EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Concept paper on the need for a reflection paper on quality aspects of medicines for older people

Agreed by QWP	30 January 2013
Agreed by CHMP	11 February 2013
Start of public consultation	5 April 2013
End of consultation (deadline for comments)	30 June 2013

Comments should be provided using this template. The completed comments form should be sent to **QWP@ema.europa.eu**

Keywords	elderly, older people, age-appropriate formulation, packaging

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1. Introduction

According to Eurostat, the number of people aged 65 years or over in the EU is expected to grow from around 84 million in 2008 to approximately 141 million by 2050. As a consequence, older patients (>65 years of age) represent a large proportion of patients and the very elderly (> 75 years) are the fastest growing population group.

Unlike the paediatric case (regulation (EC) No 1901/2006), there is no specific legal requirement for the development of medicines for geriatric use. Nevertheless, there is a need to ensure that medicines are fit for use by patients of all ages within the indicated patient populations. Given the growing older population, the agency recognizes that it should ensure that the specific needs of the elderly are integrated during the development, approval and use of medicines.

A valuable first step would be to investigate to which extent the specific needs of the elderly are already met in clinical, pharmacy and industry practice. This information can be used to identify the main issues that should be addressed in the pharmaceutical development of medicines to assure that they are also suitable for older patients.

2. Problem statement

Elderly patients may face physical and cognitive impairment and hence they may have difficulties in taking their medicines e.g. swallowing tablets, opening packagings or reading the user instruction and patient information leaflet. Older people may also more frequently require the assistance of caregivers than the overall adult population. In addition, physiological changes such as hepatic impairment, renal impairment or altered gastrointestinal motility may require a re-evaluation of the benefit/risk profile of the medicine and warrant adapted dosing regimens. The pharmaceutical development of medicines for use by older patients should take such aspects into consideration.

As older patients comprise a heterogeneous population which is often using several medicines at the same time (polypharmacy) the difficulty to accept non-appropriately designed medicines is expected to be greater as already outlined before. In addition, polypharmacy may in itself cause adherence problems which may be partly overcome by the pharmaceutical design of the medicines used (e.g. a wider range of colours, sizes and tablet shapes is known to assist the recognition of medicines and hence to reduce errors).

3. Discussion (on the problem statement)

The reflection paper should provide an overview of all aspects requiring special consideration for older patients that need to be addressed in the pharmaceutical development of a medicine. A three pillar approach is anticipated to identify the quality aspects that are unique to geriatric medicines:

- An analysis of relevant scientific literature and post-marketing data.
- A liaison with stakeholders on practical issues.
- A gap analysis of how existing marketing authorizations are not fully meeting the needs of elderly patients.

This 3-pillar approach should allow the identification of the quality aspects that are unique to medicines for older patients which are not addressed by the current guidelines or other regulatory provisions (e.g. Ph. Eur.) and that thus require further reflection.

4. Recommendation

In the light of the increasing elderly patients population, it is recommended that a reflection paper concerning quality aspects of medicines for elderly patients is developed. Where possible, it is intended that the increased focus on medicines for older patients will result in either the more appropriate use of existing guidance or in the minor revision of this guidance to accommodate the needs of the elderly patients rather than to the development of new guidance that is specific to elderly patients alone.

5. Proposed timetable

It is anticipated that the drafting of the reflection paper will start in Q3 2013 and that it will be finalized in Q3 2014, with an external consultation in Q1/Q2 2015 and finalization by the end of that year.

6. Resource requirements for preparation

The drafting group will include experts from the EU member states or academia. The following expertise should be represented within the group: 1) regulatory affairs; 2) clinical needs; 3) practical use (in-patient and out-patient); 4) pharmaceutical development. The group will work closely together with the EMA geriatric Expert group.

7. Impact assessment (anticipated)

The reflection paper should assist industry in the development of medicines with a potential use by older people and in the regulatory review of such applications.

Some guidelines may need to be amended or updated as a result of the reflection paper.

8. Interested parties

The interested parties include regulators, pharmaceutical industry, pharmacists, medical practitioners, academic groups, patient associations and national bodies responsible for medicines' reimbursement.

9. References to literature, guidelines, etc.

Studies in support of special populations: Geriatrics E7:

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E7/Step4/E7_Guideline.pdf

ICH topic E7 studies in support of special populations: Geriatrics questions and answers:

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500005218.pdf

EMA webpage for geriatrics:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000249.jsp&mid=WC0b01ac058004cbb9

Draft guideline on pharmaceutical development of medicines for paediatric use (EMA/CHMP/QWP/180157/2011)