1. Meetings scheduled for 2011

- 11-12 January 2011
- 7-9 February 2011
- 7-9 March 2011
- 4-6 April 2011
- 10-11 May 2011
- 14-15 June 2011
- 11-13 July 2011
- 12-14 September 2011
- 10-12 October 2011
- 7-9 November 2011
- 5-7 December 2011

2. Product related issues

(Such as support to Marketing Authorisation Assessment, Post-marketing Data Evaluation, Scientific Advice, Protocol Assistance and Peer Review)

- Recommendation to CHMP on applications for marketing authorisations and variations
• Recommendation to CHMP and SAWP on applications for scientific advice and protocol assistance
• Recommendation to CHMP on applications for PMF certificates
• Recommendation to CHMP on applications for VAMF certificates
• Recommendation to CHMP on quality and safety in relation to quality aspects of human blood derivatives used as ancillary substances in medical devices
• Recommendation to CHMP, as appropriate, on other ancillary biological substances in medical devices
• Recommendation to CHMP, as appropriate, on scientific opinion in cooperation with WHO for evaluation of medicinal products intended exclusively for markets outside the community
• Recommendation to the CAT on the quality aspects of application for certification of the quality and non-clinical data of an Advanced Therapy medicinal product, in accordance with article 18 of Regulation (EC) 1394/2007

<table>
<thead>
<tr>
<th>Working Party¹</th>
<th>Expected contribution in Product Assessment</th>
<th>Expected contribution in Post-authorisation issues</th>
<th>Expected contribution to scientific opinions in cooperation with WHO</th>
<th>Expected contribution in Scientific Advice</th>
<th>Expected contribution in Protocol Assistance</th>
<th>Expected contribution in PMF re-certificates (annual updates, variations)</th>
<th>Expected contribution in certification of Advanced Therapy Products</th>
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</table>

3. CHMP Guidance Documents

3.1. Spongiform Encephalopathies

3.1.1. Animal spongiform Encephalopathies

Revision of Note for guidance on minimising the risks of TSE transmission via medicinal products (EMEA/410/01 rev. 4)

Action: Revision of guideline in the light of scientific and legal developments
Comments: Revision of guideline forwarded to EC.
Other involved WP(s): Vet IWP

Preparation, as necessary, of additional position papers and explanatory notes, questions and answers documents, to provide additional guidance or information to industry and patients

¹ Number of MAA
² Between January and November 2010 the BWP produced 26 reports on 21 MAA in the pre-authorisation phase, 8 reports on 6 medical products in the post-authorisation phase, 2 reports on 2 human blood derivative incorporated into a medical devices, 51 scientific advice, 15 protocol assistance reports, 30 reports covering 13 plasma master files (initial certification, re-certification/annual update, variations)
3.1.2. Human Spongiform Encephalopathies

CHMP Position Statement on Creutzfeldt-Jakob Disease and plasma-derived and urine-derived medicinal products (EMEA/CPMP/BWP/2879/02)


Comments: To provide guidance, as needed, to support the recommendation of the position statement on investigation of manufacturing processes for removal/inactivation of TSE agents.

CHMP Position Statement on Creutzfeldt-Jakob Disease and advanced therapy medicinal products (EMEA/CHMP/BWP/353632/2010)


3.2. Plasma Derived Medicinal Products

Note for guidance on Plasma-derived medicinal products (CPMP/BWP/269/95, rev 4)

Action: To include consideration of viral risk assessment methodologies

Comments: Revised guidance released for external consultation until October 2009. Guidance note is expected to be finalised in Q1 2011.

Note for Guidance on the warning on transmissible agents in Summary of Product Characteristics (SPCs) and package leaflets for plasma-derived medicinal products (EMEA/CPMP/BPWP/BWP/561/03)

Action: Discussion on whether to make specific reference to vCJD expected to be finalised in 2011. (Decision in 2008 that no warning needed where albumin is used as excipient to be added to the guideline).

Comments: To provide guidance as needed to support use of the revised warning statements for SPCs and patient leaflets.

Other involved WP(s)/parties: BPWP

Blood Product Working Party guidelines and Core SPCs

Action: Input on quality aspects

Revision of Annex 14 of the GMP Guidelines

Action: BWP input into revision

Other involved parties: Inspections Working Group

Medical devices incorporating stable derivatives of human blood or human plasma

Action: Scientific input

Other involved WP(s)/parties: BPWP, Commission
Guideline on the scientific data requirements for a plasma master file (PMF)
(CPMP/BWP/3794/03)

Action: Maintenance of PMF guideline and scientific input on implementation of guidance for variations to the PMF.
Other involved parties: Commission

Technical Directives under the Blood Directive

Action: Scientific input into liaison with Commission on legal interpretation in relation to plasma-derived medicinal products, as needed
Other involved parties: Commission, Inspections Working Group

3.3. Production and control of Biotechnological and Biological Medicinal Products

Production and Quality Control of Medicinal Products Derived by Recombinant DNA Technology (Ref. 3AB1A, Dec 1994)

Action: Maintenance of guideline; update in the light of scientific developments e.g. reflection papers on peptide mapping test, qualification of tests for residual host cell proteins and residual DNA, particulate matter (in line with guideline on monoclonal antibody), filiation, requirements for process changes, specifications, etc.
Comments: Possible workshop with industry on specifications.

Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substances: Quality issues (EMEA/CHMP/BWP/49348/2005)

Action: Review of guideline in light of experience, and contribution to meetings of the BMWP dealing with clinical and pre-clinical issues of comparability
Comments: Other involved WP(s): BMWP

Guideline on immunogenicity assessment of biotechnology - derived therapeutic proteins (CHMP/BMWP/14327/06)

Action: Comments as needed in relation to the maintenance of the guidelines and the development of specific guidance for classes of products
Other involved WP(s): BMWP


Action: Comments as needed on quality aspects in relation to the development of the guideline.
Other involved WP(s): BMWP

Guideline on development, production, characterisation and specifications for monoclonal antibodies and related products (EMEA/CHMP/BWP/157653/2007)

Action: Maintenance of guideline
Comments: Guideline entered into force in 2009
Guideline on radiopharmaceuticals based on monoclonal antibodies (3AQ21a)
Action: Scientific input for the revision of the guideline
Other involved WP(s): QWP

Guideline on similar biological medicinal products containing monoclonal antibodies
Action: Comments as needed in relation to the development of the safety and efficacy guideline (BMWP)
Other involved WP(s): BMWP

Process analytical technology (PAT)
Action: Scientific input for biological medicinal products and interaction with EMA PAT team
Other involved WP(s): EMA PAT Team QWP, Inspectors Working Party
Comments: Discussion with interested parties (e.g. EFPIA, Vaccines Manufacturers) to share experience gained with PAT in the production process of biologicals/biotech derived products

Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products (EMEA/CHMP/BWP398498/2005-corr)
Action: Maintenance of guideline

Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials (CHMP/BWP/534898/2008)
Action: Finalisation of guideline in Q2 2011.

Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products (EMEA/CHMP/SWP/28367/07)
Action: If needed, any follow-up action on quality aspects for biological medicinal products

Biological products derived from human urine. Update of Guidance (CPMP/118/95)
Action: Discussion on the need to update the referred guidance and the need to include any statement on transmissible agents in the product information. If update needed, to be released for consultation in S2 2011.

Request for CHMP opinion under Article 5(3) regarding any potential public health concern arising from detection of genomic fragments from endogenous and adventitious viral agents in live attenuated vaccines and need to revise available guidance on biologicals.
Action: Scientific input on quality aspects
Note for Guidance on the use of bovine serum used in the manufacture of human biological medicinal products (CPMP/BWP/1793/01)

**Action:** Maintenance of guideline

**Comments:** Consideration on need to review guideline in respect of testing requirement for BVD

Guideline on potency testing of cell based immunotherapy medicinal products for human use (EMEA/CHMP/BWP/271475/2006)

**Action:** Maintenance of the guideline

Other involved WP(s): CPWP

Note for Guidance on the Production and Quality Control of Animal Immunoglobulins and Immunosera for Human Use (CPMP/BWP/3354/99)

**Action:** Maintenance of guideline

Guideline on the use of transgenic animals in the manufacture of biological medicinal products for human use 3AB7a (revision) of July 1995

**Action:** Revision of the guideline. Draft to be published in 2011. Guideline is expected to be finalised in 2012

Guideline on the quality of biological active substances produced by stable transgene expression in higher plants (EMEA/CHMP/BWP/48316/2006)

**Action:** Maintenance of guideline

**GMP of starting materials**

**Action:** Scientific input into maintenance of guidance document

**Similarity of Orphan Medicinal Products**

**Action:** Scientific input for biological medicinal products: Review in the light of experience

Other involved WP(s)/parties: COMP, QWP, EWP, SWP, Commission

Concept paper on potency declaration / labelling for biological medicinal products modified proteins for which an International Standard exist for the non-modified product

**Action:** Development of concept paper and guideline

Other involved WP(s)/parties: QRD, EWP

### 3.4. Vaccines

**Influenza vaccines: Strain selection**

**Action:** To propose the strain composition of the influenza vaccine for the forthcoming annual vaccination campaign

Other involved parties: VWP, CMD(h), WHO
Guideline on harmonisation of requirements for influenza vaccines (CPMP/BWP/214/96)

**Action:** Maintenance of guideline

**Comments:** Review of guideline in the light of lessons learnt during the pandemic, including need to characterise and to assay neuraminidase content and also serology assays for immune response.

Procedural advice on the submission of variations for annual update of human influenza inactivated vaccines applications in the centralised Procedure. (EMA/CHMP/BWP/99698/2007)

**Action:** Finalisation and revision in 2011 of guideline and extension to cover for data set required for annual strain update of live attenuated influenza vaccines (quality aspects)

**Comments:** An Annex is proposed to be developed specifically for LAIV.

Guideline on quality aspects on the isolation of candidate influenza vaccine viruses in cell culture (EMA/CHMP/BWP/68803/2010)

**Action:** Release of draft guideline for comments in June 2010. Expected to be finalised in Q4 2010 or Q1 2011.

**Comments:** Update with respect to the derivatisation of cell-isolated influenza vaccine viruses

Guideline on dossier structure and content for pandemic influenza vaccine marketing authorisation application (Revision) (EMEA/CPMP/VEG/4717/2003/-Rev.1)

**Action:** Consideration on need to review of guideline in light of lessons learnt during the pandemic.

**Comments:** Input for quality aspects

Input into maintenance of the guideline on the procedure for the authorisation of influenza vaccine in pandemic situation

**Action:** Review of guideline in the light of new information/developments in 2010

**Comments:** Input for quality aspects

Contribution to the maintenance of the Guideline on influenza vaccines prepared from viruses with the potential to cause a pandemic and intended to be used outside of the core dossier context (EMEA/CHMP/VWP/263499/2006)

**Action:** Review of guideline in the light of lessons learnt during the pandemic. BWP will continue to contribution to Joint Agency – Industry Task Force

**Comments:** Input for quality aspects
Guideline on stability data for cumulative storage periods for vaccines/intermediates

Action: Development of concept paper and guideline

Guideline on Quality, non-clinical and clinical aspects of live recombinant vectored vaccines (EMEA/CHMP/VWP/141697/2009)

Action: Input into maintenance of quality aspects of the guideline
Other included WP(s): Joint VWP, GTWP, SWP

Comments: Guideline adopted in July 2010

Guideline on development of DNA vaccines

Action: Draft guideline to be developed
Other included WP(s): Joint VWP, GTWP, SWP

Comments: Development of quality aspects of multidisciplinary guideline.

Guideline on Requirements for Vaccine Antigen Master File (VAMF) Certification (EMEA/CHMP/4548/03)

Action: Maintenance of guideline in the light of experience
Other involved parties: Commission


Action: Input into maintenance of the Quality Section of the guideline
Other involved WP(s): VWP, EWP, SWP, PhVWP

Points to Consider on the Reduction, Elimination or Substitution of Thiomersal in Vaccines (CPMP/BWP/2517/00)

Action: Maintenance of guideline and position statements and contribution to assessment of dossiers
Other involved WP(s): VWP, EWP, SWP, PhVWP

Guideline on pharmaceutical aspects of the product information for human vaccines (EMEA/CPMP/BWP/2758/02)

Action: Scientific input for the revision of the guideline
Other involved WP(s): QRD

Bioterrorism

Action: At the request of CHMP, input into guidance documents on use of medicinal products for treatment and prophylaxis of biological agents that might be used as weapons of bioterrorism
3.5. Advanced Therapy Medicinal Products (ATMPs)

Guideline on dossier requirements for combined Advanced Therapy Medicinal Products (ATMPs)

Action: Scientific input for quality requirements
Other involved WP(s)/Committee(s): CPWP, GTWP, SWP, CAT

Guideline on Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products (EMEA/CHMP/BWP/3088/99)

Action: Following publication of concept paper development of quality aspects for revision of guideline
Other involved WP(s)/Committee(s): GTWP, CPWP, SWP, EWP, CAT

Comments:

Reflection paper on stem cell-based medicinal products (EMA/CAT/571134/09)

Other involved WP(s): CPWP, EWP, SWP, PhVWP, CAT

Comments: Input on quality aspects


Action: Maintenance of multidisciplinary guideline on cell-based products in conjunction with CPWP.
Other involved WP(s): CPWP

Guideline on the quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells (EMEA/CHMP/GTWP/67639/2008)

Action: Development of guidance on quality aspects as part of multidisciplinary guideline (CHMP/GTWP/58311/2007)
Other involved WP(s) / Committee(s): GTWP, CPWP, EWP, SWP, CAT

Guideline on the risk-based approach according to annex I, part IV of directive 2001/83/EC applied to advanced therapy medicinal products (EMA/CHMP/CPWP/708420/2009)

Action: Development of quality aspects as part of this multidisciplinary guideline
Other involved WP(s) / Committee(s): CPWP, GTWP, CAT

Question and Answer document on pharmaceutical, non-clinical and clinical development of cell-based medicinal products

Action: Development of quality aspects as part of this multidisciplinary document
Other involved WP(s) / Committee(s): CPWP, CAT

Scientific guideline on the minimum quality and non-clinical data for certification of advanced therapy medicinal products (EMEA/CAT/486831/2008/corr)

Contribution to Commission for community legal framework for advanced therapies

**Action:** Scientific input in development of technical requirement and procedures
Other involved WP(s) / Committee(s): CPWP, GTWP, EWP, SWP, CAT, Commission

Guideline/Reflection paper on comparability of cell-based medicinal products

**Action:** Scientific input in development of guidance on comparability of cell-based MPs.
Other involved WP(s) / Committee(s): CPWP, CAT

Guideline/Reflection paper on investigational cell-based medicinal products

**Action:** Scientific input on quality aspects in development of guidance on investigational cell-based medicinal products
Other involved WP(s) / Committee(s): CPWP, SWP, CAT, Clinical trial facilitation group

3.6. **Post-Authorisation Issues**

Sampling and Testing of centrally authorised products

**Action:** Scientific input on quality aspects
Other involved WP(s)/parties: QWP, EDQM, Inspector’s Working Party

Variation Regulations

**Action:** Contribution to Agency input into development of guidelines and classification of variations for biological medicinal products for updated variation regulations

4. **ICH Guidelines and Activities**

The Working Party shall contribute to applicable ICH guidelines under development that are identified after the adoption of this Work Plan:

**ICH Guideline (Q11) on Development and Manufacture of Drug Substances**

*(chemical entities and biotechnological entities)*

**Action:** Development of draft guideline
Other involved WP: QWP

**ICH Q8 Pharmaceutical Development / ICH Q9 Quality Risk Management / ICH Q10 Pharmaceutical Systems**

**Action:** Input for biological medicinal products into development/ implementation of guidelines – contribution to PAT reflection
Other involved WP(s): QWP, Inspector ad-hoc WP

**Activities on gene therapy medicinal products**

**Action:** Input on quality aspects for gene therapy medicinal products
Other involved WP(s): GTWP, CAT
5. EU Regulatory Activities

Environmental Risk Assessments for Medicinal Products containing, or consisting of, Genetically Modified Organisms (GMOs) (Module 1.6.2) (EMEA/CHMP/BWP/135148/04)

**Action:**
Scientific contribution to maintenance of guideline
Other involved WP(s)/parties: NTA, VWP, GTWP, EWP, SWP, GTWP, CVMP, Commission

Clinical Trial Directive 2001/20/EC - Draft Guidance documents

**Action:**
Input, as required, on the development of guidance documents (see also guidelines listed under Section 3 of this work programme)
Other involved WP(s): QWP, EWP, SWP

Scientific input for the elaboration and revision of European Pharmacopoeia monographs

**Action:**
Scientific input
Other involved parties: Ph.Eur.

Scientific input on specific issues from OMCL

**Action:**
Scientific input
Other involved parties: EDQM, OMCL

Common Technical Document

**Action:**
Scientific input to questions arising on the use of the CTD

Guideline on Summary of Product Characteristics

**Action:**
Scientific Input into guideline for biological medicinal products
Other involved WP(s): EWP, NTA, BPWP

European Union Telematics Controlled Terms Project

**Action:**
Input, as needed, into development of terms for biological medicinal products

Structure and recommendation for reporting biological medicinal products for individual case safety reports and Eudravigilance

**Action:**
Input into the Agency’s contribution into development of ISO standards
Other involved WPs: BPWP, CPWP, GTWP, BMWP, VWP, PhVWP

Guideline on Procedural Aspects Regarding a CHMP Scientific Opinion in the context of cooperation with WHO for the Evaluation of Medicinal Products intended Exclusively for Markets outside the Community

**Action:**
Scientific input into maintenance of the guideline
Other involved WP(s): VWP, EWP, WHO, Commission
6. Activities with External Parties

**Drug Regulatory Authorities Outside the EU** (excluding ICH activities, already mentioned)

**Action:** Contribution to discussions with accession countries
- International cooperation as appropriate (including WHO, FDA and Japan)

**Comments:** Contribution on quality aspects for blood, vaccines, and ATMP clusters with FDA

**Meeting with Interested Parties** (e.g. Learned Societies, Public health Stake Holders) (Public Health professionals, Patients’ organisations, Pharmaceutical Industry Representatives)

**Action:** Meeting with pharmaceutical industry representatives on issues of joint interest including EFPIA, EVM, GME, APAG, PPTA, IPFA, EuropaBio, EBE, EGA, Pharma-Planta

**Joint Forum between the Agency and European Directorate for the Quality of Medicines and HealthCare (EDQM)**

**Action:** Participation in the Joint Forum in relationship to the co-ordination of activities for quality aspects of biological medicinal products

7. Organisational Matters

**Participation in the Coordination Group for coordination of activities with other Working Parties, dealing with biological medicinal products**

**Action:** Participation in Coordination Group

**List of adopted organisational documents (e.g. mandate, template, SOP)**

**Action:** Mandate of the CHMP Biologics Working Party (BWP), (Ref: EMEA/CPMP/BWP/206296/2004) January 2005

**Development of a PMF database**

**Action:** Input on scientific aspects as needed

8. Workshops 2011

- Workshop with industry on setting specifications for biological medicinal products
- Workshop on development and review of assays for content and of serology assays for influenza vaccines

9. Assessor Training 2011

- Joint training with BPWP on blood products