

Member States

Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Kazakhstan
Kyrgyzstan
Latvia
Lithuania
Luxembourg
Malta
Monaco
Montenegro
Netherlands
Norway
Poland
Portugal
Republic of Moldova
Romania
Russian Federation
San Marino
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Tajikistan
The former Yugoslav
Republic of Macedonia
Turkey
Turkmenistan
Ukraine
United Kingdom
Uzbekistan

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

World Health Organization
Regional Office for Europe
Scherfigsvej 8,
DK-2100 Copenhagen Ø, Denmark
Tel.: +45 39 17 17 17. Fax: +45 39 17 18 18.
E-mail: postmaster@euro.who.int
Web site: www.euro.who.int



© World Health Organization 2007
All rights reserved. This information material is intended for a limited audience only. It may not be reviewed, abstracted, quoted, reproduced, transmitted, distributed, translated or adapted, in part or in whole, in any form or by any means.



Background document for the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) process

WHO Regional Office for Europe,
April 2007



EUROPE

Background document
for the Intergovernmental
Working Group on Public Health,
Innovation and Intellectual
Property (IGWG) process

WHO Regional Office for Europe, April 2007

© World Health Organization 2007

All rights reserved. This information material is intended for a limited audience only. It may not be reviewed, abstracted, quoted, reproduced, transmitted, distributed, translated or adapted, in part or in whole, in any form or by any means.

What is the IGWG?

The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) was established in 2006 by resolution WHA59.24 of the World Health Assembly on public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action.

The IGWG is open to all Member States and held its first session from 4 to 8 December 2006, in Geneva.

The Working Group elected Mr P. Oldham (Canada) as Chairman, and the following vice-chairmen: Mr B. Wijnberg (Netherlands), Dr H. Gashut (Libyan Arab Jamahiriya), Dr A.E.O. Ogwel (Kenya), Mr Jaya Ratnam (Singapore), and Mr N. Dayal (India). Dr Ogwel was also designated Rapporteur. The Chairman and vice-chairs constitute the Bureau of the IGWG. The Secretariat on Public Health, Innovation and Intellectual Property (PHI) was established by WHO to facilitate implementation of Resolution WHA 59.24 and the follow-up to the report of the Commission on Intellectual Property Rights, Innovation and Public Health (see <http://www.who.int/phi>).

In addition to Member States, representatives of non-Member States, organizations of the United Nations system, intergovernmental organizations with which WHO has established effective relations, and nongovernmental organizations in official relations with WHO, can attend the sessions of the working group as observers, in accordance with the relevant Rules of Procedure and resolutions of the World Health Assembly. The Director-General also invites experts and a limited number of concerned public and private entities to attend the sessions to provide advice and expertise, as necessary, upon request of the Chairman, taking into account the need to avoid conflicts of interest.

Background

In 2003 the World Health Assembly (WHA), through its resolution WHA56.27, requested the Director General to establish an appropriate time-limited body to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation and public health. The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was created in May 2003 and produced its report in April 2006 (see <http://www.who.int/intellectualproperty>).

Recalling resolution WHA56.27 and having considered the report of the CIPIH, the following issues were highlighted in resolution WHA59.24.

- The world is facing a growing burden of diseases and conditions disproportionately affecting developing countries, particularly those affecting women and children, including an upsurge in noncommunicable diseases;
- There is thus a need to continue to develop safe and affordable new products for such communicable diseases as AIDS, malaria and tuberculosis, and for other diseases or illnesses disproportionately affecting developing countries;

- There are opportunities opened up by advances in biomedical science, and these need to be harnessed more effectively to develop new products, particularly in order to meet public health needs in developing countries;
- In recent years there has been considerable progress by governments, industry, charitable foundations, and nongovernmental organizations in funding initiatives to develop new products to fight diseases affecting developing countries, and to increase access to existing ones; but much more needs to be done in relation to the scale of avoidable suffering and mortality;
- There is an urgent need to develop new products to address emerging health threats such as multidrug-resistant tuberculosis, and other infectious diseases of particular relevance to developing countries;
- Additional funding is needed for research and development for new vaccines, diagnostics and pharmaceuticals, including microbicides, for illnesses, including AIDS, that disproportionately affect developing countries;
- Public/private partnerships are important for the development of new essential drugs and research tools, and governments need to set a needs-based priority agenda for health, and provide political support and sustainable sources of funding for such initiatives;
- A number of developing countries have been strengthening their research and development capacity in new health technologies and their role will be increasingly critical. There is a need for continued support for research in and by developing countries;
- Intellectual property rights can be beneficial for public health by offering incentives for research into medicines and diagnostics. However where the potential paying market does not provide an adequate return, companies will not invest the necessary funds to develop new medicines;
- The Doha Ministerial Declaration on the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement and Public Health confirms that the Agreement does not and should not prevent Members from taking measures to protect public health (see http://www.wto.org/english/tratop_e/trips_e/trips_e.htm).
- The Doha Declaration, while reiterating commitment to TRIPS affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all;
- Article 7 of the TRIPS agreement states that “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”;

- The Universal Declaration of Human Rights provides that “everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits” and that “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”;
- There is worldwide concern about the impact of high prices of medicines on access to treatment;
- There is a need to promote new thinking on the mechanisms that support innovation;
- It is important to strengthen capacity of local public institutions and businesses in developing countries to contribute to, and participate in, research and development efforts.

Resolution WHA59.24 urged Member States:

(1) to make global health and medicines a priority sector, and take determined action to emphasize priorities in research and development addressed to the needs of patients, especially those in resource-poor settings, and harness collaborative research and development initiatives involving disease-endemic countries;

(2) to consider the recommendations of the report and contribute actively to the development of a global strategy and plan of action, and to take an active part, working with the Secretariat and international partners, in providing support for essential medical research and development;

(3) to work to ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products – drugs, vaccines and diagnostics – to respond to all patients’ and clients’ needs, especially those living in poverty, taking into account the critical role of gender, and to ensure that capacity is strengthened to support rapid delivery of essential medicines to people; and

(4) to encourage trade agreements to take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health.

What are the issues?

Tackling diseases depends on preventive actions and on the access to effective and safe treatments. Access to medicines does not only depend on developing the right products, but also on ensuring that these products are affordable and that they are appropriately used. Access to medicines also depends on ensuring that countries have an effective health system with adequate supply mechanisms and sustainable financing policies in place.

Intellectual property rights can be beneficial for public health by offering incentives for research into medicines and diagnostics. However where the potential paying market does not provide an adequate return, companies will not invest the necessary funds to develop new medicines, and additional mechanisms and policies will need to be used .

Numerous other factors contribute to innovation for the improvement of public health in developing countries including, regulation and the determinants of access to new and existing medicines, as well as political commitment. In industrialized countries, there is largely a self-sustaining innovation cycle in biomedical research, however this is generally not present in low-income countries. The CIPIH has drawn up an agenda of key issues that should be considered in order to build up research and development in diseases that predominantly affect the developing world.

Industrialized countries have long recognized these market failures and have developed a series of legislative instruments and policies to incentivise R&D in those areas. These include, but are not limited to, public sector biomedical research, public-private partnerships and orphan drug legislation.

Almost all industrialized countries are members of the World Trade Organization (WTO). These countries have well developed systems for regulating medicines and many of them have a pharmaceutical industry (this can be an R&D based industry, including biotechnology firms, and/or a generics industry). Access to medicines is guaranteed through their health systems largely funded through social insurance premiums and taxes.

On the other side of the spectrum, most developing countries do not have functioning regulatory systems for medicines, a substantial pharmaceutical industry, nor any significant biomedical research capacity. Access to medicines is insufficient and as many developing countries have joined WTO, the prices of new innovative patent-protected medicines are often prohibitive.

The 2003 decision of the TRIPS Council that permitted compulsory licensing for export purposes, permitted countries without their own production capacity to secure the supply of relevant medicines. However, putting this into practice has proven cumbersome. Some Member States made provision for compulsory licensing and have started using the “government use” clause. Parallel importation has also been introduced in several countries in order to stimulate competition and reduce prices for pharmaceutical products, in particular.

What will be the outcome of the IGWG?

The IGWG will draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission; such strategy and plan of action would aim, inter alia, at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area.

The Working Group will 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.

The IGWG shall submit the final global strategy and plan of action to the Sixty-first World Health Assembly through the Executive Board.

What has been achieved so far?

The IGWG agreed upon a first outline with “elements for global strategy and a plan action” and “areas for early action” were discussed, but not endorsed. WHO continues to issue public health-based research and development reports, identifying from a public health perspective gaps and needs related to pharmaceuticals. WHO also continues to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the CIPIH report, on the development of, and access to, health care products. Furthermore, WHO continues to implement the recommendations of the Commission that are specifically addressed to WHO.

All documentation of the IGWG is available on <http://www.who.int/phi/>

In order to obtain inputs from interested stakeholders, the WHO Secretariat held a web-based public hearing in the autumn of 2006. Submissions were received from governments, academia, public-private partnerships, product-development partnerships and industry, and proved constructive.

The first session of the IGWG addressed the following issues:

Prioritizing research and development needs

The plan of action will need to set out ways to identify gaps in research on diseases that disproportionately affect developing countries. A significant improvement in the understanding of the determinants of disease is essential to drive research on new products in a sustainable fashion. This is closely linked to the need for developed and developing countries to prioritize innovation in a coordinated way. The plan of action should encourage countries to define explicit strategies for research and development, to devote a growing proportion of their budget for health research and development to research objectives in developing countries, and to provide support for establishing, implementing or strengthening the latter's programmes for health research.

In general, delegations were in favour of a coordinated long-term, needs-driven approach to research and development support in which the views of developing countries were prominently represented.

Promoting research and development

The plan of action should also identify gaps in the discovery, development and delivery of products for diseases affecting developing countries. Product development brings together several sectors of society, so the promotion of research and development should take account of their needs and objectives. One of the areas for action would be to promote early-stage drug research and development in developing countries (including basic research, lead identification, lead optimization and pre-clinical trials)

It was noted that the promotion of research and development should be needs-driven and encompass diseases that were not regarded as financially attractive. Some delegations recommended adoption of a global research and development treaty to fund upstream research and development. In the context of ensuring the sustainability

of funding, advance-purchase commitments and establishment of a dedicated research and development fund were mentioned.

Building innovative capacity

Developing innovative capacity requires an approach that interconnects education, intellectual property and technology transfer. The innovation cycle in low-income countries is generally not self-sustaining, and developing countries depend upon the products of innovation designed to meet needs of developed countries. Ways to overcome this difficulty could include framing of patenting and licensing policies that maximize access to innovations for development of products of relevance to the public health needs of developing countries, and support for developing countries to consider legislation containing research exemptions in order to foster health-related research and innovation.

One of the areas for action would be to strengthen product regulatory capacity in developing and transitional countries, including improvement of ethical-review standards and clinical-trials capacity. Better management of intellectual property and investment in human resources were essential in order to attain the objectives of the global strategy and plan of action, and pointed out the need to avoid the “brain drain” or migration of health workers and its damaging effect on health systems. The benefits of recognizing, developing and promoting traditional medicines were highlighted.

Transfer of technology to improve innovation capacity

The plan of action should address the inadequate capacity and skills in developing countries to adopt and develop new technologies for discovery, development, manufacturing and delivery of products.

This could be achieved by promoting North–South and South–South collaboration, and by collaboration between institutions in developing countries and industry. Developed countries are encouraged to assure compliance with their obligations under Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including a focus on the transfer of health-related technologies. Patent pools of upstream technologies or other mechanisms to promote innovation of products for priority diseases in developing countries should also be explored.

Management of intellectual property

The plan of action should address the development of capacities for the management of intellectual property and technologies in developing countries.

Some delegations felt that the management of intellectual property did not fall within WHO's remit. However, others accorded it strategic importance given that the intellectual property system was poorly understood in some parts of the world, noting that collaboration between health, trade and intellectual property officials at a regional level would help to promote a better understanding of its implications for health. The need to strike a balance between protection of intellectual property and innovation in public health while avoiding the creation of obstacles for developing countries was highlighted, as was the importance of education and training in that area. Although the patent system successfully promoted innovative interventions for a number of diseases, it was widely acknowledged that it did not provide enough of an incentive where

neglected infectious diseases were concerned. Alternative incentive systems for research and development to address public-health needs in developing countries were also discussed. It was also suggested that the plan of action include provisions to enact legislation in developed and developing countries for application of the flexibilities provided for in TRIPS and other international agreements. WHO will also continue to work with the World Intellectual Property Organization (WIPO) to compile and update regularly databases on patent status, and to improve dissemination of information.

There was support from some delegations for the inclusion, in the areas of action, of the Commission's recommendation that bilateral trade agreements should not seek to incorporate "TRIPS-plus" protection in ways that might reduce access to medicines in developing countries.

Improving delivery and access

Governments need to invest appropriately if existing and new products are to be made available and accessible to those in need. The governments need to invest in the health-delivery infrastructure and in financing the purchase of medicines and vaccines through insurance, to institute mechanisms to regulate the quality, safety and efficacy of medicines and other products, and to adopt measures to promote competition and ensure that pricing of medicines is consistent with public-health policies.

It was suggested that countries explore the possibilities to eliminate customs duties and charges on pharmaceutical products and, in general, review their pricing policies for medical products. One delegation considered that it would be useful for the Working Group to have at its next session an assessment of the implementation in developing countries of legislation on application of the flexibilities contained in TRIPS.

Ensuring sustainable financing mechanisms

Additional and sustainable financing for research and development is needed in order to address the health needs of developing countries. The plan of action could include steps to secure such financing for developing and making accessible products to combat diseases that disproportionately affect developing countries, for underpinning public-private partnerships and local research and development institutions, and for boosting resources channeled to research organizations in developing countries in both the public and private sectors. It is important to take account of current activities of entities such as the International Drug Purchase Facility (UNITAID), International Finance Facility for Immunization, the Bill & Melinda Gates Foundation and other philanthropic organizations making contributions to innovation and services in the health sector, and advance-market commitments. Some delegations emphasized that duplication of these initiatives should be avoided.

Establishing monitoring and reporting systems

WHO should continue to monitor from a public-health perspective the impact of intellectual property rights and other factors on the development of new products, and on access to medicines and other health-care products in all countries, especially developing ones. Systems need to be established that can monitor the impact on innovation and on access to medicines and other health-care products of TRIPS and of the Doha Declaration on the TRIPS Agreement and Public Health.

In view of the difficulties inherent in evaluating the impact of the intellectual property system on development and access to medicines in countries at different stages of development, it might be feasible to focus on monitoring the availability of medicines for diseases that disproportionately affected developing countries. WHO is currently working with WTO to devise a methodological framework for developing countries. There is a need to issue periodically public health-based research and development reports, identifying from the public-health perspective gaps and needs related to pharmaceuticals.

Areas for early implementation

In accordance with resolution WHA59.24, paragraph 3(3), the Working Group will give particular attention to potential areas for early implementation. At the first session of the IGWG, delegations presented a number of suggestions based on some of the CIPIH recommendations that might lend themselves to early implementation and the IGWG will need to consider all the proposals before taking a definitive decision.

What are the next steps?

In the European Region the WHO Regional Office for Europe is organizing two sub-regional consultations in Moscow on April 26-27 for the countries in the Commonwealth of Independent States, and in Istanbul on April 30-May 1 for the south eastern European countries. The European Commission together with the German European Union (EU) presidency organized a consultation for the EU countries on April 2, 2007.

WHO EURO will organize a European consultation on that draft global strategy and plan of action in late August with the 53 EURO Member States. The WHO Regional Committee for Europe will be informed about the outcome of that consultation in Belgrade in September 2007 at its 57th session.

The WHO Secretariat together with the IGWG Bureau will produce a revised working document containing the draft global strategy and plan of action in July 2007 that will provide the basis for negotiation at the second session of the IGWG.

The second and final session of the Working Group will be held in Geneva on the 5th-10th of November, 2007.

Glossary of key terms:

CiPIH	The Commission on Intellectual Property Rights, Innovation and Public Health (CiPIH), created in May 2003. See http://www.who.int/intellectualproperty/en/
DoHa Declaration	The Doha Declaration on the TRIPS Agreement and Public Health agreed at the Doha WTO Ministerial Meeting in 2001.
IGWG	Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)
TRIPS	The Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement was initiated by WTO to narrow the gaps in the way intellectual property rights are protected around the world, and to bring them under common international rules. The TRIPS agreement establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members.
TRIPS-plus	The Trade Related Aspects of Intellectual Property Rights (TRIPS) plus agreements are bilateral and regional trade agreements that go beyond the minimum standards defined in the TRIPS agreement
WIPO	World Intellectual Property Organization (WIPO) is responsible for the promotion of the protection of intellectual property throughout the world through cooperation among States.
WTO	The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. It develops ground-rules for international commerce and mediates trade disputes.