

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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University of Oslo
Harvard School of Public Health



Access

Innovation

Innovation and Access



Innovation and Access

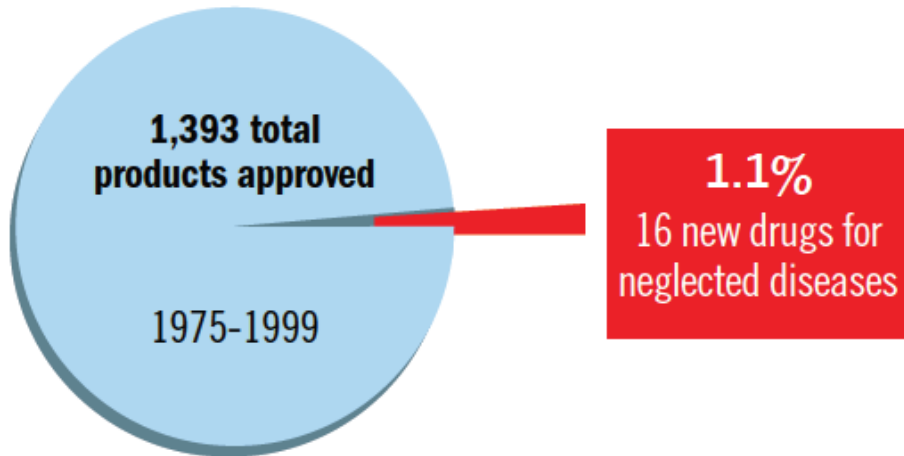


Innovation and Access

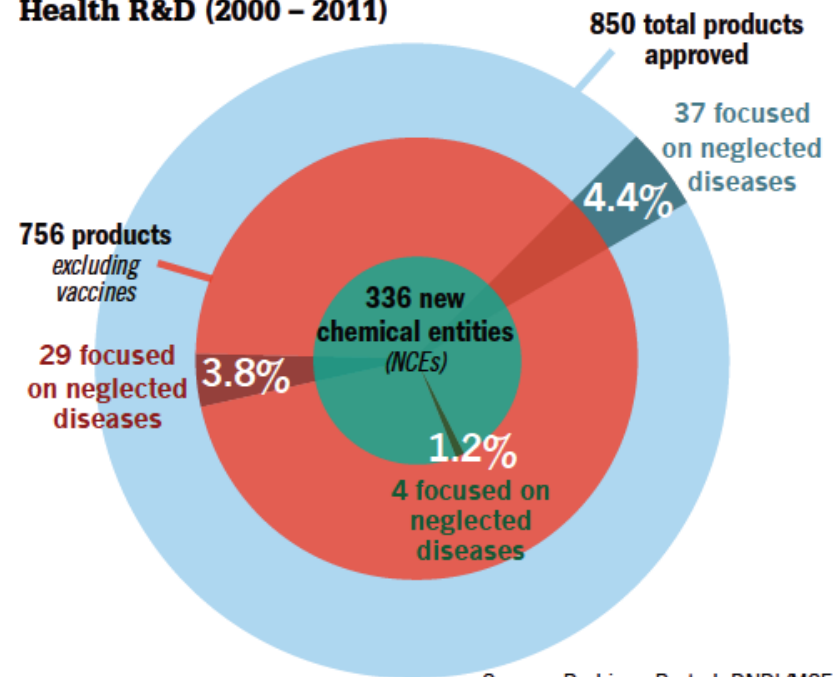


Imbalances in R&D

Health R&D (1975 – 1999)



Health R&D (2000 – 2011)



Source: Pedrique B et al, DNDI/MSF forthcoming publication, 2013'

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

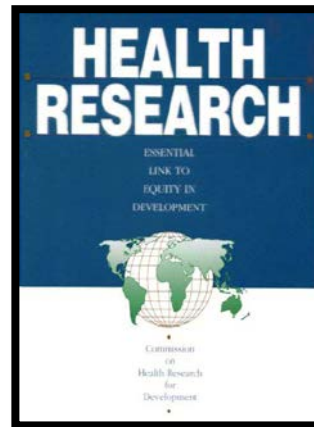
Only \$3 billion (1-2% of total) invested globally on R&D for neglected diseases

Calls for Increased R&D

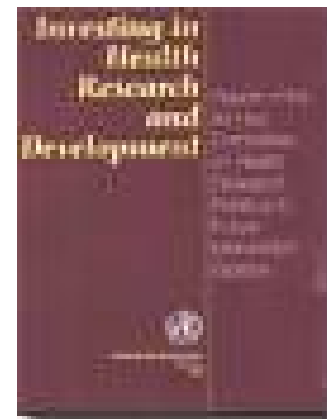
Longstanding recognition: market-driven global R&D system does not sufficiently meet the needs of majority of the world's population, 80% of which lives in developing countries



WHO-UNICEF-UNDP-World Bank
Special Programme for Research
and Training in Tropical Diseases
(1975)



Commission on
Health Research
for Development
(1990)



Investing in Health
Research
and Development
(1996)



Commission on
Macroeconomics
and Health
(2001)

A 10-year process 2003-2013 at WHO

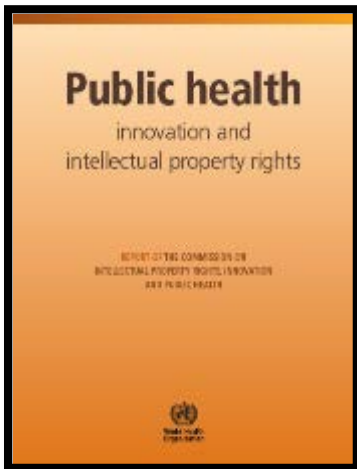
2003

Resolution
WHA56.27

Intellectual property rights, innovation and public health



Commission on Intellectual Property Rights, Innovation and Public Health



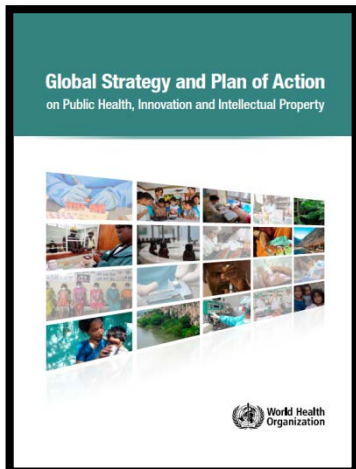
2006

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



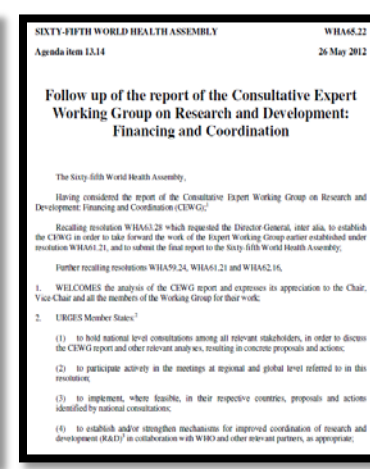
2012

Resolution
WHA65.22

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

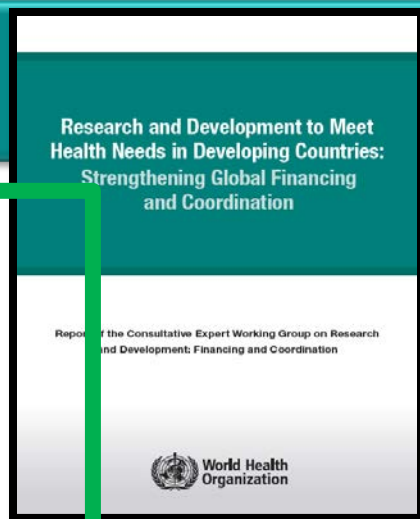
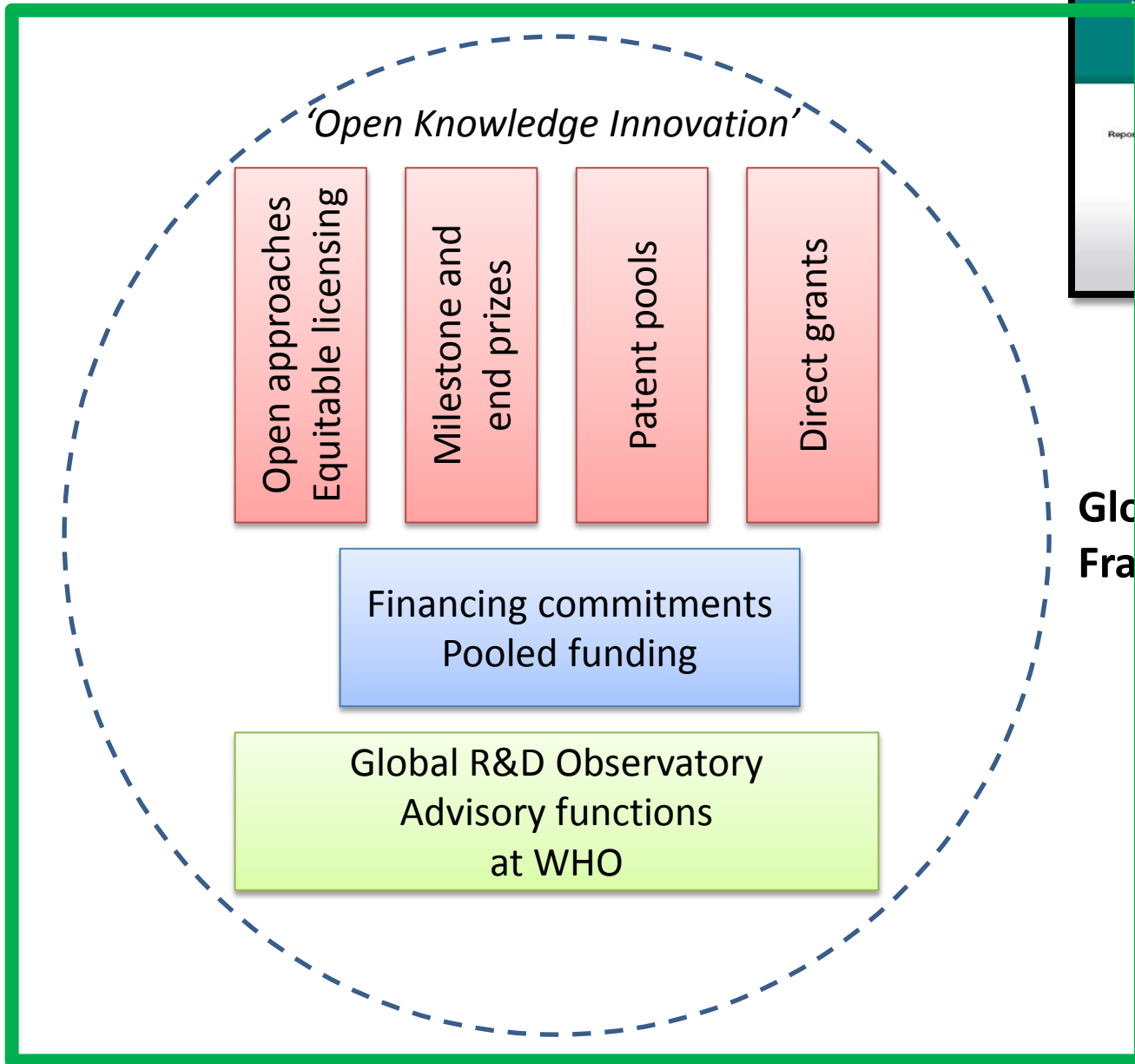


WHO Governing Bodies (EB/WHA)



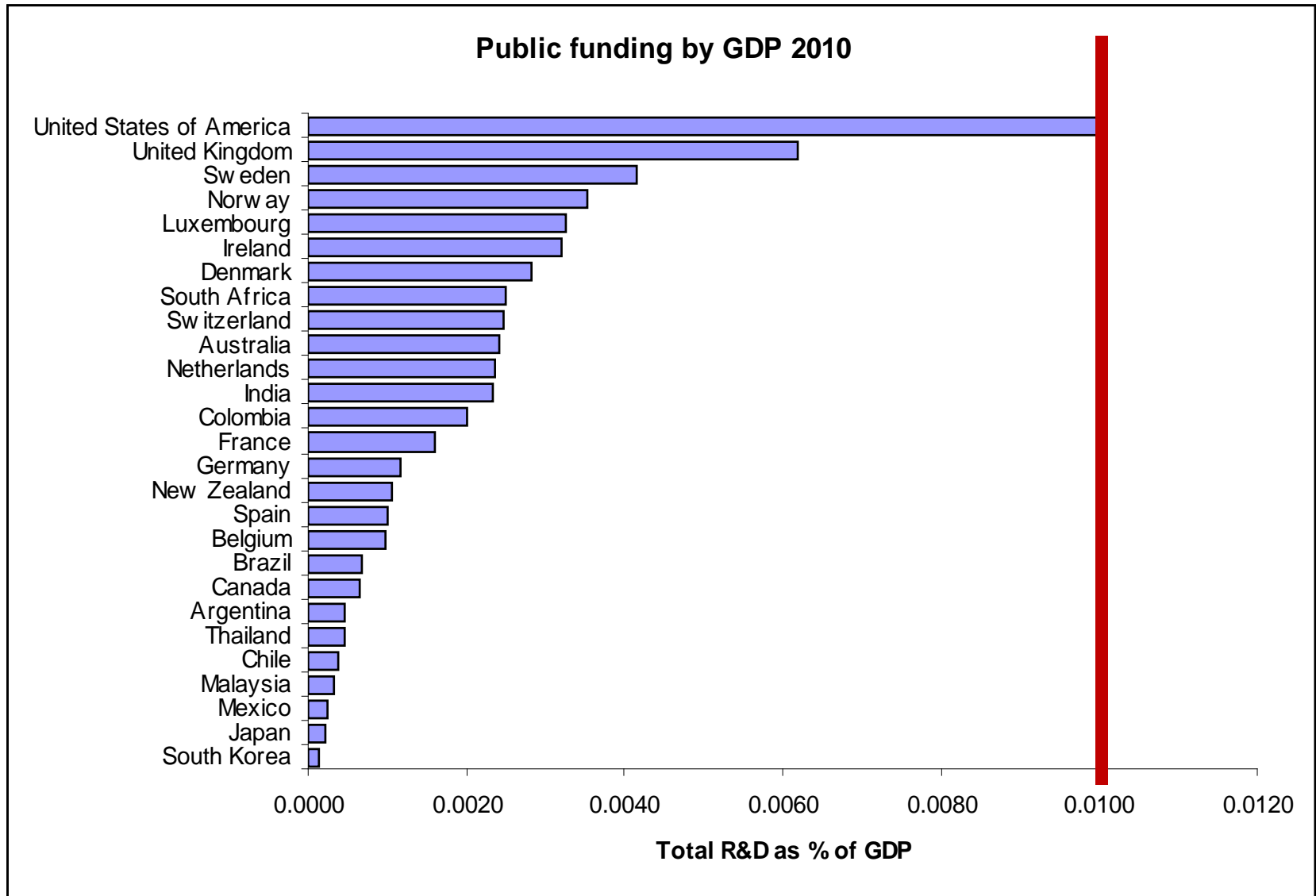
CEWG recommendations

Convention on Global Health R&D

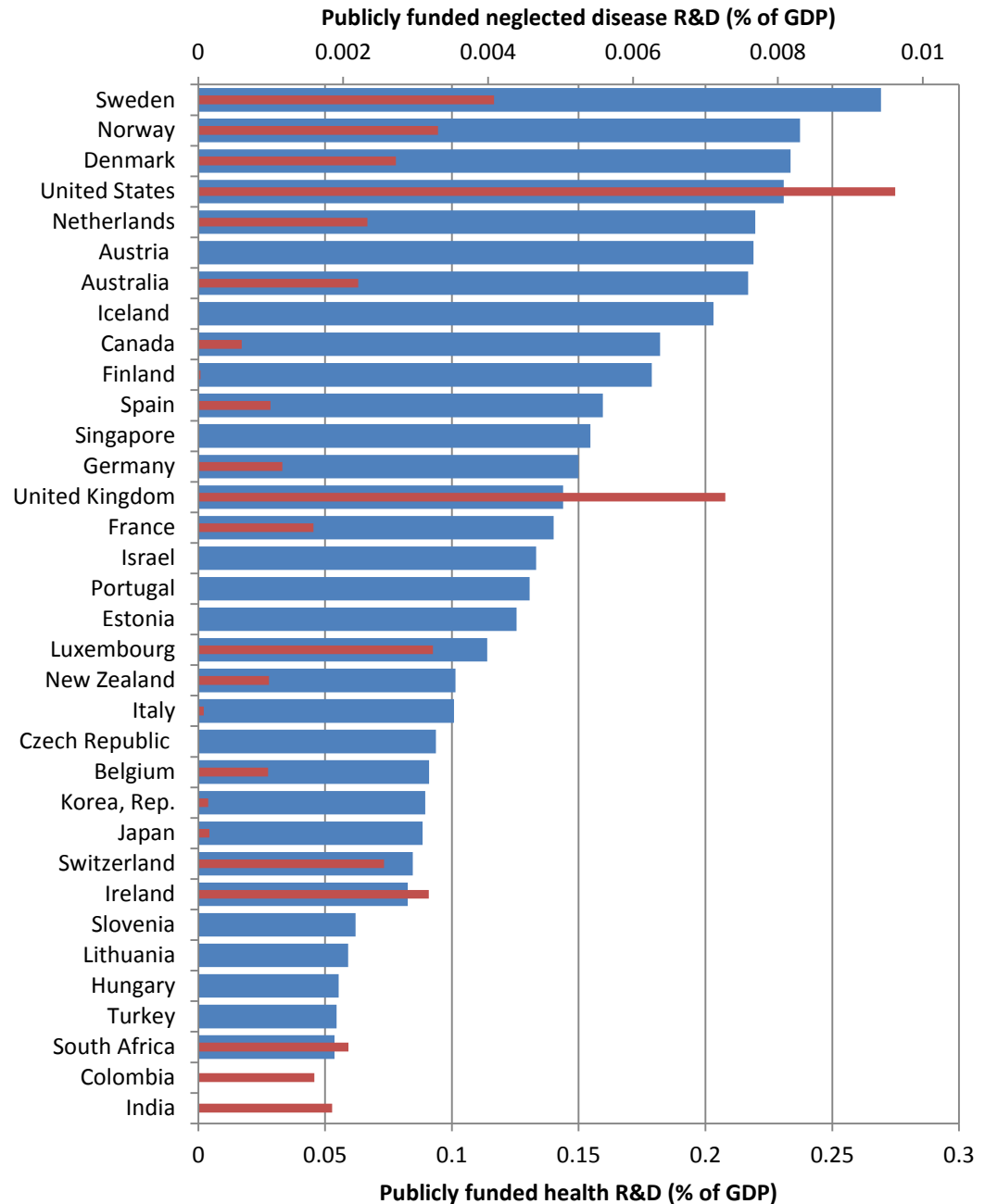
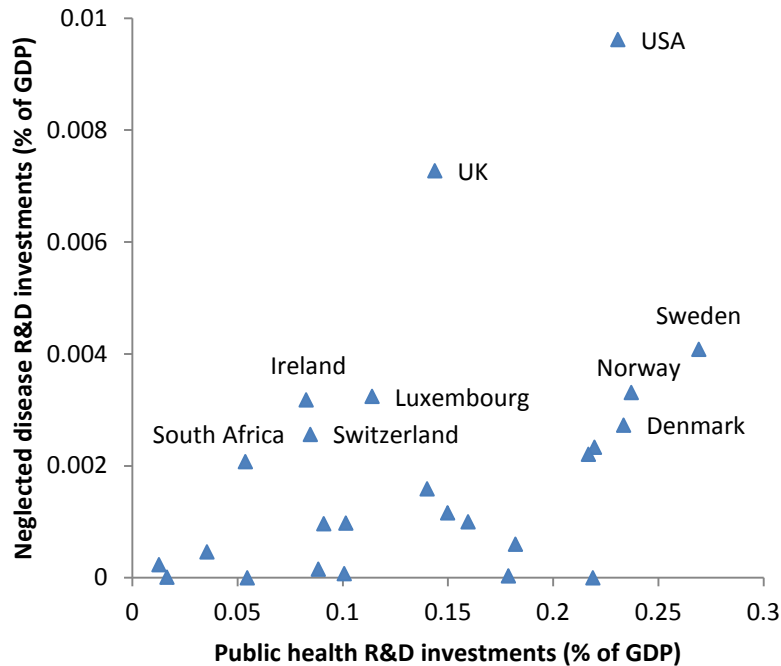


Global
Framework

Public Funding for R&D for Neglected Diseases



Public funding for neglected disease R&D



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



Public health
innovation and
intellectual property rights

REPORT OF THE COMMISSION ON
INTELLECTUAL PROPERTY RIGHTS, INNOVATION
AND PUBLIC HEALTH



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

2012

Resolution
WHA65.22

*Follow up of the report of the Consultative Expert
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Research and
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Financing and
Coordination*



WHO Governing
Bodies (EB/WHA)



SIXTY-FIFTH WORLD HEALTH ASSEMBLY
Agenda item 13.14

WHA65.22

26 May 2012

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

The Sixty-fifth World Health Assembly,

Having considered the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWGC),¹

Recalling resolution WHA63.28² which requested the Director-General, inter alia, to establish the CEWGC in order to take forward the work of the Expert Working Group earlier established under resolution WHA61.21, and to submit the final report to the Sixty-fifth World Health Assembly,

Further recalling resolutions WHA59.24, WHA61.21 and WHA62.16,

1. WELCOMES the analysis of the CEWGC report and expresses its appreciation to the Chair, Vice-Chair and all the members of the Working Group for their work;

2. URGES Member States³

(1) to hold national level consultations among all relevant stakeholders, in order to discuss the CEWGC report and other relevant analyses, resulting in concrete proposals and actions;

(2) to participate actively in the meetings at regional and global level referred to in this resolution;

(3) to implement, where feasible, in their respective countries, proposals and actions identified by national consultations;

(4) to establish and/or strengthen mechanisms for improved coordination of research and development (RD) in collaboration with WHO and other inter- and multi-partners, as appropriate.

A 10-year process 2003-2013 at WHO

2003

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WHA56.27

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rights, innovation and
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Commission on Intellectual
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Public health
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REPORT OF THE COMMISSION ON
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AND PUBLIC HEALTH



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 the this option with TDR

2012

Resolution
WHA65.22

*Follow up of the report of
the Consultative Expert
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WHO Governing
Bodies (EB/WHA)



SIXTY-FIFTH WORLD HEALTH ASSEMBLY WHA65.22
Agenda item 13.14 26 May 2012

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Commission on Intellectual
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Public health
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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**

2012

Resolution
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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

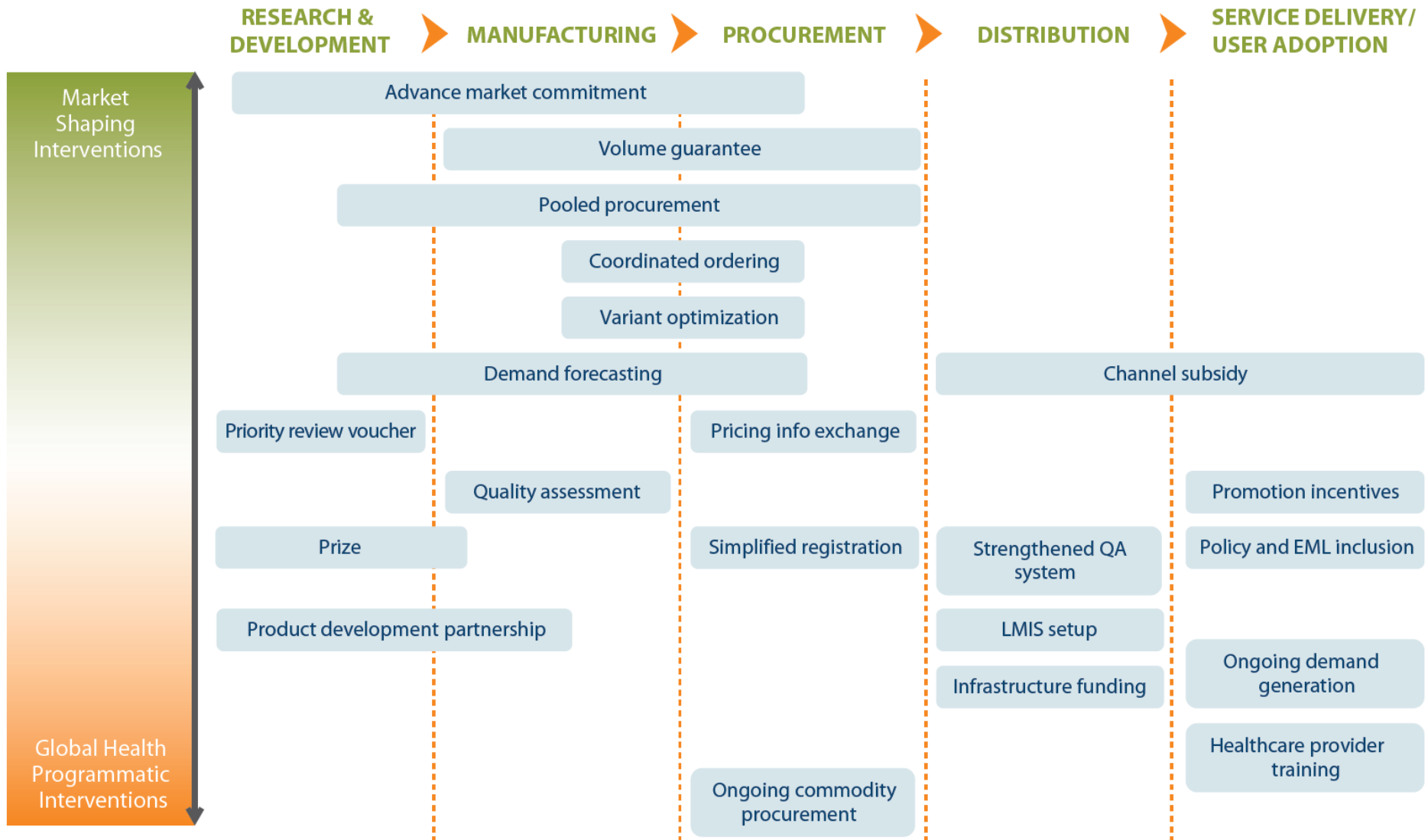
Pull mechanisms

E
X
A
M
P
L
E
S

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

- Advance Market Commitment (AMC)
- Debt / loans
- Equity / bonds
- Government-backed volume guarantees

Market shaping and product uptake mechanisms

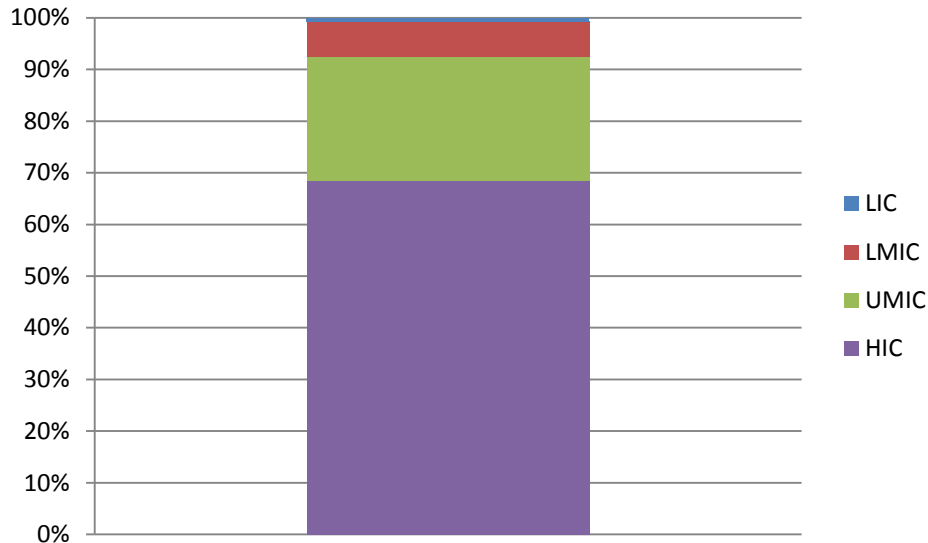
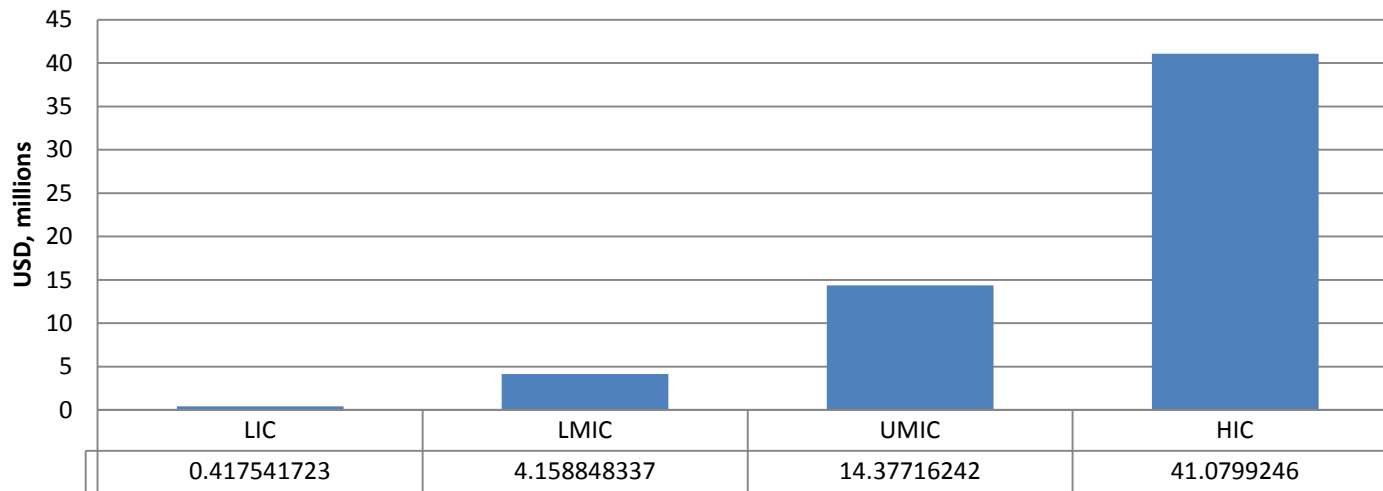


Demonstration projects – Criteria (WHO CEWG follow up)

- 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

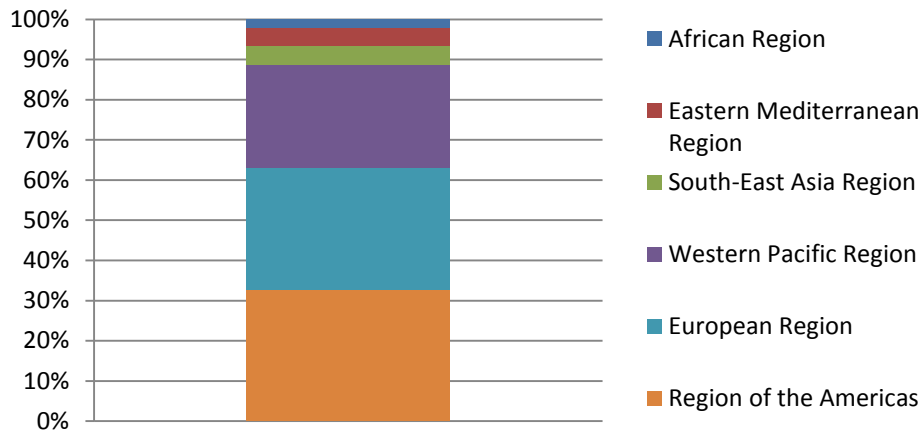
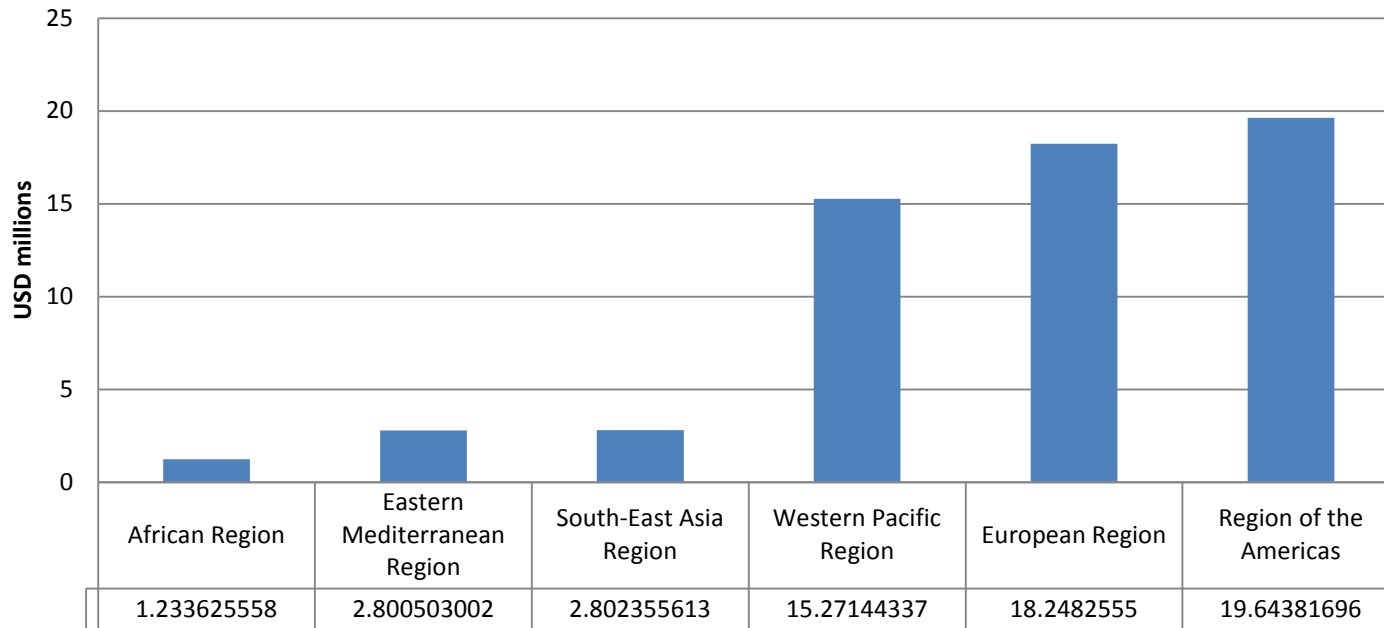
Dividing the USD 60m for the four demonstration projects, by WB income groups



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

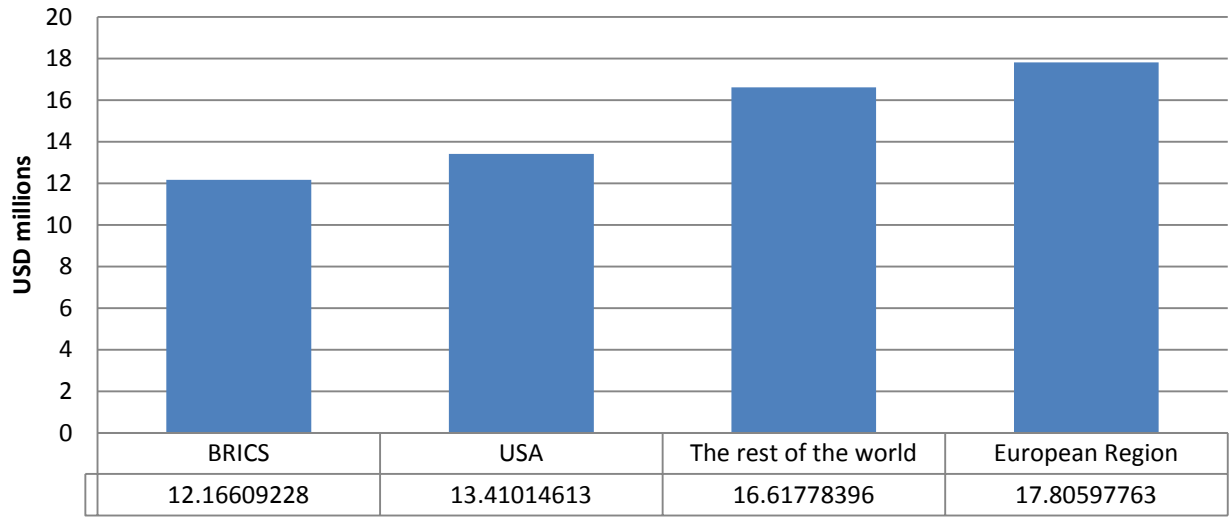
Millions of US dollars to be paid for R&D, by WHO region



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).

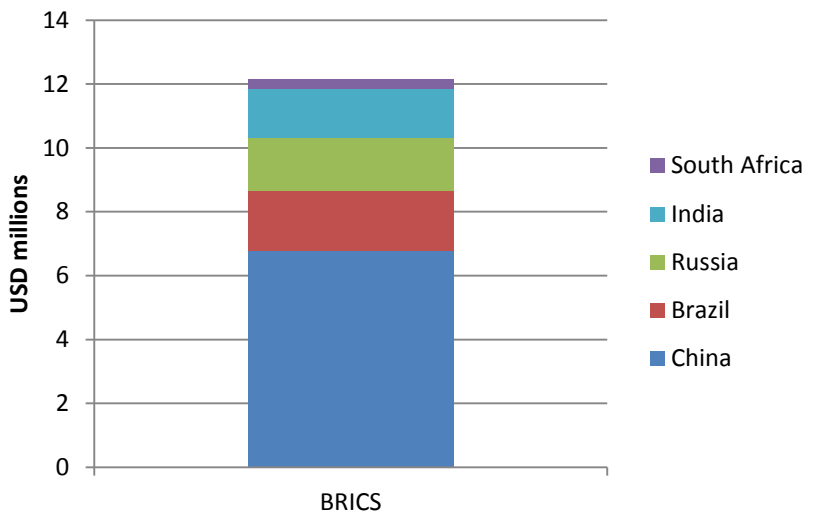
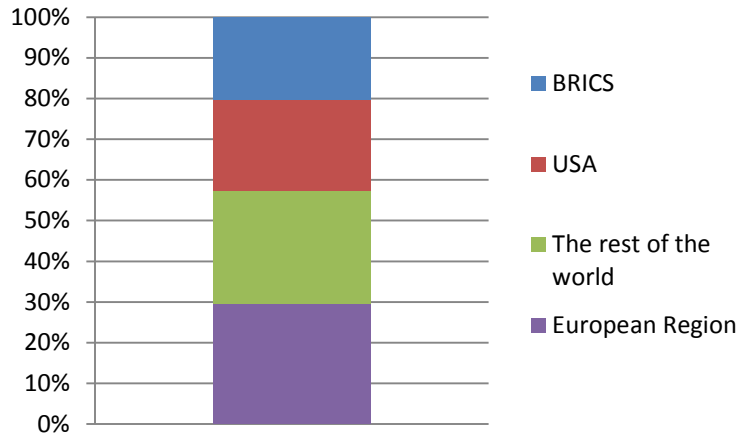
3. Dividing the costs between USA, Europe, BRICS and the rest of the world

Millions of US dollars to be paid for R&D



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).

Millions of US dollars to be paid for R&D



Notes: Based on GDP in 2012. Data on European Region retrieved from WHO: <http://apps.who.int/nha/database/Select/Indicators/en>
 All other data retrieved from World Bank Data: <http://data.worldbank.org/data-catalog/GDP-ranking-table>

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