



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Improving
medicines for
older people

An agency of the European Union



Safe and effective medicines for older people

One of the drivers of the European Medicines Agency's 'Road map to 2015' is the challenge stemming from population ageing.

To ensure that the needs of older people are taken into account in the development and evaluation of new medicines, the Agency:

- has produced a 'Geriatric medicines strategy', based on two main pillars, namely evidence-based medicine and informed prescription;
- established a Geriatric Expert Group to advise Agency committees on geriatric-specific issues.

The European Medicines Agency will ensure that medicines for older people are of high quality and appropriately researched and evaluated throughout their lifecycle.

This is the Agency's vision for geriatric medicines. Older people form a sizeable proportion of the general patient population, and it is part of the Agency's mission to make sure they are included in its efforts to safeguard public health.

Action in the geriatric field is a priority for the Agency, as set out in its 'Road map to 2015' and in the 2013–15 work programme of its Committee for Medicinal Products for Human Use (CHMP).

The Agency is working to achieve its vision by optimising and focusing the use of existing regulatory tools in four key areas.

Key area 1: Safety and efficacy evaluation

During medicinal product development, questions pertaining to older people can be discussed in scientific-advice or business-pipeline meetings.

During product evaluation, specific consideration will be given to geriatric safety and efficacy aspects, in accordance with current guidelines, particularly ICH E7. CHMP assessment-report templates have been updated to present information in a clear and uniform manner.

Age-appropriate formulations should be developed if needed, and measures to improve treatment compliance considered. The Quality Working Party (QWP) is developing a 'points to consider' document on these issues.

Product information

It is expected that, as a result of the increased focus during assessment, the summary of product characteristics, package leaflet and European public assessment report will reflect geriatric aspects appropriately and clearly, with the aim of assisting informed prescription.

Key area 2: Addressing knowledge gaps

Inclusion of safety and efficacy geriatric requirements, as appropriate, will be routinely considered by the Agency and the CHMP Guidelines Consistency Group for the papers under consultation (guidelines, concept papers, reflection papers), particularly for conditions where the concerned patient population is likely to include a large proportion of geriatric patients.

The Agency is also working to identify available and validated tools/methods (e.g. scales) that can be used to examine effect and safety in frail patients. Frailty is one of the priority areas identified for action by the European Commission Innovation Partnership on Active and Healthy Ageing.

A group of 'sponsor' members of the CHMP, the Pharmacovigilance Risk Assessment Committee (PRAC) and the Scientific Advice Working Party (SAWP) has been established to prioritise activities.

Key area 3: Pharmacovigilance

The CHMP will consider the need for specific activities to be included in the risk-management plan, or as post-authorisation commitments, concerning aspects such as co-morbidities and the monitoring of specific side effects.

A specific module of the guideline on good pharmacovigilance practice will be developed.

Key area 4: Fostering expertise

A Geriatric Expert Group (GEG) was established in May 2011 to advise the CHMP on specific geriatric issues. Its mandate can be found on the Agency's website.

Geriatric medicines strategy

More detailed information on actions the Agency is taking to improve medicines for older people is available in its 'Geriatric medicines strategy' (EMA/CHMP/137793/2011), available on the Agency's website under:

Special topics > Medicines for older people



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