PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

The Fifty-ninth World Health Assembly in May 2006 adopted resolution WHA59.24, establishing an intergovernmental working group (IGWG) open to all Member States interested in helping to develop a global strategy and plan of action that could serve as a medium-term framework based on the recommendations of the WHO Commission on Intellectual Property Rights, Innovation and Public Health.

The IGWG which includes delegates from almost 100 countries, held its first meeting in Geneva from 4 to 8 December 2006. The Western Pacific Region was represented by delegates from Australia, China, Japan, the Lao People's Democratic Republic, Malaysia, New Zealand, the Republic of Korea, Samoa, Singapore and Viet Nam. The meeting was chaired by Canada and five vice chairs were elected from WHO regions. From the WHO Western Pacific Region, Singapore was elected as vice chair. The IGWG meeting agreed upon a draft document, *Elements of a global strategy and plan of action*. The next IGWG meeting will be held from 5 to 10 November 2007 to negotiate and finalize the draft global strategy and plan of action. The plan will be presented to the Sixty-first World Health Assembly through the Executive Board.

Member States are strongly encouraged to participate in negotiations during the second meeting of the IGWG. They may wish to undertake a national consultation involving relevant ministries to discuss related issues concerning public health, innovation and intellectual property. The working document for the second session of the IGWG entitled Global Strategy and Plan of Action: Public Health, Innovation and Intellectual Property and other documents are available for discussion at the fifty-eighth session of the Regional Committee.
1. CURRENT SITUATION

It has become increasingly clear in recent years that an insufficient level of research and development is taking place that specifically targets diseases that disproportionately affect developing countries. Data show that only 13 of about 1400 new drugs developed between 1975 and 1999 were for tropical diseases or neglected diseases. Concerned about these developments, the Fifty-sixth World Health Assembly in resolution WHA56.27 requested the Director-General to establish “an appropriate time-limited body” to produce an analysis of intellectual property rights, innovation and public health, including the issue of appropriate funding and incentive mechanisms for the creation of new medicines and other products for diseases that disproportionately affect developing countries.

Thus, a broad-based Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was created. The CIPIH submitted its report in April 2006. The report addresses a wide range of issues, from basic research to the delivery of medicines to end-users. It contains 60 recommendations targeting various stakeholders.

Subsequently, the Fifty-ninth World Health Assembly in May 2006 adopted resolution WHA59.24, establishing an intergovernmental working group (IGWG) open to Member States interested in helping to develop a global strategy and plan of action which could serve as a medium-term framework based on the recommendations of the WHO Commission on Intellectual Property Rights, Innovation and Public Health.

The tasks of the Intergovernmental Working Group are to:

(a) draw up a global strategy and plan of action that aims, among other goals, to secure an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries;

(b) report to the Sixtieth World Health Assembly through the Executive Board on the progress made, giving particular attention to needs-driven research and other potential areas for early implementation action; and

1 http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf
(c) submit the final global strategy and plan of action to the Sixty-first World Health Assembly through the Executive Board.

In response to the resolution, a secretariat has been established within WHO Headquarters, drawing on key staff from across the Organization, in order to support the work of the IGWG. A steering committee has also been established that includes an Assistant Director-General from Headquarters and senior staff from all regional offices.

In November 2006, a web-based public hearing was conducted to solicit input from interested stakeholders for the elements of global strategy and plan of action. Elements of the global strategy and plan of action were drafted by the secretariat and were discussed at the first IGWG meeting.

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The outcome of this first IGWG meeting is a draft document *Elements of a global strategy and plan of action*.

The IGWG listed the following elements for the draft plan of action:

- prioritizing research and development needs;
- promoting research and development;
- building and improving innovative capacity;
- transfer of technology;
- management of intellectual property;
- improving delivery and access;
- ensuring sustainable financing mechanisms; and
- establishing monitoring and reporting systems.

The meeting also discussed the draft global strategy, which was developed based on WHO consultations, the report of CIPIH and relevant resolutions in related subjects. Both documents are early drafts. Additionally, written input and comment were sought from Member States, and as of

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2 http://www.who.int/gb/phi/PDF/phi_igwg1_5-en.pdf
15 June 2007, 20 submissions from Member States\(^3\) were received and are available for review at [www.who.int/phi](http://www.who.int/phi). These have been used by the secretariat to produce a revised working text. Based on the additional input and suggestions from Member States, a revised working document was prepared for review in July 2007. It will serve as a basis for negotiation during the second meeting of the IGWG in November 2007.

A report by the secretariat was submitted to the Sixtieth World Health Assembly on progress made by the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property.\(^4\) Based on the proposals from Member States, the Director-General, in consultation with the Bureau, also identified a pool of experts and concerned entities to ensure balanced regional, gender and developed/developing country representation.

The Sixtieth World Health Assembly, in resolution WHA60.30 (Annex 1), requested WHO to provide support for regional consultative meetings in order to set regional priorities that will inform the work of the Intergovernmental Working Group. Therefore, in the Western Pacific Region, two intercountry consultative meetings have been organized—the first in Tonga for the Pacific island countries (7–9 August 2007) and the second in Manila for Asian countries (5–7 September 2007).

### 2. ISSUES

Worldwide, so-called "diseases of poverty" contribute to over 50% of the burden of disease in low-income developing countries. Reducing the high incidence of communicable diseases is a chief priority. However, it is important to ensure that the growing problem of noncommunicable diseases in developing countries also is addressed. Given current awareness of the fundamental inequities inherent in the disproportionate burden of disease on developing countries, ways must be found to tackle more effectively the health needs of the poor and vulnerable, in particular women and children.

While considerable progress has been made in recent years by governments, industry, charitable foundations and nongovernmental organizations in funding initiatives to develop new products and increase access to existing products to fight diseases affecting developing countries, much more needs to be done.

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\(^3\) Argentina, Australia, Bangladesh, Bolivia, Brazil, Colombia, Egypt, Iran, Japan, Kenya, Kuwait, Malaysia, Norway, Pakistan, Portugal, Romania, Spain, Thailand and the United States of America.

\(^4\) [http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_27-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_27-en.pdf)
Opportunities made possible by advances in biomedical science to develop new products, and in particular to meet public health needs in developing countries, need to be harnessed more effectively and more urgently. Intellectual property rights are an important incentive for the development of new health products, but this incentive alone does not meet the need for development of new products to fight diseases for which the potential paying market is small or uncertain. The contribution that innovation can make will be meaningful only if products are affordable and accessible.

Global responsibility for implementation of the strategy and plan of action will rest with a range of key actors, including WHO Member States and the WHO Secretariat, in collaboration with other international organizations such as the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO), national institutions, development partners, pharmaceutical companies, product development partnerships and civil society. Together they can ensure that the discovery and development of health products are funded and promoted in a sustainable manner in order to address the health needs of developing countries, and that the delivery of health products is accessible and affordable by the people and governments in developing countries. Successful implementation will require common and joint action.

The issues related to intellectual property, innovation and access to medicines for diseases disproportionately affecting developing countries are complex and interrelated. The topics will be discussed at the two regional consultative meetings. However, some Member States have requested for relevant information and a brief review of the topics, which is attached (Annex 2).

3. ACTIONS PROPOSED

The next IGWG meeting will be held from 5 to 10 November 2007. It will negotiate and finalize the draft global strategy and plan of action. The plan will be presented to the Sixty-first World Health Assembly through the Executive Board.

As follow-up of the first meeting of IGWG, WHO will undertake the following actions prior to the second meeting:

1. The secretariat will hold a second web-based public hearing to solicit additional input and comments on the working document from other stakeholders, e.g. civil society, academia, private sector, etc.
(2) The IGWG Bureau will continue to meet as necessary to consider other possible intersessional work and detailed arrangements for the second session. The IGWG Bureau is made up of the chair and vice chairs.

(3) The secretariat will also continue to implement CIPIH recommendations specifically addressed to WHO and any additional early implementation activities endorsed by Member States.

(4) The secretariat will help Member States in need to prepare to participate in the IGWG process, e.g. through national consultation process.

In order to participate in the IGWG process and negotiations during the second meeting, the following actions are proposed to the Member States:

(1) undertake a national consultation involving relevant departments to discuss related issues concerning intellectual property, innovation and public health in order to develop a national consensus on priorities and positions; and

(2) appoint relevant officials who will represent their national interest in the negotiation process during the second meeting of the IGWG in November 2007.

The working document for the second session of the IGWG entitled _Global Strategy and Plan of Action: Public Health, Innovation and Intellectual Property_ and other documents are available for discussion at the fifty-eighth session of the Regional Committee.
PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

The issues related to public health, innovation, intellectual property and access to medicines for diseases disproportionately affecting developing countries are complex and interrelated. Considerations include, but are not limited to, the following:

1. **Innovation and research and development**

   Medical innovation, including the development of new diagnostics, vaccines and treatments, is an important factor in addressing the burden of disease, and there is widespread agreement that it should continue. Moreover, scientific progress, exemplified by the decoding of the human genome, appears to hold enormous promise for the development of new and better medicines. But this promise has failed to materialize as the number of new drugs entering the market appears to be decreasing rather than increasing.\(^1\) There also are concerns that the number of products in research and development (R&D) pipelines are insufficient.\(^2\) While some 1400 new drugs have been developed between 1975 and 1999, only 13 were for tropical diseases or neglected diseases.\(^3\)

   Because the intellectual property rights system does not provide sufficient incentives for the development of medicines that are mainly needed in developing countries, complementary mechanisms to spur innovation have been devised. A well-known example is the public-private partnership. These partnerships generally bring together donors, researchers and private sector actors. The private sector usually contributes "in kind" expertise and is involved in screening drug candidates. Most partnerships focus on a specific issue or disease, with such examples as the Medicines for Malaria Venture and the Global Alliance for TB Drug Development. Others, such as the Drugs for Neglected Diseases Initiative, target several diseases. Public-private partnerships have successfully revitalized R&D in some disease areas that were previously neglected. It is, however, too early to assess whether these partnerships will succeed in effectively developing new products and

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\(^3\) http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf
making them affordable enough to improve the options for prevention and treatment in developing countries. Moreover, the long-term sustainability of such partnerships is often not ensured.⁴

Meanwhile, a number of innovative solutions to tackle the problem of a lack of incentives for R&D that targets type II and III diseases have been proposed.⁵ These solutions include prize funds for R&D,⁶ advance market commitments,⁷ and proposals for a treaty on R&D for neglected diseases.⁸ Some of these proposals would separate the R&D costs from the cost of the final product. These proposals, which probably should be considered as additions to—rather than replacements of—the intellectual property system, may merit further exploration and discussion by the IGWG.⁹

2. Intellectual property rights and access to medicines

The phrase "intellectual property rights" refers to a number of different rights, such as copyright, trademarks and patents. From the perspective of access to medicines, patents are the most important form of intellectual property rights; thus this discussion largely focuses on patents. Patents are a public policy tool that seeks to promote and reward innovation while at the same time ensuring disclosure of the invention, in order to make it widely known and available. A patent tries to balance these two objectives by on one hand providing exclusive rights (or monopoly rights) over an invention which can result in high prices, but on the other hand limiting the duration of those exclusive rights.

Access to medicines depends on a number of factors, namely rational selection and use, sustainable financing, affordable prices, and a reliable supply system. Medicine prices are only one factor. Yet prices are an important factor, especially in developing countries where needed medicines are predominantly paid for by patients themselves. Thus, in developing countries prices have direct implications on access to medicines.

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⁵ The CIPHI has defined Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable population in each. Type II diseases that are prevalent in both rich and poor countries, but with a substantial proportion of the cases in poor countries (e.g. HIV/AIDS and Tuberculosis). Type III diseases are those that are overwhelmingly or exclusively found in developing countries.
⁹ http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R30-en.pdf
TRIPS and access to medicines

The agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a multilateral binding agreement among World Trade Organization (WTO) member countries. The TRIPS Agreement makes it mandatory for all WTO member countries to ensure that patent protection is available in all fields of technology, including medicines, for both product and process.

The TRIPS Agreement has to a large extent harmonized the standards of patents. Except for least developed countries, after 2005 it is mandatory for all WTO member countries to implement the patent protection as stipulated in the TRIPS Agreement.

The TRIPS Agreement also requires that the minimal duration of patent protection is 20 years. This has led to concerns about its impact on access to medicines.

TRIPS also contains a number of flexibilities that member countries can use to protect the public health interest and access to medicines. The Doha Declaration on TRIPS and Public Health has confirmed that countries can use those mechanisms in order to have access to less costly and more affordable generic equivalents of patented medicines. In order to legitimately use the public health safeguards under the TRIPS Agreement, these provisions must be incorporated in national legislation. The most important safeguards are (1) compulsory licensing, (2) parallel importation, and (3) the Bolar provision, which permits initial work for the speedy registration of generics.

A compulsory license is a license to use an invention, which has been granted without the permission of the patent holder. A compulsory license can be used to allow the production, importation and sale of generics before expiry of the patent.

The TRIPS Agreement leaves countries free to determine the grounds or reasons for issuing a compulsory license, but it also specifies conditions that have to be met when a government decides to issue a compulsory license.

Parallel importation refers to importation without the consent of the patent holder of a patented product that is marketed in another country. Parallel importation allows countries to "shop around" on the international market in order to buy a patented product at the best possible price.

The Bolar provision allows testing and regulatory approval of generic versions of a drug before its patent expires, thus allowing generic producers to prepare so that they can start the production and
Annex 2

sale of a generic drug as soon as its patent expires. Thus, a Bolar provision accelerates generic competition upon expiry of the patent.

Further reading:


Studies commissioned by the CIPIH. Available at http://www.who.int/intellectualproperty/studies/en/


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10 In the absence of such provision, generic manufacturers can only start the time consuming process of testing and registration after the expiry of the patent; this can easily delay the marketing of generic drugs to 2-3 years after the patent expiry.