



**The Way Forward for
Needs Driven Public
Health Research**



**Katy Athersuch
Médecins Sans Frontières
Access Campaign**

Which path for R&D?

MONOPOLY MODEL: LINKAGE

Conditions:

- Profits set priorities
- High public funding
- Collaboration and data sharing discouraged



**HIGH-COST
R&D**

Result:

- Monopoly market: anti-competitive
- No accountability on price setting



**HIGH
PRICES**

NEEDS-DRIVEN MODEL: DELINKAGE

Conditions:

- Health needs set priorities
- Collaboration and data sharing encouraged



**PRO-HEALTH
R&D**

Result:

- Free-market: competition
- Accountability on price setting: focus on quality, fair prices



**FAIR
PRICES**

The Process

2003

Resolution WHA56.27

Intellectual property rights, innovation and public health



Commission on Intellectual Property Rights, Innovation and Public Health



2006

Resolution WHA59.24

Public Health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action



Intergovernmental Working Group



2008

Resolution WHA61.21

Global strategy and plan of action on public health, innovation and intellectual property



Expert Working Group on Research and Development: Financing and Coordination



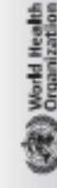
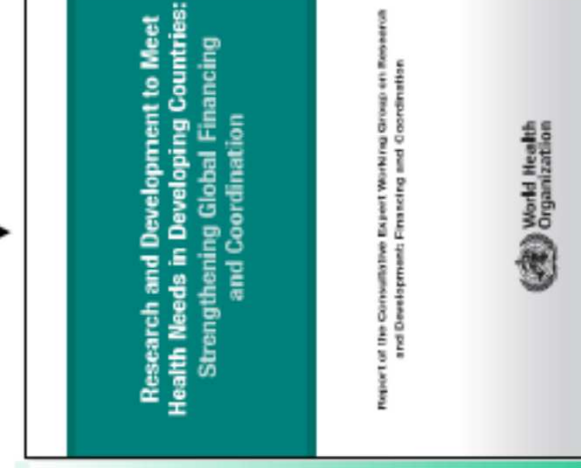
2010

Resolution WHA63.28

Establishment of a consultative expert working group on research and development: financing and coordination



Consultative Expert Working Group on Research and Development: Financing and Coordination





What was CEWG really about?

- How to finance research and development to meet the needs of people in developing countries
- Global agreement: set priorities, coordinate, ensure financing, norms for access (delinkage).

Research and Development to Meet
Health Needs in Developing Countries:
Strengthening Global Financing
and Coordination

Report of the Consultative Expert Working Group on Research
and Development: Financing and Coordination





Specifically...

... we considered that the time had now come for considering a coherent & comprehensive international framework or convention under the auspices of WHO for supporting priority medical R&D aimed at diseases that are prevalent in developing countries...

Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination

Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination





What happened in 2012

- Lack of political will to take forward the main recommendation
- Discussions had limited focus - seen as HICs had to finance developing countries needs.
- Over-focusing on the need for increased funding

=> maximal to minimal level of ambition:

- observatory & pilot projects (underfunded - but by key BRICS countries)



Norms for R&D: WHA66.22

- ...Recalling the GSPA, with one objective being **the de-linkage of the cost of research and development from the price of health products...**
- ...Underscoring the health R&D should be **needs-driven** and **evidence-based** and guided by the following core principles:
 - **affordability, effectiveness, efficiency, equity and should be considered a shared responsibility.**



What has happened since the last discussions

- Ebola outbreak: no vaccines, no drugs, cumbersome diagnostics
- Rising levels AMR: no new drugs for decades, challenges with diagnostics, some vaccines, but very expensive.
- High prices blocking access to medicines in Europe and US



=> all global issues, high on political agenda, discussions in the EU, G7 and G20, O'Neill Review, Chatham House AMR report



2016: UNHLP



- Transparency
- Innovative financing mechanisms
- A binding R&D Convention that delinks the costs of R&D from end prices to promote access to good health for all
- Code of Principles for Biomedical R&D.



HIGH-LEVEL MEETING ON ANTIMICROBIAL RESISTANCE



21 SEPTEMBER 2016, UN HEADQUARTERS, NEW YORK

‘Greatest and most urgent global risk, requiring increased attention and coherence at the international, national and regional levels’

‘...Underline also that all research and development efforts should be **needs-driven, evidence-based and guided by the principles of affordability, effectiveness and efficiency and equity, and should be considered as a shared responsibility: in this regard, we acknowledge the importance of **delinking** the cost of investment in research and development on antimicrobial resistance from the price and volume of sales...’**



Where Next?

From Political Statements to Concrete Change

- Ensure norms for financing R&D:
 - Based on de-linkage, affordability, effectiveness, efficiency, equity and a shared responsibility.
 - Combining ‘push’ & ‘pull’ funding in innovative ways
 - Pooling of knowledge, data and IP
 - Licensing for access
- Need for a global Agreement
- Observatory: Important that this goes beyond the functions of a policy think tank- added value is the involvement of MSs
- Pooled Fund: Sufficiency and sustainability, collective responsibility - Ambition



Set innovation free - Time to fix the patent system



Thank you!

 **@MSF_Access**
@Kathersuch

www.msfacecess.org

Extra Slides

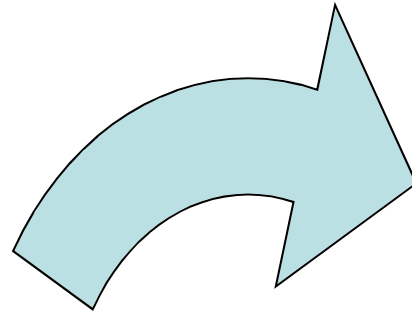
Objectives of a global binding instrument

- Implementing States' obligations and commitments.
- Promoting R&D for developing new health technologies.
- Securing sustainable funding.
- Improving the coordination of public and private R&D.
- Enhancing the innovative capacity in developing countries and technology transfer to these countries.
- Generating R&D outcomes as public goods, freely available for further research and production.
- Improving priority setting based on the public health needs of developing countries.
- Focus on development of health technologies for Type II and Type III diseases as well as the specific needs of developing countries related to Type I diseases.

Funding model is a barrier to innovation for NTDs
→ it is necessary to “delink” or “separate” the market for R&D from the market for product manufacturing

Delinkage provides a path way to focus R&D towards health needs

R&D priorities driven by health needs not marketing opportunities



Cost R&D

Price Product =



No R&D for 'poor' markets

