



# Revision of European Guidelines on clinical investigation of medicinal products: Treatment of Asthma

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## INTRODUCTION

In order to help applicants to prepare the dossier for a MAA, the European Medicines Agency, prepares Scientific Guidelines. The Committee for Human Medicinal Products (CHMP) delegated these tasks in different Working Parties. The Efficacy Working Party (EWP) has been responsible for the development and update of clinical scientific guidelines (Figure 1).

## AIM

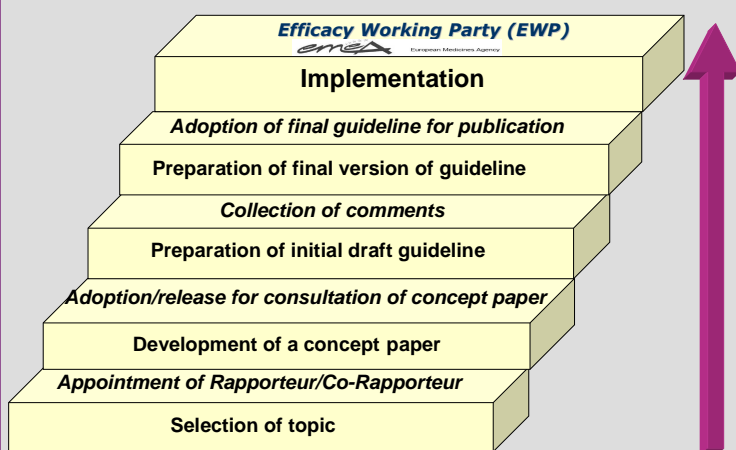
To describe the update of the European guideline on clinical investigation of medicinal products in the treatment of asthma (CPMP/EWP/2922/01).

## METHODS

Co-Rapporteurs, from Spain and Sweden, were appointed by the Committee for Proprietary Medicinal Products (CHMP) Efficacy Working Party (EWP). Based on the complexity of the disease, internal and external experts were also involved and an ad-hoc expert meeting convened prior to starting the revision of the document. The following issues were considered when updating the guideline:

- 1) Updated categorisation of asthma patients;
- 2) Representativeness of the population studied across the entire clinical development while keeping the necessary assay sensitivity of individual studies;
- 3) Value of "asthma control" as a tool for assessing drug efficacy;
- 4) Value and limitations of lung-function parameters in drug development;
- 5) Reinforce the use of clinical measurements (symptoms) and patient-reported outcome measures;
- 6) Improved judgement of the contribution of individual drugs in the context of the stepwise therapeutic strategy in asthma;
- 7) The need for a dedicated chapter on children, bearing in mind the specificity of the disease in children and adolescents and age-related differences in drug effects in terms of both safety and efficacy.

## Figure 1. Process for drafting a guideline



## RESULTS

The first step included the elaboration, adoption and consultation of the concept paper EMEA/CHMP/EWP/10797/2009 (need for revision of the asthma guideline). The preliminary concept paper was circulated to interested learned societies and patients associations on October 2009. Any organisation or individual was allowed to submit comments using a publicly available template. The first step ended on 31st January 2010 (see figure 2).

The second step (ongoing) includes the drafting of the guideline and further consultation and adoption. A preliminary draft version was circulated to the EWP members on July 2010. The draft revised guideline is expected for public release by end 2010.

## Figure 2. First step: Concept paper

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Topic	Documents	Reference number	Publication date	Effective date	Remarks
Concept paper on the need for revision of the CHMP note for guidance on the clinical development of medicinal products in the treatment of asthma (CPMP/EWP/2922/01)	 <a href="#">Concept paper</a>	CHMP/EWP/10797/2009	Release for consultation Oct 2009		Deadline for comments 31 Jan 2010

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## CONCLUSIONS

The update of European guidelines on clinical investigation follows a well established public procedure in which many agents are involved (Rapporteurs, EWP members, CHMP, internal and external experts, interested parties and individuals).

## ACKNOWLEDGEMENTS

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