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EMA geriatric medicines strategy

1. Introduction

The Agency's Road Map to 2015 takes into account the changing environment in which the Agency will have to operate over the next four years, ensuring that its vision is consistent with, and complementary to, strategic directions provided by the European Commission and Heads of Medicines Agencies.

In particular, one of the drivers is the challenge stemming from demographic changes, as regards population ageing. The Agency will undertake specific efforts to ensure that the needs of older people are taken into account in the development and evaluation of new medicines.

This document details how the Agency intends contribute to this challenge in line with its legal role and responsibilities in the evaluation and supervision of medicines for the benefit of public health.

2. Vision

The key aspects of the European Medicines Agency (EMA) vision for geriatric medicines are to further strengthen the protection and promotion of public health in the European Union, by:

- In line with the EMA Mission Statement, ensuring 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.
- Improving the availability of information on the use of medicines for older people, thereby helping informed prescription.

This will be achieved by:

- ensuring that the development and evaluation of new medicines takes into account specific safety and efficacy aspects related to aging, in accordance with current guidelines, particularly ICH E7;
- identifying gaps in regulatory and scientific knowledge and taking appropriate measures to tackle them (e.g. in the provision of Scientific Advice, in the drafting of guidelines, and during business pipeline meetings);
- consideration for the need of specific pharmacovigilance activities;
- ensuring relevant regulatory guidelines contain appropriate guidance on the development and assessment of products to be used in geriatric patients;
- provide advice to applicants on regulatory requirements for the development of



- products likely to be used in the elderly;
- and, finally, by fostering and utilising a relevant experts' pool to address specific issues as requested by the CHMP, making full use of its Working Parties and experts groups where appropriate.

3. Actions

Medicines Development

- Scientific Advice and Innovation Task Force

The EMA will ensure that the best regulatory and scientific expertise is available to provide advice to pharmaceutical companies during the development of medicines used by geriatric patients, particularly for innovative medicines and novel therapeutic approaches. The appropriate number of geriatric patients to be included in the trial, the distinct needs of older people, consideration of age specific endpoints and any specific safety issues (either pre- or post-authorisation) will be kept in mind when providing Scientific Advice.

- Identification of validated tools

The Agency should perform a search among available documentation and other scientific data to identify available and validated tools/methods (e.g. scales) which can be used to examine effect and safety in "frail" patients. This will most likely be used in the post authorization phase.

- Guidelines

Inclusion of safety and efficacy geriatric requirements, as appropriate, will be routinely considered by the EMA and the CHMP Guidelines Consistency Group for the papers (Guidelines, Concept papers, Reflection Papers) under consultation, particularly for conditions where the geriatric population will constitute a sizeable amount of the concerned patient population.

Medicines evaluation

The EMA will ensure that the assessment process gives adequate consideration to the information available to ensure safety and effective use of products in the elderly. The patient and prescribing information will present the available information in the most appropriate way.

- Data collection

The Agency will check the dossiers of relevant products at the stage of both Opinion and of List of Questions with respect to the amount and extent of data collected or requested in the geriatric population. These data will be recorded in order to help the EMA's Committees and working parties build an overall picture of the representativeness of geriatric patients in the studies conducted, and to ensure consistency in future decisions.

- List of Questions

For products under evaluation, as part of the Peer review comments, the Agency will send any comments considered relevant concerning geriatric aspects of the List of Questions to the CHMP for consideration prior to the adoption of the List.

- Assessment Report

The template will be updated to include a section concerning the experience in the geriatric population, including a discussion concerning what can be expected in geriatric patients based on PK and other characteristics of the drug.

- Post-authorisation

The CHMP will consider the need for specific activities to be included in the RMP or as post-authorisation commitments, concerning aspects such as comorbidities and the monitoring of

specific side effects.

Product Information and EPAR

Accurate reflection in the product information of any geriatric findings, or lack of data in the geriatric population, will be ensured in order to assist informed prescription.

Available data in the geriatric population should be accurately presented and critically discussed in the EPAR. CHMP AR templates will be reviewed to emphasize this requirement and provide adequate guidance to assessors.

CHMP Advisory Group on Geriatrics

The EMA and CHMP will identify a pool of experts with experience in the geriatric field. Due to the multidisciplinary approach required by the care of the geriatric patients, such experts will include not only physicians with experience of treating geriatric patients, clinical pharmacologist with an interest in the elderly, physicians and regulators, but also independent experts from other fields, as needed.

The experts will be consulted in writing on specific issues as requested by the CHMP.

Interaction with stakeholders

Providing integrated healthcare solutions for the ageing population is key to meet the healthcare needs of geriatric people. Representatives of geriatric organisations already participate to the EMA Patients and Consumers Working Party and the Health Care Professionals Working Group. Furthermore, the EMA will work with all relevant stakeholders and in close collaboration with the European Commission, on ongoing and future initiatives pertaining to healthy ageing.

The EMA dedicated webpage on medicines for older people will be kept updated to provide information on the work the Agency is doing in the area of geriatric medicines. Appropriate workshops will be organized.