



Revision of European Guidelines on clinical investigation of medicinal products: Treatment of Chronic Obstructive Pulmonary Disease (COPD)

Arantxa Sancho López¹, M^a Luisa Suárez Gea², Antonio Gómez Outes², Gonzalo Calvo Rojas³

¹ Departamento de Farmacología Clínica, Hospital Puerta de Hierro Majadahonda, Madrid

² División de Farmacología y Evaluación Clínica, Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Madrid

³ Departamento de Farmacología Clínica, Hospital Clinic, Barcelona

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 key aspects of the update of the European guideline on clinical investigation of medicinal products in the treatment of chronic obstructive pulmonary disease (COPD) (CPMP/EWP/562/98).

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.

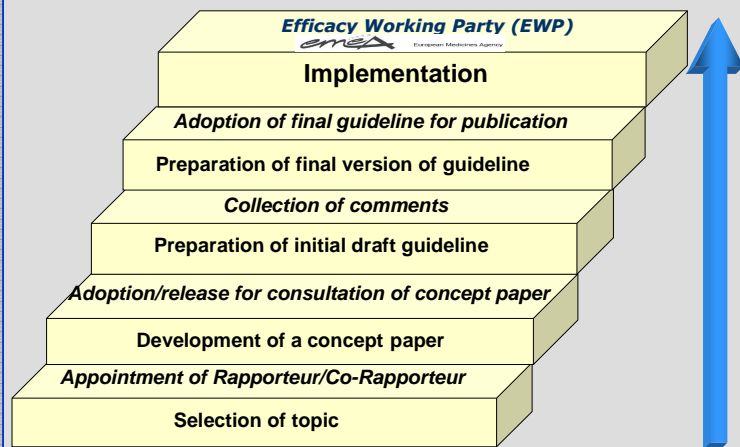
The following issues were considered when updating the guideline:

- 1) Implementation of updated clinical guidelines;
- 2) Implementation of new scientific knowledge (e.g. epidemiological and pathophysiological information; reversibility test of pulmonary function in COPD patients and possible influence on outcome; severity staging of the disease; definition of exacerbation and severe exacerbation);
- 3) usefulness and validation of biomarkers;
- 4) updated requirements for pivotal study/ies, including: a) possible influence of concomitant pharmacological (e.g. acetylcysteine) and non-pharmacological treatments (e.g. smoking cessation, surgical measurements, physical action, pneumo-sport); b) standardisation of clinical trials, recommendation of primary [e.g. rate of moderate/severe exacerbations, pre-bronchodilator Forced Expiratory Volume in one second (FEV1)] and secondary endpoints; c) critical discussion of active controlled clinical trials vs. placebo-controlled trials; d) discussion on clinically relevant differences in key endpoints; e) duration of pivotal studies;
- 5) Discussion of safety requirements (e.g. investigation of drug interactions, data on renal and hepatic dysfunction); and
- 6) implementation of pharmaceutical particularities [need of spacer development in case of orally inhaled treatment with Metered Dose Inhalers (MDI's), statement of orally inhaled treatment and flow rate dependency].

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).
- ✓ A final version of the COPD Guideline can be expected by end 2011.

Figure 1. Process for drafting a guideline



RESULTS

The first step included the elaboration, adoption and consultation of the concept paper EMEA/CHMP/EWP/8197/2009 (need for revision of the COPD guideline). The preliminary concept paper was circulated to interested learned societies and patients associations on February 2009. Any organisation or individual was allowed to submit comments using a publicly available template. The first step ended on 31st May 2009. The second step (ongoing) includes the drafting of the guideline and further consultation and adoption. Three versions were drafted and internally discussed at the EWP before a final version was agreed in the July 2010 EWP meeting. The draft revised guideline has been released for consultation. Deadline for comments is March 2011 (Figure 2).

Figure 2. Draft guideline

Clinical efficacy and safety: Respiratory system

Email a friend Print page

Help

If you have comments on a document which is open for consultation, please use the Form for submission of comments on scientific guidelines.

Topic	Documents	Reference number	Publication date	Effective date	Remarks
Draft guideline on clinical investigation of medicinal products in the treatment of Chronic Obstructive Pulmonary Disease (COPD)	Draft guideline *	CPMP/EWP/562/98 Rev. 1	Release for consultation Jul 2010		Deadline for comments 1 March 2011 Replaces CPMP/EWP/562/98

* Comments to the drafted revised guideline can be sent to the EWPsecretariat@ema.eu.int

ACKNOWLEDGEMENTS

Thanks to the clinical experts consulted during the elaboration of this draft, Dr F.J. García Río, Hospital La Paz, Madrid, and Dr G. Peces Barba, Fundación Jiménez Díaz, Madrid.