New financing and incentive mechanisms to boost R&D for poverty-related diseases: challenges and opportunities ahead

Elimination of Neglected Tropical Diseases: progress and future challenges in sleeping sickness

GLOBVAC conference
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Access Innovation
Innovation and Access
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Imbalances in R&D

1,393 total products approved
1975-1999

1.1%
16 new drugs for neglected diseases

Neglected diseases: Tuberculosis, malaria and tropical diseases, around 12% of GBD

Only $3 billion (1-2% of total) invested globally on R&D for neglected diseases

Source: Pedrique B et al, DNDI/MSF forthcoming publication, 2013
**Longstanding recognition:** market-driven global R&D system does not sufficiently meet the needs of majority of the world’s population, 80% of which lives in developing countries.
A 10-year process 2003-2013 at WHO

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

2012
Resolution WHA65.22
Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
WHO Governing Bodies (EB/WHA)

Public health innovation and intellectual property rights

Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

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

Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
Assessment of 15 grouped proposals

CEWG recommendations

Open approaches Equitable licensing
Milestone and end prizes
Patent pools
Direct grants

Financing commitments
Pooled funding

Global R&D Observatory
Advisory functions at WHO

‘Open Knowledge Innovation’

Global Framework

Convention on Global Health R&D
Public Funding for R&D for Neglected Diseases

Public funding by GDP 2010

United States of America
United Kingdom
Sweden
Norway
Luxembourg
Ireland
Denmark
South Africa
Switzerland
Australia
Netherlands
India
Colombia
France
Germany
New Zealand
Spain
Belgium
Brazil
Canada
Argentina
Thailand
Chile
Malaysia
Mexico
Japan
South Korea

Total R&D as % of GDP
Public funding for neglected disease R&D

Neglected disease R&D investments (% of GDP)

Publicly funded neglected disease R&D (% of GDP)

Publicly funded health R&D (% of GDP)

Public funding for neglected disease R&D
A 10-year process 2003-2013 at WHO

2013
Resolution WHA66.22
Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

Endorses the following strategic work plan...

URGES Member States to:
... increase investments in health R&D for diseases disproportionately affecting developing countries

REQUESTS the Director-General to
• develop norms and standards for classification of health R&D
• establish a Global Health R&D Observatory
• facilitate implementation of a few health R&D demonstration projects
• review existing mechanisms to assess their suitability to perform the coordination function of health R&D
• explore and evaluate existing mechanisms for contributions to health R&D, and if there is no suitable mechanism, to develop a proposal for effective mechanisms, including pooling resources and voluntary contributions, as well as a plan to independently monitor their effectiveness

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Public health innovation and intellectual property rights

2014
Decision point WHA67.xx

Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

... recognized the indicators to measure success in implementing the health research and development demonstration projects and requested the addition of an analysis of the extent of innovative components being implemented by the projects including financing, the use of open access models, multisectoral research platforms, and delinkage, among other criteria;

... noted, without prejudice to future discussions in the context of CEWG recommendations and actions on other sustainable mechanisms for financing health research and development, the assessment made by the Secretariat and the possibility of using an existing mechanism to host a pooled fund for voluntary contributions towards research and development for type III and II diseases and the specific research and development needs of developing countries in relation to type I diseases;

... requested the Director-General to further explore this option with TDR

2012
Resolution WHA65.22

Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

WHO Governing Bodies (EB/WHA)
A 10-year process 2003-2013 at WHO

**2003**

Resolution WHA56.27

Intellectual property rights, innovation and public health

**2015**

Report by the DG, EB136/30

Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

... The **fund** will be managed by the Special Programme [for Research and Training in Tropical Diseases, TDR], and the Global Observatory and the coordination mechanism will be managed by the Secretariat;

... The priorities of the fund would be informed by the analysis of the research landscape provided by the Global Observatory. General priority areas would be recommended by the coordination mechanism. WHO is currently examining options for such a mechanism;

... The Board is invited to note the report and to consider the establishment of a pooled fund for voluntary contributions towards research and development for type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases to be hosted by the Special Programme for Research and Training in Tropical Diseases

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Innovation and Access –
Delinkage – a separate innovation market
Innovation and Access –
Market shaping – expand market
R&D financing and incentive mechanisms

- Discovery
- Preclinical
- Phase I
- Phase II
- Phase III
- Licensure

**Delinkage / Push mechanisms**

- Open knowledge innovation
- Milestone and end prizes
- PDP financing
- Grants
- Subsidies
- Tax breaks

**Pull mechanisms**

- Advance Market Commitment (AMC)
- Debt / loans
- Equity / bonds
- Government-backed volume guarantees
Market shaping and product uptake mechanisms

**RESEARCH & DEVELOPMENT**
- Advance market commitment
- Priority review voucher
- Prize
- Product development partnership

**MANUFACTURING**
- Volume guarantee
- Pooled procurement
- Coordinated ordering
- Variant optimization
- Demand forecasting
- Quality assessment

**PROCUREMENT**
- Pricing info exchange
- Simplified registration
- Ongoing commodity procurement

**DISTRIBUTION**
- Channel subsidy
- Strengthened QA system
- LMIS setup
- Infrastructure funding

**SERVICE DELIVERY/USER ADOPTION**
- Promotion incentives
- Policy and EML inclusion
- Ongoing demand generation
- Healthcare provider training

Source: Healthy Markets for Global Health. A Market Shaping Primer
Demonstration projects – Criteria  
(UNICEF follow up)

• Intends to delink the price of the final product from the cost of the R&D.
• Utilizes collaborative approaches, especially open knowledge innovation approaches.
• Utilizes licensing approaches that secure access to your research outputs and final products.
• Plans to mobilize innovative financing mechanisms, such as pooled funding or prizes.
• Fosters effective and efficient coordination mechanisms amongst existing organizations/initiatives.
• Strengthens capacity for research, development and production, including through technology transfer, in developing countries.
1. Proportional Financing By World Bank income groups

In this slide, GDP is aggregated to World Bank income groups. Then each groups’ percentage of total GDP is calculated (left). This percentage is then applied to USD 60m to determine a proportional financing responsibility for each of the income groups (over).

2. Proportional Financing By WHO regions

In this slide, GDP is aggregated to WHO region. Then each region’s percentage of total GDP is calculated (left). This percentage is then applied to USD 60m to determine a proportional financing responsibility for each of the regions (over).

Notes: Based on GDP in 2012. Data retrieved from WHO: [http://apps.who.int/nha/database/Select/Indicators/en](http://apps.who.int/nha/database/Select/Indicators/en)
3. Dividing the costs between USA, Europe, BRICS and the rest of the world

In this slide, GDP is aggregated to four groups: BRICS, Europe, USA and the rest of the world. Then each groups’ percentage of total GDP is calculated (below). This percentage is then applied to USD 60m to determine a proportional financing responsibility for each of the groups (left).

A global preparedness framework for innovations of public health importance

• Different, but similar challenges
  – Neglected diseases
  – Antibiotics (i.e. AMR)
  – Emerging infections, e.g. Ebola

• All need
  – More collaboration
  – Better coordination
  – Sustainable financing