EMA Geriatric Medicines Strategy

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Objectives

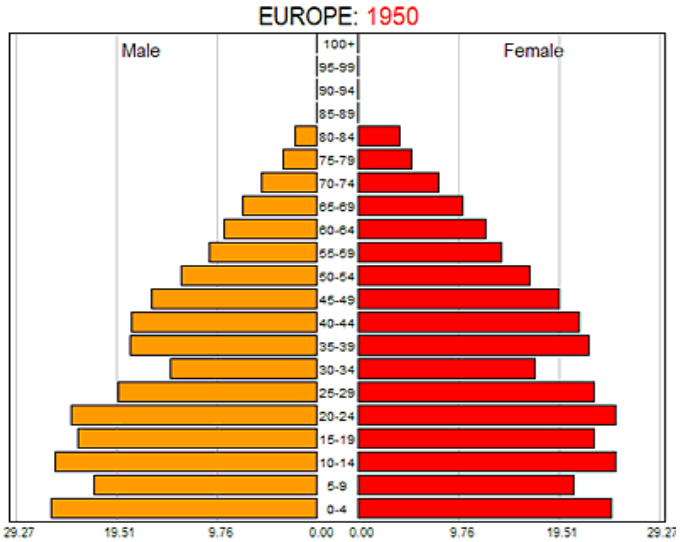
- Why did we need a strategy?
- Focus on key points of strategy and update on their implementation
- Presentation of initial findings and results
- Geriatric Needs Survey and Workshop

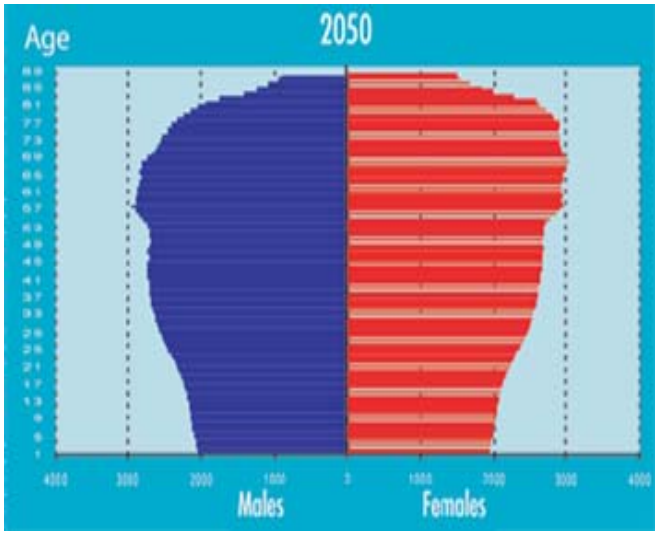
Why did we need a strategy?

- 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 Active ageing/ EC Partnership)





Evidence Biased Medicine?

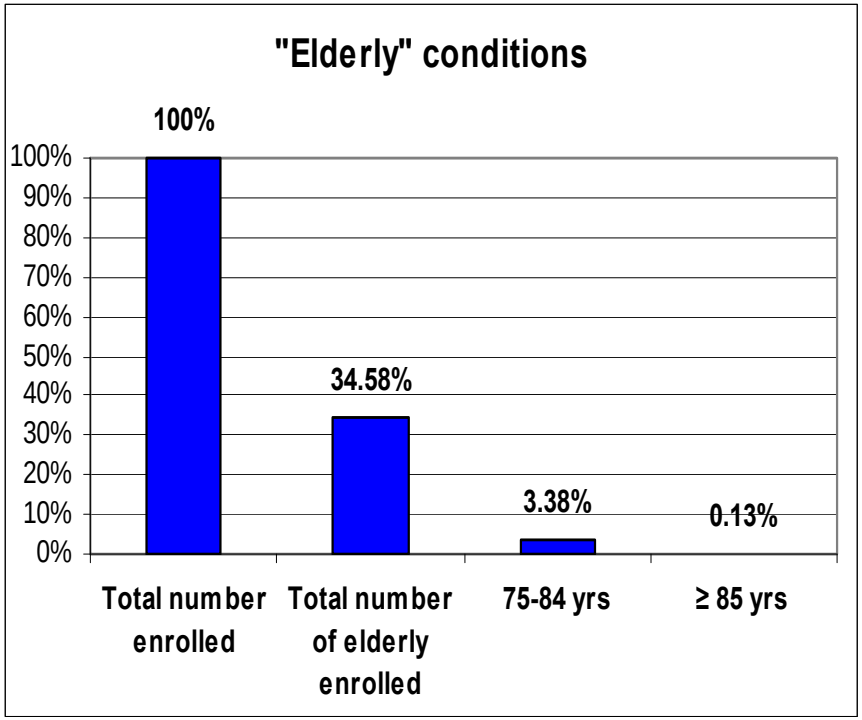
Gurwitz et Al, JAMA 1992
60,7% MI trials age as exclusion criterion.

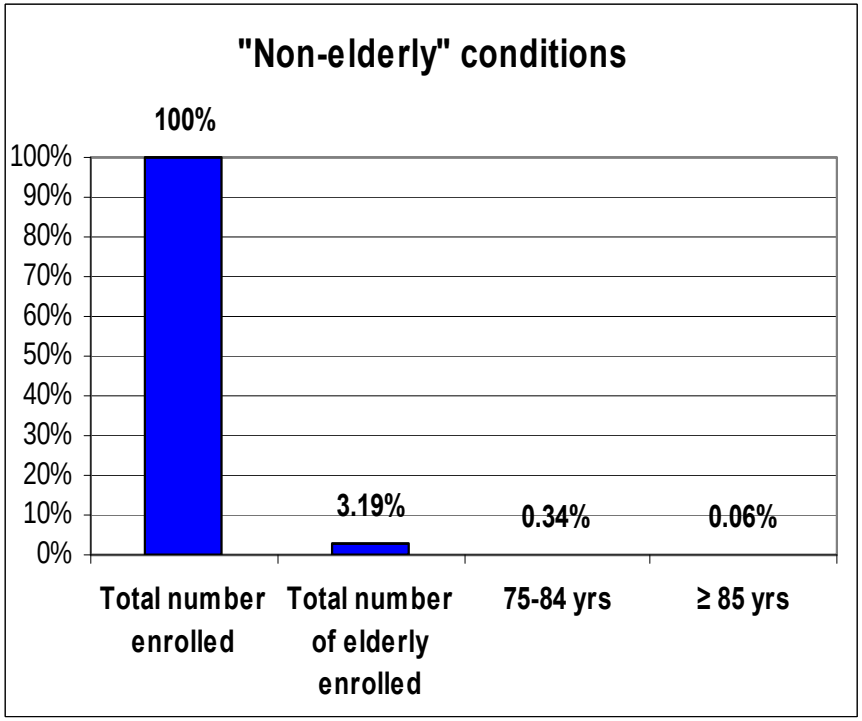
PREDICT 2010

EORTC 2010
“statistically significant under-representation of the elderly was noted in registration trial 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”

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





ICH E7 and its Q&A addition (2010)

- Encourage inclusion of 75+ in RCT
- Requires appropriate representation of older people in study population (not anymore only 100 patients)
- Consider comorbidities and try to include
- Better in same RCT, sometimes a separate study might be more appropriate
- Age-specific endpoints should be actively sought

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

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?

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

!! No new processes or requirements !!

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 template)
- SmPC/PL and EPAR to reflect data appropriately
- Guideline drafting and revision

Changes to the CHMP AR

- Both AR templates and guidance
- Changes in line with the spirit of ICH E7
- Approved September 2011
- Published on website October 2011
- Aim is to focus attention of reviewer on geriatric data:
  - Amount
  - Context
  - Missing information

Changes to the CHMP AR (Efficacy)

- Include a clear description of epidemiology in relation to age within special populations
- Describe PK or discuss absence
- Need for dose adjustment discussed
- Demographic table:

	Age 65-74	Age 75-84	Age 85+
PK Trials	number /total number		
Controlled Trials			
Non Controlled trials			

Changes to the CHMP AR (Safety -1)

- Specific consideration to risk-benefit analysis in this population

- available information on concurrent pharmacotherapy should be discussed, particularly when a potentiation of adverse effects could be expected in combination with concurrently administered drugs.

- RMP: Comment on how robustly the safety data is going to be collected. Consider how the data will be summated, in order to avoid a signal dilution

Changes to the CHMP AR (Safety -2)

Following table included:

	Age <65 yrs	Age 65-74	Age 75-84	Age 85+
Total				
Fatal				
Serious				
Withdrawal				
CNS (confusion/extrapyramidal)				
AE related to falling				
CV events				
Cerebrovascular events				
Infections				

EMA Geriatric Medicines Strategy – Key points (2)

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

- Provision of Scientific Advice
- Comments during drafting of guidelines
- Stakeholders input in public consultation of guidelines
- Frailty definition and scales
- Geriatric formulations and compliance
- Geriatric Needs Survey (PhV)
- Workshop 20-22 March 2012

Identifying the needs:
EMA workshop on medicines for older people
22-23 March 2012

Sessions around the main themes of the EMA geriatric medicines strategy:

- Healthy ageing and medicines (2012 European Year of Healthy Ageing)
- Demonstrating safety and efficacy in the older population
- Geriatric Pharmacovigilance
- Compliance and formulation issues
- The role of regulatory agencies in providing information to the prescriber and the older population

Identifying the needs: Geriatric Needs Survey to PhVWP

Objective:

Identify geriatric activities and instruments (or lack of) at national and European level in post-authorisation of medicines. Identify priority therapeutic areas.

Steps:

1. Initial discussion at informal PhVWP, Warsaw, Oct 11
2. Focus group to finalise questions
3. December 2011: run the survey

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? RMP?
- Specific consideration of undesirable effects (eg sedation, orthostatic and cardiovascular effects)
- Signal detection (and problems in ADR reporting)

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
- The group works on topics mandated by CHMP
- Three teleconferences to date

Thank you!

Some dates:

14 December 2011, Brussels: EC open day on the call for proposals for Active and Healthy Ageing Public Health Programme
http://ec.europa.eu/eahc/health/projects.html

22-23 March 2012

EMA geriatric Medicine Workshop

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References

- EMA web page “Medicines for older people”

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000249.jsp&murl=menus/special_topics/special_topics.jsp&mid=WC0b01ac058004cbb9

- EMA geriatric medicines strategy

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/02/WC500102291.pdf

- CHMP Geriatric Experts Group mandate and composition

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CHMP/people_listing_000100.jsp&mid=WC0b01ac0580473f01

- EMA web page “Working with Patients and Consumers”

http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000317.jsp&murl=menus/partners_and_networks/partners_and_networks.jsp&mid=WC0b01ac058003500c