European Medicines Agency

London, 25 September 2008
EMEA/CHMP/BMWP/340689/2008

WORK PLAN

FOR THE BIOSIMILAR MEDICINAL PRODUCTS WORKING PARTY (BMWP)

2009

CHAIRPERSON: Christian Schneider

VICE-CHAIRPERSON: Martina Weise

STATUS: September 2008

1. MEETINGS SCHEDULED FOR 2009

- 25-26 February 2009
- 30 June - 1 July 2009
- 7-8 October 2009

2. EMEA/CHMP guidelines

- **Guideline on Similar Biological Medicinal Products containing Low Molecular Weight Heparins** (CHMP/BMWP/496286/06)

  Action: Finalisation of the guideline

- **Revision of Guideline on Similar Biological Medicinal Products containing Recombinant Erythropoietins** (EMEA/CHMP/BMWP/301636/2008)

  Action: Draft Guideline to be released for external consultation
  Finalisation of the guideline

- **Annex guideline for monoclonal antibodies for the CHMP Guideline on Immunogenicity Assessment of Therapeutic Proteins**

  Action: Discussion on need and feasibility
  Preparation of concept paper

- **Reflection Paper on non-clinical and clinical development of similar biological medicinal products expressed in novel/different expression systems**

  Action: Preparation of concept paper

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3. Product related matters

Action: 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 Biosimilar medicinal products

4. Activities with external parties

- Meeting with interested parties (e.g., learned societies, patients' organisations, Academia networks, pharmaceutical industry representatives)
- Cooperation on Biosimilar-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

5. Workshops

Stakeholder Workshop on Biosimilar Monoclonal Antibodies

6. Maintenance and revision of existing guidelines in the light of experience