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


Briefing to Representatives of Permanent Missions in Geneva

Geneva
27 April 2012
The Context

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

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Public health innovation and intellectual property rights

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
a) take forward the work of the Expert Working Group;

b) deepen the analysis of the proposals in the Expert Working Group’s report, and in particular:

i. examine the practical details of the four innovative sources of financing proposed by the Expert Working Group in its report;

ii. review the five promising proposals identified by the Expert Working Group in its report; and

iii. further explore the six proposals that did not meet the criteria applied by the Expert Working Group;

c) consider additional submissions and proposals from Member States, any regional and subregional consultations, and from other stakeholders.
Guidance from WHA 63.28

• 2.2.e: CEWG shall…observe **scientific integrity** and be free from conflict of interest in its work;

• 5: to put particular emphasis on the **transparent management of potential conflicts of interest** by ensuring full compliance with the mechanisms established by the Director-General for that;

• 6: to ensure **full transparency for Member States** by providing the Consultative Expert Working Group’s regular updates on the implementation of its work-plan, and by making available all the documentation used by the Consultative Expert Working Group at the conclusion of the process;

• 7: to submit the work-plan and inception report of the Consultative Expert Working Group to the Executive Board at its 129th session and a progress report to the Executive Board at its 130th session with a view to **submitting the final report to the Sixty-fifth World Health Assembly**.
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.
# Members of the CEWG

**Designated by governments and appointed by the Director General of WHO**

<table>
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<tr>
<th></th>
<th>Name</th>
<th>Country</th>
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<tbody>
<tr>
<td>1</td>
<td>Professor John Arne Røttingen</td>
<td>(Chair) Norway</td>
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<tr>
<td>2</td>
<td>Professor Claudia Inês Chamas</td>
<td>(Vice Chair) Brazil</td>
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<tr>
<td>3</td>
<td>Professor Carlos Maria Correa</td>
<td>Argentina</td>
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<tr>
<td>4</td>
<td>Dr Pichet Durongkaveroj</td>
<td>Thailand</td>
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<td>5</td>
<td>Professor Rajae El Aouad Berrada</td>
<td>Morocco</td>
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<tr>
<td>6</td>
<td>Mr L. C. Goyal</td>
<td>India</td>
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<tr>
<td>7</td>
<td>Ms Hilda Harb</td>
<td>Lebanon</td>
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<tr>
<td>8</td>
<td>Professor Paul Linus Herrling</td>
<td>Switzerland</td>
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<tr>
<td>9</td>
<td>Professor Albrecht Jahn</td>
<td>Germany</td>
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<tr>
<td>10</td>
<td>Dr Meri Tuulikki Koivusalo</td>
<td>Finland</td>
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<tr>
<td>11</td>
<td>Dr Leizel Lagrada</td>
<td>Philippine</td>
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<tr>
<td>12</td>
<td>Professor Peilong Liu</td>
<td>China</td>
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<tr>
<td>13</td>
<td>Dr Kovana Marcel Loua</td>
<td>Guinea</td>
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<td>14</td>
<td>Dr Hossein Malekafzali</td>
<td>Islamic Republic of Iran</td>
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<tr>
<td>15</td>
<td>Professor Bongani Mawethu Mayosi</td>
<td>South Africa</td>
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<tr>
<td>16</td>
<td>Dr Steven George Morgan</td>
<td>Canada</td>
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<tr>
<td>17</td>
<td>Dr Samuel Ikwaras Okware</td>
<td>Uganda</td>
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<tr>
<td>18</td>
<td>Professor Jean de Dieu Marie Rakotomanga</td>
<td>Madagascar</td>
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<tr>
<td>19</td>
<td>Professor Laksono Trisnantoro</td>
<td>Indonesia</td>
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<tr>
<td>20</td>
<td>Mr Shozo Uemura</td>
<td>Japan</td>
</tr>
<tr>
<td>21</td>
<td>Dr Christy Hanson</td>
<td>United States of America (withdrew)</td>
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</tbody>
</table>
Process: CEWG meetings:


2. Geneva, 7 and 8 July 2011;


4. Conference call, 23 February 2012;


• Sub-committee of chair, vice-chair and 4 rapporteurs together representing all regions met in Oslo in September 2011.
• Open briefing sessions were held at the end on each meeting.

All relevant documents were made public on WHO/PHI web site at: http://www.who.int/phi/news/cewg_2011/en/index.html
In accordance with WHA63.28, regional consultations were held in order to examine the appropriateness of different R&D financing approaches and the feasibility of implementing these approaches in each of the 6 WHO regions.

1. **AFRO** (27 August 2011);

2. **SEARO** (7 October 2011);

3. **WPRO** (13 October 2011);

4. **PAHO** (informal briefing, conference call, 7 November 2011);

5. **EURO** (3–6 October 2011)- special session during the 7th European Congress on Tropical Medicine & International Health;

6. **EMRO** could not take place due to the unavailability of Regional members on the proposed dates.
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.
**Trends in R&D**

- Fall in the approval of new drugs while investment in R&D has increased.

- Top-selling medicines going out of patent but are not replaced by new patented products with comparable commercial prospects.

- Return from new drugs has declined.

- Spate of mergers and acquisitions resulting in a decline of the number of traditional PhRMA companies researching any particular area.

- Greater focus on emerging markets which offer opportunities for rapid growth.

- Increased attention to new approaches to R&D: i.e. “open innovation”, product development partnerships (PDPs).
Number of new drug approvals and R&D expenditures (as reported by PhRMA) (US$ billions) in the 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.  

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.  
*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 countries (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
Progress in product development for Type II and Type III diseases

• **16 out of 1393** new medicines for neglected diseases 1975-2000.

• **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.
II. Proposals Assessment Process

• Assessment of the 109 proposals - reduced to 91 proposals and grouped under 22 proposals- examined by the EWG.

• Assessment of 22 new submissions reduced to 15 (5 outside the mandate and 2 unsuccessfully supported).

• All proposals regrouped in 15 groups.
Criteria for proposals' evaluation

- **Public health impact**: potential health impact in developing countries – but little evidence relating to new proposals or even existing ones.

- **Efficiency/cost-effectiveness**: An assessment of the cost of implementation in relation to potential benefits.

- **Technical feasibility**: The ease with which the proposal can be implemented from a technical point of view – from relatively automatic rule-based systems to proposals that involve a degree of complexity in their start-up and in their operation.

- **Financial feasibility**: An assessment of the direct costs (normally to government) of the scheme, and also indirect costs or savings imposed on others such as patients (e.g. as a result of changing exclusivity arrangements).

- **Intellectual property**: How far the use of intellectual property in a proposal will promote innovation and enhance access.

- **Delinking**: The extent to which product pricing and the financing of R&D are determined independently.

- **Access**: Whether the proposal has an element which promotes access, including the potential for lower prices as well as measures to promote effective demand for needed products.

- **Governance and accountability**: The extent to which governance arrangements are adequately transparent and accountable, and their complexity. This is often difficult to assess because schemes vary widely in their governance arrangements or they are ill-defined in new proposals.

- **Capacity-building**: How far the proposal is aimed at promoting technology transfer and capacity-building in R&D in developing countries.
# Assessment of 15 grouped proposals

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<tr>
<th>#</th>
<th>Proposal</th>
<th>Assessment</th>
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<tbody>
<tr>
<td>1</td>
<td>Global Framework on Research and Development</td>
<td>met criteria well</td>
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<tr>
<td>2</td>
<td>Direct grants to companies</td>
<td>met criteria well</td>
</tr>
<tr>
<td>3</td>
<td>Patent pools</td>
<td>met criteria well</td>
</tr>
<tr>
<td>4</td>
<td>Pooled funds</td>
<td>met criteria well</td>
</tr>
<tr>
<td>5</td>
<td>Open approaches to research and development</td>
<td>met criteria well</td>
</tr>
<tr>
<td></td>
<td>and innovation</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Milestone prizes and end prizes</td>
<td>met criteria well</td>
</tr>
<tr>
<td>7</td>
<td>Purchase or procurement agreements</td>
<td>met criteria less well</td>
</tr>
<tr>
<td>8</td>
<td>Priority review voucher</td>
<td>met criteria less well</td>
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<tr>
<td>9</td>
<td>Green intellectual property</td>
<td>met criteria less well</td>
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<tr>
<td>10</td>
<td>Health Impact Fund</td>
<td>met criteria less well</td>
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<td>11</td>
<td>Orphan drug legislation</td>
<td>met criteria less well</td>
</tr>
<tr>
<td>12</td>
<td>Tax breaks for companies</td>
<td>met criteria less well</td>
</tr>
<tr>
<td>13</td>
<td>Transferable intellectual property rights</td>
<td>met criteria less well</td>
</tr>
<tr>
<td>14</td>
<td>Removal of data exclusivity</td>
<td>not relevant to CEWG's mandate</td>
</tr>
<tr>
<td>15</td>
<td>Regulatory harmonization</td>
<td>not relevant to CEWG's mandate</td>
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</tbody>
</table>
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.
III. 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 and the disease prevention programme.
• **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)*
Financing: 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.

• No countries have met the 2% target for health research.

• Developed countries, on average, meet or exceed both these targets and spend around 0.15% of GDP on health research. In 2008 OECD countries spent on average about 2.3% of GDP on R&D in total in the public and private sectors but there is a wide variation around this figure.

• 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 relevant to our mandate would be US$ 6 billion annually, 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.

• Developing countries with a potential research capacity should aim to commit 0.05-0.1% of GDP for health research of all kinds.

• Developed countries should aim to commit 0.15-0.2% of GDP to government-funded health research of all kinds.

• 20–50% of funds raised for health R&D addressing the needs of developing countries should be channeled through a pooled mechanism.
IV. Global Coordination: Existing mechanisms

- **Council on Health Research and Development (COHRED)** - support to countries and capacity-building in research.

- **Global Forum for Heath Research (GFHR)** - annual forum, monitoring financial flows on health research and analytical work. In 2010 GFHR merged with COHRED.

- **Advisory Committee on Health Research**: focus on research-related activities associated with WHO programmes.

- **Special Programme for Research and Training in Tropical Diseases (TDR and Initiatives i.e. ANDI and ESSENCE)**. Strengthen research capacity, build research networks, harmonize donor practices and promote coordination.

- **WHO International Clinical Trials Registry**: better availability and more structured information on clinical trials.

- **WHO research strategy**: “management and organization of research activities within WHO”.

- **Other initiatives** (IPPPH; IFORD; EDCTP).
Challenges for 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.
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** that may include specialized sections according to the subject of research, e.g. type of disease, based on an electronic platform supported by WHO, and which may provide inputs to the advisory committee
   - **An Advisory Committee.** This could be based on the current ACHR and also the ACHRs of the WHO regions, with suitably revised terms of reference and ways of operation. Sub-committees could be established to tackle specific topics and facilitate regional inputs.

→ **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. Global Environment Facility (GEF) is the financing mechanism for four international treaties, including the UNFCCC; examples of funds include Multilateral Fund and Green Climate Fund).

→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. (...).
Principles of a global binding instrument

• Under the Auspices of WHO (Article 19).

• Delinking of the cost of R&D and the price of the product.

• Involvement of all governments in setting priorities, coordinating and funding R&D efforts.

• A funding mechanism to ensure the sustainable financing of all activities under the convention.

• A supplementary instrument to the IPR based incentive 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.
Financing mechanisms

- All countries should aim to achieve specified levels of public funding on health R&D relevant to the needs of developing countries.

- A financing mechanism should be established under the convention based on contributions by governments.

- Financing mechanisms need to be supportive to the broader context of overall allocation of public financing to health research.

- The convention should define which research entities should be eligible for funding.

- Funding should be directed so as to promote cost-effective R&D.

- Funding should promote capacity building and technology transfer to the public and private sectors in developing countries.
A coordination mechanism to promote the objectives in Element 2.3 of the GSPA-PHI - “improving cooperation, participation and coordination of health and biomedical research and development”.

It should improve the measurement of the volume, type and distribution of relevant R&D and the evaluation of R&D outcomes, in particular so that progress against commitments and compliance could be measured.

Compliance mechanisms, including through cooperation of the parties to the convention.
Next Steps

• The WHA should consider establishing a working group or technical committee composed of two Member States from each WHO region to undertake preparatory work on the elements of a draft agreement.

• It should also provide for the establishment of an intergovernmental negotiating body open to all Member States, to be established under Rule 40 to draft and negotiate the proposed R&D agreement following on from the report of the proposed working group.

• WHO would need to provide appropriate resources to support the working group or technical committee.
CEWG's Key Recommendations

• **Principles:**
  – Affordable products can best be achieved through free open market competition.
  – Requires delinking of R&D costs and prices of products.

• **Approaches to R&D:**
  – More efficient and collaborative through sharing of results.
  – *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.

• **Financing mechanisms:**
  – Need to double existing public investments to $6 billion annually.
  – 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 to improve efficiency and coordination.
CEWG's Key Recommendations

• **Funding allocation:**
  – Should require appropriate open licensing or use of public domain, whether through conditional grants or prizes.

• **Strengthening research and development capacity and technology transfer:**
  – Address the capacity needs of academic and public research organizations in developing countries
  – Utilize direct grants to companies in developing countries.

• **Coordination:**
  – Establish a Global Health R&D Observatory and relevant advisory mechanisms under the auspices of WHO.

• **Implementation through a binding global instrument for R&D and innovation for health:**
  – Formal negotiations on an International Convention on Global Health R&D should be initiated.
  – A convention will be complementary to the current IPR based incentive system.
  – First instrument to regulate production of global public goods within health.
Thank you for your attention!

For additional information see:

http://www.who.int/phi/en/
Backup Slides
## Top Neglected Disease Funders 2010
(2007 $US)

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<tr>
<th>Funder</th>
<th>2010 ($US)</th>
<th>2010 (%)</th>
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<tr>
<td>US National Institutes of Health (NIH)</td>
<td>1,211,704,054</td>
<td>39.6</td>
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<tr>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>455,832,350</td>
<td>14.9</td>
</tr>
<tr>
<td>Aggregate pharmaceutical and biotechnology companies^A</td>
<td>503,525,794</td>
<td>16.4</td>
</tr>
<tr>
<td>European Commission</td>
<td>92,529,756</td>
<td>3.0</td>
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<tr>
<td>US Department of Defence (DOD)</td>
<td>69,942,925</td>
<td>2.3</td>
</tr>
<tr>
<td>United States Agency for International Development (USAID)</td>
<td>85,975,465</td>
<td>2.8</td>
</tr>
<tr>
<td>UK Department for International Development (DFID)</td>
<td>97,229,720</td>
<td>3.2</td>
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<tr>
<td>Wellcome Trust</td>
<td>80,459,662</td>
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<tr>
<td>UK Medical Research Council (MRC)</td>
<td>60,857,019</td>
<td>2.0</td>
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<tr>
<td>Dutch Ministry of Foreign Affairs</td>
<td>-</td>
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<tr>
<td>Inserm-Institute of Infectious Diseases</td>
<td>20,196,417</td>
<td>0.7</td>
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<tr>
<td>Institut Pasteur</td>
<td>45,158,519</td>
<td>1.5</td>
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<tr>
<td>Australian NHMRC</td>
<td>19,464,047</td>
<td>0.6</td>
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<tr>
<td><strong>Subtotal top 12 funders</strong></td>
<td><strong>2,742,875,728</strong></td>
<td><strong>89.6</strong></td>
</tr>
<tr>
<td><strong>Total R&amp;D funding</strong></td>
<td><strong>3,062,669,973</strong></td>
<td><strong>100</strong></td>
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Source: G-Finder Report 2011
### Top product development partnership funders, 2010 (2007 US$)

<table>
<thead>
<tr>
<th>Funder</th>
<th>To PDPs 2010 (US$)</th>
<th>Proportion of total spending by funder (%)</th>
<th>Share of total PDP funding 2010 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>253 755 901</td>
<td>55.7</td>
<td>52.5</td>
</tr>
<tr>
<td>United Kingdom Department for International Development (DFID)</td>
<td>97 229 720</td>
<td>100.00</td>
<td>20.1</td>
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<tr>
<td>United States Agency for International Development (USAID)</td>
<td>40 243 034</td>
<td>46.8</td>
<td>8.3</td>
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<tr>
<td>Dutch Netherlands Ministry of Foreign Affairs</td>
<td>15 833 146</td>
<td>92.1</td>
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<tr>
<td>Royal Norwegian Ministry of Foreign Affairs</td>
<td>9 047 299</td>
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<tr>
<td>European Commission</td>
<td>7 914 688</td>
<td>8.6</td>
<td>1.6</td>
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<tr>
<td>Spanish Ministry of Foreign Affairs and Cooperation for Development (MAEC)</td>
<td>7 159 668</td>
<td>100.00</td>
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<td>Irish Aid</td>
<td>6 508 789</td>
<td>99.7</td>
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<td>Médecins Sans Frontières (MSF)</td>
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<td>Swedish International Development Agency (SIDA)</td>
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<tr>
<td>World Bank</td>
<td>2 757 154</td>
<td>100.00</td>
<td>0.6</td>
</tr>
<tr>
<td>Subtotal top 12 PDPs funder*</td>
<td>453 170 675</td>
<td>56.9</td>
<td>93.8</td>
</tr>
<tr>
<td>Total PDP funding</td>
<td>483 166 820</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of total PDP funding (top 12)</td>
<td>93.8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: G-Finder Report, 2011
### Total R&D funding by disease, 2010 (2007 US$)

<table>
<thead>
<tr>
<th>Disease</th>
<th>2010 (US$)</th>
<th>2010 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td>1 073 033 520</td>
<td>35.0</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>575,361,902</td>
<td>18.8</td>
</tr>
<tr>
<td>Malaria</td>
<td>547 042 394</td>
<td>17.9</td>
</tr>
<tr>
<td>Dengue</td>
<td>177 643 516</td>
<td>5.8</td>
</tr>
<tr>
<td>Diarrhoeal diseases</td>
<td>158 918 128</td>
<td>5.2</td>
</tr>
<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>
</tr>
<tr>
<td>Helminth infections (worms &amp; flukes)</td>
<td>73 685 406</td>
<td>2.4</td>
</tr>
<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>
</tr>
</tbody>
</table>

Source: G-Finder Report, 2011
Innovative Financing Sources
1. A new indirect tax
2. Voluntary contributions from businesses and consumers
3. Taxation of repatriated pharmaceutical industry profits
4. New donor funds for health research and development

Promising Proposals
1. Open source
2. Patent pools
3. Health impact fund
4. Priority review voucher
5. Orphan product legislation

Further Proposals
1. Transferable intellectual property rights
2. Green intellectual property
3. Removal of data exclusivity
4. Biomedical R&D treaty
5. Large end-stage prizes
6. Neglected disease tax breaks for companies.
5 proposals relating to funding allocation:
1. Product development partnerships
2. Direct grants to small companies and for trials in developing countries
3. “Milestone” prizes
4. “End” prizes (cash)
5. Purchase or procurement agreements

2 proposals to improve efficiency:
1. Regulatory harmonization
2. Precompetitive research and development platforms
Proposals submitted to the CEWG
directly related to the EWG

1. Innovation inducement prizes.

2. A global framework on health research and development.

3. Consideration of an essential health and biomedical R&D treaty.

4. Submission to the CEWG.

5. Investing in Small- and Medium Sized Enterprises in Innovative Developing Countries.

6. International Fund for Innovation (IFI) ("Green intellectual property").

7. Fund for research and development in neglected diseases.

8. A milestone-based prize to stimulate R&D for point-of-care fever diagnostics.


10. A new incentive system for technological innovation in developing countries (ISTI).

11. Submission to the CEWG.


13. Financing & incentives for neglected disease R&D.
14. Equitable licensing/med4all.
15. The ANDI model. African Network for Drugs and Diagnostics Innovation (ANDI).
16. Open source software for improving maternal, neonatal and child health services in Pakistan.
18. Employees' food safety knowledge and practices in foodservice operations serving high risk populations.
19. Limbal stem cell bioengineering.
21. Optimal hedging against the premature obsolescence of available treatments.
22. Reduction of patents' duration to prevent collusion at industry level.
III. Global Financing of Health R&D

Analysed in the EWG Report:

- **New donor funds for health research and development** - from new or existing providers of development assistance.

- **Taxation of repatriated pharmaceutical industry profits** - proposal from Brazil to tax pharmaceutical industry profits.

- **Voluntary contributions from businesses and consumers** - i.e. airline ticket purchases, lotteries, project RED, mobile phone usage.

- **A new indirect tax** - such as tobacco, alcohol, the arms trade, airline travel, Internet traffic or financial transactions.
(1) Neglected disease tax breaks for companies

**Key Concept:**
- This proposal is a provision in tax laws allowing companies to set expenditures on R & D for neglected diseases against their tax liabilities.
- The proposal may be classified as allocation type.

**Assessment by the CEWG:**
- The proposal is not considered appropriate as a global solution, since tax breaks scheme is essentially of national nature.
- Even as a national scheme, it does not necessarily stimulate industry to work on neglected diseases.
- The proposal is thus not considered meeting most of the criteria set by the CEWG and not recommendable as a solution.

**Relevance to AFRICAN Region:**
- For individual countries to consider.
(2) Removal of data exclusivity

Key Concept:
— Data exclusivity means that for a period of several years from the date an originator non-biological product is approved for marketing, no other company may seek regulatory approval of an equivalent product based on data submitted by the originator company without the latter’s approval.
— The effect of data exclusivity is to prevent, for a period of time, the entry of generic competition, even if the originator product is not protected by a valid patent.
— Removal of data exclusivity addresses IP management issues by removing one form of IP protection and promoting earlier generic competition.

Assessment by the CEWG:
— The CEWG considered that there was no evidence that data exclusivity contributed to innovation related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases.
— Its implementation would adversely affect access to medicines through increasing prices.

Relevance to AFRICAN Region:
— No reason to introduce data exclusivity in countries where it does not exist.
Key Concept:
– The proposal for Green Intellectual Property proposes in principle to introduce charges for patenting and a 10% premium for profits gained from patents so as to fund access to products and support R&D.

Assessment by the CEWG:
– While the proposal would address some of the criteria of assessment of the proposal, it does not adequately address all of these.
– It could end up in further legitimising higher prices for products on ordinary markets, while promising to address problems for those in need.

Relevance to AFRICAN Region:
– Caution is indicated.
(4) Health Impact Fund

Key Concept:
— All pharmaceutical firms worldwide would have the option of registering new medicines with the HIF. By registering, a firm agrees to provide its medicine at a price near the cost of production anywhere it is needed. In exchange, they will be paid by the Fund annually for ten years based on the HIF’s assessment of the actual global health impact of the medicine as a proportion of the global health impact achieved by all products registered with the HIF.
— HIF say it is designed to bridge an access-to-medicine gap created by the current system of medical research and development.

Assessment by the CEWG:
— The CEWG considered that the ideas underpinning the HIF were of interest and that it addressed many of its criteria., but issues of assessment of health impact in developing countries and governance need to be clarified.

Relevance to AFRICAN Region:
— HIF is designed to bridge an access-to-medicine gap created by the current system of medical research and development, and therefore relevant to Africa.
(5) Orphan drug legislation

Key Concept:

– An orphan drug is a pharmaceutical agent that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease.

– The assignment of orphan status to a disease and to any drugs developed to treat it is a matter of public policy in many countries, and has resulted in medical breakthroughs that may not have otherwise been achieved due to the economics of drug research and development.

– In the US and EU it is easier to gain marketing approval for an orphan drug, and there may be other financial incentives such as extended exclusivity periods.

Assessment by the CEWG:

– Market exclusivity which often leads to high prices

– Does not meet most criteria for the CEWG

Relevance to AFRICAN Region:

– For individual countries to consider.
(6) Priority review voucher

Key Concept:
— In the US scheme, those who obtain marketing approval from the Food and Drug Administration (FDA) for a product to treat or prevent one of 16 neglected tropical diseases are entitled to receive a priority review voucher (PRV) which entitles the bearer to receive priority review of another product that would not otherwise qualify for priority review.
— By this means a company could advance the approval of a potentially “blockbuster” product with correspondingly increased revenues during the lifecycle of the product (i.e. until patent expiry).
— The PRV can be used by the recipient or sold to another company.

Assessment by the CEWG:
— The CEWG did not consider that the PRV met many of its criteria
— It does not address IP management (prolongs patents), it does not delink prices from the cost of research and development, it does not improve availability in developing countries, and has no impact on capacity building or technology transfer to developing countries.

Relevance to AFRICAN Region:
— Limited.
Key Concept:
– The idea is that a reward would be offered to companies which developed a product to fight neglected diseases in the form of an extension of market exclusivity which could be used on another top selling product.
– Such a reward would be tradable and thus potentially monetisable.
– Unlike PRV, which is intended to accelerate introduction of products onto the developed country market, TIPR will work by extending market exclusivity for top selling products in developed country markets.
– This will delay the time at which generic companies can enter the market and increase healthcare costs accordingly.

Assessment by the CEWG:
– The CEWG did not consider the TIPR proposal met many of its criteria, for similar reasons to the Priority Review Voucher.

Relevance to AFRICAN Region:
– Limited.
Key Concept:
– In 2008, UNITAID began to investigate the creation of a "patent pool" to hold patents of AIDS drugs so that they could be manufactured cheaply for use in developing countries. The creation of such a pool was authorized by UNITAID's board in December 2009, and the pool opened for business in October 2010 as a Swiss foundation. The Patent Pool proposed by UNITAID is a PH version. Its main objectives are: (1) To accelerate the availability of generic version of new ARVs in developing countries so as to bring down the price of these drugs; (2) To stimulate the development and production of needed formulations, of which the patents are owned by different holders; and (3) To facilitate the development and production of adapted formulations of HIV drugs such as pediatric and heat-stable formulation;

Assessment by the CEWG:
– These objectives are achieved by receiving different related patents that the patent holders supply voluntarily to the Pool. Developing countries based manufacturers may obtain a license of any patent in the pool against negotiated royalties and use it to develop new or produce cheaper products.

Relevance to AFRICAN Region:
– This is an allocation mechanism that is relevant to the African region.
(9) Open Source

**Key Concept:**

– Open source promotes collaboration of independent researchers to contribute voluntarily to a research project.

– In addition, this mechanism reduces research costs by tapping volunteer researchers and by sharing the research outputs available in public domain.

– Open source is more consistent with coordination than financing as it prevents unnecessary duplication of efforts and funding in doing research.

**Assessment by the CEWG:**

– Open source principles as mandatory condition for awarding research grants provided by international funders, particularly diseases that affect the developing countries.

**Relevance to AFRICAN Region:**

– As a mechanism for coordination and improving access to health research.
(10) Pooled Funding

**Key Concept:**
- The proposals on pooling of funds under Product Development Partnerships.

**Assessment by the CEWG:**
- There is no assurance that sustained level of financing for R&D can be maintained once a time-bound agreement to pool funds expires.
- Governance structure to prevent conflict of interest by those who are managing the pooled funds is an issue, and accountability in a sustained set-up has yet to be demonstrated.

**Relevance to AFRICAN Region:**
- For discussion.
(11) Grants

**Key Concept:**
- Schemes to provide seed funding to small and medium sized enterprises to bring a potential new medicine through Phase 1 trials, at which stage it may be possible to attract commercial funding in one form or another.

**Assessment by the CEWG:**
- The potential public health impact of these schemes would depend on how they are formulated (e.g. they could specify disease areas, priority health needs and/or affordability criteria), their success in stimulating new product development and the extent to which there are reliable plans to promote access to new products in developing countries.

**Relevance to AFRICAN Region:**
- They are worth of further consideration in the African region.
(12) Prizes

**Key Concept:**
- Prizes are rewards for successful completion of a specified set of R&D objectives.
- There are basically two kinds of prizes – for reaching specified milestones in the R&D process, or for reaching a specified endpoint such as a new diagnostic, vaccine or medicine with a specified profile in terms of performance, cost, efficacy and/or other important characteristics.
- The CEWG considered that they should have as a central purpose delinking the costs of R&D from product prices in order to promote access to products.

**Assessment by the CEWG:**
- The CEWG considered that a number of prize proposals could meet many of its criteria, in particular milestone prizes.

**Relevance to AFRICAN Region:**
- For consideration.
Key Concept:
– Purchase or procurement agreements are contracts between a purchaser, normally a government or an international financing agency, and suppliers which involve some form of guarantee as regards price and/or volume.
– One variant of such an agreement is the Advanced Market Commitment (AMC) which seeks to promote research and development and accelerated introduction into developing countries by offering an enhanced price to suppliers if they offer a product which meets a particular specification in terms of its public health impact.

Assessment by the CEWG:
– The CEWG considered that normal procurement agreements, although they might have some incentive effect in relation to R&D, were outside its mandate and in any case met few criteria.
– As regards AMCs they were not convinced that experience to date had demonstrated their value.

Relevance to African Region:
– For discussion.
(14) Regulatory Harmonisation

**Key Concept:**
- A large proportion of the cost of developing and marketing new products in the developed world is to meet the costs of clinical trials required by regulatory authorities to establish that the product is safe, effective and of high quality. Costs can be increased further when different countries have different regulatory requirements, each requiring its own set of information as the basis for national approval and use.
- The aim of regulatory harmonization is to improve this situation, by aligning the requirements of a number of developing countries

**Assessment by the CEWG:**
- Improved regulation and harmonisation might improve access to medicines though quicker availability of new products needed by patients but it was not clear that any cost savings generated by companies through more efficient regulation would necessarily be passed on to patients.

**Relevance to AFRICAN Region:**
- For discussion.
Key Concept:

- Policy makers need a new framework that has the flexibility to promote both innovation and access, and which is consistent with efforts to protect consumers and control costs.
- Similarly, the WHO Global Strategy and Plan of Action noted the need for Member States to consider establishing a Medical R&D Treaty.

Assessment by the CEWG:

- The proposals/submissions envisage raising of a global health research fund by way of earmarked sources of funding such as air travel tax., setting up of a transparent participative and effective governance structure for needs assessment of R&D gaps, priority setting and allocation of funds for enhanced R&D efforts for conditions prevalent in developing countries.
- The proposals/submissions meet almost all of the elements of the criteria that CEWG had set for itself for analysis of such proposals.

Relevance to AFRICAN Region:

- Worthy of serious consideration in this meeting.