European Medicines Agency
Veterinary Medicines and Inspections

London, 12 November 2008
EMEA/CHMP/CVMP/QWP/455946/2008

Joint CHMP/CVMP Quality Working Party Work programme 2009

The following work programme is a joint human and veterinary programme
H - Indicates a Human only topic
V - Indicates a Veterinary only topic
H/V - Indicates a joint Human/Veterinary topic

I Meetings scheduled for 2009

I.1 Plenary meetings (4/year)

Dates for QWP meetings in 2009:

24-26 February
2-4 June (including QWP/Interested Parties Meeting)
9-11 September (including Joint QWP/GMDP IWG Meeting)
24-26 November

All QWP plenary meetings have participants with expertise in quality of human and veterinary medicinal products, observers from EDQM (European Directorate for Quality of Medicines and HealthCare), EU accession countries and occasionally from Regulatory Authorities outside the EU.
Each meeting is scheduled to take 3 days involving maximum 60 members per meeting. Break Out Sessions on specific subjects, involving a subset of the participants are organised during the meetings.
Additional expert-days expected (10/year).

I.2 Workshops or training of assessors (1/year)
H/V To be held jointly with GMP/GDP inspectors working group, EDQM, representatives of other EMEA working parties and/or interested parties, as appropriate.

I.3 **H/V** Joint QWP/GMP Inspectors Meeting (1/year)

I.4 **H/V** Interested Parties Meetings (1/year).

I.5 Drafting/expert groups*
Involving, if appropriate, external experts and representatives of other working parties and/or inspectors:

- **H/V** Joint QWP/BWP/GMP Inspectors EMEA Process Analytical Technology Team (4 x 1 day meetings);
- **H/V** Near Infrared Spectroscopy Drafting Group (see also section III.1) (1/2 x 1 day meetings);
- Other drafting/expert groups, as deemed necessary (expected: 2-4 x 1 day meetings).

*Virtual meetings are mainly regarded as complementary meetings. However, if feasible and depending on its size and workload, it might be possible to replace a drafting/expert meeting by a virtual meeting.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 95
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

II Product related issues

II.1 **H/V** Involvement in product dossiers

The following table provides the expected number of Quality Working Party contributions (number of involvements in dossier) in 2009 for Scientific Advice, Protocol Assistance, Product Assessment, and Post-Authorisation issues.

	Expected Contributions in Scientific Advice and/or Protocol Assistance [1]	Product Assessment (Pre- and Post-authorisation issues)
Expected contribution	40	6

II.2 **H/V** Review quality matters arising from assessment of applications and scientific advice/protocol assistance for the need to develop additional QWP Concept Papers and Guidelines.

II.3 **H/V** Provide advice on product related issues referred by the Committee on Herbal Medicinal Products (HMPC).

III CHMP/CVMP Guidance documents

The QWP welcomes the contribution of interested parties to the consideration of additional topics for CXMP Concept Papers and Guidelines. Contributions should preferably be made during the interested party meetings and in any case before the third quarter of a year to ensure consideration for the work programme of the following year.

III.1 New technologies and approaches to quality:

- **H/V** Guideline on the Use of Near Infrared Spectroscopy (CPMP/QWP/3309/01): Finalisation of revision to take account of advances in this area;
- **H** Guideline on Radiopharmaceuticals (Eudralex 3AQ2oA): Finalisation of revision to take account of advances on this area (e.g. PET radiopharmaceuticals);
- **H** Guideline on Radiopharmaceuticals Based on Monoclonal antibodies (Eudralex 3AQ21A): Publication of the Concept Paper for the revision of the guideline and release of the draft revised guideline for public consultation;
- **H** Guideline on Parametric Release (CPMP/QWP/3015/99): Publication of the Concept Paper for the revision of the guideline to take into account Real Time Release concepts and release of the draft revised guideline for public consultation;
- **H/V** Discussion on the impact of new technologies and approaches as described in ICH Guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality Systems) on other quality guidelines, e.g.:
  - Guidelines on Specifications (CPMP/ICH/367/96, 3AQ11a Volume IIIA & EMEA/CVMP/815/00);
  - Guidelines on Process Validation (CHMP/QWP/848/96 & EMEA/CVMP/598/99);
  - Guideline on Manufacture of the Finished Dosage Form (CPMP/QWP/848/96 & EMEA/CVMP/126/95)
  - Chemistry of New Active Substance (CPMP/QWP/130/96Rev1 & EMEA/CVMP/541/03)

[1] This includes formal scientific advice procedures as well as other referrals

III.2 **H** Guideline on Pharmaceutical Development of Medicines for Paediatric Use: Release of the draft guideline for public consultation.

III.3 **H/V** Guideline on Setting Specifications for Related Impurities in Antibiotics: Release of the draft guideline for public consultation.

III.4 **H/V** Guidance document on Assessment of Quality of Products Containing Existing/Known Active Substances: Finalisation.

III.5 Quality of Veterinary medicinal products:

- **V** Guideline on Spot-on Products: finalisation;
- **V** Guideline on Dossier Requirements for Oncology Products: contribution to finalisation of the guideline;
- **V** Guideline on Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMEA/CVMP/019/00): Contribution to revision prior to its release for consultation;
- **V** Review of applicability and adaptation of CPMP/CHMP Guidelines to veterinary medicinal products;
- **V** Review and update the quality parts of the Guideline for Assessors Preparing Reports for Veterinary Medicinal Products (after revision of Annex I of the Directive)

III.6 **H/V** QWP Questions/Answers document (EMEA website): Update of the document after any QWP meeting.

III.7 **H/V** Review of validity of existing Human and Veterinary Quality Guidelines and other QWP guidance documents.

IV (V)ICH Guidelines and Activities

The Quality Working Party will contribute to development and implementation of applicable (V)ICH guidelines, in particular by contributing to the following activities:

IV.1 **H** ICH:

- Contribution to the development of an annex to the ICH Q8 Guideline on Pharmaceutical Development (Q8R);
- Contribution to the development of the ICH Q11 guideline on development and manufacture of the active substance;
- Contribution to the implementation in the EU of ICH Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality Systems);
- Contribution to the discussion on Common technical document (ICH topic M4);
- Contribution to the development, review and update of other ICH Quality Guidelines, as requested.

IV.2 **V** VICH:

- Contribution to draft Guideline on Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substance and Products;
- Contribution to other VICH quality developments, including application of ICH Q8, Q9 and Q10 to veterinary products;
- Contribution to the development, review and update of other VICH Quality Guidelines, as requested.

V EU Regulatory Activities

V.1 **H/V** Provide advice/active participation for training of assessors.

V.2 **H/V** Revision of the Variations Regulations 1084/2003 and 1085/2003:

- Technical contribution to the revision of the Variations Regulations and/or related Guidelines, as requested.

V.3 **H/V** Co-operation with EMEA Committees

In addition to the activities listed in sections II and III:

- Provide recommendations to EMEA committees (CHMP, CVMP, HMPC, COMP, PDCO), on matters relating directly or indirectly to the quality of medicinal products (other than product specific issues, see section II.1);
- Update QWP Guidelines or other guidance documents to take into account herbal medicinal products, also in relation to the legislative provisions for traditional herbal medicinal products.

V.4 **H/V** Co-operation with GMP/GDP inspectors working group:

- Facilitate the cooperation between quality assessors and GMP inspectors on general topics of mutual interest and in the assessment of applications;
- Facilitate the introduction of new approaches to manufacturing and control methodologies (e.g. PAT) through the EMEA PAT team: discussions on further development of the team and its mandate once sufficient experience is gained;
- Contribution to discussions on anti-counterfeiting activities.

V.5 **H/V** Co-operation with other Working Parties and groups, as appropriate, operating in the field of pharmaceutical quality (e.g. BWP).

VI Activities with external parties

VI.1 **H/V** Collaboration with EDQM on:

- Project for impurities: review of qualification and limits of impurities of existing medicinal products authorised on the market in the EU/EEA, having regard to general chapters and monographs of the European Pharmacopoeia and article 23 of Council Directive 2001/83/EC and article 27 of Directive 2001/82/EC;
- Development and review of Pharmacopoeial monographs and general chapters and notices;
- Certification of Suitability Scheme policies and other related documents, including contribution to the setting up of a procedure to deal with withdrawals of Certificates of Suitability;
- Sampling and testing of Centrally Authorised Products;
- Pharmacopoeial Discussion Group (PDG), through matters referred to the QWP by EDQM;
- Involvement in and contribution to quality related seminars organised by EDQM.

VI.2 **H/V** Collaboration with Drug Regulatory Authorities outside the EU/EEA in addition to (V)ICH activities:

- Liaison with FDA (e.g. through the EMEA PAT team), Health Canada and Japanese Ministry of Health, Labour and Welfare, on matters of common interest.

VI.3 **H/V** Collaboration with Interested Parties, including industry associations on:

- Consultation on QWP Concept Papers and Guidelines;

- Continue dialogue on new technologies and approaches (e.g. through workshops with interested parties on topics of common interest, see also section I.1).

VII Organisational matters

VII.1 Maintenance of adopted organisational documents:

- Mandate for Joint CHMP/CVMP Quality Working Party;
- Work programme;
- Tracking of documents table.