CEWG Report: What next

Global Health Policy Forum

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DG DEVCO
European Commission
Brussels

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Department of Public Health, Innovation and Intellectual Property



Resolution WHA56.27

Resolution WHA59.24

Intellectual property rights, innovation and public health

Public Health, innovation, essential health research an intellectual property rights: towards a global strategy and plan of action

Commission on Public Health, Innovation and Intellectual Property Rights

Intergovernmental Working Group

Public health

innovation and intellectual property rights

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WHA 61.21

REQUEST THE DIRECTOR GENERAL

(7) to establish urgently a results-oriented and timelimited expert working group to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases, and open to consideration of proposals from Member States, and to submit a progress report to the **Sixty-second World Health** Assembly ...

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Organization

The Consultative Expert Working Group on R&D: Financing and Coordination

- 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.
- 20 members from all the WHO regions
- 3 meetings in Geneva in April, July & November 2011
- Public call for proposals: 22 submissions
- Report was adopted by the group with consensus and made public on 5th April and discussed in the 65th WHA in May

Members of the CEWG

Designated by governments and appointed by the Director General of WHO

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

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R&D to Meet Health

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Research and Development to Meet
Health Needs in Developing Countries:
Strengthening Global Financing
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Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

for Type II



of this US\$ 3.2 billion...

- 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

Important perspectives

- "... current incentive system fail to generate enough research and development, in either the private or public sectors, to address the needs of developing countries..."
- "...global public goods, including for health and health R&D relevant to developing countries."
- "There is therefore an economic case, based on market failure, for public action."
- "We note the importance of linking research strategies to access considerations and, in that context, the relevance of delinking the costs of R&D from the price of products."

Proposals to address the problem

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	

1. A Global Health R&D Observatory:

Financial flows to R&D The R&D pipeline

2. Coordination Mechanisms:

A Network of Research Institutions and Funders supported by WHO.

An Advisory Committee. This could be based on the current ACHR and also the ACHRs of the WHO regions.

3. 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.

4. 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.

Some Key Recommendations

- 5. Implementation through a binding global instrument for R&D:
 - Negotiations on an int. convention on global Health R&D should be initiated under Article 19 of WHO Constitution
 - A convention will be complementary to the current IPR based incentive system.
 - 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.

What Next

Follow up of the report of the CEWG: WHA 65.22

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

- 2. URGES Member States and, where applicable, regional economic integration organizations:
 - (1) to hold national level consultations among all relevant stakeholders, in order to discuss the CEWG report and other relevant analyses, resulting in concrete proposals and actions;

Follow up of the report of the CEWG: WHA 65.22

- 3. CALLS UPON Member States and, where applicable, regional economic integration organizations, the private sector, academic institutions and nongovernmental organizations to increase investments in health research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases;
- 4. REQUESTS regional committees to discuss at their 2012 meetings the report of the CEWG in the context of the implementation of the global strategy and plan of action on public health, innovation and intellectual property in order to contribute to concrete proposals and actions;

Follow up of the report of the CEWG: WHA 65.22

REQUESTS the Director-General to hold an open-ended meeting of Member States and, where applicable, regional economic integration organizations, that will thoroughly analyse the report and the feasibility of the recommendations proposed by the CEWG, taking into account, as appropriate, related studies as well as the results from national consultations and regional committee discussions, and will develop proposals or options relating to (1) research coordination, (2) financing and (3) monitoring of R&D expenditures, to be presented under a substantive item dedicated to the follow up of the CEWG report at the Sixtysixth World Health Assembly, through the Executive Board at its 132nd session.