European Medicines Agency

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE

(CHMP)

RECOMMENDATION FOR REVISION OF THE GUIDELINE ON THE CLINICAL DEVELOPMENT OF MEDICINAL PRODUCTS FOR THE TREATMENT OF HIV INFECTION (CPMP/EWP/633/02 REV. 1)

AGREED BY THE EFFICACY WORKING PARTY	January 2007
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	22 February 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 May 2007

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1. INTRODUCTION

Late 2006, the current HIV Notes for Guidance document was reviewed by the anti-viral Scientific Advisory Group (SAG) of the CHMP and further discussed at a pan-European HIV assessors meeting. A need to revise the document was identified in these discussions.

2. PROBLEM STATEMENT

While the general outlines of the document remain valid, especially the design of confirmatory studies in heavily pre-treated patients may need revision highlighting concerns raised in relation to the large proportion of patients on functional monotherapy in recent studies. Other areas in need for further clarification include pharmacokinetic (PK) interaction studies, PK studies in children and conditional approval.

There is also a need to provide guidance as regards the reporting of interaction studies and viral resistance data in the SPC in order to make these documents more informative and user friendly.

3. RECOMMENDATION

The Efficacy Working Party recommends a revision of the HIV Notes for Guidance in order to update sections related to confirmatory studies in heavily pre-treated patients, studies in children, PK interactions, conditional approval and information in the SPC.

4. PROPOSED TIMETABLE

Release for consultation is foreseen third quarter 2007, followed by a three-month consultation phase and adoption by CHMP second quarter 2008.

5. RESOURCE REQUIREMENTS FOR PREPARATION

It is foreseen that the work will be conducted within an EWP drafting group followed by consultation with the SAG prior to release for consultation.

6. IMPACT ASSESSMENT (ANTICIPATED)

A harmonised view on the reporting of data in SPC and the European Public Assessment Reports in relation to complex areas such as PK interaction studies will facilitate regulatory procedures and increase the clinical usefulness of these documents. It is also found likely that a common view on drug development for treatment of heavily pre-treated patients and other defined areas as discussed above will facilitate interactions between regulators and sponsors.