24 February 2005

World Health Assembly Executive Board
World Health Organization Commission on Intellectual Property, Innovation and Health

Re: Request to Evaluate Proposal for New Global Medical R&D Treaty

Dear Members of the Executive Board and the Commission on Intellectual Property, Innovation and Health:

The current global framework for supporting medical R&D suffers from profound flaws. A growing web of multilateral, regional, bilateral and unilateral trade agreements and policies focus nearly exclusively on measures that expand the scope and power of intellectual property rights, or reduce the effectiveness of price negotiations or controls.

These mechanisms are plainly designed to increase drug prices, as the sole mechanism to increase investments in R&D. Stronger intellectual property rights and high drug prices do create incentives to invest in medical innovation, but also impose costs, including:

1. problems of rationing and access to medicine,
2. costly, misleading and excessive marketing of products,
3. barriers to follow-on research,
4. skewing of investment toward products that offer little or no therapeutic advance over existing treatments, and
5. scant investment in treatments for the poor, basic research or public goods.

A trade framework that only relies upon high prices to bolster medical R&D investments anticipates and accepts the rationing of new medical innovations, does nothing to address the global need for public sector R&D investments, is ineffective at driving investments into important priority research projects, and when taken to extremes, is subject to a number of well-known anticompetitive practices and abuses. 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.

To this end, a number of experts and stakeholders have proposed a new global treaty to support medical R&D. This effort has produced a working draft (the original draft in English is here http://www.cptech.org/workingdrafts/rndtreaty4.pdf, and there are also translated versions in French http://www.cptech.org/workingdrafts/rndtreaty4fr.pdf and Spanish http://www.cptech.org/workingdrafts/rndtreaty4es.pdf) that illustrates a particular approach for such a treaty -- one that seeks to provide the flexibility to reconcile different policy objectives, including the promotion of both innovation and access, consistent with human rights and the promotion of science in the public interest. The draft treaty provides new obligations and economic incentives to invest in priority research projects, and addresses several other important topics.

1. The World is Changing

The global trade framework for pharmaceuticals is changing. The pace of change is accelerating; the direction is toward higher prices and rationing of access, and the target of policy is often the elimination of basic government interventions to protect consumers. Most important, the world is increasingly locked-in to a rigid and increasingly controversial approach to financing R&D. It is thus urgent to propose and evaluate alternative trade frameworks.

2. The Draft R&D Treaty Project

The current draft R&D treaty seeks to stimulate discussion, noting of course that the development of a treaty is a democratic process involving negotiations between member states with input from civil society. The draft treaty text is a work in progress, representing a collaborative effort with contributions from many persons over the past two years.

The discussion below concerns draft 4, and some provisions will change in later drafts. The objective of the project is to propose an international system that (1) ensures sustainable investments in medical innovation, (2) provides a fair allocation of the cost burdens of such innovation, (3) creates mechanisms to drive R&D investment into the areas of the greatest need, and (4) provides the flexibility to utilize diverse and innovative methods of financing innovation while protecting consumers and ensuring access.

3. Obligations to finance R&D

At the core of the proposed treaty is an obligation to finance Qualified Medical Research and Development (QMRD). This obligation is tied to country GDP. In Draft 4, two different methods of determining the fraction of GDP for QMRD are presented. Alternative 1 uses different rates for each of four income groups (high, high medium, low medium, and low). Alternative 2 is a graduated rate.

QMRD would include (1) basic biomedical research, development of biomedical databases and research tools, (2) development of pharmaceutical drugs, vaccines, medical diagnostic tools, (3) medical evaluations of these products, and (4) preservation and dissemination of traditional medical knowledge,

There is a separate obligation to finance Priority Medical Research and Development (PMRD), and two alternative methods of setting benchmarks for PMRD. In the current draft at least half of PMRD investments must be targeted for neglected diseases.

4. Methods of financing R&D

While virtually all of today's trade agreements focus exclusively upon purchase of medicines at high prices as the sole method of financing R&D, the Draft R&D Treaty takes a much broader view. Acceptable methods of finance include such items as direct public funding, tax credits or other expenditures, philanthropic spending, research funding obligations imposed on sellers of medicines, purchases of relevant medical products (to the degree that such expenditures induce investments in medical R&D), and innovation prizes (to the degree that such prizes induce investments in medical R&D).

5. Benefits of Meeting Obligations to Finance R&D

The proposed treaty would require member states to forgo dispute resolution over intellectual property or pricing issues relating to the products covered by the agreement. This would include all multilateral, regional, bilateral and unilateral intellectual property and trade agreements.

6. Tradable Credits for Investments in Certain Public Goods

In addition to the basic obligations outlined above, the draft treaty proposes a system for assigning credits for projects that are considered socially important. Member countries could use these credits to satisfy treaty obligations. Similar to the Kyoto climate treaty, credits would be traded across borders -- and countries that exceed the benchmark obligations can sell excess credits. The credits will be given for a variety of projects including:

- R&D for neglected diseases and other priority research projects,
- "Open public goods," such as free and open source public databases,
- Projects that involve the transfer of technology and capacity to developing countries,
- The preservation and dissemination of traditional medical knowledge, and
- Exceptionally useful public goods.

7. Promotion of Open Access Research

The draft treaty proposes adoption of a best practices model for the support of open access biomedical research, and obligations that research supported by public funds enter open access archives.

8. Equitable Access to Publicly Funded Inventions

Member countries would be obligated to provide equitable access to publicly funded inventions.

9. Changes in laws for patents, copyright and related rights

The draft treaty text provides for minimum exceptions to patent rights for research, and a novel agreement to not accept patent applications for inventions that are based upon data from certain open public databases (like the HapMap Project), as well as a best practice for practices model for exceptions in laws on copyright and related rights, including laws on databases.

10. Global Norms / Decentralized Control of R&D Spending

While the draft treaty proposes global norms regarding obligations to invest in R&D, and tradable credits as incentives to invest in certain types of R&D projects, the management of specific R&D outlays would be decentralized, and controlled by Member countries.

Members would be free to embrace a diversity of management approaches to support R&D, including the direct funding of profit or non-profit research projects, market transactions such as purchases of medicine that provide incentives for research and development, payment of royalties to patent owners, tax credits, innovation prizes, investments in competitive research intermediators, mandated research and development obligations on sellers of medicines or other alternatives that have the practical effect of either directly or indirectly financing medical R&D.

11. Transparency and Measurement

Members would agree to adopt consistent approaches to measuring R&D flows and outcomes. The measurement of investment flows will follow three principles.

(1) No double counting (mechanisms to finance R&D are complex, involving mixed sources of finance and transnational flows of products and investments, but each investment will only be counted once).

(2) Source of finance rather than location of investment. For example, if products are purchased in one country but R&D is performed in another, the country that paid for the products would receive credit for funding the R&D. The county that performed the R&D would not.

(3) Evidence based estimates. In cases where measured investments are based upon estimates of the relationship between outlays on products (or other incentives) and actual R&D investments, the estimates are based upon the best empirical evidence of such relationships.

12. Evaluate Proposals for New Global Frameworks to Support Medical R&D

We call upon the WHO CIPIH to engage in debates over the appropriate global framework to support medical R&D, and to evaluate the Draft R&D Treaty proposal. This initiative seeks to refashion global policy to better fulfill the objective of providing "access to medicine for all."

The treaty proposal recognizes the importance of ensuring sustainable sources of finance for innovation, including R&D for neglected diseases and other public health priorities, and it provides opportunities to experiment with new and promising mechanisms to finance R&D, such as prize funds, competitive intermediators, compensatory liability regimes, or open collaborative projects such as the Human Genome Project. We are at a key moment in history, as we rapidly create new rules that will long determine the nature, costs and distribution of benefits of medical knowledge goods. In order to create the best

possible systems, policy makers should consider the fullest range of options, including this innovative, flexible and choice preserving idea.

Sincerely

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