14 October 2013
EMA/352591/2013
Human Medicines Evaluation Division

EMA Geriatric Medicines Strategy

Report analysis of scientific guidelines

Introduction

One of the key aspects of the European Medicines Agency (EMA) vision for geriatric medicines is to ensure that medicines used by geriatric patients are of high quality, and appropriately researched and evaluated, throughout the lifecycle of the product, for use in this population.

To help fulfil this goal, it was foreseen that inclusion of safety and efficacy geriatric requirements would be routinely considered particularly for conditions where the geriatric population will constitute a sizeable amount of the concerned patient population. This was achieved by the EMA commenting on Guidelines, Concept papers, Reflection Papers under consultation, at the finalisation stage (Guidelines Coordination Group step); and the Geriatric Expert Group (GEG) review and comments on the guidelines released for public consultation.

Objectives

This analysis quantifies of the number of Scientific Guidelines reviewed, and commented, and which have included the comments on geriatric aspects during the period January 2011 – April 2013.

Methods

The guidelines selected for analysis were identified as relevant to the older population, and included both guidelines under first drafting and revision. Guidelines in all areas (quality, safety and efficacy) were considered for geriatric relevance. Clinical guidelines were evaluated for their compliance with ICH E7 requirements in terms of pharmacokinetics, efficacy, safety and requests of specific drug-drug interaction studies. When guidelines did not comply with ICH E7 requirements, comments were sent on specific points that might be improved.

Comments sent by the EMA were part of the guideline drafting process prior to publication, while comments sent by the GEG during the public consultation are available, for each guideline, on the EMA website in a document outlining the overview of comments received.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

All guidelines adopted by the end of the study period are accounted for the analysis of whether the comments were taken into consideration or not.

Results

A total of 28 guidelines relevant to the older population have been analysed during the study period. Of these guidelines, 18 have been finalised and adopted.

Table 1. Number of guidelines analysed. Period: 01/2011 – 04/2013	
Total Guidelines	28
Guidelines adopted	18
Guidelines for adoption	10

93% (n=26) of the analysed guidelines did not fully comply with ICH E7 requirements hence comments were sent for improvement. (Figure 1)

Of the 18 guidelines adopted in the study period, 65% have taken the comments into consideration (fully or partially). 35% don't reflect the comments sent. (Figure 2)

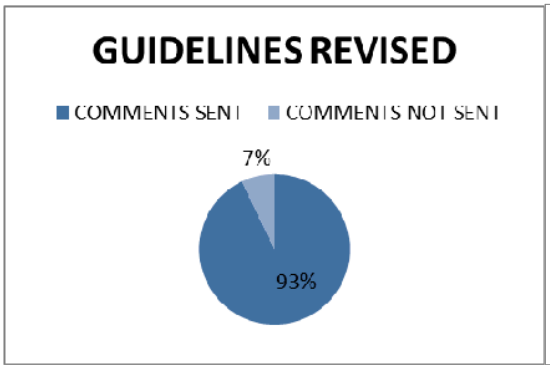

Figure 1

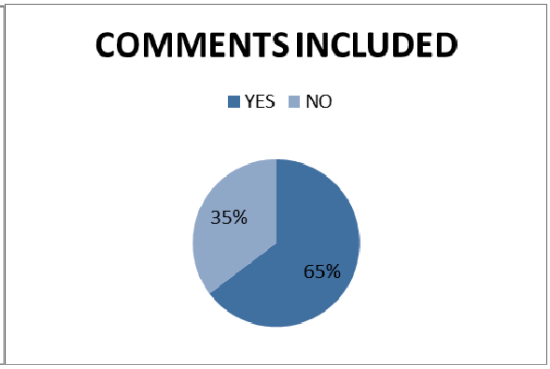

Figure 2

Conclusion

A high percentage of guidelines received comments with the aim of clarifying the amount and type of data expected in the development programme with regards to safety and efficacy aspects the older population, however these were taken on board only in 2/3 of the cases. Several comments were received from the guideline drafting groups and working parties to indicate that an earlier interaction with the Geriatric Expert Group would have been beneficial in order to allow a more in-depth discussion of the proposed modifications. Intervention at an almost-final stage was considered less useful. The CHMP has therefore modified in May 2013 the mandate of the GEG, in order to request comments on guidelines at earlier stages of the drafting process.

We plan to conduct a further review once a sufficient number of guidelines has been reviewed under this new scheme.