PROPOSAL by Bangladesh, Barbados, Bolivia and Suriname

Proposal for WHO Discussions on a Biomedical R&D Treaty

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Executive Summary

The Expert Working Group (EWG) on Research and Development (R&D) Financing has been requested to evaluate current financing and coordination of research and development, and to consider "proposals for new and innovative sources of funding to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases."

In addressing these topics, the issue of a global agreement to address health-related R&D looms large. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property contain an agreement to "encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including *inter alia*, an essential health and biomedical R&D treaty[1]."

The EWG exploratory discussions about a possible biomedical R&D treaty should begin now, to provide initial comments on the possible elements of such a treaty and to propose a schedule for taking the discussions forward.

Scope of a WHO Biomedical R&D Treaty

While the WHO frequently considers the importance of global cooperation and coordination in various areas of biomedical R&D, there has not been an extended discussion of the purposes and objectives of a possible biomedical R&D treaty by member states.

Article 19 of the WHO constitution explicitly authorizes the Health Assembly to adopt conventions or agreements with respect to any matter within the competence of the Organization.

In the academic and policy literature—and among various WHO member states and stakeholder groups—there have been a variety of proposals for global R&D agreements, including submissions to the WHO CIPIH and the WHO IGWG PHI.[2] These proposals are diverse in objectives and scope. Some focus on specialized areas of research (such as R&D for specific diseases or categories of

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1 During the WHO IGWG negotiation at least the following countries explicitly supported further discussions on a WHO R&D Treaty: Bangladesh, Kenya, Bolivia, Thailand (on behalf of the WHO South East Asian Region) and Iran (on behalf of the WHO Eastern Mediterranean Region).

2 Note: Trouiller P, Olliaro P, Torreele E, Orbinski J, Laing R, et al. (2002) Drug development for neglected diseases: A deficient market and a public-health policy failure. Lancet 359: 2188–2194; James Love and Tim Hubbard. "A New Trade Framework for Global Healthcare R&D". PLOS Biology. 2(2): e52 DOI: 10.1371/journal.pbio.0020052; Dentico N, Ford N (2005) The Courage to Change the Rules: A Proposal for an Essential Health R&D Treaty. PLoS Med 2(2): e14. doi:10.1371/journal.pmed.0020014; Commission on Intellectual Property Rights, Innovation and Public Health. Public health, innovation and intellectual property rights: report of the Commission on Intellectual Property Rights, Innovation and Public Health. April 2006. Page 90; Thomas Faunce, "Toward a Multilateral Treaty on Safety and Cost-effectiveness of Medicines and Medical Devices," WHO Public Hearing on Public Health, Innovation and Intellectual Property, 14 November 2006; Carl Nathan, "Aligning pharmaceutical innovation with medical need," Nature, Vol 13, No. 3, March 2007; Manish Ashiya and Anu Jindal, Medical Research and Development Treaty: A New R&D Framework, Icfai Journal of Systems Management, Vol. 5, No. 1, pp. 23-31, February 2007.

diseases), while others are more general. Some proposals focus on global sharing of the costs of financing clinical trials, while others address such topics as medical ethics, transparency, priority setting, open medicine projects, or transfer of technology, to mention only a few. Some proposals would link innovation and access in the same agreement, while others focus only on research or product development. While not all major stakeholder groups have agreed on proposals for global R&D initiatives, nearly all have acknowledged the need for some initiatives that require international cooperation and new rules.

The challenge currently facing the EWG and WHO Member States lies in identifying areas where global cooperation and global norm setting are both useful and feasible. In this regard it is important to maintain a balance between setting appropriate long-term goals, and charting a short- and medium-term course that is realistic in the current environment.

The WHO Constitution states that "the objective of WHO shall be the attainment by all peoples of the highest possible level of health." A biomedical R&D treaty should also be anchored in, consistent with, and designed to advance the objectives contained in resolution WHA 61.21, the most recent, comprehensive and relevant WHO statement on these issues.

In terms of overall policy coherence, a biomedical treaty should advance the goals of the UN Declaration on the Right to Development[3] and to provide a concrete, coherent and effective implementation of the United Nations Millennium Development Goal Number 8 (MDG-8), "to develop a global partnership for development."

Possible Elements of a WHO Biomedical R&D Treaty

Discussions on a biomedical R&D treaty should focus on a wide range of issues that would benefit from global coordination, collaboration and norm setting, including, but not limited to, creation of a framework for sustainable funding support for priority medical R&D.

A comprehensive biomedical R&D treaty should address, at a minimum, the following elements:

1. Coordination and facilitation of periodic global priority assessments—including estimates of funding needs—for R&D to address public health needs.

2. Norms and mechanisms to ensure sustainable financing for R&D, including funding for:

   (a) the development and delivery of health products and medical devices to address the special health needs of developing countries;

   (b) the development of new antibiotics, vaccines, and other global priority health products and medical devices;

   (c) funding of basic health-related science, open libraries for materials, open databases, open access medical publishing, and other initiatives to enhance and expand access to medical knowledge;

   (d) the global sharing of costs for clinical trials associated with the development and independent evaluation of new medical products; and

[3] Adopted by General Assembly resolution 41/128 of 4 December 1986.

(e) other relevant matters.

3. Measures to facilitate, encourage, and otherwise stimulate new incentive schemes for R&D (such as medical innovation inducement prizes, advanced market commitments, openness dividends, and other new innovative approaches), with special attention to measures that de-link R&D incentives from product prices, and reward innovations that improve health outcomes.
4. Possible governmental agreement to contribute to the global cost of R&D, considering each nation's level of development, size of economy and capacity to pay, in order to establish global norms for R&D contributions. Contributions should be allowed through multiple means.
5. Global norms and best practices to facilitate access to government funded research.
6. Norms and measures regarding the transparency of global medical innovation, including but not limited to:
   (a) Agreements on the required disclosures of clinical trials, including results, in publicly accessible registries;
   (b) Requirements for greater disclosure of the costs of R&D inputs, such as the costs of clinical trials;
   (c) Standards for reporting and sharing information on resource flows used to support R&D; and
   (d) Greater transparency of the terms under which intellectual property rights are licensed, including, for government funded research, disclosures of licensing provisions regarding access to inventions.
7. Mechanisms to develop and improve innovative capacity for research and development, particularly in developing countries.
8. Measures to facilitate encourage or otherwise stimulate the transfer of technology between developed and developing countries as well as among developing countries.
9. Norms promoting the management of intellectual property rights in a manner that reconciles the public interest in access to knowledge and health-related innovation, including the R&D needs of developing countries and that protects public health and promotes access to medicines.
10. Relevant measures to improve the delivery of and access to health products and medical devices.
11. Mechanisms to monitor and evaluate both the performance of global R&D efforts and the implementation of the treaty, including appropriate reporting systems.
12. Measures to more effectively achieve compliance with appropriate ethical standards for medical research.

Beginning the Discussion of a WHO R&D biomedical treaty

The proponents recommend that WHO undertake the following steps:

1. Undertake studies on the different possible elements and models for a biomedical R&D treaty, including one or more studies that consider different approaches to providing sustainable financing for priority biomedical R&D.

2. Solicit the views of member states and the public.

3. Hold three meetings in 2010 to discuss a biomedical treaty. These meetings should address the following topics:

   (a) What should be the objectives of a biomedical treaty, as they relate the funding of priority R&D?

   (b) What are alternative ways of providing sustainable sources of funding for priority R&D that should be incorporated into a biomedical R&D treaty?

   (c) What should be the objectives of a biomedical treaty, as they relate to issues other than funding of priority R&D?

   (d)

Annex I: Global Cooperation in the area of Funding Clinical Trials

Clinical trials provide evidence regarding the safety and efficacy of medicines, including also the relative efficacy of different products used treat the same illness. A growing number of experts say the system of relying upon trials performed by the owners/manufacturers of products is plagued with controversy and ethical lapses, and the high cost of undertaking clinical trials is both a barrier to innovation and a rationale for high drug prices.[4]

Clinical trials are first and foremost methods of generating information. Once the findings associated with a clinical trial are published and known, the benefits of the trials can be used everywhere.

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[4] For discussions of the rationale for and the possibility of funding clinical trials as public goods, see: I. Chalmers, "Underreporting research is scientific misconduct," *JAMA*, 1990, 263:1405-1408.; T. Bodenheimer, "Uneasy alliance: Clinical investigators and the pharmaceutical industry," *N Engl J Med*, 2000, 342:1539-1544; Rich McManus, "'Abolitionist' Angell Calls for Clinical Trial Reform," *The NIH Record*, July 24, 2001, Vol. LIII, No. 15; John Yaphe, Richard Edman, Barry Knishkowy, and Joseph Herman, "The association between funding by commercial interests and study outcome in randomized controlled drug trials," *Family Practice*, Vol. 18, No. 6, 2001: 565-568; Sameer S. Chopra, "Industry Funding of Clinical Trials: Benefit or Bias?" *JAMA*, 2003, 290:113-114; Joel Lexchin, Lisa A Bero, Benjamin Djulbegovic, "Pharmaceutical industry sponsorship and research outcome and quality: systematic review," *BMJ*, May 31, 2003, 326:1167-1170; Samuel O. Thier, Hamilton Moses III, MD, E. Ray Dorsey, MD, MBA; David H. M. Matheson, JD, "Financial Anatomy of Biomedical Research," *JAMA*, 2005, 294:1333-1342; Marcia Angell, *The Truth About The Drug Companies: How They Deceive Us And What To Do About It*, Random House, 2005; Thomas Alured Faunce, "Intellectual Monopoly Privileges, Cost-Effectiveness Evaluation and the Knowledge Commons-New Political Paradigms for Wisdom in the Age of Corporate Globalisation," Presentation at TACD meeting on the politics and ideology of intellectual property rights, March 2006; Thomas Faunce, "Toward a Multilateral Treaty on Safety and Cost-effectiveness of Medicines and Medical Devices," WHO Public Hearing on Public Health, Innovation and Intellectual Property, 14 November 2006; Tracy R. Lewis, Jerome H. Reichman, and Anthony D. So, "The Case for Public Funding and Public Oversight of Clinical Trials," *The Economists' Voice*, 2007, Vol. 4, Issue. 1, Article 3; Dean Baker, *The Benefits and Savings from Publicly-Funded Clinical Trials of Prescription Drugs*, the Center for Economic and Policy Research, March 2008; Djulbegovic B, et al., "Treatment success in cancer: New cancer treatment successes identified in phase 3 randomized controlled trials conducted by the national cancer institute-sponsored cooperative oncology groups, 1955 to 2006," *Arch Intern Med*, 2008, 168: 632-642; Crystal Phend, "NCI-Sponsored Cancer Trials Offer Decent Clinical Return on Investment," *MedPage Today*, March 24, 2008.

Some governments have tried to assign exclusive rights in pharmaceutical test data as a method of appropriating the value of the test and protecting the investments associated with the trials. However, the potential negative impact of doing so is large. By creating a monopoly on the evidence that a drug is safe and effective—as a barrier to competitive entry against manufacturers offering the same molecule—governments encourage very high prices. The exclusive rights system also requires competitors to replicate known experiments on humans, a process that is not only time consuming, expensive and wasteful, but which violates ethical restrictions regarding experiments involving humans, including those set out in the Declaration of Helsinki, which is referenced in Section 6.2(g) of the WHO Global Strategy on Public Health, Innovation and Intellectual Property.

Direct funding of independently managed clinical trials reduces the costs of product development and evaluation, increases the utility of the trials as a source of unbiased information, and avoids unethical experiments involving humans.

Governments can and do fund clinical trials, but not to the degree that is needed. This is largely because clinical trials have the characteristics of global public goods. No one government has the incentive to subsidize such trials. Therefore, governments need to undertake greater cooperation in the funding of such trials, and to address other concerns regarding the management of clinical trials as global public goods.

As a possible element of a WHO biomedical R&D treaty, could exist an agreement among governments to share the costs of independently managed clinical trials for medicines and vaccines. Evaluation of this element may involve the following steps:

1) Identification of the amount of money that is currently invested annually in clinical trials, disaggregated by the stage of the trial, and the area of research, and whether the source of funding is public or private;

2) Identification of areas where governments benefit from independently managed clinical trials;

3) Analysis of the benefits of global clinical trial registries and other transparency issues;

4) Alternatives to regulations concerning exclusive rights on pharmaceutical test data; and

5) Priority-setting in terms of clinical trial testing, including:

    a) New drug and vaccine development, and

    b) The evaluation of safety and cost-effectiveness of existing products.

Annex II: The Need for Better Regulation of Ethical Standards in the Conduct of Clinical Trials

In many areas of the WHO Global Strategy on Public Health, Innovation and Intellectual Property, member states and other stakeholders are urged to ensure that products are developed in an ethical manner.

For example:

> (2.2) promoting upstream research and product development in developing countries
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> (f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries.
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> (3.3) providing support for improving innovative capacity in accordance with the needs of developing countries
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> (c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries.
>
> (6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices
>
> (a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards.
>
> (g) promote 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.
>
> (h) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval.

A WHO Biomedical R&D Treaty would be the appropriate framework to implement these

recommendations.