



EMA Geriatric Medicines Strategy

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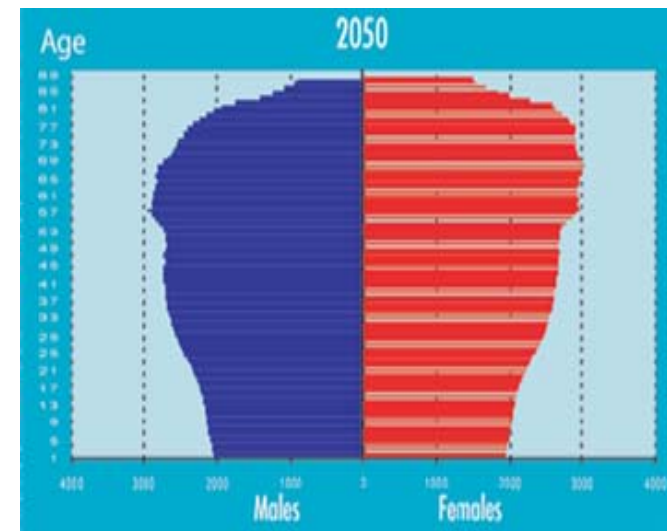
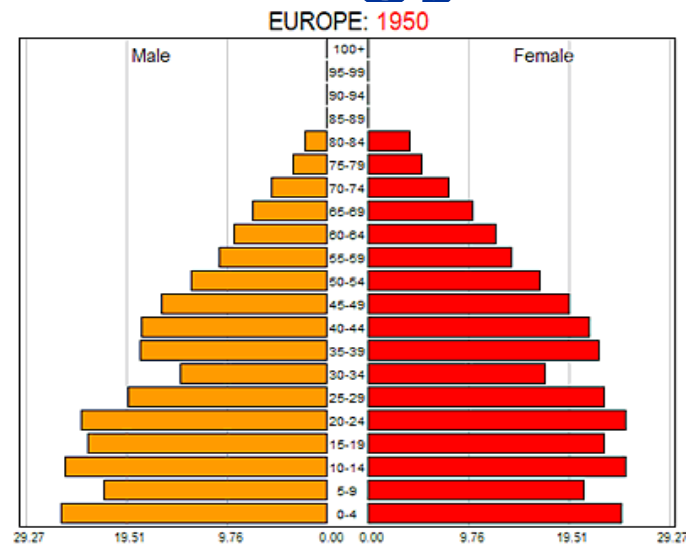
Objectives

- 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

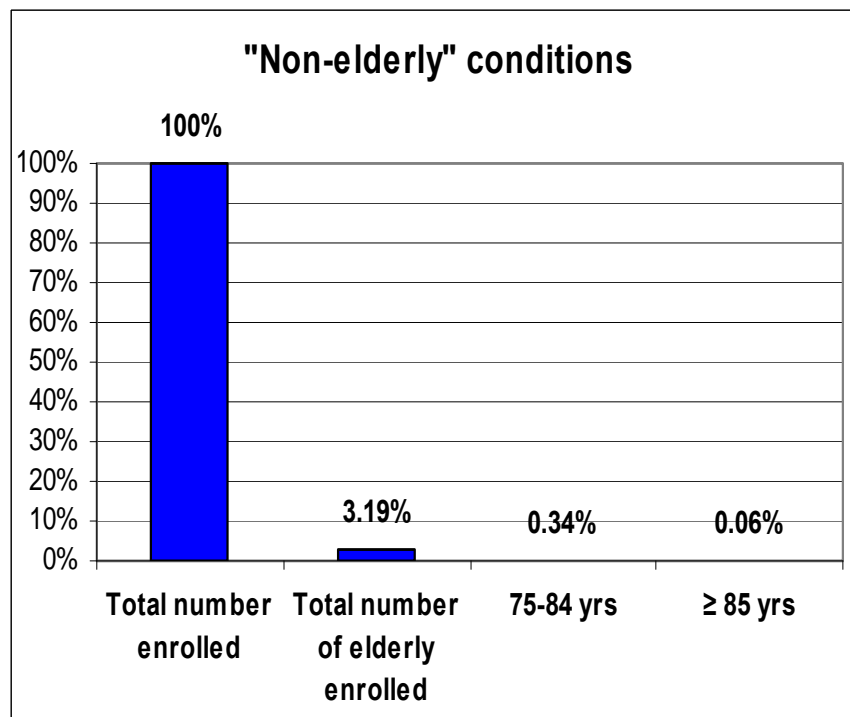
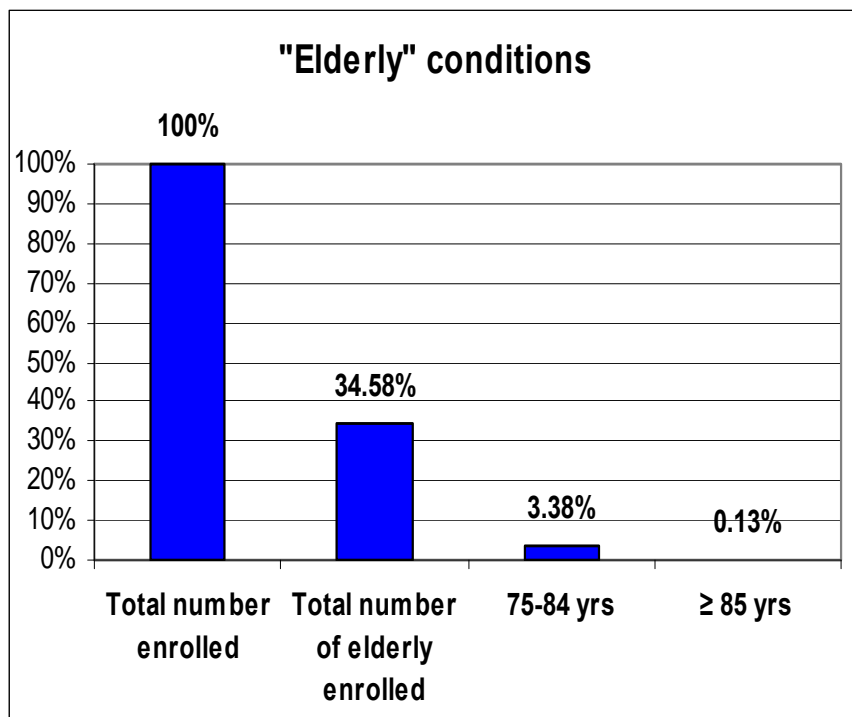
EORTC 2010

“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)

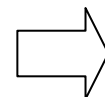
- Encourage inclusion of 75+ in RCT
- Requires appropriate representation of older people in study population (not anymore only 100 patients)
- Consider comorbidities and try to include
- Better in same RCT, sometimes a separate study might be more appropriate
- Age-specific endpoints should be actively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



EMA Vision for a geriatric strategy: TWO PRINCIPLES

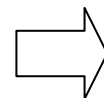
Medicines used by geriatric patients must be of high quality, and appropriately researched and evaluated..

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=menu/partners_and_networks/partners_and_networks.jsp&mid=WC0b01ac058003500c