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

London, 17 September 2008
EMEA/CHMP/BWP/207941/2008

CHMP Biologics Working Party (BWP) Work Programme 2009

I. Meetings scheduled

- Dates Plenary meeting:

  - For 2009: 12-14 January, 9-11 February, 9-11 March, 14-16 April, 18-20 May, 15-17 June, 13-15 July, 14-16 September, 12-14 October, 9-11 November, 7-9 December
  - For 2010: 11-13 January, 8-10 February, 8-10 March, 12-14 April, 10-12 May, 14-16 June, 12-14 July, 13-15 September, 11-13 October, 8-10 November, 6-8 December

II. 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.

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	Expected contribution in Product Assessment[1]	Expected contribution in Post-authorisation issues	Expected contribution to scientific opinions in cooperation with WHO	Expected contribution in Scientific Advice	Expected contribution in Protocol Assistance	Expected contribution in PMF re-certificates (annual updates, variations)	Expected contribution in certification of Advanced Therapy Products
Working Party[2]	2009 44	2009 18	2009 1	2009 33	2009 10	2009 35	2009 15

III. CHMP Guidance documents

1. Spongiform Encephalopathies

1.1 Animal Spongiform Encephalopathies

- Revision of Note for guidance on minimising the risks of TSE transmission via medicinal products (EMEA/410/01 rev. 2) Action: Revision of guideline in the light of scientific and legal developments.
  Other involved WP(s): Vet IWP

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

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)
  Action: Revision of position statement in and publication of report of 2005 and 2007 Workshops. To provide guidance, as needed, to support the recommendation of the position statement on investigation of manufacturing processes for removal/inactivation of TSE agents
  Actions related to the position statement (e.g. to provide additional information for the public).

2. Plasma Derived Medicinal Products

- Note for guidance on Plasma-derived medicinal products (CPMP/BWP/269/95, rev 3):
  Action: Concept paper on revision in 2007, release for consultation in 2008/2009. To include consideration of viral risk assessment methodologies. Addendum on the replacement of rabbit pyrogen testing by an alternative test for plasma derived medicinal products (CHMP/BWP/452081/07) to be finalised and incorporated in guideline.

- Guideline on the scientific data requirements for a plasma master file (PMF) (CPMP/BWP/3794/03)
  Action: Finalisation of template for evaluation report

- Guideline on validation of immunoassay for the detection of antibody to human immunodeficiency virus (Anti-HIV) in plasma pools (CHMP/BWP/188268/05)
  Action: maintenance of guideline.

- Guideline on validation of immunoassay for the detection of Hepatitis B virus surface antigen (HBsAg) in plasma pools (CHMP/BWP/188270/05)

[1] Number of MAA

[2] Between January and September 2008 the BWP produced 35 reports on 29 MAA in the pre-authorisation phase, 4 reports on 3 medical products in the post-authorisation phase, 2 reports on 2 human blood derivative incorporated into a medical device, 28 scientific advice, 8 protocol assistance reports, 23 reports covering 10 plasma master files (initial certification, re-certification/annual update, variations)

Action: maintenance of guideline.

- 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: To provide guidance as needed to support use of the revised warning statements for SPCs and patient leaflets.
  Possible revision in 2009. Possible Assessors Workshop in 2009.
  Other involved WP(s)/parties: BPWP

- Blood Product Working Party guidelines and Core SPCs:
  Action: Input on quality aspects

- Guideline on epidemiological data on blood transmissible infections (CPMP/BWP/125/04)
  Action: Implementation of the guideline to be monitored in 2007-2008 in relation to PMF dossiers. Workshop with stakeholders early 2009.

- Information for the public on how safety with respect to transmissible agents is evaluated for plasma-derived medicinal products (see also 1.2 human spongiform encephalopathies).
  Action: To be initiated in 2009

- Revision of Annex 14 of the GMP Guidelines
  Action: BWP input into revision
  Other involved parties: Inspections Working Group

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 etc

- Guideline on similar biological medicinal products containing biotechnology derived proteins as active substances: Quality issues (EMEA/CHMP/BWP/49348/2005)
  Action: Maintenance of guideline and contribution to meetings of the BMWP dealing with clinical and pre-clinical issues of comparability.
  In conjunction with BMWP, Stakeholder Workshop on Biosimilar Monoclonal Antibodies
  Other involved WP(s): BMWP

- Guideline on immunogenicity of biotechnological medicinal products.
  Action: Development of quality aspects of guideline.
  Other involvedWP(s): BMWP

- Guideline on Production and Quality Control of Monoclonal Antibodies (EMEA/CHMP/BWP/261157/2008)
  Action: Maintenance of guideline

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

- Guideline on Clinical Investigation of the Pharmacokinetics of Therapeutic Proteins (EMEA/CHMP/89249/2004)

Action: Scientific input into maintenance of guideline.
Other involved WP(s): EWP

- Guideline on virus validation studies: The design, contribution and interpretation of studies validating the inactivation and removal of viruses (EMEA/CPMP/BWP/268/95)
  Action: Clarification concerning GLP/GMP to be added in 2008/2009

- Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products (EMEA/CHMP/BWP/388681/2005)
  Action: Maintenance of guideline

- Guideline on biological quality aspects of biological medicinal products to be used in Clinical Trials.
  Action: Development of guideline

- 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 following publication in July 2007

- 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

- 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

- Note for guidance on the use of transgenic animals in the manufacture of biological medicinal products for human use *(revision)*
  Action: Development of concept paper and possible revision of guideline

- 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

- Manufacture and control of allergens including recombinant allergens
  Action: Finalisation of the revised guideline following public consultation.

- GMP of starting materials
  Action: Scientific input into maintenance of guidance document.
  Other involved WP(s)

- CHMP recommendations on transmissible agents and urinary derived medicinal products.
  Action: Topic to be kept under review in the light of new information/developments.

- Guideline on Similarity of Orphan Medicinal Products
  Action: Scientific input for biological medicinal products
  Other involved WP(s)/parties: QWP, EWP, SWP, Commission

4. Vaccines

- 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 harmonisation of requirements for influenza vaccines (CPMP/BWP/214/96)
  Action: Maintenance of guideline
  Other involved WP(s): VWP, EWP, SWP, PhVWP, CMD(h)

- Points to Consider on the Development of Live Attenuated Influenza Vaccines (CPMP/BWP/2289/01)
  Action: Maintenance of guideline
  Other involved WP(s): VWP, EWP, SWP, PhVWP

- Guideline on Dossier Requirements and content of Applications for Pandemic Influenza Vaccines
  Action: Finalisation of Revision of guideline, contribution to Joint EMEA-Industry Task Force.
  Other involved WP(s)/parties: VWP, CMD(h), Commission

- 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.
  Actions: maintenance of guideline, contribution to Joint EMEA – Industry Task Force.
  Other included WP(s)/parties: VWP, CMD(h), Commission.

- Guideline on stability data for cumulative storage periods for vaccines/intermediates
  Action: Development of concept paper and guideline

- Guideline on development of live recombinant vector vaccines
  Action: Finalisation of the guideline
  Other included WP(s): Joint VWP, GTWP, SWP

- Guideline on development of DNA vaccines
  Action: Draft guideline expected for release for consultation
  Other included WP(s): Joint VWP, GTWP, SWP

- Note for guidance on pharmaceutical aspects of the product information for human vaccines (EMEA/CPMP/BWP/2758/02)
  Action: Maintenance of guideline
  Other involved WP(s): QRD

- Guideline on Adjuvants in Vaccines for Human Use (EMEA/CHMP/VEG/234716/2004)
  Action: Input into maintenance of the Quality Section of the guideline
  Other involved WP(s): VWP, EWP, SWP, PhVWP

- Bioterrorism: 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

- Annex to Guideline on cell culture Inactivated influenza vaccines (CPMP/BWP/2490/00)
  Action: Update with respect to the derivatisation of cell-isolated influenza vaccine viruses
  Other involved WP(s): VWP

5. Gene Therapy and Cell Therapy

- Guideline on Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products (EMEA/CHMP/BWP/3088/99)
  Action: Development of quality aspects for revision of the guideline
  Other involved WP(s): GTWP, CPWP, SWP, EWP

- Guideline on xenogeneic cell-based products (EMEA/CHMP/410869/2006)
  Action: Finalisation of the revision of points to consider on xenogeneic cell-therapy products (CPWP/BWP/1199/02)
  Other involved WP(s): CPWP, EWP, SWP, PhVWP, IWP

- Guideline on human cell-based medicinal products
  Action: Maintenance of multidisciplinary guideline on cell-based products. An assessor training on the evaluation of cell-based medicinal products will be organised, jointly with the CPWP, in Q1/Q2 2009
  Other involved WP(s): CPWP

- Guideline on the quality, preclinical and clinical aspects of medicinal products containing genetically modified cells
  Action: Development of guidance on quality aspects as part of multidisciplinary guideline (CHMP/GTWP/58311/2007).
  Other involved WP(s): GTWP, CPWP, EWP, SWP,

- Guideline on the application of the risk analysis approach for cell-based medicinal products
  Action: Development of quality aspects as part of this multidisciplinary guideline
  Other involved WP(s): CPWP

- 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): CPWP

- Guideline on the scientific details for the certification of quality and non-clinical data of advanced therapy medicinal products
  Action: Development of quality aspects as part of this multidisciplinary guideline
  Other involved WP(s): GTWP, CPWP

6. Post-Authorisation Issues

IV. 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 of guideline – 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

V. EU Regulatory Activities

- Influenza vaccines: strain selection
  Action: to propose the strain composition of the influenza vaccine for the forthcoming vaccination campaign.
  Other involved parties: VWP, CMD(h), WHO

- Guidance for Fast Track procedure for seasonal strain update of live attenuated influenza vaccines (LAIV)
  Action: to develop concept paper and guideline.
  Other involved WPs: VWP, CMD(h)

- Input into maintenance of the guideline on the procedure for the authorisation of influenza vaccine in pandemic situation
  Other involved WP(s)/parties: VWP, CMD(h), Commission
  Action: Maintenance of guideline in the light of new information/developments

- 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

- Vaccine Identification Standards Initiative
  Action: scientific input into developments at community level
  Other involved WP(s)/parties: VWP, PhVWP, QRD, CMD(h), Commission, Ph.Eur.

- Environmental Risk Assessments for Medicinal Products containing, or consisting of, Genetically Modified Organisms (GMOs) (Module 1.6.2) (EMEA/CHMP/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: Follow-up of BWP contribution – input on the development of guidance documents. (See also guidelines listed under Section III.3 of this work programme.)
  Other involved WP(s): QWP, EWP, SWP

- Contribution to Commission for community legal framework for advanced therapies
  Action: Scientific input in development of technical requirement and procedures
  Other involved WP(s): CPWP, GTWP, EWP, SWP, PLVWP, Commission

- Sampling and Testing of centrally authorised products
  Action: scientific input
  Other involved WP(s)/parties: QWP, EDQM, Inspector's Working Party

- 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

- Medical devices incorporating stable derivatives of human blood or human plasma
  Action: scientific input
  Other involved WP(s)/parties: BPWP, Commission

- Plasma Master File
  Action: Maintenance of guideline and scientific input on legislative proposal for variations to the PMF. Second Step procedure for already centrally authorised products.
  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

- Common Technical Document
  Action: Scientific input to questions arising on the use of the CTD.

- NTA Group: Contribution to NTA regarding classification of variations to biological medicinal products
  Action: Scientific input
  Other involved WP(s)/parties: IWP, Commission

- 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 EMEA'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

- Variation Regulations
  Action: Contribution to EMEA input into development of guidelines and classification of variations for biological medicinal products for updated variation regulations

VI. Activities with external parties

- **1. Drug Regulatory Authorities Outside the EU** *(excluding ICH activities, already mentioned)*
  - Contribution to discussions with accession countries
  - International cooperation as appropriate (including WHO, FDA and Japan).

- **2. Meeting with Interested Parties (e.g.** Learned Societies, Public health Stake Holders (Public health professionals, Patients' organisations, ...), Pharmaceutical Industry Representatives).
  - Meeting with pharmaceutical industry representatives on issues of joint interest including EFPIA, EVM, GME, APAG, PPTA, IPFA, EuropaBio, EBE, EGA, Pharma-Planta

- **3. Joint Forum between EMEA and European Directorate for the Quality of Medicines and HealthCare (EDQM)**
  - Participation in the Joint Forum in relationship to the co-ordination of activities for quality aspects of biological medicinal products.

VII. Organisational matters

1. Participation in the Biocoordination Group for co-ordination of activities with other Working Parties, dealing with biological medicinal products.

2. List of adopted organisational documents (e.g. mandate, template, SOP)
   - Mandate of the CHMP Biologics Working Party (BWP), (Ref: EMEA/CPMP/BWP/206296/2004) January 2005

3. Development of a PMF database

4. List of proposed scientific guidelines for the next work programme/workplan.
   - See Section III