European Medicines Agency

London, 25 September 2008
EMEA/CHMP/GTWP/168855/2008

**WORK PLAN**

**GENE THERAPY WORKING PARTY (GTWP)**

**2009**

CHAIRPERSON: Klaus Cichutek

VICE-CHAIRPERSON: Maria Cristina Galli

STATUS: September 2008

## 1. MEETINGS SCHEDULED FOR 2009

- January 29-30, 2009
- March 26-27, 2009
- July 9-10, 2009
- September 9-10, 2009
- November 5-6, 2009

Additional meetings:

To allow a rapid exchange of information when new information relevant to gene therapy becomes available, one extraordinary meeting may be convened with CHMP agreement.

## 2. PRODUCT-RELATED ISSUES[1]

Contribution to the scientific advice and protocol assistance provided by the Scientific Advice Working Party of the CHMP, and to CHMP marketing authorisation or post-authorisation procedures on gene therapy or gene transfer medicinal products, upon request.

| | Expected briefing meetings | Expected meetings with stakeholders | Expected contribution in Scientific Advice/ Protocol assistance | Expected contribution in product assessment/ certification |
|---|---|---|---|---|
| Gene Therapy Working Party | 6 | 4 | 6 | 2/ 8 |

Informal briefing sessions with companies may take place upon request (around 6 sessions expected per year).

[1] These might have to be adjusted taking into account the activities of the new Committee on Advanced Therapies (CAT) in 2009. Some of the product-related discussions could take place in the CAT instead of the Working Party.

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## 3. EMEA/ CHMP GUIDELINES

- **Revision of the Note for guidance on quality, preclinical and clinical aspects of gene transfer medicinal products (CPMP/BWP/3088/99)**
  Action: Start of the revision after finalisation of the revision of Annex 1, part IV of Dir 2001/83, as amended
  Comments: Joint GTWP and Biologics Working Party (BWP) document

- **Guideline on the quality, preclinical and clinical aspects of medicinal products containing genetically modified cells (EMEA/GTWP/58311/2007)**
  Action: Finalisation of the guideline
  Comment: Joint GTWP, CPWP, BWP, PhVWP and safety Working Party (SWP) document

- **Guideline on clinical monitoring and follow-up of patients exposed to gene therapy/gene transfer medicinal products (EMEA/GTWP/60436/2007)**
  Action: Finalisation of the guideline
  Comments: Joint GTWP and PhVWP document

- **Guideline on live recombinant viral vectored vaccines (EMEA/GTWP/405677/2006)**
  Action: Finalisation of the guideline
  Comments: Joint VWP, GTWP, BWP, SWP document

- **Guideline for DNA vaccines**
  Action: Draft guideline expected for release for consultation
  Comments: Joint VWP, GTWP, BWP, SWP document

- **Reflection paper on quality, pre-clinical and clinical issues relating specifically to recombinant adeno-associated viral vectors (EMEA/CHMP/GTWP/587488/2007)**
  Action: Finalisation of the reflection paper
  Comments: Joint GTWP, BWP, SWP document

- **Reflections on changes during gene therapy medicinal product development**
  Comments: Joint GTWP, BWP, SWP, CPWP document

- **Reflection papers and Question and Answer documents on current topics in gene therapy**
  Action: Current issues under discussion include different viral vectors, dose ranging studies, emerging products in the field

## 4. ICH GUIDELINES AND ACTIVITIES

- **ICH Considerations on oncolytic viruses**
  Action: Input to the Consideration paper

- **ICH Considerations on virus/vector shedding**
  Action: Input to the Consideration paper

- **ICH Gene Therapy Discussion Group activities**
  Exchange of information, including:
  - Follow-up of the development of integrating vectors including update on clinical use
  - Update on long-term follow-up of participants in gene therapy clinical trials

**Input, in liaison with other CHMP Working Parties.**

The working party shall contribute to the relevant ICH guidelines under development that are identified after adoption of this work plan.

## 5. EU REGULATORY ACTIVITIES

- Contribution to legislative activities of the European Commission, upon request
- Exchange and dissemination in the CHMP network of new information on gene therapy
- Contribution to new processes related to Advanced Therapy Regulation (e.g. to the Guideline on scientific requirements for certification of quality and non-clinical data for Advanced Therapy Medicinal Products, together with BWP and CPWP)

## 6. ACTIVITIES WITH EXTERNAL PARTIES

- Meeting with interested parties (e.g., learned societies such as ESGCT, patients' organisations, Academia networks, pharmaceutical industry representatives)
- International cooperation on gene therapy-related matters in conjunction with other appropriate working parties, reinforcing the networking and exchange of experience, e.g., with FDA and other Agencies
- Briefing sessions with stakeholders
- Contribution to EMEA public workshop on advanced therapy products
- International cooperation with the ISO International Standards project for standardisation of structures and vocabularies for gene therapy medicinal products

## 7. ORGANISATIONAL MATTERS

- Liaison with CHMP Biologics Coordination Group
- Liaison as appropriate with Committee for Advanced Therapies, other Working Parties, or Ad-Hoc Expert Groups on gene therapy medicinal product- related matters