London, 7 February 2011
EMA/CHMP/BWP/617111/2010
Committee for Medicinal Products for Human Use (CHMP)

Concept paper on the revision of the guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues

Agreed by BWP	**December 2010**
Adoption by CHMP for release for consultation	7 February 2011
End of consultation (deadline for comments)	31 May 2011

Comments should be provided using this template. The completed comments form should be sent to bwp.biosimilar.revision@ema.europa.eu

Keywords	***Similar biological medicinal product, Biosimilar, Comparability***

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

1. Introduction

The Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (EMEA/CHMP/BWP/49348/2005) lays down the quality requirements for a biological medicinal product claiming to be similar to another one already marketed.

2. Problem statement

The current quality guideline was published in 2006, at a time where little experience was available on the registration of biological medicinal product claiming to be similar to another one already marketed. Significant experience has now been gained through Scientific Advice, Marketing Authorisation Applications and Workshops. It is recognised that the guideline needs refinements taking into account several practical considerations relating to the lifecycle (from development to product discontinuation) of similar biological medicinal products.

3. Discussion (on the problem statement)

Manufacturers of biotechnological/biological products (i.e. respectively reference and biosimilar manufacturers) frequently make changes to manufacturing processes of products both during development and after approval. When changes are made to the manufacturing process, the manufacturer generally evaluates the relevant quality attributes of the product to demonstrate that modifications would not adversely impact the safety and efficacy of the drug product. As a consequence, such change may result in an evolution of quality profile during the product lifecycle. In the context of a biological medicinal product claiming or claimed to be similar to another one already marketed, the conclusion of a comparability exercise performed with a reference product at a given time may not hold true from the initial development of the biosimilar, through marketing authorisation, until the product's discontinuation.

4. Recommendation

The Biologics Working Party (BWP) recommends revising the guideline on "similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues" to reflect the experience gained.

This revision should:

- Reflect on the evolution of the quality profile of the similar biological medicinal product and the reference product throughout their respective lifecycles;

- Clarify some expectations (e.g. structure, use of different expression system, formulation sample preparation).

5. Proposed timetable

It is anticipated that the draft revised guideline will be released for consultation in the last quarter of 2011.

6. Resource requirements for preparation

BWP will be responsible for the revision of the guideline and will seek advice, if needed, from BMWP, EWP, SWP and PhVWP.

7. Impact assessment (anticipated)

It is important to keep the guidance up-to-date in the currently rapidly moving field of similar biological medicinal products. The revised guideline will provide improved guidance for both industry and Regulatory Authorities regarding the development and assessment of biosimilar medicinal products.

8. Interested parties

Competent authorities of the member states and pharmaceutical industry.

9. References to literature, guidelines, etc.

N/A