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


Albrecht Jahn, Institut für Public Health, Universität Heidelberg
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

Underlying determinants: water, sanitation, food, nutrition, housing, healthy occupational and environmental conditions, education, information, etc.

Health-care

AAAQ: Availability, Accessibility, Acceptability, Quality

The International Covenant on Economic, Social and Cultural Rights:
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

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

Public health
innovation and intellectual property rights

Research and Development
Coordination and Financing

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

- Priority Reviews
- Standard Reviews
- Total Priority and Standard Reviews
- Total R&D
✓ 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.
• 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$)

<table>
<thead>
<tr>
<th>Disease</th>
<th>2010 (US$)</th>
<th>2010 (%)</th>
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<tbody>
<tr>
<td>HIV/AIDS</td>
<td>1 073 033 520</td>
<td>35.0</td>
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<tr>
<td>Tuberculosis</td>
<td>575,361,902</td>
<td>18.8</td>
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<tr>
<td>Malaria</td>
<td>547 042 394</td>
<td>17.9</td>
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<tr>
<td>Dengue</td>
<td>177 643 516</td>
<td>5.8</td>
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<tr>
<td>Diarrhoeal diseases</td>
<td>158 918 128</td>
<td>5.2</td>
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<tr>
<td>Kinetoplastids</td>
<td>147 867 513</td>
<td>4.8</td>
</tr>
<tr>
<td>Bacterial pneumonia &amp; meningitis</td>
<td>92 866 038</td>
<td>3.0</td>
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<tr>
<td>Helminth infections (worms &amp; flukes)</td>
<td>73 685 406</td>
<td>2.4</td>
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<tr>
<td>Salmonella infections</td>
<td>43 982 149</td>
<td>1.4</td>
</tr>
<tr>
<td>Leprosy</td>
<td>8 840 532</td>
<td>0.3</td>
</tr>
<tr>
<td>Buruli ulcer</td>
<td>5 456 026</td>
<td>0.2</td>
</tr>
<tr>
<td>Trachoma</td>
<td>4 507 718</td>
<td>0.1</td>
</tr>
<tr>
<td>Rheumatic fever</td>
<td>1 736 877</td>
<td>0.1</td>
</tr>
<tr>
<td>Platform technologies</td>
<td>27 358 501</td>
<td>0.9</td>
</tr>
<tr>
<td>Core funding of a multi-disease R&amp;D organization</td>
<td>76 884 279</td>
<td>2.5</td>
</tr>
<tr>
<td>Unspecified disease</td>
<td>47 485 474</td>
<td>1.6</td>
</tr>
<tr>
<td>Disease total</td>
<td>3 062 669 973</td>
<td>100.0</td>
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</tbody>
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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
<table>
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<tr>
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<th>CEWG proposals assessment</th>
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<tbody>
<tr>
<td>1</td>
<td>Global Framework on Research and Development</td>
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<tr>
<td>2</td>
<td>Direct grants to companies</td>
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<tr>
<td>3</td>
<td>Patent pools</td>
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<td>4</td>
<td>Pooled funds</td>
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<tr>
<td>5</td>
<td>Open approaches to research and development and innovation</td>
</tr>
<tr>
<td>6</td>
<td>Milestone prizes and end prizes</td>
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<td>7</td>
<td>Purchase or procurement agreements</td>
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<td>8</td>
<td>Priority review voucher</td>
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<td>Green intellectual property</td>
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<td>10</td>
<td>Health Impact Fund</td>
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<td>11</td>
<td>Orphan drug legislation</td>
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<td>12</td>
<td>Tax breaks for companies</td>
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<td>13</td>
<td>Transferable intellectual property rights</td>
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<td>14</td>
<td>Removal of data exclusivity</td>
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<td>15</td>
<td>Regulatory harmonization</td>
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<td>Assessment of 15 grouped proposals</td>
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</table>
Key recommendations

Open Knowledge Innovation

- 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 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.*
• 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.
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 21st 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)
• 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.
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.
• 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

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<th>0.01% of GDP (mill USD)</th>
<th>20% pooled (mill USD)</th>
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<tbody>
<tr>
<td>EU</td>
<td>1,758</td>
<td>352</td>
</tr>
<tr>
<td>USA</td>
<td>1,509</td>
<td>302</td>
</tr>
<tr>
<td>BRICS</td>
<td>1,373</td>
<td>275</td>
</tr>
<tr>
<td>Others</td>
<td>2,326</td>
<td>465</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>6,966</strong></td>
<td><strong>1,393</strong></td>
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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 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 collaboration through hubs and African centers of excellence and involves diaspora
• Promotes technology transfer and South-South cooperation
• Hosted by UNECA
• Aims at developing a local funding base
• 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

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<th>No.</th>
<th>Name</th>
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<tr>
<td>1.</td>
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<td>8.</td>
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<td>19.</td>
<td>Professor Laksono Trisnantoro</td>
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<td>20.</td>
<td>Mr Shozo Uemura</td>
<td>Japan</td>
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Thank you for your attention!

For additional information see:

http://www.who.int/phi/en/

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.