WHO Commission on IPR, Innovation and Public Health

5 April 2004, Geneva

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Access to Essential Medicines Campaign
Médecins Sans Frontières

www.accessmed-msf.org
Lack of Effective, Affordable and Easy-to-use Medicines

- Increasing resistance to older medicines
- Discontinued production of effective medicines
- Existing –new- drugs are too expensive
- Very few new drugs are developed to tackle major diseases affecting the poorest countries (despite significant scientific/technological advances)

>>> lack of R&D
Intellectual Property Rights

IPR is a social policy tool. Primary justification for granting intellectual property rights is the benefit to society as a whole by promoting innovation in exchange for a limited monopoly.
Drug Development Outcome

1975-1999: 1393 new chemical entities marketed

Tropical diseases: 13
Tuberculosis: 3

11.4% of total disease burden

Trouiller et al., Lancet 2002, 359:2188-94
Innovation, Therapeutic Advance?

• 1981 – 2000 In France of the 2257 new products (1)
  – 63 % were me-too products, offering nothing new to the therapeutic arsenal
  – 7 products (0.13%) represented a real therapeutic breakthrough.

• 1981 – 1991 In the United States less than 5% of the drugs introduced by the top 25 pharmaceutical companies were therapeutic advances

• Prescrire International April 2001/Volume 10 No 52. Pages 52-54
(2) Human Development Report 1999
The R&D Process

Scientific literature (patent applications)

Basic research

Pre-clinical research

Clinical research

Post-Marketing

Pharmaceutical Industry

Patients

Public sector

2-5 years

3-10 years

Cumulative efforts scientific community. Includes discovery research leading to the identification of targets and lead-compounds

Screening and optimization
Synthesis, extraction
Dosage & stability
Toxicology-safety

Phase I-II-III clinical studies
Bioavailability
Upscaling production
Regulatory review
The Gaps for Neglected Diseases

Scientific literature (patent applications)

Basic research

Pre-clinical research

Clinical research

Post-Marketing

Public sector

Patients
Health R&D spend

- Worldwide spending on health R&D was never so high (estimated at US$ 70-75 billion for 2002)
- Since 90’s: private sector has become biggest investor (and pharma/health industry highly profitable)

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

Sources:
(1) PhRMA 2000
(2) National Science Foundation 1999
Public Policy Failure

• **Societal choice** to confine drug development to the private sector

• **Medicines are commodities** that need to generate profit in return for private investment

• **Public policies** to stimulate private R&D investments and ensure attractive returns

This system:

• Stimulated drug development for rich country markets

• But **limited innovation**

• And **failed** to provide effective, affordable and easy-to-use medicines for 75-80% of the world population
3 types of diseases

Global Diseases

WHO HAS ACCESS??

Most Neglected Diseases

Neglected Diseases

World pharmaceutical market
> $400 bn in 2002
Innovation and Health

• Therapeutic innovation – advances that contribute to the ability to better treat, cure or prevent diseases

• The patent system as the principle financing mechanism will not fill the key health innovation gaps

• The patent system comes with high cost
Overcoming the

- Ensuring access to essential medicines = public responsibility
- Where the market fails governments need to react
- Not-for-profit approaches
  - DNDi
- Increasingly the needs will demand international action
• Define a needs-driven international R&D priority agenda
• Outline an agreement and clear rationale for sharing the burden of the cost of this R&D
• Commit all countries to contribute to R&D for health
• Define appropriate funding and incentive mechanisms for governments to fulfil their commitments to health R&D
• Establish and strengthen international mechanisms for exchanging and transferring research results, knowledge, and technology
• Deal with regulatory barriers to drug/vaccine development
• Ensure that developing country involvement in R&D is central, including through north-south and south-south collaboration, and through the conduct of such R&D in disease-endemic countries