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Written submission of Knowledge Ecology International (KEI) to the French Ministry of Foreign Affairs to the national consultation on financing and coordination of research and development for the health needs of developing countries

KEI avails itself of the opportunity to thank the Government of France for affording our organization the possibility of presenting our views on the Report of the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination released in April 2012. We take note that the Government of France is implementing operative paragraph 2(1) of resolution WHA65.22 which urges member states to

“ 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”.

Background

Prior to submitting our responses to the questions posed by the Ministry of Foreign Affairs below, KEI would like to provide historical background on the antecedents of the WHO CEWG, including the WHO Commission on Intellectual Property, Innovation and Public Health and the Intergovernmental Working Group on Public Health, Innovation and Public Health (CIPIH) and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA).

At the 56th World Health Assembly in May 2003, the Assembly provided the WHO Director-General the mandate to create the WHO Commission on Intellectual Property, Innovation and Public Health. The Assembly instructed the CIPIH to:

“collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries (WHA56.27)”

Following this, in November 2005, Kenya tabled a resolution to the WHO for consideration at the Executive Board in January 2006 on a “Global Framework on Essential Health Research and Development”. In its rationale, the Kenyan resolution (co-sponsored by Brazil during the EB) cited the “paucity of safe, adapted and affordable new medicines developed for infections diseases like Aids, malaria and tuberculosis and the lack of drugs, vaccines and diagnostics for tropical diseases or other illnesses” that primary affected the world's poorest populations. The resolution highlighted the importance of global public goods and the promise held by new open collaborative models for the development of biomedical R&D. While acknowledging the contribution of product development partnerships, the Kenyan resolution stressed the necessity for governments in taking a more pro-active role in priority-setting and “granting political support and sustainable sources of funding”. In its operational language, the Kenyan text called upon WHO member states, to collaborate with the WHO

and other international actors, in the “development and establishment of a global framework for defining global health priorities, supporting essential medical research and development predicated upon the principles of equitable sharing of the costs of research and development, and the incentives to invest in useful research and development in the areas of patients' need and public interest”.

In April 2006, the CIPIH published its report. In relation to the R&D treaty, the CIPIH concluded the following:

Recognizing the need for an international mechanism to increase global coordination and funding of medical R&D, the sponsors of the medical R&D treaty proposal should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision (Report of the Commission on Intellectual Property Rights, Innovation and Public Health, 2006)

Amidst the confluence of the WHO CIPIH report and the Kenya/Brazil resolution, the intense negotiations at WHA59 in 2006 engendered the establishment of the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property.

The original mandate of the WHO IGWG aimed to secure "an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries". This two year process resulted in the passage of the historic WHO Global Strategy on Public Health, Innovation and Intellectual Property (GSPOA) at the 61st WHA in May 2008 (WHA61.21).

De-linkage is a concept anchored in the WHO Global strategy and plan of action on public health, innovation and intellectual property and embedded in resolution WHA63.28 establishing the CEWG. De-linkage refers to the de-coupling of the costs of R&D from the price of health technologies including diagnostics, medicines and vaccines.

Paragraph four of the “context” section of the GSPOA states,

“Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the delinkage of the costs of research and development and the price of health products”.

With respect to actions to be taken on the promotion of R&D in improving the coordination, participation and coordination of health and biomedical research and development, element 2.3(c) of the Global Strategy stated,

“(c) 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”.

In 2008, the WHO Expert Working Group on R&D was created (EWG). Among the submissions to the WHO EWG was the proposal by the governments Bangladesh, Barbados, Bolivia and Suriname tabled in April 2009 requesting WHO to convene one or more meetings to discuss possible elements of a biomedical R&D treaty. The BBBS submission cited a number of different proposals and models for a biomedical R&D treaty which included suggested norms or mechanisms for identifying and funding priority

research, and may also have other elements, such as norms on medical ethics or the transparency of research. In its deliberations, the WHO EWG rejected any further consideration of a possible biomedical R&D treaty.

However, as the 63rd WHA, as noted in resolution 63.28, recorded that “there was divergence between the expectations of Member States and the output of the Group, underlining the importance of a clear mandate”. Consequently, WHA63.28 established the Consultative Expert Working Group on R&D (CEWG). WHA63.28 instructed the CEWG to take forward the work of the EWG and deepen the analysis contained in the EWG. The CEWG’s mandate was set out in the GSPOA:

“to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing 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”.

The CEWG assessed the 22 proposals mentioned in the EWG report in addition to the 22 submissions received as a result of the CEWG's own call for submissions. The criteria employed by the CEWG to evaluate proposals were the following: 1) public health impact, 2) efficiency/cost-effectiveness, 3) technical feasibility, 4) financial feasibility, 5) intellectual property, specifically, how far the use in a proposal would promote innovation and enhance access, 6), de-linkage, 7) access, 8) governance and accountability and 9) capacity building.

The CEWG concluded that the following proposals best met its criteria: 1) Global framework on research and development, 2) Open approaches to research and development and innovation; which include pre-competitive research and development platforms, open source and open access schemes, 3) pooled funds, 4) direct grants to companies, 5) milestone and end prizes and 6) patent pools.

The principle recommendation of the CEWG is the following:

“[T]he time has now come for WHO Member States to begin a process leading to the negotiation of a binding agreement on R&D relevant to the health needs of developing countries” [under Article 19 of the WHO Constitution]”.

“On balance we consider that the time has come for Member States to begin a process leading to the negotiation of a binding agreement on R&D relevant to the health needs of developing countries. This would also be in order to put on a secure footing the implementation of the GSPA-PHI which Member States agreed in 2008, and in particular the sustainable financing of R&D”.

- Limitations of the R&D model and intellectual property regime; (Limitations du modèle de R&D et du régime de propriété intellectuelle)

At present, the primary funding for medical R&D comes from private investments by for-profit drug companies and governments. There are also significant contributions of private donors, such as the Gates Foundation, for certain diseases or health problems.

The private investments are typically motivated by the possibility of a government granted intellectual

property right, and in particular, the exclusive rights to make and sell products for a period of several years. The granting of patents and other IPR legal monopolies predictably leads to high prices for products. High prices for products predictably leads to barriers to access, and lesser access for poor people living in countries with lower average incomes.

The negative impact of these IPR monopolies are becoming more important, and the world is also facing an expansion of newer and more restrictive international trade agreements that feature tougher IPR obligations on both developed and developing countries.

These IPR norms are typically justified by the need to provide sustainable mechanisms to fund R&D, and seem particularly compelling if there are not other mechanisms to address the funding issue.

The exclusive rights regime is expensive, and a fair evaluation will show that it is inefficient. The cost of exclusive rights in terms of higher drug prices are huge, perhaps reaching more than \$500 billion per year. In any given year, the amount reinvested in R&D is only a small fraction of total sale. For example, in 2010 estimates for global sales for drug sales and private sector outlays were \$856 billion for sales and \$67.4 billion for R&D – less than 8 percent of turnover. Moreover, more than half of new drug registrations have almost no compelling medical benefits over existing drugs, and a considerable amount of reported R&D outlays are spent on studies of little scientific merit, used to influence the marketing of products.

A system of incentives that is based upon temporary monopolies encourages wasteful outlays on marketing of products, excessive investments in me too products, and stimulates very little investment in a number of important areas, such as for diseases and conditions that primarily impact poor persons living in developing countries, but also such things as antibiotic research, or R&D that is precompetitive, including basic research.

To further elaborate on the limitations of the R&D model and intellectual property regime, please see an extract of the joint submission of Health Action International Global, Initiative for Health & Equity in Society, Knowledge Ecology International, Médecins Sans Frontières, Third World Network (TWN) to the WHO CEWG on 22 June 2011 (Consideration of an essential health and biomedical R&D treaty. Health Action International Global, Initiative for Health & Equity in Society, Knowledge Ecology International, Médecins Sans Frontières, Third World Network: http://www.who.int/phi/news/phi_1_joint_submission_en.pdf).

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 law¹. Directly related to the question of access is that of innovation, and the mechanisms to ensure sustainable sources of funding for the development of new medical tools² including in particular those that address pressing health need

The international community needs an international legal framework to ensure (1) sustainable

1 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”).

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

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.³ 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 burdensharing, 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.

The WHO GSPOA and resolution WHA63.28 do not attempt to address all of the ills of the current system of R&D financing, focusing instead on areas where the flaws are most evident, and proposing

3 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.

new approaches there.

The WHO GSPOA and resolution WHA63.28 identified de-linkage as a means of reconciling the twin goals of spurring innovation and ensuring access to health technologies. The de-linkage approach is profoundly different than one that seeks to sustain R&D through legally enforced time-limited monopolies on new products, and it provides opportunities to improve efficiencies, lower costs and address disparities of access.

With full de-linkage and the elimination of product monopolies, there would be a separation between the markets for innovation and the markets for products. Cheap generic copies of products would make it easier to expand access, eliminating the policy induced scarcity of products that leads to underutilization of new medicines.

However, for de-linkage to work, the lost profits from monopoly pricing have to be replaced with new revenue streams. Government have to either expand direct funding of research, create new incentive mechanisms such as hefty innovation inducement prizes, or some combination of both approaches.

When incentives are created under de-linkage, it is possible to reward investments in products that have the greatest impact on health outcomes, when compared to benchmarks of existing treatments. It is also possible to introduce incentives for a wide range of science, engineering and product development activities, including basic research, pre-commercial and transitional product development, the supply of knowledge as a public good, and research that leads to more rationale and informed use of existing products.

In the more sophisticated incentives, there are combinations of end product and upstream prizes, open source dividends, and other new approaches that are feasible because incentives are now longer tied to product prices.

-Comprehensive Framework for R & D in health. (- Cadre global pour la R&D en santé.)

As regards the CEWG proposal for an R&D treaty, it is the view of KEI that the proposal has great merit, but that it needs to be modified in important areas, in order to make the proposal more compelling for member states. These changes are as follows:

1. The types of health care research should be broadened to including R&D for health problems that have a more global impact, and not be limited to health problems of developing countries only. High-income countries are not anxious to make commitments to obligations to fund R&D that is seen as having no benefit to domestic populations. Examples of areas where multilateral cooperation on funding might make sense in terms of an R&D treaty or agreement would be funding of R&D for new antibiotic drugs, low cost diagnostics, pre-competitive research, and collaborations on funding independent clinical trials to evaluate drugs.
2. The structure of the agreement should be reconsidered, so that specific funding commitments do not have the status of a treaty requiring complex ratification procedures. The treaty or agreement can set up a general structure, and different approaches can be used to periodically revise funding levels and mechanisms to make such funding binding.
3. France and others should consider a variety of ways of making funding commitments binding.

Among several alternatives, France and the European Union may wish to evaluate proposals for the creation of a schedule within the WTO that would permit voluntary commitments to fund specific R&D projects to become binding upon the inclusion of such commitments on a schedule for the supply of public goods. Another approach, which has been explored in the context of vaccine development, is for countries to commit to paying back bonds that finance research. This said, it may also be necessary to begin with softer norms, as confidence building steps, so long as these are seen as steps toward a more binding legal framework that addresses the need to have global sharing of the costs of paying for R&D that becomes a public good.

- Next Steps

(Propositions et mesures concrètes pour la suite des négociations)

In terms of next steps for the WHO,

- The WHA should consider establishing a working group or technical committee 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.

Governments and non-government stakeholders and experts need to provide advice on such topics as the appropriate subject matter for such a treaty, and the details.

- What would be the government obligations to pay for R&D?
- What other norms and coordination mechanisms are needed to address other topics, including but not limited to technology transfer and capacity building?
- How is “de-linkage” implemented, so that R&D costs are no longer linked to high product prices?