

Fourth European Healthcare Policy Deciders Forum

Is industry developing the medicines needed?
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Disclaimer

- The content of this presentation reflects only my personal views

Is industry developing the medicines needed?

Content

- Public health needs
- Published studies addressing the question
- The pipeline today
- The therapeutic value of medicines coming to the market
- Mechanisms that steer R&D in the pharmaceutical field
- Initiatives to address public health needs
- Conclusion

The public health needs

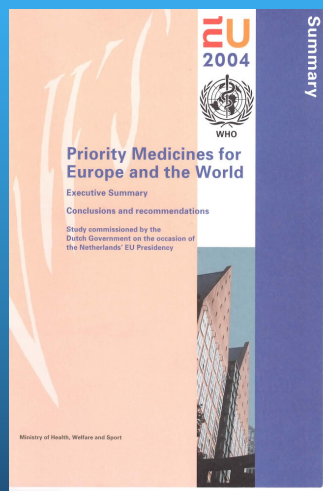
- Depending on disease patterns today and in the future
- Geographical differences, age groups, gender ...
- How well do existing interventions cover the needs by
 - Prevention
 - Treatment
- The delta will define the gaps and needs

Disease patterns

- Burden of disease
 - Mental 23%, CVD 17%, Cancer 16.7, Injuries 11%, Respiratory 7.8
- Mortality
 - CVD 42%, Cancer 27%, Injuries 5.2, Mental 4.2%

Published studies addressing the question

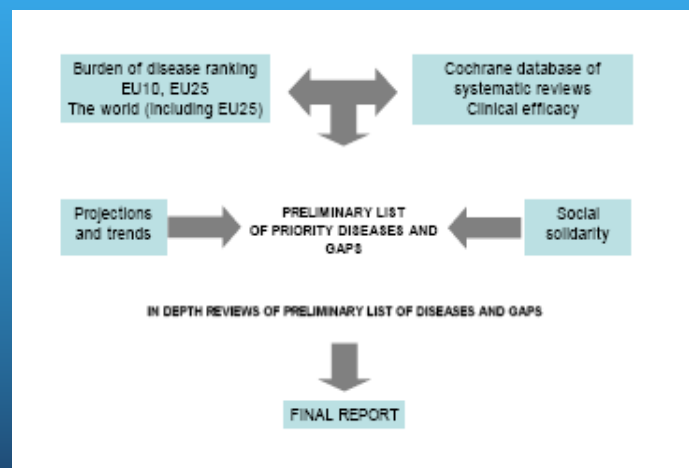
Are there any published studies addressing the question? Yes



WHO methodology

- What is the size and nature of the disease burden
- What is the control strategy
- What can be learnt from past/current research into pharmaceutical intervention for this condition
- What is the current pipeline of products that are to be used for this particular condition
- What are the opportunities for research into new pharmaceutical interventions
- What are the gaps between current research and potential research issues which could make a difference, are affordable and could be out in a five year or longer term.
- For which of these gaps are there opportunities for pharmaceutical research

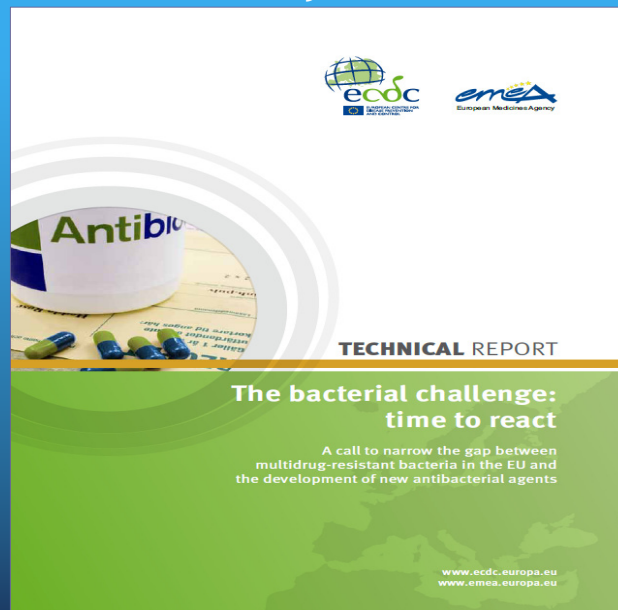
WHO Methodology



Gaps identified in the report

- Infections due to antibacterial resistance
- Pandemic influenza
- Smoking cessation
- Cardiovascular disease (secondary prevention)
- Diabetes
- Cancer
- Acute stroke
- HIV/AIDS
- Tuberculosis
- Neglected disease
- Malaria
- Alzheimer
- Osteoarthritis
- Chronic obstructive pulmonary disease
- Alcohol use disorders
- Depression in elderly and adolescents
- Postpartum hemorrhage

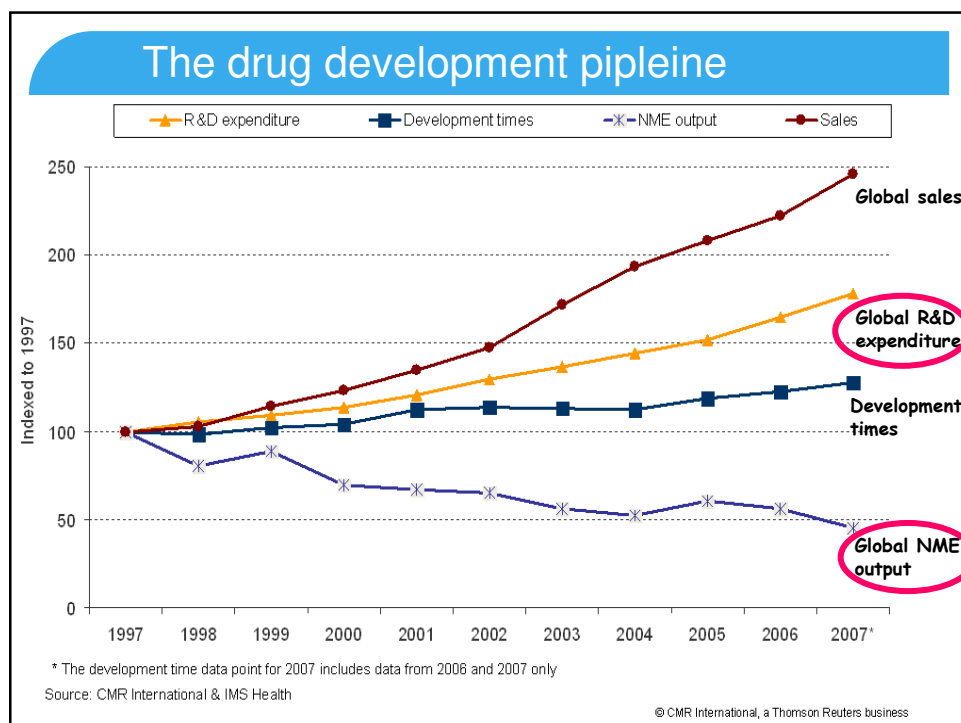
Another study



The pipeline today

The pipeline today

- Record number of substances in early drug development
- Fewer substances in late drug development
- Some therapeutic areas have more substances than others Eg Cancer
- Very few candidates in the areas of neglected disease
- Very few substances make it to approval
- And a only a few of them reach the patients



The therapeutic value of medicines entering the market

- The many steps to determine the value

- The value set by the industry prior to authorization
- The value set by regulators in the marketing Authorization based on quality, safety and efficacy
- The value set by HTA bodies, pricing and reimbursement authorities based on medical value +cost
- The value set by the healthcare provider
- The value set by the prescribing doctor
- The value in the eye of the patients

Mechanisms that steer R&D in the pharmaceutical industry

Individual and organisations
behave as they are measured and
rewarded

Research-based pharmaceutical industry

- Factors influencing decisions on research
 - Measured on return on investment by shareholders
 - IP rights
 - Scientific opportunities
 - Market size
 - Availability and required resources
 - Medical need

Research and development in prevention and treatment of disease

- Question to this audience
- Is the existing IP protection steering R&D in the wrong direction?
- Will only commercial based priorities give us the medicines we need?

Initiatives to address public health needs where we have well known gaps

Successful initiatives to address public health needs

- REGULATION (EC) No 141/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 1999 on orphan medicinal products
- patients suffering from rare conditions should be entitled to the same quality of treatment as other patients; it is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry; incentives for the development of orphan medicinal products have been available in the United States of America since 1983 and in Japan since 1993;

Other initiatives to address public health needs

- Private fund raising such as Bill and Melinda's global fund
- Public private partnerships
- Pediatric legislation in EU
- Research funds
- Will there be any initiative in the areas of the need for new antibiotics?

Conclusion

- Is industry developing the medicines needed ?
- Answer: In some therapeutic areas NO. In others "I don't know"
- We need more systematic studies
- The drug development process is extremely expensive and the output of therapeutic valuable medicines is pore.
- I have pointed on factors that influence how R & D are directed- is this the key to the problem?
- Hopefully I have stimulated this audience to reflect and continue to discuss the topic