



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Proposal for the development of a points to consider for baseline characterisation of frailty status

For decision

Background

As part of the EMA geriatric medicines strategy, the CHMP asked the Geriatric Expert Group (GEG) to perform an exploratory analysis of available scales for the characterisation of frailty status. This analysis was completed in February 2012, and presented at CHMP and ORGAM. In October 2012, the joint informal CHMP/PRAC decided on the establishment of a group of CHMP/PRAC/SAWP sponsors to discuss and coordinate actions in the geriatric area across the product lifecycle. Among these was the discussion on the fate of the frailty analysis.

The first teleconference of the CHMP/PRAC/SAWP geriatric sponsors took place on the 4th May 2013.

It discussed whether the scope of the document should be for baseline characterisation of a clinical trial population, or for development of products for frailty.

As a first step, it was decided that it should focus on the analysis of the elderly population enrolled in clinical trials (if appropriate according to expected population of use), and use this tool to identify uncertainties and assist decision on post-authorisation activities (PAES studies or registries in the elderly). This work could also assist in on-going activities on a GVP module in elderly.

The group felt that several points should be taken into consideration for a frailty analysis:

- physical frailty
- comorbidity status
- mental frailty

so the current document should be expanded to take into account comorbidity and cognitive aspects.

Proposal

It is proposed to develop a Points to Consider.



The drafting group will consist of the GEG in cooperation with other experts identified in the internal agencies' network through a call for expression of interest across the Committees and working parties.

The work of the group will be by teleconference only.