EMA Geriatric Medicines Strategy

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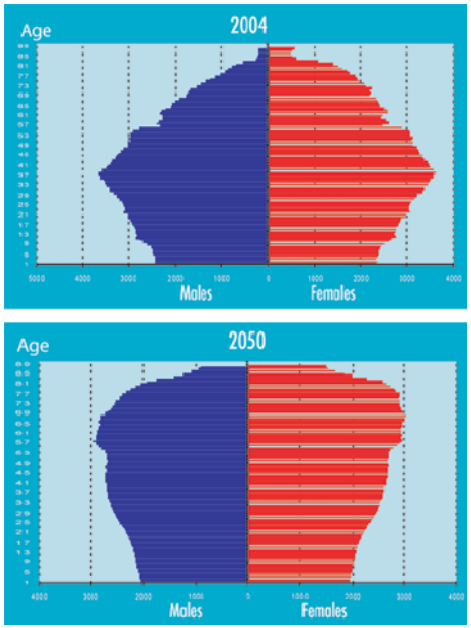
Objectives

- Reasons why we need a strategy
- Focus on key points of strategy and their implementation
- Discussion with the group

Why did we need a strategy?

- Demographic challenge
- Stakeholder expectations
- EMA Roadmap to 2015
- CHMP workprogramme 2010-13
- Follow up to 2006 analysis requested by EC
- EU political agenda (parliament intergroup/2012 EU year of ageing)

Evidence Biased Medicine?



Gurwitz et Al, JAMA 1992
60,7% MI trials age as exclusion criterion

PREDICT 2010

EORTC 2010
"statistically significant under-representation of the elderly was noted in registration trials for all cancer treatments except for breast cancer hormonal therapies"

"The evidence-base for clinical decision-making in this age group is poor even though older patients are the core business of health services"

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The Vision:

- 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.

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Are we doing it already?

- SA, special population sections in templates (AR, SPC, guidelines)

- 2006 analysis (adequacy of guidance on the elderly regarding medicinal products for human use- limited)

- More recently: ongoing evaluation of new MAA dossiers (DB of all products to obtain a baseline)

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Can we do better?

Two-pronged approach is needed to better use the tools we already have:

- Industry: follow guidelines. Discuss innovative solutions with the regulators
- Regulators: coordinate activities and improve communication to the patient and to the prescriber

!! Use existing processes !!

EMA Geriatric Medicines Strategy-Key points (1)

"..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"

- Peer Review comments (EMA)
- AR template (+RMP)
- SmPC/PL and EPAR to reflect data appropriately
- Guideline drafting and revision

EMA Geriatric Medicines Strategy – Key points (2)

"..identifying gaps in regulatory and scientific knowledge and taking appropriate measures to tackle them"

- Lack of guidance? Scientific Advice
- Comments during drafting of guidelines (EMA,GEG)
- frailty definition (GEG)
- Ongoing discussion with regulators: Business pipeline, other meetings.
- Geriatric formulations
- Workshop early 2012

EMA Geriatric Medicines Strategy – Key points (3)

"..consideration for the need of specific pharmacovigilance activities"

- We recognise recruitment in CT is difficult- but..
- Benefit/risk balance?
- Specific consideration of undesirable effects? (eg sedation, orthostatic and cardiovascular effects)
- Signal detection
- Strategy presented at PhVWP in May

EMA Geriatric Medicines Strategy – Key points (4)

"..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."

- Establishment of the CHMP Geriatric Advisory group

- Mandate adopted May 2011

Your Comments?

Needs of the patients

Needs of the prescriber