

Panel Session - 8th HTAi Annual Meeting
Medicines for diseases that affect the world's poor – Research and Development in the
perspective of sustainability and human rights

Exploring alternative mechanisms to fund innovation for medicines for diseases that affect the world's poor

Michelle Childs
Director of Policy & Advocacy



About Médecins Sans Frontières

Independent Medical humanitarian organization
founded in 1971 and working in over 70 countries

- ~ 150,000 HIV patients on ARV treatment
- ~ 25,000 cases of TB treated per year
- > 1 million cases of Malaria treated per year
- ~ 7 million vaccinated against meningitis in 08/09 season
- ~40,000 cases of sleeping sickness treated in the past 20 years
- ~75,000 cases of kala azar treated in Sudan alone
- ~ 3,800 treated (of 67,217 tested by May 2011) for Chagas disease

Campaign for Access to Essential Medicines since
1999

Medical staff frustrated at not being able to diagnose and treat patients with appropriate and effective tools

Outline

- Problems
- Reasons for gaps in the current medical innovation system
- Some proposals to be explored and some opportunities to be considered

Outline

- Problems
- Reasons for gaps in the current medical innovation system
- Some proposals to be explored and some opportunities to be considered

The Access Campaign's main issues:

Unaffordable, Unavailable, Unsuitable

Unaffordable: Existing medicines, vaccines and diagnostics are priced out of reach -too expensive for individuals and mass government treatment.

Unavailable:

Certain diseases 'neglected' few or no drugs or diagnostics exist or are being developed. (NTD TB) Production of essential medicines and diagnostics that are needed but do not make profits are abandoned

Unsuitable:

Not adapted for needs of developing countries e.g heat stable, child formulations, diagnostic tools (HIV pediatric formulations and FDCs, Chagas test of cure)

Problems trying to solve

Lack of needs-driven **Innovation**

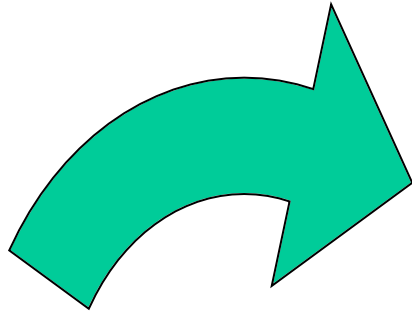
Lack of affordable **Access**

Innovation is pointless in the absence of favourable conditions for people to access existing, as well as new, products

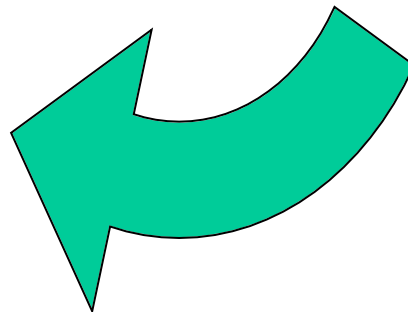
Outline

- Problems
- Reasons for gaps in the current medical innovation system
- Some proposals to be explored and some opportunities to be considered

Funding model barrier to low cost



Cost R&D Price Product =



No R&D
for 'poor'
markets

Working towards a global framework for R & D

Why? Current global framework supporting R&D series of trade agreements on protection of IP rights (TRIPS FTA, ACTA etc)

But:

Does not accommodate a needs based stimulation on R&D

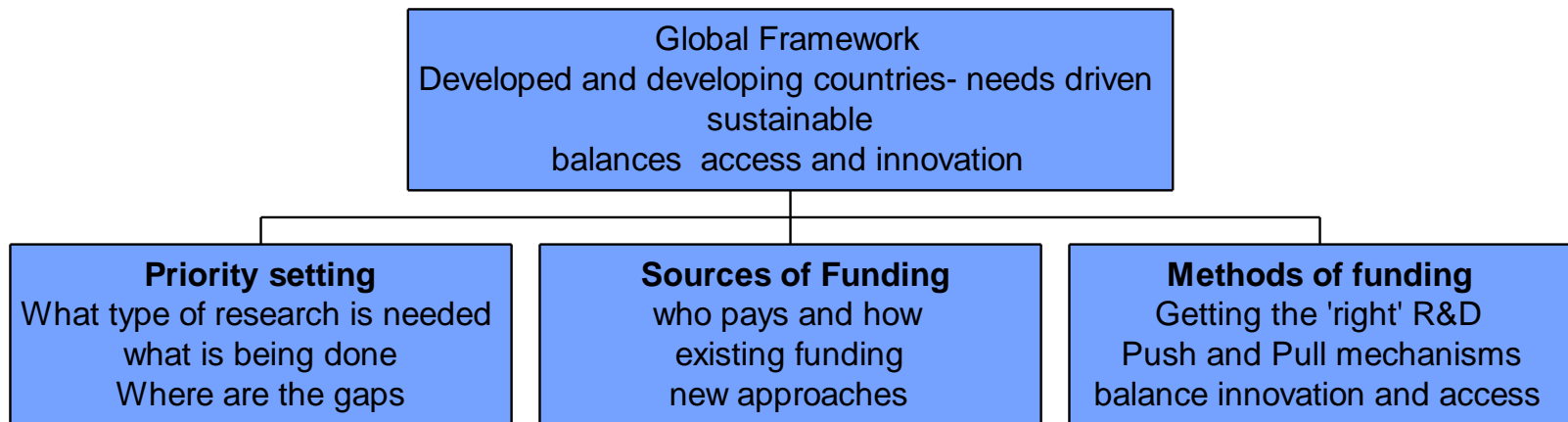
Least of all for needs based neglected diseases for which there is no market

Does not ensure access for developing countries to new processes, products, knowledge technology and capacity transfer

Net effect is to concentrate these in existing developed countries with only secondary peripheral effects in developing countries.

So: global framework for R&D - its not just IP !

Funding, priorities, but other norms?



Working towards a global framework for R & D

Challenge : What should framework cover - where is global agreement needed?

Funding focused on key areas of need, priorities developed with developing countries

Developing medical tools that are designed from start to be effective, safe, affordable and easy to use

Other issues e.g transparency, medical ethics, technology transfer
developing countries' capacity to research, develop and produce their own medical tools will be a key part of a sustainable solution

Discussions started WHO : GSPA: take forward discussion on development of biomedical R&D treaty

Bangladesh, Barbados, Bolivia and Suriname : proposals for WHO discussions on biomedical R&D Treaty.

Currently proposals for innovation and access including R&D treaty being reviewed by expert group at WHO

How is the money best spent?

Number of different proposals some appear the same but have significant differences in relation to costs and access provisions

No single proposal will deliver for all needs

Current approaches such as direct grants or financing PDPs are important but not sufficient

What is the appropriate starting point?

Start with priority medical needs and need for end product to be accessible and affordable.

need to move beyond main reliance on adaptation model

Outline

- Problems
- Reasons for gaps in the current medical innovation system
- Some proposals to be explored and some opportunities to be considered

De-linkage – key issues 1

TRIPS Agreement: IP protections used to enforce monopoly to recover cost of R&D development through high prices = linkage

But

separating the payment for the cost of R&D development for health technologies from price of the product - delinkage provides a path way to focus R&D towards health needs

R&D priorities driven by health needs not marketing opportunities

Aim: innovation and access

Does not mean that IP will never used but not to enforce high prices

De-linkage – key issues 2

Reconciling innovation and access: affordability and accessibility need to be considered up front when funding/ creating incentives for R&D

Must be included at all stages of research from the basic research through to product development and delivery

As de-linkage provides pathway to orient R&D towards health needs

Delinkage can and should apply across the full range ways of funding R&D

grants , PDPS (push) and rewards at the end prizes (pull)

Key issue for how to implement it.

Principle options to ensure affordability and accessibility

Third party competition

highly efficient to reduce price (more efficient than tiered pricing)

Requires dealing with patents, i.e. no patent, no enforcement or appropriate licensing strategy (voluntary/compulsory, patent pooling)

Additional benefit: allows for further adaption and innovation by third parties

Where quick competition may be not feasible, e.g. vaccines, complex diagnostics

Needs short term strategy: possibly tiered pricing (but who decides on price level and when?),

Pathway to accelerate time to competition: technology transfer- meningitis A vaccine produced by Serum Institute of India to be sold at \$ 0.50 /dose.

De-linkage and R&D push and pull funding

PDP

De-linkage possible

Donors can/do request global access policies

Too early to assess: most products still in pipeline and IP and access agreements kept confidential

Example: DNDi-sanofi malaria ASAQ: patentfree

But if no producer?

Direct grants to small companies

De-linkage only realistic if grant covers full R&D cost

Access provisions should be a minimum requirement –

Government grants in general

Need to ensure public access to the results of government funded research. This is not always the case, e.g.

rBCGΔureC:Hly (VPM1002) – TB vaccine candidate

De-linkage and R&D and pull funding

Medicial innovation inducement Prizes

New eyes to old problems,

Pull reward that provides de-linkage, if appropriately designed

Prizes instead of patent

E.g. Innocentive: depending on type of prize innovator need to transfer IP in return for reward

Can be designed to fit needs of researchers – payment to develop proof of concept and key milestones

Access : Different options: patent buy-out, open licensing (+/- no profit/low margin pricing and production guarantees) etc

Applying de-linkage: Medical innovation inducement Cash Prizes

Large cash prizes have not yet been trialed

Models to ensure affordability and allow to
leap frog technological hurdles

Pilot for

TB POC Diagnostics

Or chagas test of cure



The TB test we need !

Point-of-care: easy to perform in peripheral health centres

Detect active TB in adults regardless of HIV status

Improved diagnosis of TB in children

[Detailed specifications: 'New diagnostics for tuberculosis: fulfilling patient needs first', Lemaire J, Casenghi M, J Int AIDS Soc 2010, 13:40]

Some new tests becoming available (eg Xpert MTB) but can only be 'bridging technologies'

Innovation prizes – rewards that can stimulate innovation and ensure access

- Large financial reward at the end – paying for success
- Principle of crowdsourcing
- Successfully used in many technology fields
- In return for prize reward: sell at low price and allow competition from day one
- Needed: a prize fund for a TB point-of-care test



Why it is important?

- To demonstrate effectiveness of treatment in adults
 - <15 years, probability of cure is more than 90%
 - <5 years, probability of cure is almost 100 %
- To stimulate the drug development as a means of evidence for therapeutic efficacy

What is needed?

- Test should allow confirmation of cure to be made within 1-2 years of treatment in all age groups and should be reliable, sensitive, and specific.
- There is a need to push some laboratories to invest more resources and fund in looking to other method than only Ag/Ab (antigen/antibody) combination.
- Need to identify biomarkers
- Explore concept of prize?

Opportunities in Latin America

1) Political

- PAHO Member States agreed in the regional level:

2008: regional perspective of the Global Strategy and Plan of Action on Innovation, Public Health and Intellectual property (CD48.R15)

Regional consultation for the CEWG: Meetings prior to its final report in order to explore promising mechanisms in more detail

2009: Resolution on Neglected Diseases (CD49.19)

Diagnosis + Treatment with the existing tools

R&D agenda: explore alternative mechanisms to fund R&D that delink the cost of innovation from the price of the final product

- Unasur: South American Health Council

2010: Resolution 05/2010 Chagas as priority disease for countries in the region

2) Innovation environment

- Health industrial policy in Brazil

Conclusions

Need new incentive framework

De-linkage is a key concept that enables reconciliation of innovation and access

De-linkage is a key criteria to assess proposals for stimulation of R&D related needs of developing countries

Put delinkage into practice: Attach explicit conditions to the R&D funding that will ensure public investments in health secure access to the knowledge and tools generated
Access provision should apply to both push and pull funding .

Implementation of de-linkage is uneven among push mechanisms and not yet implemented for pull financing

De-linkage should be included as one of the principles in the design of a needs driven R&D global framework

Thank you!

**For more information:
www.msfacecess.org**