





# Essential Innovation and Access to Medicines: towards new models of research and development

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## Declaration of interests

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The opinions expressed herein are those of the author. The Executive Agency for Health and Consumers is not responsible for the information presented here.





# What is HAI Europe?

- Established as a consumer network in 1981
- Members include consumers, public interest organisations, health care providers, academics, media and individuals
- Independent of pharmaceutical industry funding
- Goals: to promote access to essential medicines and their rational use

# Overview

- The Facts
- The current model of medical innovation
  - Framework
  - Myths
  - Negative Effects
- From theory to practice:
  - Policy commitments
  - New approaches to Research and Development of medicines

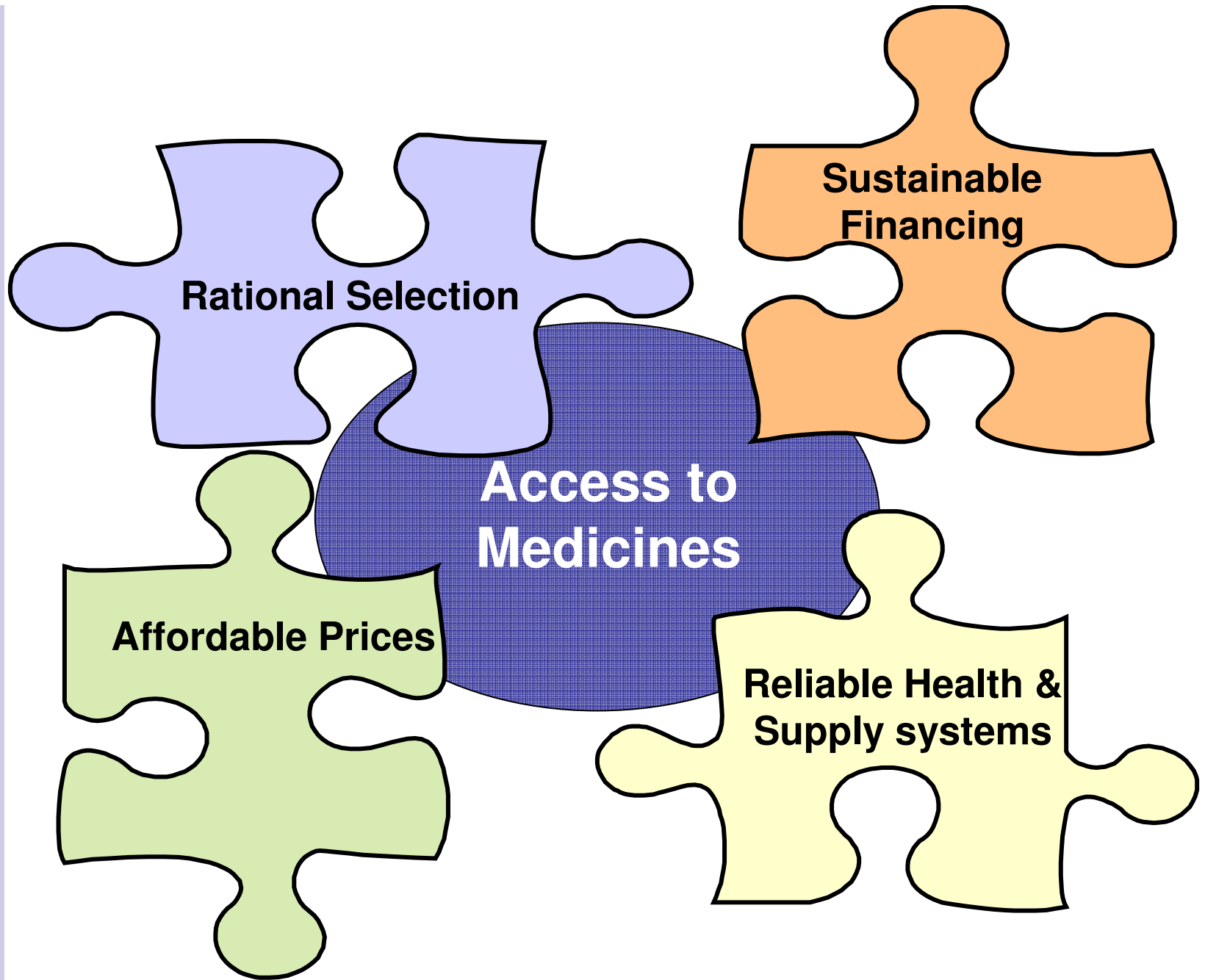


*Nearly two billion people (1/3 of world population) are not regularly receiving all the medicines they need.*

*Over one billion people – one sixth of the world's population – suffer from one or more neglected tropical disease.*

*WHO, 'Equitable access to essential medicines', 2004*

*WHO Neglected Diseases. Geneva, 2010*



# State of Affairs

- Non-communicable diseases have unleashed a new epidemic of suffering across developed and developing world
- Access to medicines is a critical challenge in developing countries:
  - Prices are high: unaffordable
  - New medicines and vaccines are lacking: unavailable or inaccessible
  - Dosage form does not meet needs: inadequate



# Current R&D model

- Patent system is the stepping stone
- Link between cost of innovation and product price
  - New medicines are developed for a market that can pay
  - Those who could benefit from medicines but have little resources are excluded
    - Lack of innovation in areas where there is no profitable market
    - Health needs of the poorest remain unattended: Neglected diseases remain neglected

***Only 10% of R&D spending is directed to the health problems that account for 90% of the global disease burden, the so-called 10/90 Gap.***

*(The Global Forum for Health Research)*

# Unfolding the myths: Costs (1)

- Lack of transparency about real costs of R&D
  - Industry estimates in 2000: 802 million USD per new drug
  - Independent estimates in 2011
    - [13 million USD – 204 million USD]
    - Median per new drug: 59.4 million USD

(Light & Warburton, 2011)

- There is a significant public contribution to innovation:
  - Worldwide on average public funding makes up for about 45 % of spending on R&D.

(WHO, 2004)

- During the last 40 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in public-sector research institutions.

(Stevens et al, 2011)

# Innovation or more of the same? (2)

**Figure 1.1: Evaluation of new medicines and indications in France, 1999-2008, la Revue Prescrire (n=961)**

