European Medicines Agency

London, 17 June 2009
Doc. Ref. EMEA/CHMP/BWP/290688/2009

CHMP

CONCEPT PAPER ON A REVISION OF THE GUIDELINE ON PHARMACEUTICAL ASPECTS OF THE PRODUCT INFORMATION FOR HUMAN VACCINES EMEA/CPMP/BWP/2758/02

AGREED BY THE BIOLOGICS WORKING PARTY (BWP)	**17 June 2009**
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	**23 July 2009**
END OF CONSULTATION (DEADLINE FOR COMMENTS)	**22 October 2009**

The proposed guideline will replace the Guideline on the Pharmaceutical Aspects of the Product Information for Human Vaccines

Comments should be provided using this template to ana.trullas@emea.europa.eu

KEYWORDS	Vaccine. Label. Summary of Product Characteristics. Patient leaflet. Braille

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

1. INTRODUCTION

In 2002 the Biotechnology Working Party at the EMEA began drafting guidance on the product information (summaries of product characteristics, labelling and patient leaflets) for human vaccines. The resulting guideline ('Guideline o the Pharmaceutical Aspects of the Product Information for Human Vaccines') was adopted by the CPMP in 2003 and came into operation in June 2004. Since that date, as well as serving to harmonise the product information for vaccines in Europe, the guideline also incidentally acted as a model for standard-setting for the product information for a number of other classes of biological medicinal product.

2. PROBLEM STATEMENT

The existing vaccines product information guideline remains valid. However, significant developments in both regulatory affairs and in vaccinology have taken place since its 2004 adoption which the guideline does not specifically address.

3. DISCUSSION

Specifically the following developments which have occurred since the original version of the guideline was adopted in 2004 should be noted:

Regulatory affairs

- All new and revised EMEA guidelines are now published in a standard format with Executive Summary, Introduction, Scope, Legal Basis, and Main Guideline Text as the major rubrics.
- While the word 'pharmaceutical' is used in the title of the existing guideline, 'quality' is an equivalent word which is more commonly used in EMEA documents.
- The European Commission has introduced requirements for Braille markings in labels and leaflets.
- In the case of certain vaccines with complex multi-component diluents, suitable short descriptions have been allowed to appear in section 6.1 of the SPC in place of full but impractically-long lists of all the diluent substances present.
- For certain vaccines, means of expressing directions for non-refrigerated storage of the product have been approved.

Vaccinology

- New vaccine classes have been approved.
- New combination vaccines have been approved.
- There is potential for applications to be made to market live recombinant and virus vectored vaccines in the future. Already for such products, EMEA guidance has been drafted, clinical trials have been approved in certain EU member states, and companies have discussed with the EMEA their activities and plans.

4. RECOMMENDATION

It is recommended that a revision of the existing guideline should be undertaken, taking into account:

- The points listed under ‘Discussion’ above.
- Comments received from both external and internal EMEA stakeholders during the proposed consultation phase for this Concept Paper.
- Any additional points which arise during the guideline drafting exercise.

5. PROPOSED TIMETABLE

A period of three months is proposed for the consultation phase for this Concept Paper.

6. RESOURCE REQUIREMENTS FOR PREPARATION

The planned revision guideline process is not predicted to impact on the workloads of the EMEA working groups unduly, because most of the drafting can be completed by the Rapporteur and the drafting group meeting separately with much less time being spent in plenary meeting discussions.

7. IMPACT ASSESSMENT

Once completed, the new version of the guideline is anticipated to facilitate the activities of relevant regulatory, industrial, health professional, and patient, users.

8. INTERESTED PARTIES

The CHMP Biologicals Working Party, because of its leading role in the assessment of the quality of human vaccines in Europe, is the group most directly connected to the subject of the title of the guideline proposed for revision. Other EMEA-level groups likely to be interested in the revision of the guideline are the Vaccines Working Party, the Medical Information Sector at EMEA and, for recombinant vaccines, the Gene Therapy Working Party. Interested parties outside the EMEA are anticipated to include the vaccines manufacturers, health care professional bodies, and patients’ associations.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

The following are the main reference documents for this Concept Paper:

- The guideline on the product information for human vaccines.
- The *European Pharmacopoeia*
- EMEA Medical Information Sector (formerly QRD) guidance documents on product literature