

# **Workshop on Mechanisms to promote Research and Development (R&D) for Tuberculosis (TB), Malaria and other Neglected Tropical Diseases**

**(NTDs)**

**South Centre/UNDP Workshop, 31 March - 2 April  
Geneva 2014**

- **The Report of the Consultative Expert Working Group on Research and Development (CEWG):  
Financing and Coordination**

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# UNIVERSAL DECLARATION OF HUMAN RIGHTS

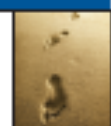


1 RIGHT TO  
EQUALITY

2 FREEDOM FROM  
DISCRIMINATION

3 RIGHT TO LIFE, LIBERTY,  
AND PERSONAL SECURITY

4 FREEDOM  
FROM SLAVERY

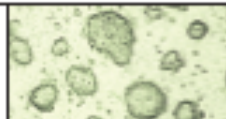


5 FREEDOM FROM TORTURE AND  
DEGRADING TREATMENT

6 RIGHT TO RECOGNITION AS  
A PERSON BEFORE THE LAW

7 RIGHT TO EQUALITY  
BEFORE THE LAW

8 RIGHT TO REMEDY BY  
COMPETENT TRIBUNAL



9 FREEDOM FROM ARBITRARY  
ARREST AND EXILE

10 RIGHT TO FAIR  
PUBLIC HEARING

11 RIGHT TO BE CONSIDERED  
INNOCENT UNTIL PROVEN GUILTY



12 FREEDOM FROM INTERFERENCE WITH PRIVACY,  
FAMILY, HOME, AND CORRESPONDENCE

13 RIGHT TO FREE MOVEMENT IN  
AND OUT OF THE COUNTRY

14 RIGHT TO ASYLUM IN OTHER  
COUNTRIES FROM PERSECUTION



15 RIGHT TO A NATIONALITY AND  
THE FREEDOM TO CHANGE IT



16 RIGHT TO MARRIAGE  
AND FAMILY



17 RIGHT TO OWN  
PROPERTY

18 FREEDOM OF BELIEF  
AND RELIGION



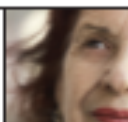
19 FREEDOM OF OPINION  
AND INFORMATION

20 RIGHT OF PEACEFUL ASSEMBLY  
AND ASSOCIATION

21 RIGHT TO PARTICIPATE IN GOVERNMENT  
AND IN FREE ELECTIONS

22 RIGHT TO SOCIAL  
SECURITY

23 RIGHT TO DESIRABLE WORK AND  
TO JOIN TRADE UNIONS



24 RIGHT TO REST  
AND LEISURE

25 RIGHT TO ADEQUATE  
LIVING STANDARD



26 RIGHT TO  
EDUCATION

27 RIGHT TO SHARE IN SCIENTIFIC  
ADVANCEMENT

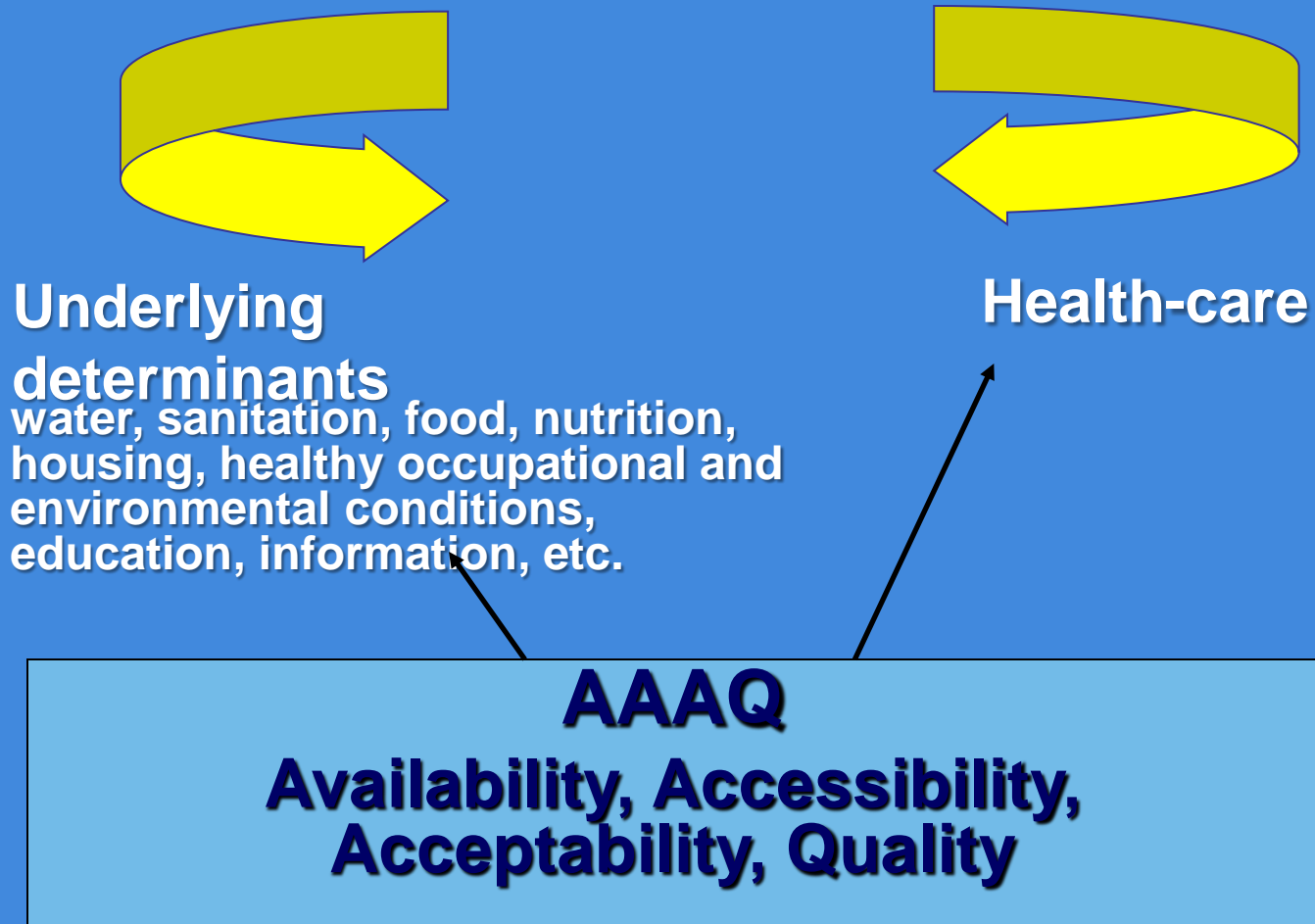
28 RIGHT TO A SOCIAL ORDER THAT  
ARTICULATES THIS DOCUMENT



29 RIGHT TO FULFILL COMMUNITY DUTIES ESSENTIAL  
TO FREE AND FULL DEVELOPMENT

30 FREEDOM FROM STATE OR PERSONAL  
INTERFERENCE IN THE ABOVE RIGHTS

# The Right to Health



## After the TRIPS on agreement: 1996-2001

- Conflicts arise on access to HIV treatment
- E.g. 39 companies sue the South African Government for violating the TRIPS agreement
- Protests from Civil Society and NGOs





# The Context

2003

## Resolution WHA56.27

*Intellectual property rights, innovation and public health*



Commission on Public Health, Innovation and Intellectual Property Rights



**Public health**  
innovation and  
intellectual property rights

REPORT OF THE 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



**Research  
and  
Development**

Coordination and Financing

Report of the  
Expert Working Group



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



**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



# Scope of CEWG Mandate

- Focus on financing and coordination of R&D for health products and technologies related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases.
- Centred on element 2 (Promoting research and development) and element 7 (Promoting sustainable financing mechanisms) of the GSPA-PHI.
- Take forward the work and deepen the analysis of the Expert Working Group (WHA 63.28).
- Examine additional submissions and proposals on R&D financing and coordination.

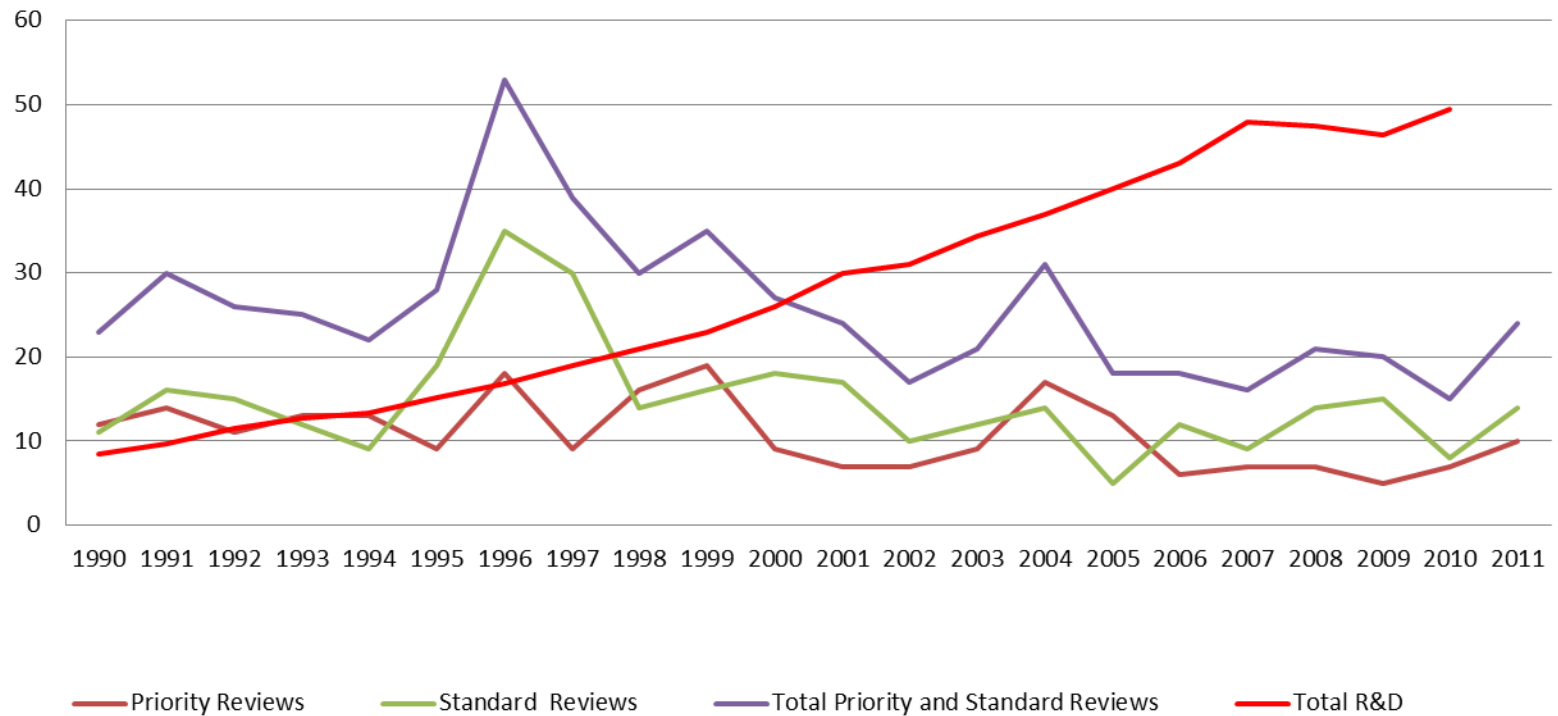
# I. Setting the Scene:

## The case for public action

- **The economic case for public action:** The incentive offered by intellectual property rights fails to be effective in correcting the market failure in developing countries due to the lack of reliable demand for the products generated by R&D .
- **The ethical and legal case for public action:** *“the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition”* (WHO Constitution).
- **R&D as a public good:** Knowledge generated by research is a true public good if it is made available to anyone to make use of without restrictions.

# Number of new drug approvals and R&D expenditures in USA 1990-2011

Number of new drug approvals and R&D expenditures (as reported by PhRMA) (US\$ billions ) in the USA, 1990-2011





# Funding for R&D relevant to developing countries

- ✓ **10% of research devoted to 90% of the world's health problems.** *The Global Forum for Health Research, 1998.*
- ✓ **In 1990, 5% or \$1.6 billion of total spending for health research devoted to the health problems of developing countries.** *The Commission on Health Research and Development (CHRD).*
- ✓ **In 1996, US\$ 2.4 billion or 4.3% of global spending on health research devoted to the health problems of developing countries.** *Ad Hoc Committee on Health Research Relating to Future Intervention Options.*
- ✓ **In 2010, nearly US\$ 3.2 billion was invested in research for Type II and Type III diseases, below 3% of overall global spending .** *G-Finder report 2011.*

# R&D Funding 2010

*Source: G-Finder Report 2011*

- **65% from public sources:** 90% increase of public funding from developed countries for “neglected” diseases (from US\$ 590 million in 1986 to US\$ 1.925 billion in 2010) but small and unclear contribution from developing country (about \$70 million not including China and other large developing countries).
- **18.5% from philanthropic sources:** a five-fold increase from US\$ 60 million in 1986 to US\$ 568 million in 2010. Bill & Melinda Gates Foundation accounted for 80% of which over half of goes to product development partnerships.
- **16.4% from industry:** US\$ 500 million in 2010, stagnating or declining in real terms since 1986

# Total R&D funding by disease, 2010 (2007 US\$)

Disease	2010 (US\$)	2010 (%)
HIV/AIDS	1 073 033 520	35.0
Tuberculosis	575,361,902	18.8
Malaria	547 042 394	17.9
Dengue	177 643 516	5.8
Diarrhoeal diseases	158 918 128	5.2
Kinetoplastids	147 867 513	4.8
Bacterial pneumonia & meningitis	92 866 038	3.0
Helminth infections (worms & flukes)	73 685 406	2.4
Salmonella infections	43 982 149	1.4
Leprosy	8 840 532	0.3
Buruli ulcer	5 456 026	0.2
Trachoma	4 507 718	0.1
Rheumatic fever	1 736 877	0.1
Platform technologies	27 358 501	0.9
Core funding of a multi-disease R&D organization	76 884 279	2.5
Unspecified disease	47 485 474	1.6
Disease total	3 062 669 973	100.0

Source: G-Finder Report, 2011

# Progress in product development

- **26 new products** approved between 2000-2009.
- Of those, **10 were for HIV/AIDS and 11 for malaria.**
- The proportion of approved products sponsored by private industry has declined from 83% to 46% while those sponsored by **PDPs had increased from 15% to 46%.**
- **97 relevant products in development**, of which 68 were for HIV/AIDS, tuberculosis and malaria.
- **Progress is very uneven:** no new products for tuberculosis or vaccines or microbicides for HIV/AIDS, or for Buruli ulcer, dengue fever, trachoma, rheumatic fever, or typhoid.

# CEWG's Criteria for proposals' evaluation

- Public health impact
- Efficiency/cost-effectiveness
- Technical feasibility
- Financial feasibility
- Intellectual property
- Delinking
- Access
- Governance and accountability
- Capacity-building

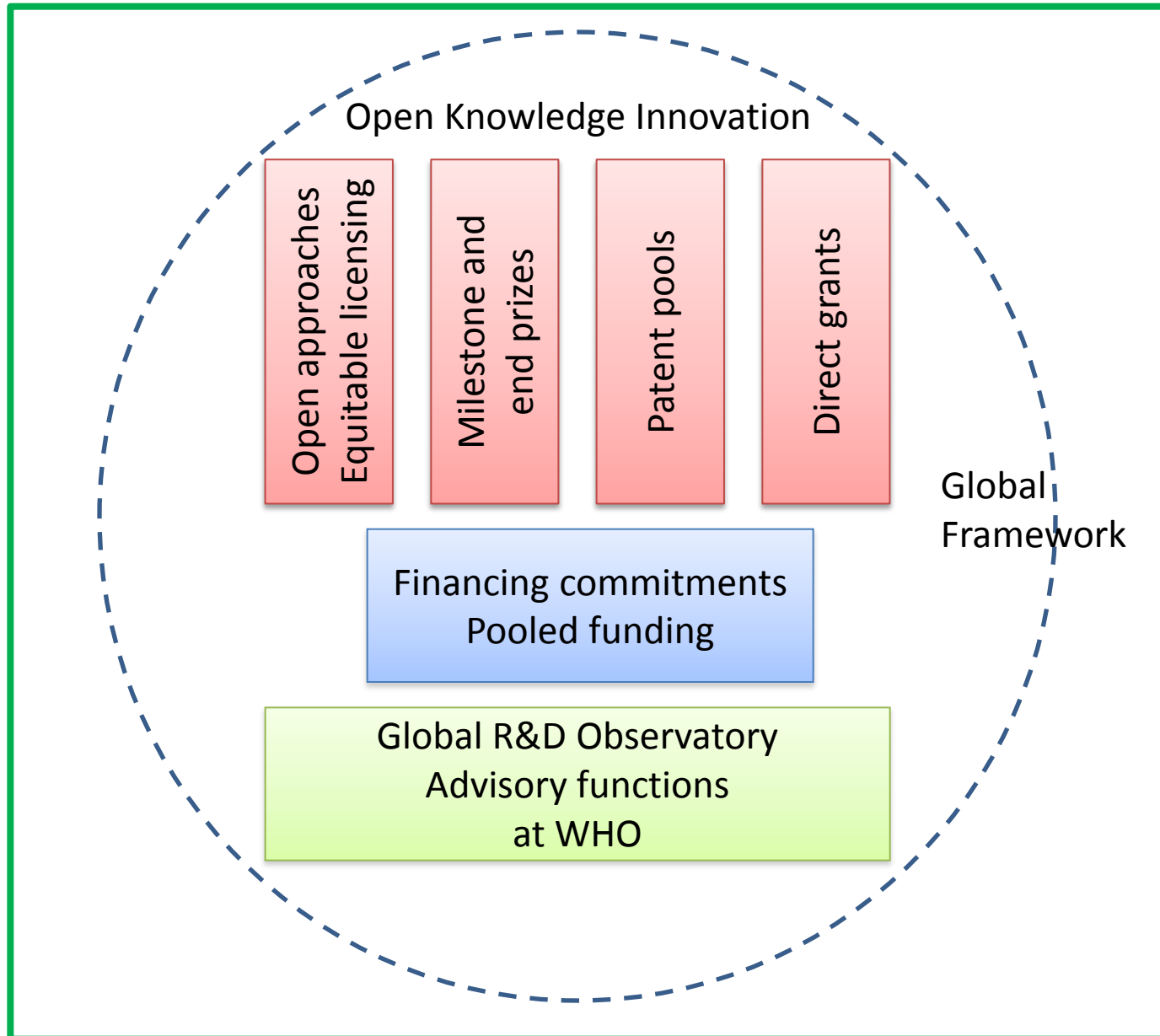


# Assessment of 15 grouped proposals

CEWG proposals assessment		
1	Global Framework on Research and Development	met criteria well
2	Direct grants to companies	met criteria well
3	Patent pools	met criteria well
4	Pooled funds	met criteria well
5	Open approaches to research and development and innovation	met criteria well
6	Milestone prizes and end prizes	met criteria well
7	Purchase or procurement agreements	met criteria less well
8	Priority review voucher	met criteria less well
9	Green intellectual property	met criteria less well
10	Health Impact Fund	met criteria less well
11	Orphan drug legislation	met criteria less well
12	Tax breaks for companies	met criteria less well
13	Transferable intellectual property rights	met criteria less well
14	Removal of data exclusivity	not relevant to CEWG's mandate
15	Regulatory harmonization	not relevant to CEWG's mandate

# Key recommendations

## Convention on Global Health R&D



# Proposals that could best promote health R&D

## "Open knowledge innovation"

- **Open approaches to research and development and innovation** which include precompetitive research and development platforms, open source and open access schemes;
- **Prizes**, in particular milestone prizes.
- **Equitable licensing and patent pools**, may facilitate access to research results on equitable terms and/or with low transaction costs

\* Open knowledge innovation can be defined as research and innovation that generate knowledge which is free to use without legal or contractual restrictions.

# TAX OPTIONS

## *National taxes*

- Ghana: 2.5% of Value Added Tax (VAT) goes to the National Health Insurance Scheme.
- Thailand : 2% surcharge on excise duty on alcohol and tobacco to fund health promotion.
- Chile: 1% of its VAT to fund health.
- Gabon: 1.5% levy on the post-tax profits of companies that handle remittances and a 10% tax on mobile phone operators to use for health care for low-income groups.
- Philippines: 2.5% of the tax on alcohol and tobacco products to fund universal coverage

# TAX OPTIONS

## *Taxes for global purposes*

- **Airline tax**- currently implemented by some countries led by France, represents 70% of UNITAID's financial base.
- **Financial transactions tax**- could yield between US\$ 9 billion in Europe alone, US\$ 48 billion in the G20, or very much more with wider scope and coverage. (*Gates W. Innovation with impact: financing 21<sup>st</sup> century development*)
- **Solidarity tobacco contribution**- could generate between US\$ 5.5 billion and US\$ 16.0 billion among the 43 "G20+" countries. (*The solidarity tobacco contribution. A new international health-financing concept prepared by the World Health Organization. WHO 2011*)



# Recommendations

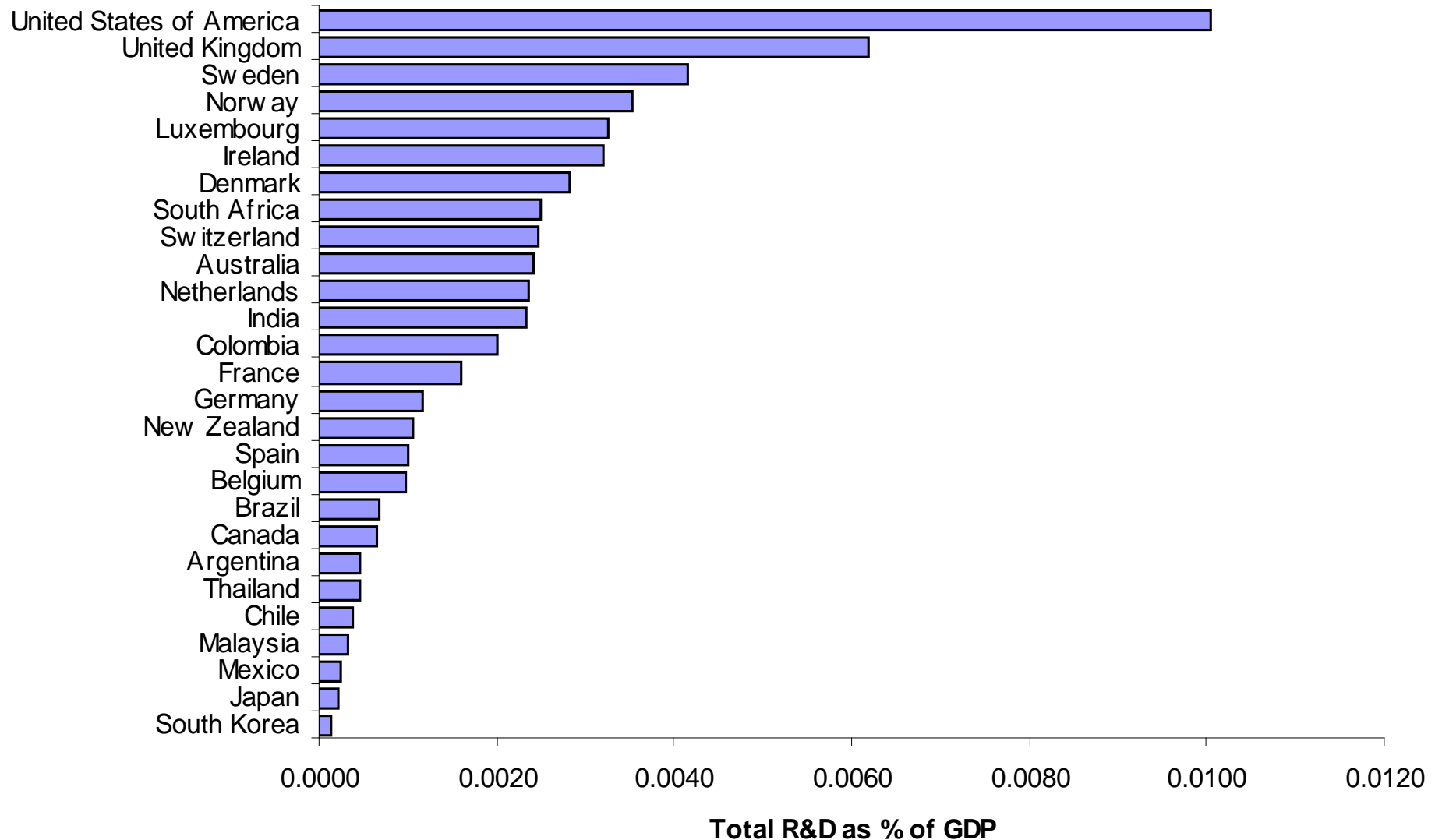
- *Traditional” financing mechanisms based on **direct or indirect taxation** are more likely to succeed than a complex landscape of uncoordinated voluntary or innovative initiatives.*
- *Countries should first consider **at national level** what tax options might be appropriate to them as a means of raising revenue to devote to health and health R&D.*

# Governments' Funding for R&D

- Most African countries do not meet the Abuja target for health spending of 15% of government expenditure and the 2% target for health research.
- 2.5% of development assistance for health is channelled to R&D, or 1.5% if we include both bilateral and multilateral assistance.
- Targets should be related to GDP since health-related public expenditure or development assistance are not accurate.
- Conservative target for total public sector R&D spending annually relevant to our mandate would be US\$ 6 billion, just 0.01% of global GDP.

# Public Funding for R&D

Public funding by GDP 2010



# Recommendations

- *All countries should commit to spend at least **0.01% of GDP** on government-funded R&D devoted to meeting the health needs of developing countries in relation to the types of R&D defined in our mandate.*
- ***20–50% of funds** raised for health R&D addressing the needs of developing countries should be channeled through a **pooled mechanism**.*

# Financial contributions for 0,01% target

	0.01% of GDP (mill USD)	20% pooled (mill USD)
EU	1,758	352
USA	1,509	302
BRICS	1,373	275
Others	2,326	465
<i><b>Total</b></i>	<i><b>6,966</b></i>	<i><b>1,393</b></i>

Source: World Economic Outlook Database April 2012 International Monetary Fund. Accessed on April 17, 2012



# Challenges for R&D coordination

- Need to review research capacity-building initiatives for coherence and effectiveness.
- Lack of standard mechanisms to record, classify and compare health research funding on a global basis.
- Lack of access to, and availability of information on, financing flows.
- Plethora of funders and research organizations, each taking decisions independently and with overlapping objectives but separate governance arrangements.
- Need to associate coordination with a **funding mechanism** (i.e. pooled funding) to increase effectiveness.

# Global Coordination - Recommendations

Building on existing financing and/or coordination institutions there is a need to strengthen global coordination through:

1) **A Global Health R&D Observatory.** This would need to collect and analyse data, including in the following areas:

- Financial flows to R&D
- The R&D pipeline
- Learning lessons.

2) **Advisory Mechanisms.**

- A Network of Research Institutions and Funders
- An Advisory Committee.

→ **WHO should play a central role in improving coordination and this should be considered as part of the WHO reform process.**

## V. A global binding instrument for Health R&D

- Need for a coherent **global framework** that combines the different elements and recommendations in a concerted mechanism.
- Conventions as a means by which countries enter into agreements with legal force to achieve common goals (i.e. WHO Framework Convention on Tobacco Control).
- Conventions can have funding provisions attached to them (i.e. Green Climate Fund).
- Propose an international **Convention on Global Health R&D** under Article 19:  
“The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. (...).”

# CEWG's Key Recommendations

- **Approaches to R&D:**
  - Open knowledge innovation: precompetitive research and development platforms, open source and open access schemes, and the utilization of prizes, in particular milestone prizes.
  - Equitable licensing and patent pools.
- **Funding mechanisms:**
  - All countries should commit to spend at least 0.01% of GDP on government-funded R&D devoted to meeting the health needs of developing countries in relation to product development.
- **Pooling resources:**
  - 20–50% of funds raised for health R&D addressing the needs of developing countries should be channeled through a pooled mechanism.
- **Binding global framework (convention)**

# What happened to the CEWG Recommendations

- **CEWG-Report was welcomed by the WHA (2012/2013)**
- **Proposals for Open knowledge innovation (e.g. Open access, equitable licensing supported) supported**
- **Coordination:**  
Establishment of a Global Health R&D Observatory and relevant advisory mechanisms under the auspices of WHO.
- **Demonstration projects proposed to test CEWG concept**
- **Binding global instrument (Convention) for R&D and innovation for health:**
  - **Rejected by many member states - Instead voluntary mechanism**
  - **Still door open for re-considering a treaty:**  
„to continue consultation, at national as well as at regional and global levels, including through the governing bodies of WHO, on specific aspects related to coordination, priority setting and financing of health research and development”



The next step:

# The WHO Demonstration Projects

## Criteria for selection:

- 1.Utilizes open knowledge innovation approaches.
- 2.Utilizes licensing approaches that secure access to your research outputs and final products.
- 3.Proposes and fosters financing mechanisms including innovative, sustainable and pooled funding.
- 4.Fosters effective and efficient coordination mechanisms amongst existing organizations/initiatives.
- 5.Strengthens capacity for research, development and production, including through technology transfer, in developing countries

The next step:

## **The 4 selected Demonstration Projects**

- 1. The Visceral Leishmaniasis (VL) Global R&D & Access Initiative - Drugs for Neglected Diseases initiative (DNDi), submitted via AFRO and EMRO.**
- 2. Exploiting the Pathogen Box: an international open source collaboration to accelerate drug development in addressing diseases of poverty – Medicines for Malaria Venture (MMV), submitted via EURO.**
- 3. Development of Class D Cpg Odn (D35) as an Adjunct to Chemotherapy for Cutaneous Leishmaniasis and Post Kala-Azar Dermal Leishmaniasis (Pkdl) - United States Food and Drug Administration (US FDA), et al., submitted via AMRO.**
- 4. Development for Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases - African Network for Drugs and Diagnostics Innovation (ANDI), et al., AFRO.**

# The example of the AfricanThe African Network for Drugs and Diagnostics Innovation (ANDI)

*"Creating a sustainable platform for R&D innovation in Africa  
to address Africa's own health needs"*

- Ownership of Scientists and African Governments
- Promotes regional collaboraration through hubs and African centers of excellence and involves diaspora
- Promotes technology transfer and South-South cooperation
- Hosted by UNECA
- Aims a developing a local funding base

# Pending Issues

- Funding and establishment of the Global WHO observatory?
- Funding of the demonstration projects?
- Mechanisms for „voluntary funding“ ???
- How to pursue the concept of binding treaty/convention ??

# Acknowledgement: Members and Chairs of the CEWG

1. Professor John Arne Røttingen ( <i>Chair</i> ) Norway	11. Dr Leizel Lagrada Philippine
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3. Professor Carlos Maria Correa Argentina	13. Dr Kovana Marcel Loua Guinea
4. Dr Pichet Durongkaveroj Thailand	14. Dr Hossein Malekafzali Islamic Republic of Iran
5. Professor Rajae El Aouad Berrada Morocco	15. Professor Bongani Mawethu Mayosi South Africa
6. Mr L. C. Goyal India	16. Dr Steven George Morgan Canada
7. Ms Hilda Harb Lebanon	17. Dr Samuel Ikwaras Okware Uganda
8. Professor Paul Linus Herrling Switzerland	18. Professor Jean de Dieu Marie Rakotomanga Madagascar
9. Professor Albrecht Jahn Germany	19. Professor Laksono Trisnantoro Indonesia
10. Dr Meri Tuulikki Koivusalo Finland	20. Mr Shozo Uemura Japan

# **Thank you for your attention!**

**For additional information see:**

**<http://www.who.int/phi/en/>**

**[http://www.who.int/phi/news/cewg\\_2011/en/index.html](http://www.who.int/phi/news/cewg_2011/en/index.html)**



# Principles of a global binding instrument

- Under the Auspices of WHO (Article 19).
- Delinking of price of product from the cost of production.
- Involvement of all governments in setting priorities, coordinating and funding R&D efforts.
- A fund to ensure the sustainable financing of all activities under the convention.
- A supplementary instrument to the IP system (Not a replacement).
- WHO Member States to decide on the institutional mechanism and *modus operandi* of the instrument.



# 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.**