EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Geriatric Medicines Strategy

Ensuring safe and effective medicines for an ageing population

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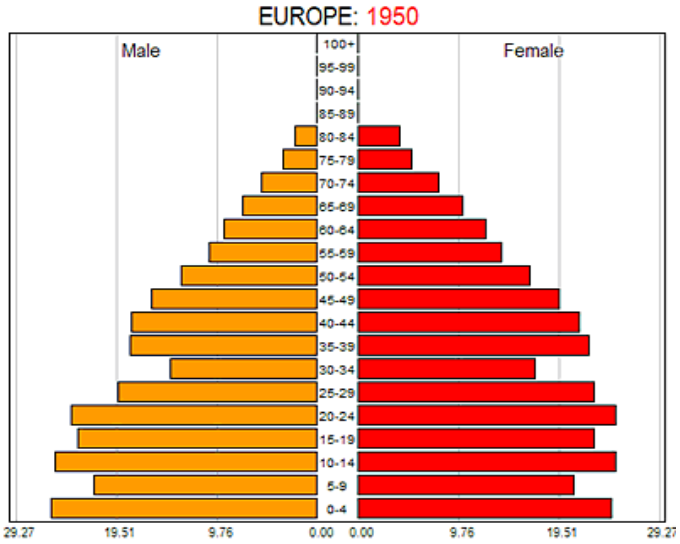
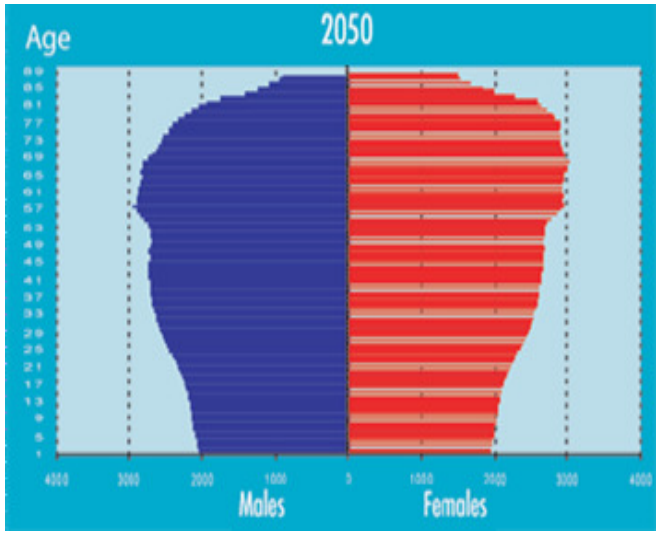
Why did we need a strategy?

- Demographic challenge
- Stakeholder expectations
- EMA Roadmap to 2015
- CHMP workprogramme 2010-13
- Follow up to 2006 analysis

  requested by EC
- A global issue- 2012: WHO health day

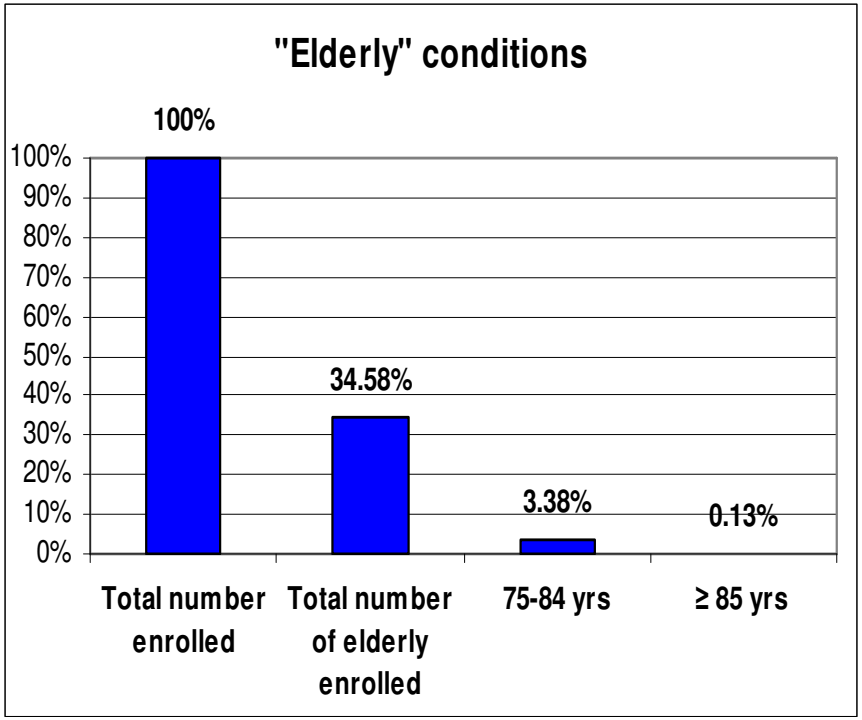
EU year of Active ageing, EC Partnership

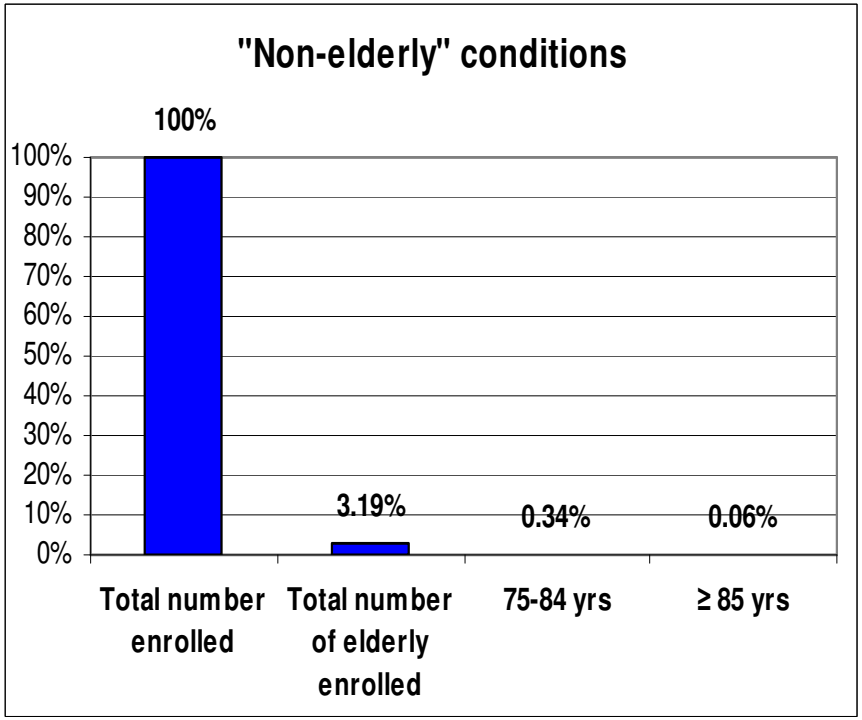




Evidence Biased Medicine?

Initial findings mid-2009 to 2011: "elderly" *vs.* "non-elderly" conditions





ICH E7 and its Q&A addition (2010)

To address:

- Inclusion of "older-old" patients in clinical trials
- appropriate representation of older people in study population
- Consideration to inclusion of comorbidities
- Age-specific endpoints

EMA Vision for a geriatric strategy: TWO PRINCIPLES

Medicines used by geriatric patients must be of high quality, and appropriately researched and evaluated.. **for use in this population**.

⇨ Evidence based medicine

Improve the availability of **information** on the use of medicines for older people

⇨ Informed prescription

The approach

Down to earth, achievable actions

- Industry: follow guidelines. Discuss innovative solutions with the regulators

- Regulators: better coordinate activities and improve communication to the patient and to the prescriber

to better use the tools we already have

What about the benefit / risk balance in the older population?

- Which studies have been carried out? Are they in line with current guidelines?
- Can relevant information be found in the EMA approval documents?
- What would prescribers, patients and HTA bodies like to know?
- How can the evaluation process improve?

EMA Geriatric Medicines Strategy – Key points (1)

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

- **CHMP:** definition of strategy; frailty analysis to GEG (definition and scales)
- **PhVWP** Informal PhVWP dedicated session: points for consideration; Geriatric Needs Survey to identify geriatric activities and instruments (or lack of) at national and European level.
- This **Workshop**
- Provision of **Scientific Advice** during product development
- Comments during drafting of **guidelines**
- Geriatric **formulations** and adherence

EMA Geriatric Medicines Strategy – Key points (2)

"..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

Four teleconferences to date

EMA Geriatric Medicines Strategy-Key points (3)

"..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"

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

Changes to the CHMP AR- October 2011

- Both in the AR templates and guidance
- Changes in line with the spirit of ICH E7
- Aim is to focus attention of reviewer on geriatric data:
  - Amount
  - Context
  - Missing information

Changes to the CHMP AR

- Include a clear description of epidemiology in relation to age
- Demographic tables in the efficacy and safety sections of Ar
- Describe PK or discuss absence
- Need for dose adjustment discussed
- Demographic tables both for safety and efficacy
- Specific consideration to risk-benefit analysis in this population
- Discuss concurrent pharmacotherapy, particularly when a potentiation of adverse effects could be expected in combination with concurrently administered drugs.
- RMP: Comment robustness of collection. Consider how the data will be summated, in order to avoid a signal dilution

EMA Geriatric Medicines Strategy – Key points (4)

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

We recognise recruitment in CT is difficult- but..

Specific consideration of undesirable effects? (eg sedation, orthostatic and cardiovascular effects)

Signal detection and underreporting

ADR reporting facilitation measures

PhV Survey results: lists of preferred medicines based on S&E + cost considerations; adaptations of packaging, formulations, PIL clarity and font; education to ADR reporting.

Initial results since inception of strategy (1)

•Tools to **track impact** of strategy: Creation of database to track geriatric info in MAA, and create baseline 2009-2010.

•Focus on **assessment**: Check 100% of LoQ and comment (where appropriate)

60 Peer Review Comments sent to PTLs for LoQ from mid 2010

- ***44*** *endorsed by the (Co)Rapp*
- ***6*** *rephrased/merged with (Co)Rapp's questions*

Note: none of the products has reached opinion stage yet.

•Comments to **Guidelines**: internal and at public consultation stage (GEG involvement).

•**Scientific advice** comments: ad hoc involvement

Initial results since inception of strategy (2)

Better **information** to patient and prescribers: safety and efficacy tables by age brackets now included in CHMP AR templates and guidance. Impact on SmPC/PIL: still too early to say (no opinions yet, only LoQ)

Post authorisation: iPhVWP session in Warsaw.

Formulations: internal processes to comment at LoQ stage and in SA (under preparation).

Thanks

to all the colleagues across EMA
and its Committees and Working Parties
who have contributed
with dedication and commitment