28/06/2013

Submission of comments on 'Concept paper on the need for a reflection paper on quality aspects of medicines for older people' (EMA/165974/2013)

Comments from:

Name of organisation or individual
European Federation of Allergy and Airways Diseases Patients' Associations

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
17-20		Comment: Older patients are also the ones that most likely suffer the most from **co-morbidities**. Therefore, the risk/benefit and the dosage of the medicines they take have to take into account this, including the polypharmacy aspect. The topic is mentioned in the following paragraph, but the issue of dosage and benefit-risk (potential combined effects etc.) is not affronted and only the adherence to treatment is presented. To solve polypharmacy, we agree that pharmaceutical industry may help by presenting drugs with different shape and/or colours, but it is not enough, the above issue being at least as important. Proposed change (if any):	
21-26		Comment: It is necessary to look at the cocktail effects/side-effects in real-life studies (especially for older people as, as previously underlined, they are the ones suffering the most from co-morbidities). This should be emphasised in the post-marketing phase of a drug and the new pharmacovigilance framework with, for example, a greater attention paid to phase IV clinical trials. Proposed change (if any):	
30-33		Comment: The three pillar approach proposed by EMA should	

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		take into account as well the pre-market authorisation stage. In particular, in the development phase of a medicine, clinical trials are often not conducted on the elderly although in some case the drug and/or therapy is used mostly by them. This problem should be addressed in the new policy framework. The participation of stakeholders, and especially of patients' representatives, should be emphasised as patients are the ones that experience the disease and the problems they encounter in their daily lives. Proposed change (if any):	
37-41		Comment: Something has to be done to investigate the quality aspects of medicines for older people. They are a special category of users and thus they deserve special attention by regulators. A particular attention to this part of the population is of valuable interest for EFA as, representing people with asthma and COPD, we are particularly aware of the problems that older people can encounter when suffering from respiratory diseases. In addition, COPD is mainly affecting older people and a special plan has to be outlined for this category of people. People with COPD also typically carry significant co-morbidities, such as diabetes and heart disease and are at risk of frailty. Proposed change (if any):	

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44		Comment: The drafting group for the above reasons should include patients or patients' representatives and, if this is not possible, they should at least be considered for an advisory role. Proposed change (if any):	

Please add more rows if needed.