

**They need new drugs,
vaccines and diagnosis now:
reality of neglected diseases**

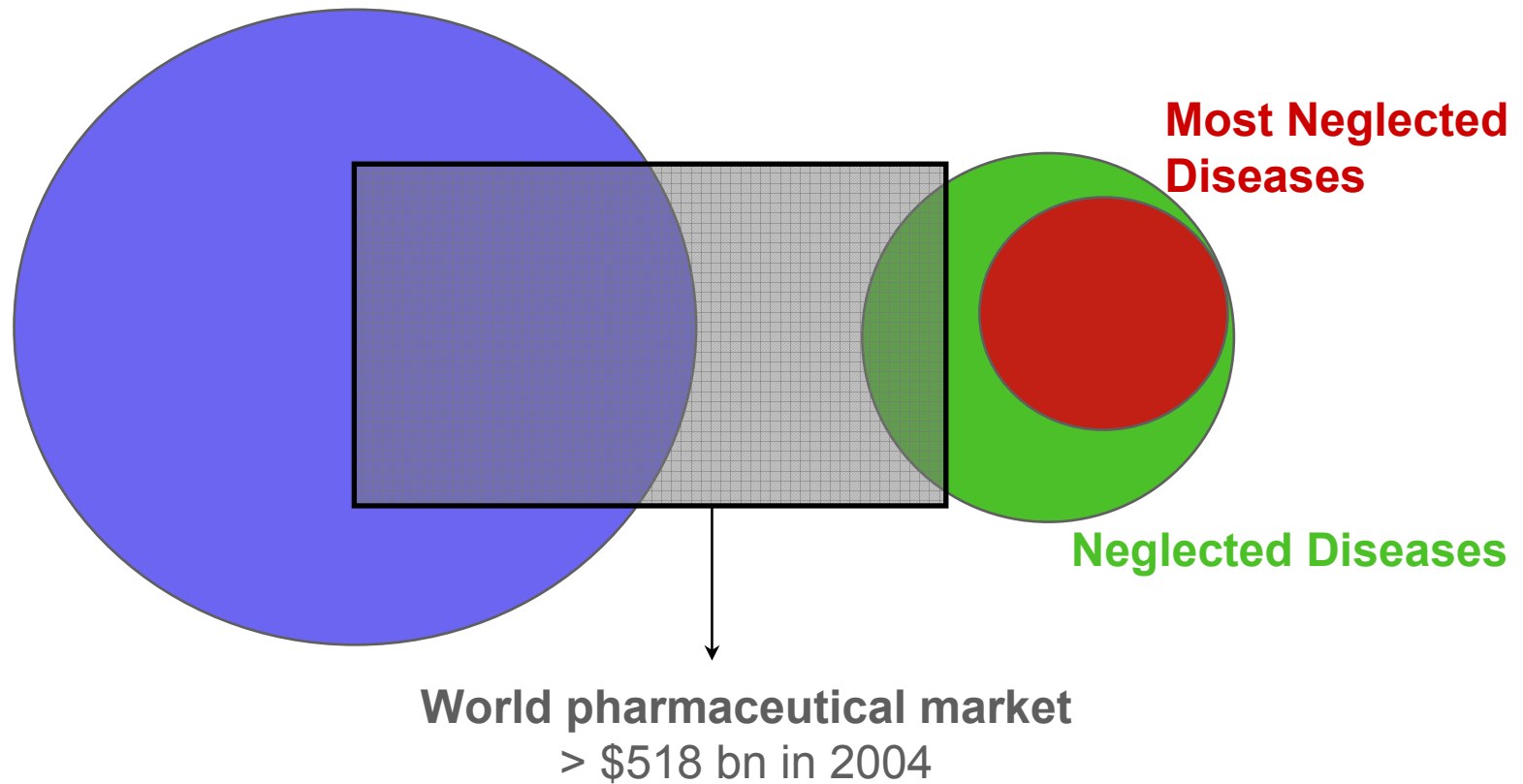
**Bernard Pecoul
Executive Director, DNDi
CIPIH, Geneva
1 June 2005**

DNDi

Drugs for Neglected Diseases *initiative*

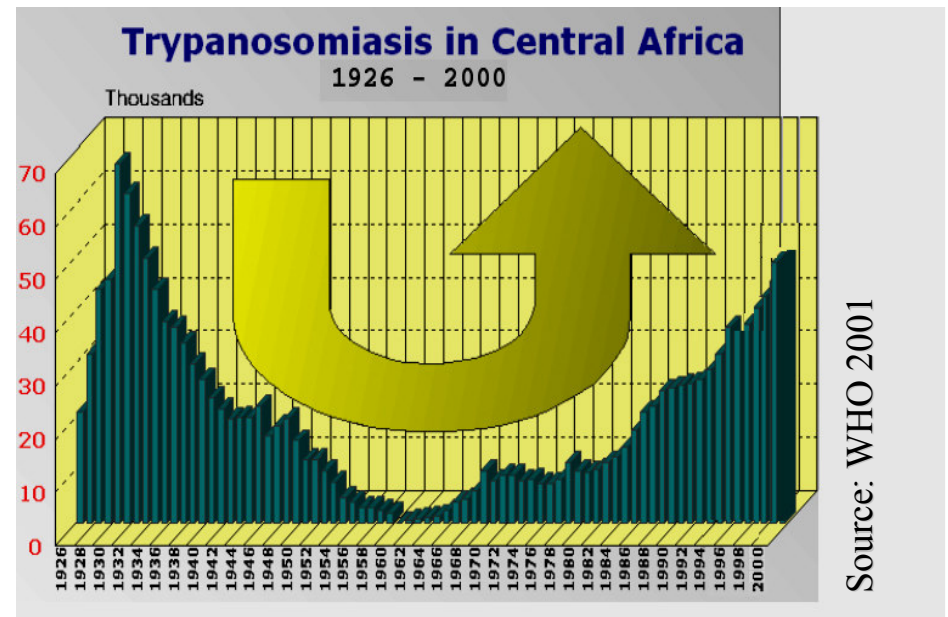
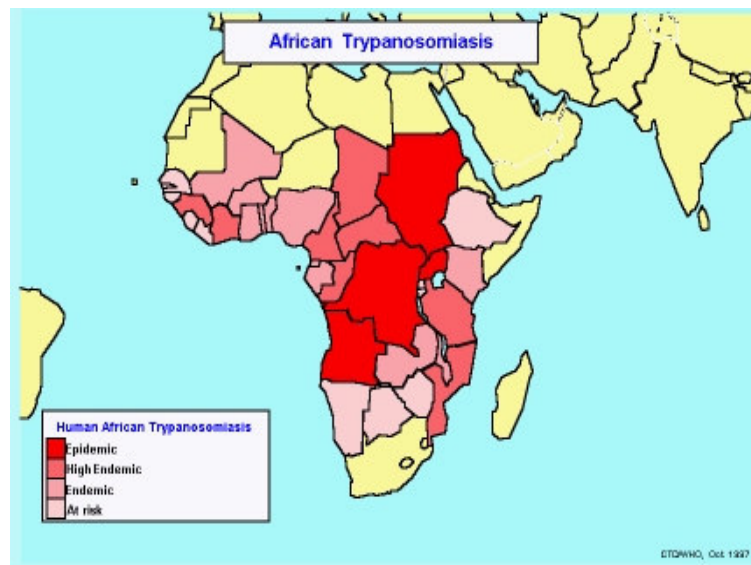
Defining neglected diseases

Global Diseases



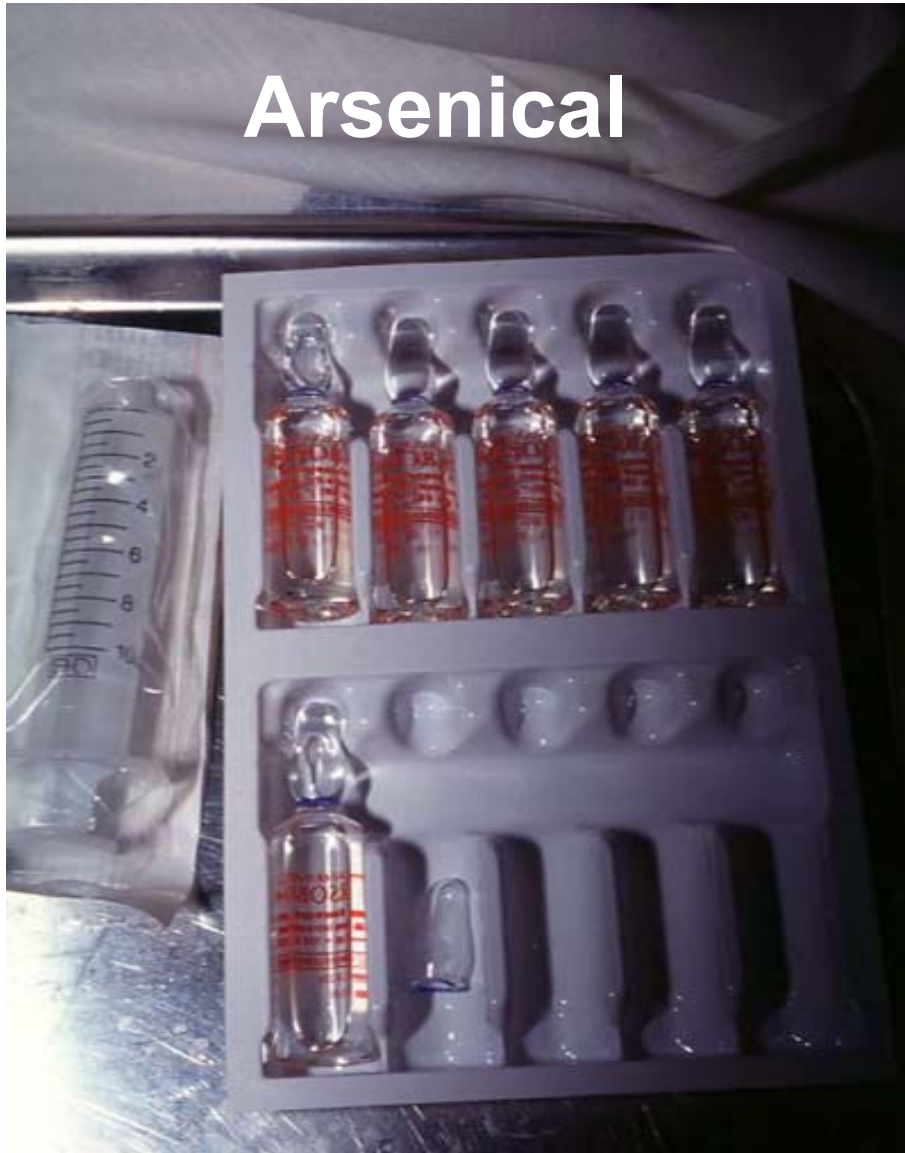
Sleeping sickness is a most neglected disease

- An estimated 300,000 infected
- 55 million at risk in sub-Saharan Africa
- Difficult to diagnose
- **Fatal** if untreated
- Existing drugs: old - toxic - resistance - difficult to use - expensive

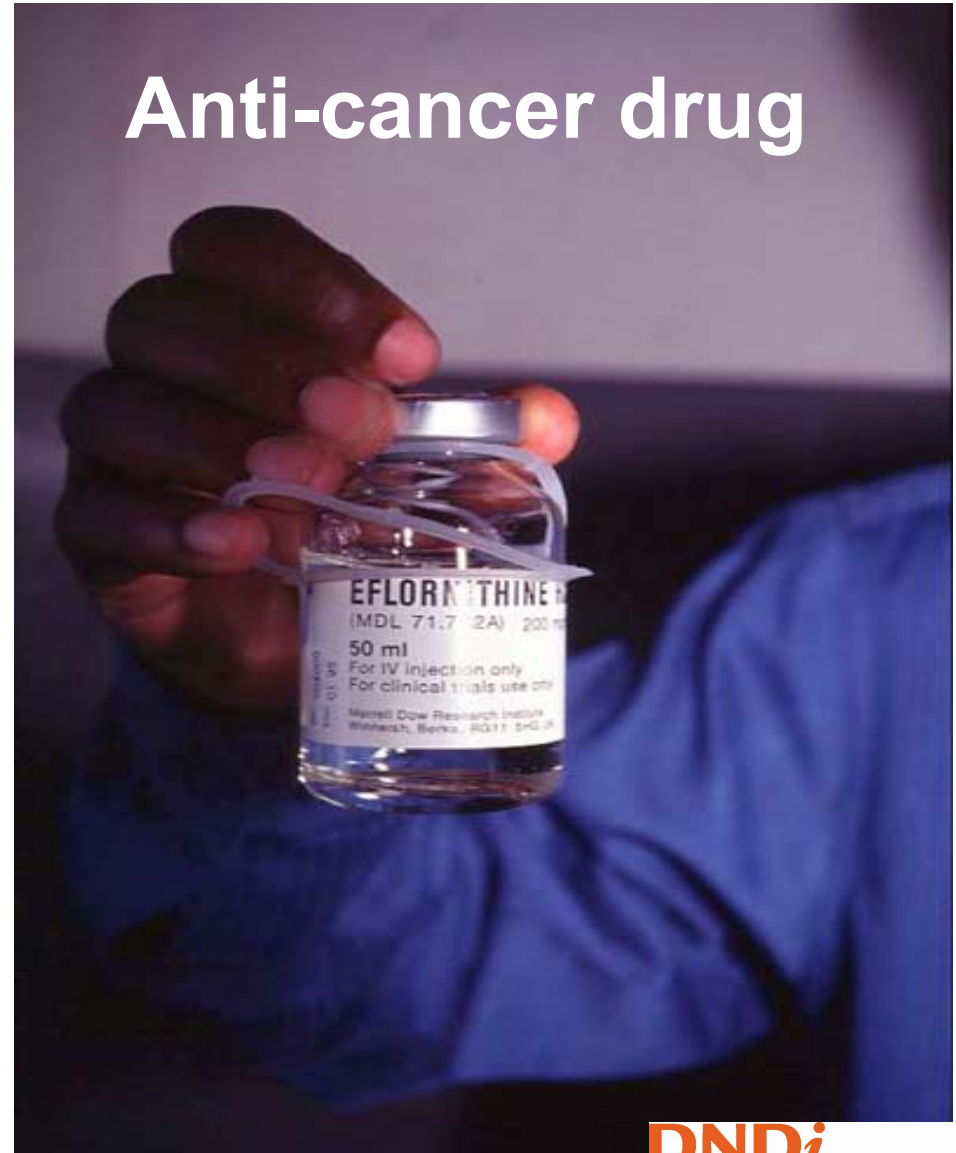


The needs remain huge

Arsenical



Anti-cancer drug



Buruli ulcer



Plate 22. Ulcerative lesion (Photo: Marco Pirovano)



Plate 23. Ulcerative lesion (Photo: Marco Pirovano)

Source: WHO, WHO/CDS/CPE/GBUI/2001.1

AIDS is a neglected disease for adults and children

- Drugs not adapted to health systems of endemic countries
- No treatment for children
- Limited tools for diagnosis and follow up
- No field-adapted preventive tools



Treatments do not exist or are inadequate and inaccessible

- Toxic
- Expensive
- Painful to deliver
- Difficult to follow up
- Not adapted to patient's needs
- Not registered in endemic regions
- Restricted by patents

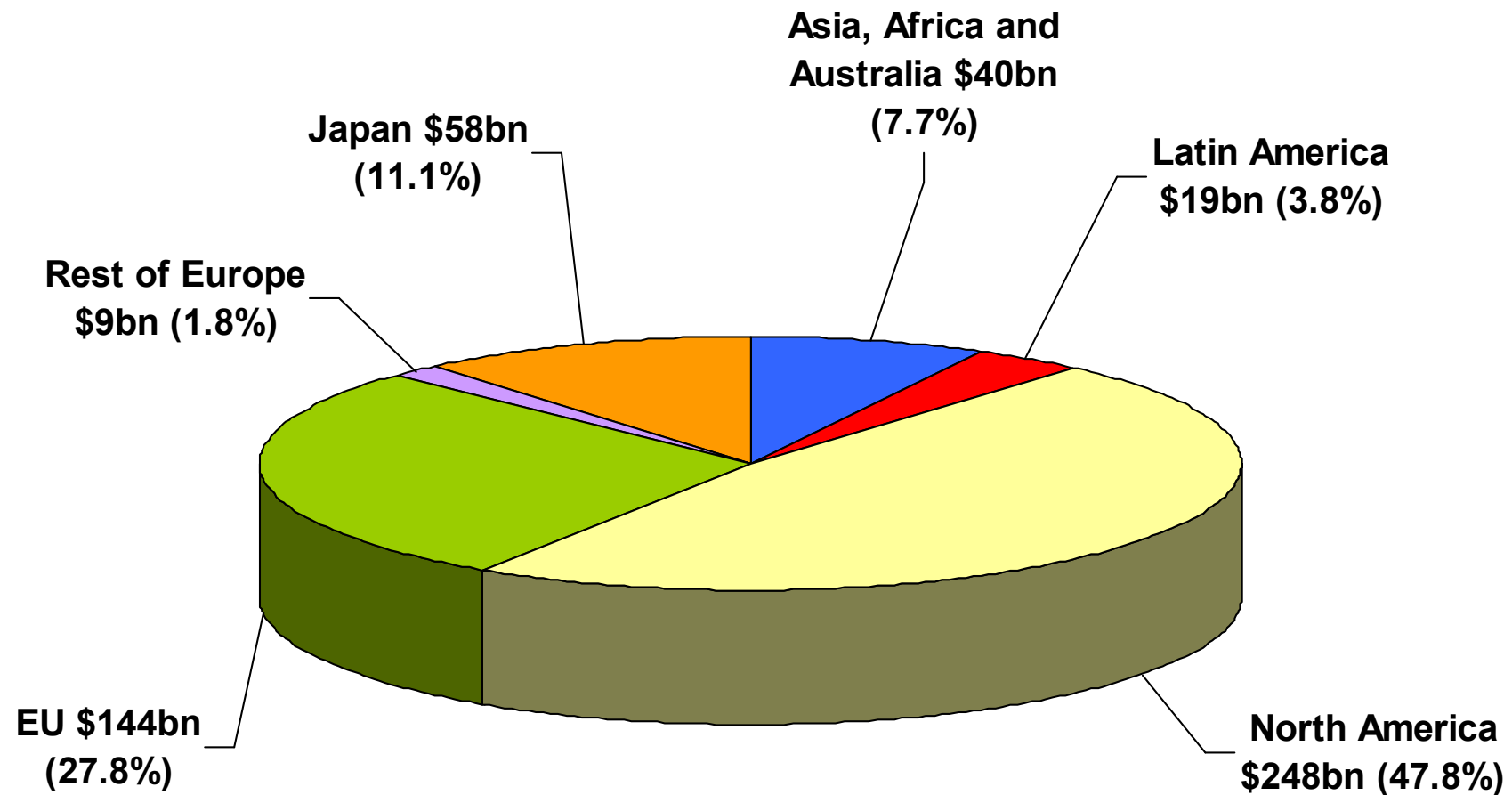


Analysing the problems: Fatal imbalance



Developing countries have a tiny share of the pharma market

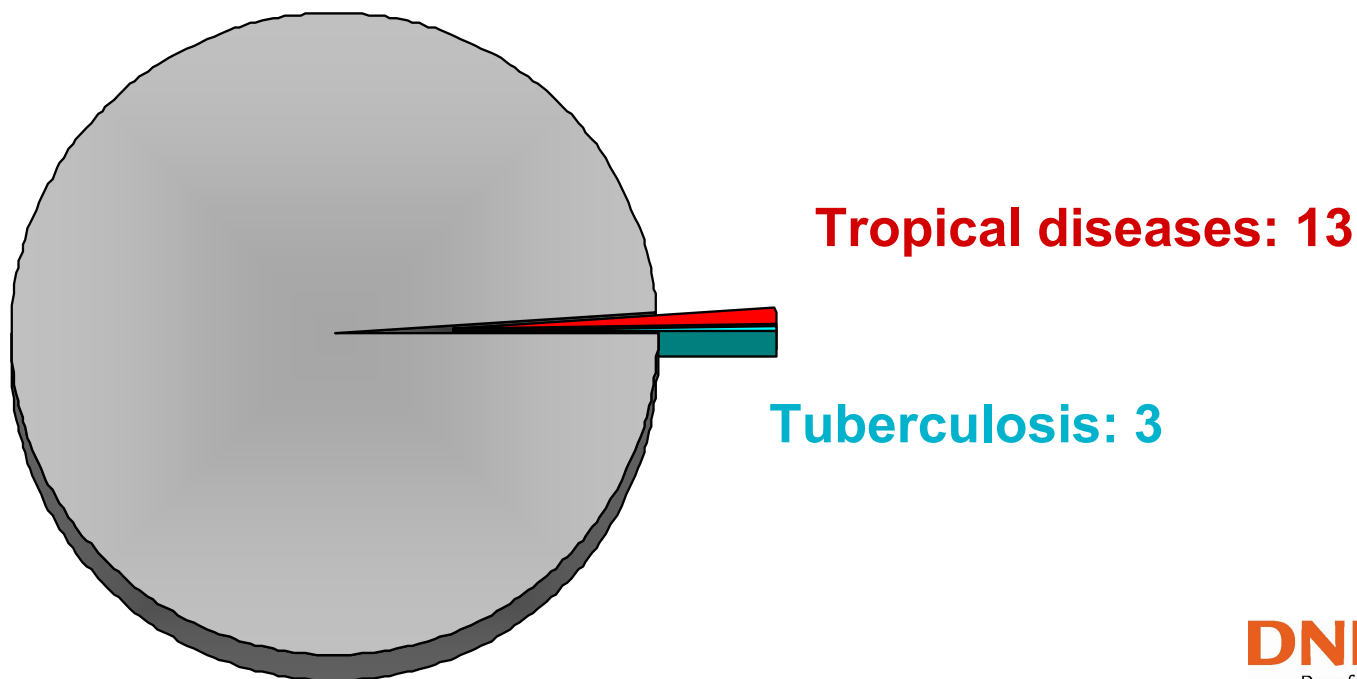
World Pharmaceutical Market, 2004: Total \$518 billion



Source: IMS Health

Only 1% of new drugs developed are for neglected diseases

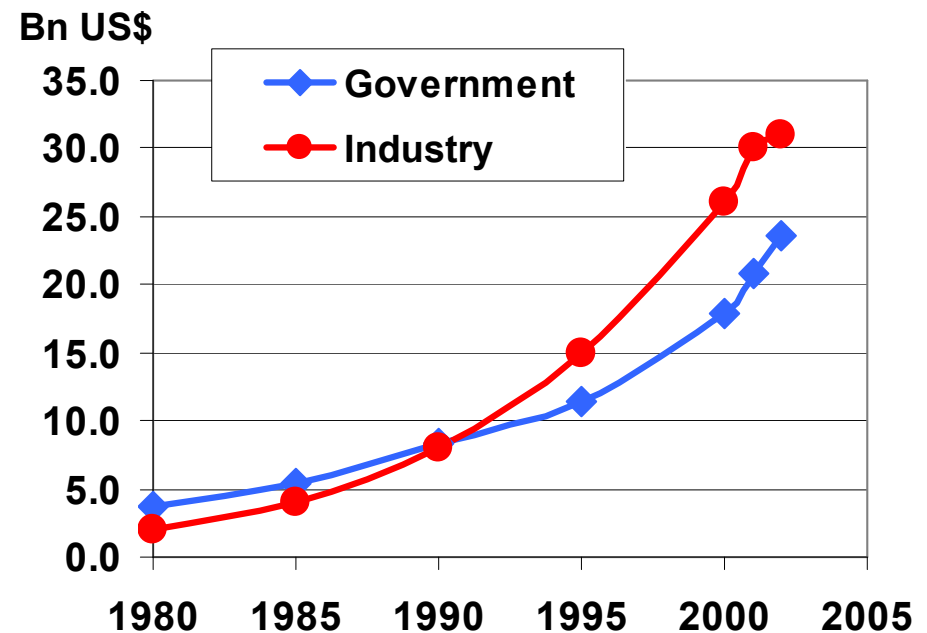
- Approx. 1-2% is spent on R&D for neglected diseases
- 10/90 gap in health research spending
- 1975-1999: **1,393** new chemical entities marketed
- **68.7%** registered products presented little or no therapeutic gain



Spending on health R&D has increased

- World-wide spending on **health R&D** was never so high
 - Estimated at US\$106bn for 2004 (GFHR, 2004)
- Since 90's: private sector has become biggest investor

*US-spending on health R&D:
(>2/3rd total)*

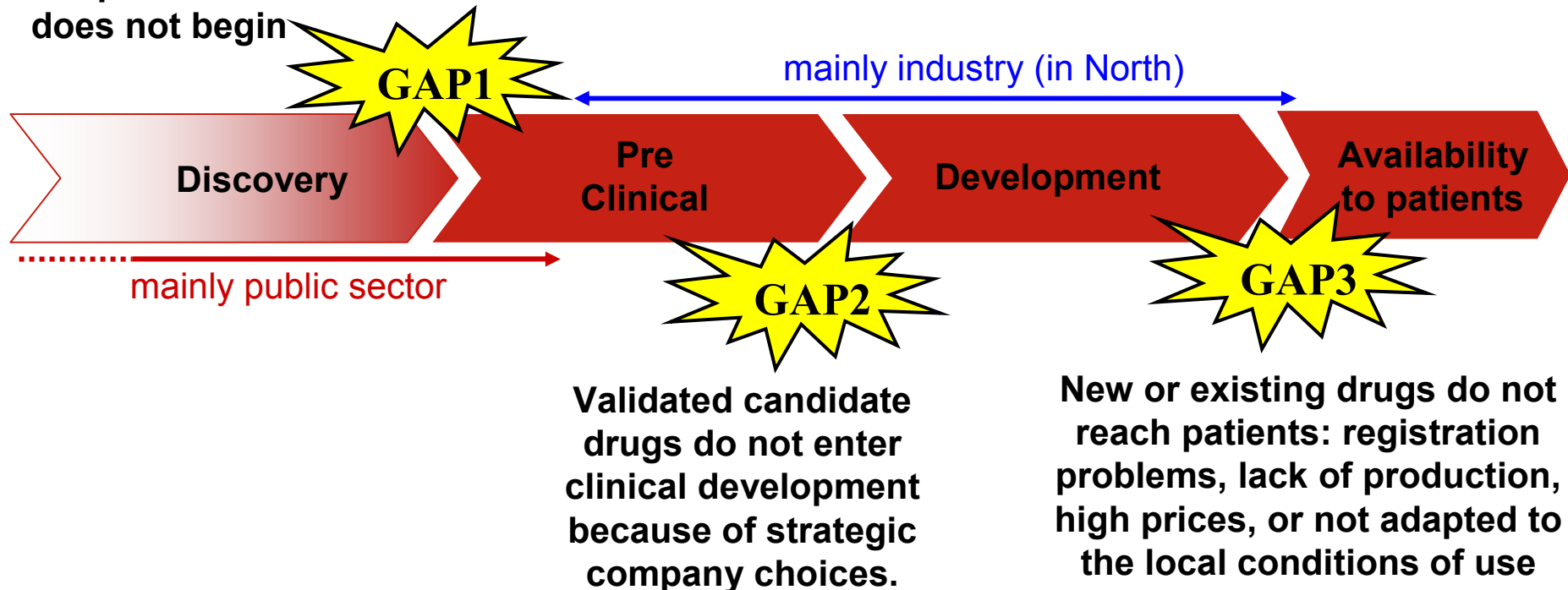


Sources:

For government: National Science Foundation 2004,
<http://www.nsf.gov/sbe/srs/nsf04329/pdf/nsf04329.pdf>
For Industry: PhRMA 2004,
<http://www.nsf.gov/sbe/srs/nsf04329/pdf/nsf04329.pdf>

Gaps exist in the R&D process for neglected diseases...

New knowledge on drug targets and lead compounds is published but pre-clinical research does not begin



...due to failure of the market and public policy

Market failure

- Drug development largely confined to the R&D-based pharmaceutical industry operating for profit
- Poorer patients are thus neglected

Public policy failure

- Public policy does not redress this imbalance

Governments should tackle this imbalance

- The response should not be purely philanthropic
- **Governments should increase public responsibility towards R&D of drugs for neglected diseases**
 - More political leadership
 - Sustained financial support
 - New rules to stimulate drug R&D

Increased public responsibility:

1. More public leadership

- Make global health and medicines a strategic priority
- Set R&D agenda according to the needs of patients

Increased public responsibility:

2. Sustained financial support

Governments need to

- Raise current levels of funding for neglected diseases by 3 **billion euros** per year to correct the 10/90 gap
- Put in place new, sustainable funding mechanisms

2. Sustained financial support

This funding should be focused on:

- A needs-driven R&D agenda for safe, effective, affordable and field-adapted treatments
- Encouraging scientific community to do basic research on neglected diseases
- Translation of basic research to new medical applications, e.g. by supporting PDPs
- Encouraging R&D capacity strengthening in disease-endemic countries
- Securing the market

Increased public responsibility:

3. New rules to stimulate drug R&D

- **Regulatory standards**
 - Streamline regulatory approval processes to rapidly deliver essential medicines to patients
 - Analyse risks and benefits of each drug or vaccine in relation to the needs of patients, severity of the disease and lack of alternative solutions
 - Regulatory authorities (FDA and EMEA) should provide support and transfer know-how to authorities in developing countries

3: New rules to stimulate drug R&D

Intellectual Property: develop drugs as public goods

- Guarantee that the public sector develops open access to information (recent Wellcome Trust policy) => open source (Human Genome Project) => freedom to operate
- Ensure that industry provides sustainable access to knowledge, chemical compounds and tools
- Make technology transfer happen to disease-endemic countries

**The world needs
policy action, not promises**

www.dndi.org

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