European Medicines Agency

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

RECOMMENDATION FOR REVISION OF THE POINTS TO CONSIDER ON THE EVALUATION OF DIAGNOSTIC AGENTS

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

The Points to Consider on the Evaluation of Diagnostic Agents was adopted by CPMP in November 2001. It is now considered prudent to revise certain aspects of the document as further discussed below.

2. PROBLEM STATEMENT

While the main scope and message in the general guideline remain valid, some methodological issues may need further refinement, e.g. in relation to the use of multiple blinded readers in confirmatory trials. Similarly, it appears appropriate to provide guidance enabling a differentiation as regards requirements for authorisation for a new chemical entity very similar to licensed products ("me too") and more innovative compounds.

Due to rapid technological development, especially within the fields of imaging, certain aspects of appendix 1 dealing with imaging agents needs revision. Issues to be discussed may include the choice of active comparator for confirmatory studies, e.g. taking into account clinical usefulness in current clinical practice of the licensed product. It is also proposed that radio-diagnostic agents are dealt with in more depths, perhaps in a separate appendix.

3. DISCUSSION (ON THE PROBLEM STATEMENT)

No major changes to the current points to consider document are foreseen, but it is considered meaningful to undertake a revision in order to bring it in line with current thinking.

4. RECOMMENDATION

The Efficacy Working Party recommends a revision of the current Points to Consider on the Evaluation of Diagnostic Agents.

5. PROPOSED TIMETABLE

Release for consultation is foreseen 4th quarter 2007 with deadline for comments after a 3-month consultation period followed by adoption by CHMP 2nd quarter 2008

6. RESOURCE REQUIREMENTS FOR PREPARATION

The revision of the current Points to Consider document will involve EWP only. Consultation with the Scientific Advisory Group on Diagnostics is foreseen.

7. IMPACT ASSESSMENT (ANTICIPATED)

A revision of the guideline is foreseen to facilitate the regulatory handling of new drug applications within this complex field and allows for a re-discussion of the problems related to the proper documentation and assessment of new diagnostic agents.