European Medicines Agency
Evaluation of Medicines for Human Use

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CONCEPT PAPER ON THE DEVELOPMENT OF A COMMITTEE FOR HUMAN MEDICINAL PRODUCTS (CHMP) REVISED GUIDELINE ON CLINICAL EVALUATION OF NEW VACCINES

INTRODUCTION

The guideline was published in May 1999 and gives guidance on the clinical development of vaccines for human use.

PROBLEM STATEMENT

Following discussions at the CHMP on how best to present the clinical data in the SPC of vaccines, a revision of the existing guideline is proposed. The proposal is to review also other parts of the guideline, as identified below, to reflect the progress in scientific knowledge and experience gained in licensing of vaccines containing single or multiple antigens. In addition, the recent development of novel vaccines has posed several challenges to Regulators that need to be addressed in the revised guideline.

RECOMMENDATION

The scope of the guideline will not be changed. It will be clarified, however, that this guideline will only be applicable to prophylactic vaccines; therapeutic vaccines will be excluded.

The following main topics were identified:

- Reformatting of the guideline, changing the order and titles of different sections to improve readability;
- Further guidance on the characterisation of the immune response and testing methodologies;
- Follow-up of immune response and documentation of the persistence of protection and the need and timing for boosting;
- Discussion of the potential effects of maternal antibodies;
- Discussion of maternal immunisation to protect infants;
- Further considerations for the development of multiple-antigen vaccines and the concept of cross-protection;
- Concomitant administration: defining the information needed for authorisation of concomitant use. Elaboration (examples) of what might constitute clinically important interference;
- Interchangeability of vaccines within schedules;
- Update of pharmacovigilance section in line with the ICH guideline;

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- The guideline will address those instances where efficacy data cannot be provided. Situations when a marketing authorisation might be granted based on immunogenicity data only and/or limited clinical data will be addressed;
- Issues related to the use of placebos, in particular in trials with children;
- Concept of lot-to-lot consistency in clinical trials;
- Consideration for vaccine evaluation in special populations (e.g. those expected to have impaired immune responses or special risk factors);
- New section on the appropriate design of bridging studies if they are needed;
- Impact of vaccination on epidemiology;
- New section on the presentation of vaccine specific information in the relevant sections of SPC, including the presentation of clinical data in section 5.1 of the SPC;
- Update of cross-references to other guidelines and reference to GCP directive.

TIMETABLE

It is anticipated that the draft of the revision of the guideline will be released for consultation by fourth quarter of 2004 / first quarter of 2005.

RESOURCES

The revision of the guideline will be developed by the VEG in collaboration with CHMP and working parties such as EWP, PEG, PhVWP. As this revision might impact on other guidelines, such as the Note for Guidance on Pharmaceutical and Biological Aspects of Combined Vaccines and the Note for Guidance on Preclinical, Pharmacological and Toxicological Testing of Vaccines, consultation with the relevant working parties concerned will be needed.

IMPACT ASSESSMENT

The revision should provide improved guidance to Industry on the development of vaccines, and to Regulators on the evaluation of vaccines. This will contribute to the availability of new vaccines to the market and thereby benefit public health.