

WHO IGWG DRAFT STRATEGY

Background

In August 2006 the World Health Organization (WHO) established the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). The IGWG must deliver by May 2008 a “global strategy and plan of action” for boosting research and development (R&D) of medicines for non-prioritized or neglected diseases, predominantly found in developing countries.

Timeline:

- The IGWG released a draft global strategy and plan of action (for boosting R&D of medicines for non-prioritized or neglected diseases, predominantly found in developing countries) on July 31, 2007.
- This draft global strategy will form the basis of the next round of IGWG negotiations that are scheduled for Nov 5-10, 2007.
- The IGWG is to make its’ final recommendations to the WHO in January of 2008 and the global strategy is to be completed by May 2008.

Summary of IGWG Draft Key Recommendations:

The report is organized into eight elements: Prioritizing Research & Development (R&D) Needs; Promoting R&D; Building and Improving Innovative Capacity; Transfer of Technology; Management of Intellectual Property; Increasing Delivery and Access; Ensuring Sustainable Financing Mechanisms; and Establishing Monitoring and Reporting Systems.

The following paper outlines the main points in the IGWG report, as well as highlighting certain issues of particular interest for patients.

PRIORITIZING RESEARCH & DEVELOPMENT NEEDS

The report states that health research and development policies in *developed* countries need to adequately reflect the health needs of *developing* countries. Specifically gaps in research on Type II and Type III diseases and on the needs of developing countries in relation to Type I diseases need to be identified urgently. The Commission defines Type I, II and III diseases in the following manner:

Identifying “Neglected Diseases”

The July 14 draft global strategy narrows the focus of the IGWG’s task from undefined “non-prioritized or neglected disease” to 14 specific diseases.

Type 1 diseases which are “incident in both rich and poor countries”: diabetes, cancer and cardiovascular disease.

Type 2 diseases which are “incident in both rich and poor countries but with substantial proportion of the cases in poor countries”: HIV/AIDS, and tuberculosis.

Type 3 disease which are overwhelmingly or exclusively in developing countries: Chagas disease, dengue, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, schistosomiasis, and human African trypanosomiasis.

Specific actions include;

- Promote the active participation of developing countries in the innovation process;
- Conduct research appropriate for resource-poor settings and research on technologically appropriate products to combat diseases in developing countries;
- Include R&D needs for traditional medicines in a prioritized strategy.

PROMOTING RESEARCH AND DEVELOPMENT

The report calls for a range of measures to promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases to be substantially enhanced. The report calls for greater investment, in both developed and developing countries into 'neglected diseases' (see above).

Specifically the report calls for:

- Developed countries to devote a greater proportion of their R&D funding on the health needs of developing countries;
- To promote cooperation between public and private sectors on R&D;
- Provide support for national health research programmes in developing countries through political action and long-term funding;
- Promote upstream research and product development in developing countries by considering legislation compliant with TRIPS research exemptions;
- Develop and implement systems for supporting health-related innovation in developing countries (including intellectual property management).

BUILDING AND IMPROVING INNOVATIVE CAPACITY

Effective policies that promote the development of capacities in developing countries related to health innovation are needed. Key areas for investment are capacities relating to science and technology, clinical trials, regulation, intellectual property and traditional medicine.

Tactics Include:

- Strengthen product regulatory capacity in developing countries;
- Encourage developing countries to ensure high standards of safety and efficacy for traditional medicines

TRANSFER OF TECHNOLOGY

"North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

Specifically, the report suggests

- That other effective and sustainable mechanisms to promote innovation of products for priority diseases in developing countries should be developed;

- Best practices in areas such as competition, transparency and proper remuneration for patent holders must be examined;
- Encourage North–South and South–South collaboration, and collaboration between institutions in developing countries and the pharmaceutical industry;
- Develop other effective and sustainable mechanisms to promote innovation of products for priority diseases in developing countries.

MANAGEMENT OF INTELLECTUAL PROPERTY

Intellectual property is a vital concept in ensuring that development of new health products continues. However, complementary, alternative and/or additional incentive schemes for research and development, especially on Type II and Type III diseases and the special needs of developing countries in respect of Type I diseases, need to be explored and implemented.

“There is a crucial need to strengthen capacities in developing countries to manage intellectual property.” The draft strategy specifically encourages WHO to get more involved in Intellectual Property (IP) in collaboration with the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) to “strengthen education and training in the management of intellectual property.”

Other tactics include:

- Promoting legislation to apply flexibilities consistent with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other international agreements;
- Promote bilateral trade deals that do not contain “TRIPS-plus” requirements and that such bilateral deals should be “regularly monitored” as to their impact on health;
- Explore and implement complementary incentive schemes for research and development that separate the incentives for innovation from the prices of health-care products;
- Assess the impact of data-exclusivity regulations

IMPROVING DELIVERY AND ACCESS

The stimulation of competition and the adoption of appropriate pricing and taxation policies for health products is vital to the success of the strategy (as is support for health systems).

International and bilateral agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries. The impact of such actions on innovation needs to be monitored.

The report suggests:

- Minimize the public health consequences of counterfeit and substandard products;
- Promote competition and ensure that pricing of medicines is consistent with public health policies;
- Encourage pharmaceutical companies to adopt transparent and consistent pricing policies, aiming to reduce prices for developing countries;
- Take necessary legislative steps in countries with manufacturing and export capacity to allow compulsory licensing for export consistent with the Agreement on Trade-Related Aspects of

Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health;

- Strengthen capacity to monitor the quality, safety and efficacy of health products, and accelerate the regulatory approval of products with potential utility;
- Support the production and introduction of generic versions of essential medicines in developing countries, including national legislation to encourage generic entry on patent expiry.

ENSURING SUSTAINABLE FINANCING MECHANISMS

In recent years donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional donor financing has also been secured for research and development activities relevant for the control and treatment of the diseases covered by this strategy.

Nonetheless, further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries. The most serious gaps in donor financing for health products and research and development covered by this strategy need to be identified and analysed.

It is important to expand current initiatives, thereby contributing to a flow of resources into innovation and implementation, including public–private partnerships, initiatives by foundations, advance-market commitment mechanisms, and the International Finance Facility for Immunization.

ESTABLISHING MONITORING AND REPORTING SYSTEMS

Systems should be established to monitor performance and progress of this strategy. Such performance and progress will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the strategy will be undertaken every four years.