Comments of Knowledge Ecology International (KEI) to the WHO public hearing for Proposals for new and innovative sources of funding to stimulate R&D

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Introduction

Since 2003, the WHO has been struggling to address flaws in the current systems for supporting biomedical R&D. The CIPIH issued a detailed and very useful report that set the stage for further policy making, touching on a wide range of topics. Following a proposed resolution by Kenya and Brazil to the WHO Executive Board in January 2006, and the issuance of the CIPIH Report in April of 2006, efforts to create a new framework to support needs drive essential medical R&D and the specific recommendations from the CIPIH were assigned to the Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property. This body negotiated a far reaching and highly regarded Global Strategy (GS), and a somewhat incomplete Plan of Action (PoA), which were formally adopted by the WHA in May of 2008. In each of the steps, the WHO has accomplished a great deal, but it has yet to confront the need for a global framework to support funding of essential biomedical R&D, particularly in a manner that addresses other elements of the GS, such as the need to ensure access to medicines for all.

The Expert Working Group (EWG) is the third stage on this broader ongoing reform effort, focusing on important elements of the financing of needs driven essential medical innovation.

Knowledge Ecology International (KEI) offers the following comments for the public hearing for consideration by the WHO Expert Working Group on R&D Financing (EWG).

There is a need to advance discussions on a biomedical R&D Treaty

Biomedical R&D is expensive, and provides global benefits. The global framework for supporting R&D today is a system of trade agreements on the protection of intellectual property rights and the pricing the pharmaceutical drugs that have as their main features measures that are designed to increase the prices of medicines.

There is a need for a new global framework for supporting the funding of medical R&D that is more comprehensive, and includes not only global incentive mechanisms, such as those addressed in the TRIPS, but also agreements to fund direct grants for research, and the funding of knowledge as a global public good. There are many challenges in doing this, but the first will be to map out the possible elements and objectives of such a treaty. A biomedical treaty should deal with more than funding issues. It should also address concerns about transparency, medical ethics, technology transfer, and other important elements of the WHO GS.

Conflicts of Interest and Governance Issues are Important

The IFPMA proposal for billions of dollars in direct grants for work on selected diseases is deeply flawed by suggestions that senior pharmaceutical industry executives would be directly involved in reviewing, approving and managing R&D proposals. Large pharmaceutical companies already have enormous influence and power over smaller firms and new non-profit partnerships, and it is not

appropriate and in fact an invitation to corruption to given these firms influence over the resources devoted to addressing R&D needs in this area. There is also a risk that the IFPMA proposal will end up being a subsidy to cover the fixed costs of the general pharmaceutical R&D budgets for large pharmaceutical companies, rather than an efficient targeting of investments in R&D for neglected diseases.

Incentive Systems Must be Reformed to Break Links Between Product Prices and Incentives

If policy makers make the primary incentive for investments in R&D the prospect of a high price, policy makers should not be surprised when they observe high prices. Because high prices are a barrier for access to all, policy makers need to design or support the implementation of new incentive systems that are not linked to product prices.

Innovation Inducement Prizes with Proportional Reward Systems Should Replace Marketing Monopolies as the Primary Incentive Mechanism for Developing Countries

In 2002 and 2003, research on innovation inducement prizes in the area of medicines and agricultural focused on new methods of valuing prize payments.

Before 2002, most work on prizes had focused on designs that involved complex and difficult standards for winning prizes, and an advanced specification of the amount of money that entrants would win for achieving such standards. The information requirements for such prizes was high, causing many to reject prizes as unworkable.

The 2002/2003 proposals explored a different approach.[1] Large prize funds would give rewards to multiple applications, so long as they met fairly low standards to qualify for prize payments, such as the registration of a new drug with a regulatory agency. The amount of money each "winner" would get would be determined by competition among the applications. In the health area, awards from a prize fund of a fixed size would be divided among competitors, in part on the basis of the impact of innovations on the improvements in health outcomes.[2]

There have been a number of proposals to implement such rewards in the area of medicine. The most advanced were the 2005 and 2007 proposals in the US Congress for a Medical Innovation Prize Fund, and the 2008 IGWG proposals by Barbados and Bolivia for innovation inducement prizes.

New Prize Designs Include Open Source Dividends

In 2008, a series on technical workshops on medical innovation prizes were held in Maastricht, Geneva and Washington, DC. At these workshops, an in the academic literature on prizes, there was concern that prizes could lead to excessive secrecy and undermine sharing and access to knowledge.[3] To

1 For a review of the development of these proposals in the area of medicine, see: Love J, Hubbard T., "The Big Idea: Prizes to Stimulate R&D for New Medicines," *Chicago-Kent Law Review* 2007. In Agricultural, see Will Masters work here: http://www.agecon.purdue.edu/prizes/

2 In agriculture, the prizes would be divided among competitors on the basis of improvement sin crop yields.

3 Marchant, Ron, "Managing Prize Systems: Some Thoughts on the Options," *KEStudies*, Vol. 2 (2008). Penin, Julien, "Patents versus ex post rewards: A new look," Research Policy 34 (2005) 641–656

respond to these concerns, proposals were made for new incentives to share access to knowledge, materials and technologies. One example is the open source dividend, a proposal to share some of the final product prize money with entities that openly share access to knowledge, materials and technology. The Open Source Dividend approach was concretely modeled in several of the 2008 Barbados/Bolivia prize proposals.

Generic Competition is a Strategically Important Issue

The world is experiencing a profound change in the global trading system. The creation of the WTO and the adoption of the TRIPS Agreement will impose a new standard for the protection of patents and other intellectual property rights in developing countries. India, China and all other developing country markets of significant size have undertaken far reaching changes in their domestic laws to implement the TRIPS Agreement. These changes will make it much more difficult for generic suppliers of medicines to operate.

If the generic medicines sector is marginalized, as some hope and others fear, it will be far more difficult for any country to benefit from compulsory licensing of patents.

Generic producers operate like other businesses, and are driven by profit opportunities, with cost structures that depend dynamically upon economies of scale and scope, and learning by doing. Pricing decisions are influenced by the number of competitors. Countries cannot simply issue compulsory licenses and expect to have low cost generic products readily available. Without sufficient markets for generic products, efficient generic suppliers will be hard to find, and it will be difficult to negotiate affordable prices for products, or to even know what cost structures are.

Some Proposals to the EWG Are Deliberately Designed to Marginalize The Generic Sector

The most problematical proposals to the EWG will be those that feature donor subsidies to producers without conditions to allow competition for the manufacturing of products. Among the proposals that are explicitly designed to protect monopoly supply models are the Health Impact Fund (HIF), which is a prize fund model without open licensing of inventions, and various versions of Advanced Marketing Commitments (AMCs), which are direct subsidies to monopoly suppliers of medicines. The decisions to forgo open licensing of inventions is motivated in part to accommodate demands of large pharmaceutical companies that generic producers be denied the ability to operate and achieve important economies of scale and scope.

The Health Impact Fund Would Undermine Generic Competition

Thomas Pogge and Aidan Hollis have abandoned their earlier positions on innovation incentives, generic competition and compulsory licensing of patents and presented in 2008 a proposal for Health Impact Fund (HIF).[4] The authors often present as their own the development of proportional reward mechanisms that in fact were first developed and promoted by others over the period of 2002 to 2005.[5] What the HIF has changed is harmful, and not helpful.. Specifically, the HIF proposes that voluntary prize funds, first proposed with open licensing of inventions to generic suppliers, instead be

4 For discussion, see: http://www.keionline.org/blogs/tag/hif/

5 In medicine, important work was done by James Love, Tim Hubbard, Terry Gardiner, Michael Behan, Senator Bernard Sanders, and the participants in more than a dozen technical workshops.

implemented with a system of negotiated prices from originators, maintaining the monopoly control of the manufacturing and sale of products, with subsidizes to the seller. This has the practical and intended effect of undermining compulsory licensing of patents (a practice now condemned in the HIF proposal), and making it difficult if not impossible for subsidized generic suppliers to compete. Because of economies of scale and scope, this will weaken the generics sector generally, and undermine the incentives for companies to choose a voluntary regime in the first place.

The decision in the HIF to oppose even voluntary licensing of patents as a condition of receiving the prize fund money was explained by its proponents as a ploy to attract support from large pharmaceutical companies.[6]

Sustainable Finance I: Funding Research and Development Entities

Drug development now depends upon a variety of different sources of revenue, including both "push" and "pull" financing mechanisms.

Push financing is often defined as measures to lower the costs of doing research, including direct grants from governments and private donors, and various less direct subsidies such as tax credits or concessionary loans. Push funding also includes funding of libraries, databases and other resources that are useful for research. The role of push funding is extremely important in advancing scientific knowledge, and ensuring there is sufficient investment in all aspects of the development of new products, including every phase of human clinical trials. Push funding can also play an important role in ensuring that society has access to unbiased information about products, promotes capacity building and technology transfer with developing countries, and that research is done in areas where risks are high or where it is difficult or impossible for an investor to appropriate the social benefits of the research, such as the knowledge gained from unsuccessful experiments, pre-commercial translational research, or easily emulated innovations.

"Pull" financing is defined as incentive mechanisms that reward certain outcomes. These outcomes might include technical achievements, or the successful development and sale of products. Pull incentives are used both to supplement push funding, and to create mechanisms to stimulate and focus private sector decision making on products that succeed in achieve milestones.

Pull incentives are often associated with a variety of traditional and *sui generis* intellectual property right regimes, including most prominently:

1. Exclusive rights or remuneration relating to the sale of patented inventions,
2. Exclusive rights to sell orphan products,
3. Extended market exclusivity as a reward for testing medicines for pediatric uses, and
4. Exclusive rights or renumeration to rely upon pharmaceutical test data for drug registration.

Pull incentives can take other forms, including but not limited to:

5. Monetary Prizes,
6. Guaranteed subsides for product sales, such as Advanced Market commitments (AMCs) or

6 "Why the HIF rejected open licensing," November 19th, 2008. http://www.keionline.org/blogs/2008/11/19/why-hif-rejected-open-licensing/

Advanced Purchase Commitments (APCs), and

7. The new US FDA Priority Review Voucher.[7]

Closely associated with pull mechanisms are discussions about the demand and price of products. An exclusive right to sell is only valuable if there is significant demand for a product at high prices. Since reward systems that rely upon high prices create hardships and barriers for access to medicine, there is an interest in using newer incentive mechanisms that separate markets for innovation from markets for products, such as is possible with innovation inducement prizes. For innovation inducement prizes to be effective, they must be large.

Relationship between Intellectual Property Rights, Access and Other R&D Mechanisms

The relationships between Intellectual Property Rights and or other funding mechanisms, such as grants, prizes, tax credits, advanced market commitments, reimbursement policies or the FDA priority review voucher, are important, and complex. Entities that fund research, directly or indirectly, can make demands regarding access to R&D outputs. This can take the form of requirements for licensing of intellectual property rights, affordable pricing, freedom for follow-on research, or other measures to protect the public interest. In many cases no such demands are made. For example, the U.S. Tax credits and market exclusivity for orphan drugs, and the U.S. FDA Priority Review Voucher for neglected diseases, have no conditions regarding making products affordable, or licensing intellectual property rights. Even when such requirements are present, such as the conditions attached to U.S. Federally funded inventions regarding licensing and pricing, they are often not exploited or enforced, except in rare circumstances.

Relationship between Intellectual Property Rights and Innovation Inducement Prizes

In general, prizes and patents are not mutually exclusive. Prizes can exist within a system of patents, either as a supplementary reward for innovation, or as an alternative reward to patent powers. As an alternative reward,prizes can be implemented in connection with a voluntary license of patents, or in connection with a compulsory licensing scheme, where the prize reward serves as the TRIPS mandated adequate remuneration. There have been proposals within the IGWG process to consider all three approaches.

Type II and III diseases

In general, if a prize is offered in connection with a global program to support R&D for Type II or III diseases, a system of voluntary licensing of intellectual property rights for developing country use in a field of technology as a condition of receiving prize money should be considered, if for no other reason than it is practically very difficult to implement non-voluntary licensing in a large number of countries at the same time, and it may not be necessary, if the prize is large relative to the potential profits

7 See: David B. Ridley, Henry G. Grabowski, and Jeffrey L. Moe, Developing Drugs For Developing Countries: Linking incentives for essential drugs in developing countries with "blockbuster" drugs in the developed world would help both achieve,better population health, *Health Affairs*, Vol. 25, No 2. Aaron S. Kesselheim, M.D., J.D., M.P.H., Drug Development for Neglected Diseases -- The Trouble with FDA Review Vouchers, *NEJM* Volume 359:1981-1983, November 6, 2008, Number 19.

without the prize. For voluntary prize mechanisms, the amount of the prize should be large enough to stimulate investment, and to induce the granting of an open license. For smaller prizes, there will not be sufficient leverage to induce sufficient investment or voluntary licensing.

Type I diseases

For Type I diseases, such as cancer, asthma, diabetes or heart disease -- the cause of significant death and suffering in developing countries -- voluntary approaches will be more difficult and expensive to implement. In such cases, the potential market for a minority of high income persons living in developing countries will influence pricing decisions, as will concerns that low prices in developing country markets will undermine high prices in developed country markets. The rationale for non-voluntary licensing of products for Type I diseases is quite strong when prices are not affordable for most people living in developing countries. In such cases, the amount of the prize payments in developing country markets is only part of a larger global market for innovation that includes high income country markets.

The use of prizes to reward patent owners would be part of different approach to rewarding innovators, and could be implemented under Articles 30, 31 or 44.2 of the TRIPS. Article 44.2 of the TRIPS would perhaps provide the greatest flexibility, a point that is not widely appreciated and one that the EWG should investigate, in the context of implementing prizes for Type I diseases.

Non-Patented Innovations

Prizes also offer the possibility of rewarding **non-patented innovations** or actions. For example, prizes could reward the development of products that are wholly in the public domain, such as products developed through open source collaborations, new uses of generic medicines, or a variety of other cases where patents are not relevant or helpful in rewarding innovators.

Sustainable Finance II: Paying for R&Ds

The core systems to support biomedical innovation are expensive. Directly or indirectly, Funding for both push and pull mechanisms come from the public, either as taxpayers, consumers, employers or philanthropic donors.

At present the primary global systems to support biomedical R&D are those associated with the growing array of intellectual property rights,[8] and other measures to promote high drug prices such as agreements to increase reimbursement rates for drug purchases.[9]

As the EWG struggles with the task of finding new sources of financing for priority needs driven R&D, it should consider a variety of approaches that can be used to support both push and pull financing. The EWG can fruitfully look to such sources as:

1. A new WTO Agreement on the Supply of Public Goods, whereby commitments to supply heterogeneous public goods become binding.

8 Most importantly, the WTO TRIPS Agreement, but the growing number of plurilateral and bilateral agreements and unilateral pressures for co called TRIPS plus intellectual property standards.

9 The E.U. has reached such agreements with Korea and Turkey. The US has negotiated the A-7 pricing agreement with Korea.

2. Global norms relating to the size of national income and level of development
3. Global taxes to support public goods, such as the model pioneered by UNITIAD, or have been frequently proposed in connection with financial transactions.
4. Shares of health budgets spend or treatment or medicines.

Finally, the EWG should consider the incentives of countries to support such initiatives. In 2005 a group of experts asked the WHO and the CIPIH to consider a medical R&D Treaty that would, among other things, provide an escape from other global obligations relating to intellectual property rights or drug pricing, if countries met medical R&D treaty obligations regarding funding for medical R&D. It may be that such an approach would be attractive for countries that are willing to support the global costs of medical R&D, but are reluctant to punish consumers to do so.