

## **An Essential Health and Biomedical R&D Treaty**

### **Submission by Health Action International Global, Initiative for Health & Equity in Society, Knowledge Ecology International, Médecins Sans Frontières, Third World Network (TWN)**

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#### **I. Introduction**

The following is a joint submission on the topic of the proposal before the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) on a possible essential health and biomedical R&D treaty, an issue that has been discussed in the CIPIH Report, the WHO Global Strategy and Plan of Action (GSPOA), and in several submissions to the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property and the previous WHO Expert Working Group on Research and Development Financing (EWG), including but not limited to the submission to the EWG by the governments of Bangladesh, Barbados, Bolivia and Suriname. This joint NGO submission also draws upon the various proposals mentioned in footnote 2 of the Bangladesh, Barbados, Bolivia and Suriname Proposal for WHO Discussions on a Biomedical R&D Treaty, dated 15 April 2009.

Some of the groups signing this joint statement have made additional submissions to the CEWG on a variety of topics, including some of the same issues raised in this submission.

Groups making the joint submission on a possible essential health and biomedical R&D treaty are in general supportive of other proposals to enhance the funding of priority medical R&D, including, for example, through the creation of new priority research and development funds, and other efforts to address norm setting in terms of R&D practices. This joint submission provides a common position on a particular proposal before the CEWG that our groups believe has merit, and deserves the attention and consideration by the CEWG.

The joint submission has three substantive parts. Part II provides the rationale for considering a treaty. Part III details the Possible Objectives and Purposes of an essential health and biomedical R&D Treaty. Part IV discusses possible elements of an essential health and biomedical R&D treaty.

#### **II. Why a treaty?**

Access to medicines forms a core part of the human right of everyone to the enjoyment of the highest attainable standard of physical and mental health, as widely recognized in international law.<sup>1</sup> Directly related to the question of access is that of innovation, and the mechanisms to

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<sup>1</sup> See, for example, the International Covenant on Economic, Social and Cultural Rights, the WHO Constitution, General Comment 14 on The right to the highest attainable standard of health (E/C.12/2000/4), resolutions of the UN Human Rights Commission/Council starting in 2001 with Resolution 2001/21, and the WTO Declaration on TRIPS and Public Health (“the Doha Declaration”).

ensure sustainable sources of funding for the development of new medical tools<sup>2</sup> including in particular those that address pressing health needs.

The international community needs an international legal framework to ensure (1) sustainable sources of financing for research and development focused on priority health needs, particularly for the needs of developing countries and especially the poorest or most vulnerable members of society, and (2) an agreement that medical tools will be affordable and widely accessible to a global population of patients once they are developed.

Our current system fails on both counts. There are inadequate resources for priority research and development, particularly for diseases and conditions that primarily impact low-income persons living in developing countries, and health products are often not affordable.

An additional shortcoming of the existing system concerns excessive secrecy and inadequate sharing of knowledge, data, materials and technology, for research.

Since the 1970s, a limited number of programs and initiatives have been put in place to address the enduring challenge of ensuring access to medicines for all, largely focused on diseases that predominantly affect developing countries.<sup>3</sup> However, such initiatives are limited in the scope of diseases they cover, comprise a very small proportion of global R&D investment, and largely rely on the largesse of donors. The existing *ad hoc* patchwork of initiatives falls far short of the politically and financially sustainable institutional arrangements that are necessary to ensure **sufficient** global investment in medical R&D, **fair and equitable** arrangements for burden-sharing<sup>4</sup>, **efficient** knowledge-sharing for scientific progress, and **equitable** access to the fruits of scientific progress.

The core policy challenge stems from the fact that medical knowledge (including R&D and basic scientific research) has the potential to be a global public good. Knowledge generated and disclosed in one country can benefit the entire global community, and sharing the knowledge with one party does not decrease the knowledge available to share with others (that is, it meets the dual public goods criteria of being both “non-excludable” and “non-rival in consumption”). However, there is a need to overcome the under investment in priority R&D. A binding international treaty that establishes a sustainable and predictable financing based on fair and equitable contributions from members could lead to increased total investment in R&D, advances in scientific progress, and a politically sustainable system for ensuring globally equitable access to health products. Guaranteeing fair contributions from all, and fair access to benefits for all, requires moving beyond an *ad hoc* system fueled by donors and development aid. It requires a politically negotiated agreement among states on the principles undergirding medical R&D, methods to generate sustainable sources of financing, and fair arrangements for sharing both the burdens and benefits of medical research. In recognition of this gap in the institutional architecture, the WHO Global Strategy and Plan of Action (WHA 61.21) noted the need for Member States to consider establishing a Medical R&D Treaty. International treaties help States to achieve shared objectives and meet shared interests by delineating roles, responsibilities, norms and expectations; surely there are few goals more universally shared than improving human health and advancing medical science.

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<sup>2</sup> The term “medical tools” hereafter should be understood to include vaccines, diagnostics and medicines.

<sup>3</sup> Notable examples include the UNICEF/UNDP/World Bank/WHO Special Programme on Tropical Disease Training and Research; the establishment of roughly two dozen public-private product development partnerships (PDPs) since the mid-1990s, and various research programs of governments and private firms.

<sup>4</sup> See discussion in of Part IV, paragraph 5.

It is for this reason that we propose that countries begin negotiations for such a treaty without delay, and under the auspices of the World Health Organization, which is mandated by its Constitution to propose such international agreements.<sup>5</sup> The following sections outline a proposed set of principles and goals that should guide such negotiations, and suggest the key elements that should be contained in such a treaty. While important details would need to be negotiated among Member States, we believe these principles and elements provide a sound foundation from which to begin such negotiations.

### III. Possible Objectives and Purposes of the R&D Treaty<sup>6</sup>

The organizations sponsoring this submission have developed the following text as regards the purpose and possible objectives that might be included in an essential health and biomedical R&D treaty:

#### **Purpose**

The Treaty seeks to create a new global framework for supporting priority medical research and development that is based upon the fair and equitable sharing of the costs, access and benefits of research and development, incentives to invest in needs driven research and development consistent with human rights and with the goal of all sharing in the benefits of scientific advancement. This will involve norms and obligations on both national governments and international institutions.

#### **Objectives**

Parties to the Treaty would seek to promote a sustainable system of medical innovation that will:

- 1) ensure adequate and predictable sources of finance for needs driven medical research and development relevant in particular to diseases and conditions which disproportionately affect developing countries.
- 2) allocate fairly the costs of supporting needs driven medical research and development, in particular, to meet the health needs of developing countries,
- 3) identify priority areas of needs driven research and development,
- 4) explore and promote a range of incentive schemes for health-needs driven research and development addressing the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes that are designed to achieve the objective of de-linkage.
- 5) encourage the broad dissemination of information and sharing of knowledge and access to useful medical inventions including the facilitation of access

<sup>5</sup> WHO Constitution, Article 2(k): "In order to achieve its objective, the functions of the Organization shall be:...(k)to propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective;" Article 19: "The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes."

<sup>6</sup> Article 31 of the Vienna Convention of the Law of Treaties): "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".

to publicly funded research,

6) promote transparent and ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines, noting also that these ethical standards are in conflict with the ill advised practice of granting of exclusive rights in test data,

7) enable medical researchers to build upon the work of others,

8) support diversity and competition,

9) utilize cost effective incentives to invest in promising and successful research projects that address health care needs

10) enhance the transfer of and building of technological knowledge and R&D capacity to further social and economic welfare and development in developing countries and

11) promote equitable access to new medical technologies, so that all share in the benefits of scientific advancement.

#### **IV. Possible Elements of a Treaty<sup>7</sup>**

The following comments address the possible elements that might be included in an essential health and biomedical R&D treaty.

1. Developing transparent and inclusive mechanisms and processes for facilitating health needs assessment, priority setting and the assessment of funding needs.
2. Developing mechanisms for coordination of R&D actors, including developing appropriate networks, facilitating periodic assessments of R&D coordination, providing guidance to R&D efforts at national, regional and international levels and advising on resource allocation, following priority setting, ,
3. Norms and mechanisms to ensure sufficient, regular, predictable and sustainable financing for R&D for type I, II and III diseases. Such financing should be primarily from government contributions based on their level of development and managed by structures that are guided by the principles of transparency, inclusiveness that stress participation of developing countries in decision-making processes, equity and high governance standards. Financing of R&D should be for:
  - (a) R&D that results in quality health products that are accessible, affordable, acceptable

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<sup>7</sup> These elements are inspired by the 15 April 2009 submission by Bangladesh, Barbados, Bolivia and Suriname to the WHO EWG entitled, "Proposal for WHO Discussions on a Biomedical R&D Treaty".  
[http://www.who.int/phi/Bangladesh\\_Barbados\\_Bolivia\\_Suriname\\_R\\_DTreaty.pdf](http://www.who.int/phi/Bangladesh_Barbados_Bolivia_Suriname_R_DTreaty.pdf)

and appropriate for the target populations;

(b) R&D incentive models that de-link the cost of R&D from the price of the product and ensure that emerging R&D outcomes are available for promoting further research and facilitating generic competition, as well as affordable to those in need. Such models can be applied across the range of current funding mechanisms such as grant funding but also to newer mechanisms such as prizes. These models must also ensure that outcomes and data generated from funded R&D are not monopolized but are available for follow-on research

(c) The development and delivery of health products and medical devices to address the special health needs of developing countries including the development of global health priority products, such as antibiotics.

(d) All aspects of R&D including basic health-related science and initiatives that facilitate wide dissemination of medical knowledge such as open libraries for materials, open databases, open access medical publishing, and other initiatives ;

(e) Conducting clinical trials associated with the development and independent evaluation of new health products with full disclosure of clinical trial data.

(f) Initiatives that build and strengthen the local R&D capacity of developing countries.

(g) Strengthening drug regulatory capacity regarding the safety and quality of medicines

4. Measures to facilitate, encourage, and otherwise stimulate new incentives for R&D that are designed to de-link R&D cost from high product prices to ensure R&D outcomes are accessible and affordable, reward innovations that improve health outcomes, such as medical innovation inducement prizes and rewards to share access to knowledge, data, materials and technology, and which do not rely on legal monopolies.

5. Norms for minimal levels of contribution to medical R&D from all Parties, considering factors such as each nation's level of development, size of economy and capacity to pay; through a variety of means, including taxes, contributions in kind.

6. Global norms to facilitate access to government funded research.

7. Norms and measures regarding transparency of global medical innovation, including but not limited to:

(a) Standards for disclosures of information regarding clinical trials that are appropriate and beneficial, regarding results and information on Safety, Quality and Efficacy, in publicly and easy accessible registries.

(b) Requirements for greater disclosure of the costs of R&D inputs, such as the costs of clinical trials;

(c) Disclosure of prices and revenues of products in order to deepen analysis of the performance of mechanisms.

- (d) Standards for reporting and sharing information on resource flows used to support R&D; and
- (e) Where R&D outcomes are licensed, increased transparency on the terms and conditions of such licenses .
8. Establish and implement norms for ethical standards for medical research as well as for clinical trials.
9. Measures and mechanisms to facilitate encourage or otherwise stimulate local R&D capacity including through the transfer of technology particularly in developing countries..
10. Norms and mechanisms to ensure management of R&D outcomes and assets including intellectual property rights in a manner that promotes open sharing of knowledge, protects the public interest in access to knowledge and health-related innovation and ensures sufficient freedom to operate, in a manner that meets the R&D needs of developing countries, protects public health and promotes access to health products.
11. Measures to overcome barriers and improve the availability of health products in the contexts where they are needed, such as those relating to regulatory requirements, supply chain, health systems, and information.
12. Mechanisms to monitor and evaluate both the performance of R&D efforts and the implementation of the treaty, including appropriate reporting and amending systems.

The undersigned organizations would request that the CEWG review this submission and other proposals for a biomedical R&D treaty. We remain available for further discussion with the Committee.

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