU

Drug regulatory authorities

Action: The PhVWP will continue the interaction with the US Food and Drug Administration (FDA) for centrally authorised products and products for which a Referral procedure is ongoing (in accordance with the Confidentiality Arrangements concluded between the EU and the FDA).

Action Observers from Health Canada attended as observers some meeting of the PhVWP in 2011. They will continue to participate in order to promote mutual exchange of information during 2012.

International organisations:

Action: The PhVWP will collaborate with the World Health Organization (WHO) and the Uppsala Monitoring Centre (UMC, the WHO Collaborating Centre for International Drug Monitoring) on topics of common interest as needed.

7. Organisational Matters

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

Action: Planning of a second development phase (European Pharmacovigilance Issues Tracking Tool 2 or "EPITT 2") - deferred from 2011 - in order to implement the requirements collected by the EPITT Task Force, the EPITT Drafting Group since June 2010, and the requirements based on the implementation of the New Pharmacovigilance Legislation.

Comments: The tool is currently fully operational following the closure of its first development phase in April 2010. The PhVWP promotes the organisation of regular trainings and assistance to users. A drafting group meets as necessary in the margin of the PhVWP to discuss issues related to its running and development.

Signal management

Action: The Drafting Group will continue to meet in the margins of the PhVWP in 2012. Its main objectives will be to make proposals on how to best improve the signal management in the EU following the closure of a pilot phase spread over the period May 2010-October 2010 (especially by promoting the use of EPITT), and to assist the PhVWP with the implementation of the new pharmacovigilance legislation requirements on data monitoring and signal detection and signal management.

Comments: A report including the outcome of the pilot performed on the "signal management in the EU", as well as some points to be considered will be issued and presented by the Drafting Group to the PhVWP and CHMP by the end of the year 2011.

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

Action: The PhVWP will continue to support as needed the operation of the worksharing

activity through the Joint PhVWP-CMDh Working Group on PSUR Assessment Worksharing in accordance with applicable guidelines. The PhVWP will contribute to the development of a harmonised list of Union Reference Dates and frequency of PSURs submission and revised procedures in preparation for the new pharmacovigilance legislation.

Transparency of pharmacovigilance matters at the level of the PhVWP

Action: The PhVWP will continue the activity relating to the publication of PhVWP Monthly Reports.

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

Action: Operation of system in accordance with the EMA Rules for the Implementation of Regulation (EC) No 1049/2001 on Access to EMA Documents (EMEA/MB/203359/2006 Rev 1) and the EMA Standard Operating Procedure on Handling of Requests for Access to Documents (SOP/EMEA/0041).

Planning for the termination of the work of the PhVWP

Action: The PhVWP will discuss plans for the transition phase of hand over of issues for discussion that will be referred to the PRAC, as prepared by EMA.

Action: The PhVWP will contribute to the discussion on guidance for the transitional regulatory handling of some procedures before the legislation comes into force (e.g. minimum requirements for risk management plans for generic products).

Comments: Implementation of the new legislation will continue during the first sixth months of 2012 and the first meeting of the Pharmacovigilance Risk Assessment Committee (PRAC) will take place in July 2012. Some aspects of the transition phase will be discussed in the context of the reflection papers developed by the Governance structure agreed by the EU network. However the PhVWP will provide input in ensuring a smooth transition and in identifying matters to be brought to the attention of the PRAC.

8. Methodological Matters

Collection of data through post-authorisation safety studies

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

Drug safety research

Action: The PhVWP will continue to give input, as requested by the European Commission DG Research, on Important Public Health Issues for Drug Safety Research to be considered within the Scope for Health Themes in the 8th Framework Programme.

Action: The PhVWP will follow-up on research carried out on funded drug safety priorities by interacting with the academic community as described above under 6.2. , "Scientific community".