

Reprinted from

**International Journal  
of  
Health Research**

**Peer-reviewed Online Journal**

<http://www.ijhr.org>

---

---

**PORACOM**

Academic Publishers

---

# International Journal of Health Research

---

The *International Journal of Health Research* is a peer-reviewed online international journal allowing free unlimited access to abstract and full-text of published articles. The journal is devoted to the promotion of health sciences and related disciplines (including medicine, pharmacy, nursing, biotechnology, cell and molecular biology, and related engineering fields). It seeks particularly (but not exclusively) to encourage multidisciplinary research and collaboration among scientists, the industry and the healthcare professionals. It will also provide an international forum for the communication and evaluation of data, methods and findings in health sciences and related disciplines. The journal welcomes original research papers, reviews and case reports on current topics of special interest and relevance. All manuscripts will be subject to rapid peer review. Those of high quality (not previously published and not under consideration for publication) will be published without delay. The maximum length of manuscripts should normally be 10,000 words (20 single-spaced typewritten pages) for review, 6,000 words for research articles, 3,000 for technical notes, commentaries and short communications.

**Submission of Manuscript:** The *International Journal of Health Research* uses a journal management software to allow authors track the changes to their submission. All manuscripts must be in MS Word and in English and should be submitted online at <http://www.ijhr.org>. Authors who do not want to submit online or cannot submit online should send their manuscript by e-mail attachment (in single file) to the editorial office below. Submission of a manuscript is an indication that the content has not been published or under consideration for publication elsewhere. Authors may submit the names of expert reviewers or those they do not want to review their papers.

## *Enquiries:*

The Editorial Office  
International Journal of Health Research  
236-202, St David Court, Cockeysville,  
MD 21030, USA  
E-mail: [editor@ijhr.org](mailto:editor@ijhr.org)  
Tel: +1-614-535-7928

**PORACOM**  
Academic Publishers

## Commentary



# Innovation and Access to Medicines: The poor should be able to have their medicine and take it too

Received: 8-Feb-08

Revision received: 23-Feb-08

Accepted for publication: 25-Feb-08

### Abstract

*The poor and vulnerable, especially in developing nations, have little access to innovative medicines. Last year the World Health Organization (WHO) established the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) to "draw up a global strategy and plan of action aimed at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries." Unfortunately the policies under consideration are short-sighted and will undermine progress toward achieving health for all. The IGWG must focus on mechanisms that both enhance access to medicines and preserve the incentives for innovation. Regrettably, the existing Draft Strategy falls short. Specifically, the policies surrounding intellectual property rights and domestic production must be reexamined.*

**Keywords:** Access to medicines, developing countries, domestic production, intellectual property rights, public health, WHO.

### Kristina M. Lybecker

Department of Economics and Business, Colorado College, 14 E. Cache la Poudre Street, Colorado Springs, Colorado 80903 USA

### For Correspondence:

Tel: +1-719-389-6445

Fax: +1-719-389-6927

E-mail: [Kristina.Lybecker@coloradocollege.edu](mailto:Kristina.Lybecker@coloradocollege.edu)

## Introduction

In recent years, technological progress and modern science have provided astounding advances in the prevention, diagnosis and treatment of many diseases. Unfortunately these advances are not available to many patients. The poor and vulnerable, especially in developing nations, have little access to innovative medicines. Last year the World Health Organization (WHO) established the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). The IGWG seeks to “draw up a global strategy and plan of action aimed at, *inter alia*, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries”<sup>1</sup>.

The Draft Strategy addresses a critical public health problem and the goals are laudable. There is near universal support for both increasing research and development (R&D) on neglected diseases and enhancing access to medicines. Regrettably, the policies under consideration are short-sighted and will undermine progress toward achieving health for all. The IGWG must focus on mechanisms that both enhance access to medicines and preserve the incentives for innovation.

The WHO’s IGWG second session is scheduled for April 2008 and the global plan of action will be presented to the World Health Assembly in mid-2008. As the process quickly moves forward, it is essential to critically examine the Draft Strategy, evaluate whether all stakeholders are included and involved in the process, and determine whether the objectives are being met and mechanisms will enhance public health.

The IGWG is tasked with examining eight elements of the Draft Strategy:

1. prioritizing health research and development needs
2. promoting research and development
3. building and improving developing-country capacity for health innovation
4. transfer of technology
5. management of intellectual property for new health products
6. improving healthcare delivery and access
7. ensuring sustainable financing mechanisms
8. establishing monitoring and reporting systems

Many of these elements are vital to improving global health, though some are neither feasible nor cost effective. Of greatest importance is a reexamination of the role of intellectual property rights and capacity building in developing countries.

## Complicated Problem

The IGWG has focused almost exclusively on intellectual property rights, neglecting the importance of a host of other factors that contribute to the problems surrounding public health policymaking in developing nations: insufficient political will, scarce medical and transportation infrastructure, poverty, and inadequate market incentives. Of these, the most important elements contributing to the lack of access are poverty and the absence of market incentives. The Draft Strategy’s focus on compulsory licensing and domestic generic production leaves the root causes underlying insufficient access to medicines unaddressed.

The goals of the Intergovernmental Working Group Draft Strategy are noble and it is difficult to find fault with them. However, their conceptualization of the problems of public health, especially those facing developing nations, is flawed. Specifically, that the international patent system and the attendant drug prices are a barrier to access for the poor. Fundamentally, the Draft

Strategy assumes that developing country patients do not have access to the drugs they need because of intellectual property rights. Regrettably the problem is not that simple. It is far more complicated and nuanced, and not so easily fixed.

### **Pharmaceutical Innovation and R&D**

The Draft Strategy describes one of its primary aims as “increasing worldwide capacity for research and development, particularly in developing countries, into diseases affecting those countries.” As envisioned, the promotion of local research and development capacity diverts scarce resources from and creates redundancies with existing research and development efforts. Beyond the pipelines and research agendas of the multinational innovative pharmaceutical industry, the plan duplicates other public initiatives and private efforts, such as the WHO’s Tropical Disease Research Programme and the Drugs for Neglected Diseases initiative (DNDi).

Moreover, it is worth questioning whether developing countries will benefit from domestic research and development capacity. These countries are certainly not endowed with the requisite resources that would give them a comparative advantage in the pursuit of such research. Nations differ greatly in their abilities to provide the necessary resources and regulations for pharmaceutical discovery and manufacture. Specifically, a successful research and development facility requires highly skilled scientists and researchers, other well-trained technicians and staff, in addition to transparency in local regulations, taxation policy and legal infrastructure, good manufacturing practice directives and regulatory oversight, strong protection of intellectual property, development of a sufficient local/regional market, political stability, and the absence of corruption. Admittedly, some nations will possess the majority of these assets. Many, however, will

not and they will be unable to follow through and build local capacity. Without sufficient oversight and regulation, the risk of producing and exporting poor quality and counterfeit drugs increases. Such products not only fail to improve patient health, they may be lethal.

In addition, economic research has determined that innovation in high tech industries is enhanced by geographic concentration which facilitates R&D spillovers. It has been established that to a remarkable degree, technology is a local rather than a global asset<sup>2</sup>. Proximity facilitates research conversations and collaboration, technological spillovers, and enhances innovative productivity. Given this, an isolated research facility in a developing nation would fail to capitalize on such benefits. It is likely that the resources required would be better invested in alternative healthcare projects.

Pharmaceutical research is a high-risk, serendipitous process. Beyond the inherent challenges to drug discovery and development, research productivity is further threatened by the proposed compulsory licenses. In essence, compulsory licensing allows a national government to forcibly take the patent rights from an innovator, in return for a reasonable royalty. This obviously disincentivizes the launch of innovative medicines in developing nations and reduces the incentives for investing in research and development. While compulsory licensing may allow for the inexpensive provision of some drugs today, the static gains are far outweighed by the dynamic losses. Over time, fewer drugs will be developed for the diseases endemic to developing countries. The incentives to develop drugs for neglected diseases and rare disorders are severely reduced when patents are vulnerable to such taking. Accordingly, under the threat of compulsory licenses, neglected diseases may be absent from the R&D agendas of innovative firms.

Developing nations face drug shortages for two reasons: a lack of access and absence of innovation. Admittedly, both of these factors may be linked to intellectual property rights, though realistically poverty is the root cause. Unfortunately, drugs are not available because there is no market for them. In the language of economics, demand results from consumers willing and able to purchase a good. Though willing, the poor in developing nations are frequently unable to purchase the needed drugs. The market incentives necessary to bring medicines to these patients are missing.

#### **Drug Prices and Market Incentives**

As noted above, pharmaceutical innovation is a difficult and expensive process to undertake, but one that is easy to replicate. At almost a billion dollars for each new chemical entity, drug development is a costly process, though the marginal costs of production are quite low. As a result, patents are the mechanism of choice for protecting pharmaceutical innovation. The pharmaceutical and chemical industries disproportionately rely on patent protection to protect their intellectual property and innovations. Pharmaceutical firms also rely upon Ramsey Pricing, specifically differential pricing based on price elasticity of demand (the ability to pay), across national markets to increase consumer access while recovering their fixed costs. In a study of differential versus uniform pricing, Dumoulin (2001) found that differential pricing across nations enhances patient access by a factor of 4 to 7<sup>3</sup>. The use of such mechanisms, in addition to the absence of competition over the life of the patent, results in a price that usually exceeds marginal cost.

Although prices in excess of marginal cost are usually out of reach for poor patients, even drugs priced at the cost of production are unaffordable for many consumers in

developing nations. For these individuals, the lack of access to medicines occurs because they lack the income to create demand. Such poverty ensures that diseases endemic to developing nations do not find a place on the R&D agenda, resulting in an absence of innovation. Without financial resources to incentivize innovation, these diseases are never researched and treatments never emerge. Innovation on these diseases may require complementary incentive mechanisms.

The 1983 U.S. Orphan Drug Act and parallel European legislation in 2001 are examples of such a mechanism. These legislative changes stimulated the development of numerous drugs for diseases with limited market potential. They work through a combination of push mechanisms (R&D tax credits) as well as pull mechanisms (market exclusivity). In reflecting on this, a similar piece of legislation for neglected diseases could be an important motivation in the development of treatments for tropical and neglected diseases.

#### **Neglected Diseases**

Although the IGWG Draft Strategy readily identifies patents held by multinational pharmaceutical firms as a primary barrier to access, it is important to acknowledge that the existing drugs available to treat 'diseases of poverty' were developed almost exclusively by the innovative global pharmaceutical industry. These same firms continue to work on neglected diseases and their pipelines hold many promising compounds. Moreover, the industry is the source of billions of dollars worth of drugs donated for treating patients in resource-poor nations. The Hudson Institute notes the "U.S. based Partnership for Quality Medical Donations (PQMD) recorded the 'value of donated products at \$4.3 billion in 2005' for the developing world. This sum alone is greater than the combined annual health budgets of the WHO, UNICEF and

the World Bank<sup>4</sup>. If resources are within reach and promising compounds are in the pipeline, one again has to question whether the domestic capacity proposed by the IGWG plan is truly in the best interest of developing country patients.

### **The Patient Perspective**

The problematic treatment of both intellectual property rights and domestic capacity forces an examination of what is best for patients and whether these priorities are reflected in the IGWG agenda. Remarkably, the Draft Strategy emerged from a process largely void of patient participation. Frustration with their exclusion from the process is evident in the patient group submissions to the public hearings. It is difficult to imagine a group with a greater stake in the issue than the patients. Nevertheless, the Draft Strategy has been crafted without their involvement.

With even a cursory look at the patient group submissions it becomes clear that many patient concerns are not reflected in the Draft Strategy in its current form. Patient groups clearly place an emphasis on continued innovation and mechanisms that provide new and more powerful incentives for research on neglected diseases. These are diseases for which the existing incentives are insufficient. The incentives for research in these areas must be enhanced rather than undermined. This is especially true in the case of truly neglected diseases. The diseases are relatively few in number and include the following: Trypanosomiasis, Chagas Disease, and Dengue Fever. Currently these diseases are missing from the research agenda of the pharmaceutical industry and treatments are not in the pipelines. Such 'diseases of poverty' remain a problem largely because of the absence of market incentives, not the presence of patents.

### **Conclusion**

The World Health Organization's Intergovernmental Working Group has tackled a problem of tremendous importance and magnitude. The challenge cannot be overestimated. Nevertheless, as the IGWG considers devoting significant resources to developing country diseases, it is important to ensure that global healthcare resources are spent wisely and truly move us toward health for all, including patients in resource-poor nations. Accordingly, the IGWG must focus on mechanisms that both enhance access to medicines and preserve the incentives for innovation. The existing Draft Strategy falls far short. Specifically, the policies surrounding intellectual property rights and domestic production must be reexamined. Although the existing strategies are attractive in the short run, the long run risks of reduced innovation are too high a price. The IGWG should stop trying to improve upon the international patent system and focus on their mandate to improve healthcare delivery and access. While the criticisms of the IGWG Draft Strategy described here are significant, there are several ideas within the document worth pursuing. The WHO Intergovernmental Working Group has a unique opportunity to contribute to enhancing the access to medicines for the world's poorest and most vulnerable populations, and improving health for the developing world. The careful redefinition of their mandate and focus is an important next step.

### **References**

1. World Health Organization. Draft global strategy and plan of action on public health, innovation and intellectual property. A/PHI/IGWG/2/2, 31 July 2007. Available from [www.who.int](http://www.who.int)
2. Jaffe AB, Trajtenberg M, Henderson R. Geographic localization of knowledge spillovers as evidenced by patent citations. *Quarter J Econ*, August 1993, 108(3): 577-598.
3. Dumoulin J. Global pricing strategies for innova-

***Lybecker KM. Access to innovative medicines***

tive essential drugs. *Int J Biotech*, 2001; 3(3/4): 338-349.

4. Norris J. An analysis of the World Health Organization Secretariat's Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. Contribution to the second public hearing, 27 September 2007. Available from: [http://www.who.int/phi/public\\_hearings/second/contributions\\_section1/Section1\\_Jeremiah%20Norris\\_Hudson%20Institute\\_Full\\_Contribution.pdf](http://www.who.int/phi/public_hearings/second/contributions_section1/Section1_Jeremiah%20Norris_Hudson%20Institute_Full_Contribution.pdf)