World Health Organization

SIXTIETH WORLD HEALTH ASSEMBLY **A60/27**
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Public health, innovation, and intellectual property: progress made by the Intergovernmental Working Group

Report by the Secretariat

1. The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property established by resolution WHA59.24 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. Ogwell (Kenya), Mr Jaya Ratnam (Singapore), and Mr N. Dayal (India). Dr Ogwell was also designated Rapporteur.

2. The task of the Working Group is to draw up a draft global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health.[1] The framework 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. Resolution WHA59.24 called for the Working Group to submit the strategy and plan of action to the Sixty-first World Health Assembly, through the Executive Board. It also called for the Working Group to 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.

3. Resolution WHA59.24 was considered by all regional committees in 2006. The Regional Committee for the Americas and the Regional Committee for South-East Asia both adopted resolutions calling on Member States to promote action at regional level.[2] A regional consultation was held in the South-East Asia Region before the meeting of the Working Group in December.

4. In order to solicit inputs from a wide group of stakeholders, web-based public hearings were organized in November 2006. Thirty-two submissions were received from governments, academia, public-private partnerships, product-development partnerships and industry.[3]

5. Member States and regional economic integration organizations that had already taken steps towards implementing aspects of resolution WHA59.24 and the Secretariat reported their progress to the first session of the Working Group.

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[1] See document A/PHI/IGWG/1/2, Annex.

[2] Resolutions CD47.R7 and SEA/RC59/R7, respectively.

[3] See document A/PHI/IGWG/1/INF.DOC./2.

6. The Working Group considered six elements of a draft plan of action: prioritizing research and development needs; promoting research and development; building and improving innovative capacity; improving delivery and access; ensuring sustainable financing mechanisms; and establishing monitoring and reporting systems. In the ensuing discussion, Member States decided that transfer of technology and management of intellectual property should be highlighted and should therefore be added as separate items. All eight elements were examined.

7. The Working Group also discussed elements of a global strategy based on WHO's Constitution, the Commission's report,[1] resolution WHA59.24 and other recent resolutions and previous work in relevant subject areas.

8. An outcome document detailing issues raised in the Working Group was prepared and circulated to participants for review and comment.[2] In accordance with resolution WHA59.24, some Member States suggested potential areas for early implementation, taking into account the Commission's recommendations. Some Member States expressed concern that too little time had been devoted at the first session to identifying and discussing adequately such areas; it was agreed to submit to the Executive Board at its 120th session and to the Sixtieth World Health Assembly the suggestions made on areas for possible early implementation, indicating that these suggestions had not been endorsed by Member States (see Annex).

9. The Working Group recommended a process for enabling nongovernmental organizations which met the requirements for admission into official relations with WHO, but have not yet been so admitted, to participate in the second session of the Working Group.

10. The Executive Board at its 120th session reviewed the progress made by the Working Group and discussed potential areas for early implementation.[3] Having considered the recommendation of the Working Group concerning nongovernmental organizations and the report of its Standing Committee on Nongovernmental Organizations, it authorized the Chairman of the Executive Board, acting jointly with the Chairman of the Standing Committee, to admit provisionally nongovernmental organizations into official relations with WHO[4] for the purpose of participating in the work of the Working Group.

11. The report of the first session of the Working Group was issued on 25 January 2007.[5] Two Circular Letters were despatched to Member States on 12 January and 15 February to solicit by the end of February 2007 additional inputs to the Working Group's elements of a global plan and strategy. The additional inputs and suggestions will be incorporated into a revised working document containing the draft global strategy and plan of action which will be made available to Member States for their review. Other background information requested by Member States at the first session of the Working Group will also be made available.

12. In order to expand the pool of experts and entities invited to attend sessions of the Working Group by virtue of resolution WHA59.24, and ensure balanced regional, gender and

[1] Document CIPH/2006/1.

[2] Document A/PHI/IGWG/1/5.

[3] See document EB119/2006–EB120/2007/REC/2, summary record of the ninth meeting of the 120th session, section 2.

[4] Decision EB120(3).

[5] Document A/PHI/IGWG/1/6.

developing/developed country representation, Member States were also invited to submit proposals for such experts and entities to attend the second session, for decision by the Director-General after consultation with the Officers of the Working Group.

13. Regional consultations organized with support of the regional offices could take place in August and September 2007. Identified experts and concerned entities from the region in question could contribute to these consultations. The regional committees might discuss the working document and the outcome of any regional consultations.

14. A second web-based public hearing to solicit additional inputs and comments to the working document will be held in August and September 2007.

15. It is intended to hold the second and last session of the Working Group from 5 to 10 November 2007 in order to finalize the draft global strategy and plan of action. In the meantime, the Officers of the Working Group will continue to meet as necessary to consider other possible intersessional work and detailed arrangements for the second session.

16. The Secretariat will continue to implement those recommendations of the Commission that are specifically addressed to WHO and fall within its mandate.

ACTION BY THE HEALTH ASSEMBLY

17. The Health Assembly is invited to note the above report.

ANNEX

PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY: TOWARDS A GLOBAL STRATEGY AND PLAN OF ACTION

Areas for early implementation

1. Suggestions made by some Member States of possible areas for early implementation within a global strategy and plan of action, based on the recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health,[1] are set out below. These suggestions have not been endorsed collectively by Member States.

Discovery

2. Developing countries should establish, implement or strengthen a national programme for health research, including best practices for execution and management of research, with appropriate political support and long-term funding.

3. When addressing the health needs of people in developing countries, it is important to seek innovative ways of combating Type I diseases, as well as Type II and Type III diseases. Governments and donors need to assign higher priority to combating the rapidly growing impact of Type I diseases in developing countries and, through innovation, to finding affordable and technologically appropriate means for their diagnosis, prevention and treatment.

4. WHO should find ways to make compound libraries more accessible in order to identify potential compounds to address diseases affecting developing countries.

5. WHO should bring together academics, small and large companies in pharmaceuticals and biotechnology, donor governments or medical research councils, foundations, public–private partnerships and patient and civil society groups for a standing forum in order to facilitate a more organized sharing of information and greater coordination between the various stakeholders.

6. Countries should seek through patenting and licensing policies to maximize the availability of innovations, including research tools and platform technologies, for the development of products of relevance to public health, particularly to conditions prevalent in developing countries. Public financing bodies should introduce policies aimed at ensuring sound patenting and licensing practices for technologies arising from their funding in order to promote downstream innovation in health-care products.

7. Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries. WHO and WIPO should consider playing a bigger role in promoting such arrangements, particularly to address diseases that disproportionately affect developing countries.

[1] See document A/PHI/IGWG/1/2, Annex.

8. Developing countries need to consider in their legislation the form of research exemption that might be appropriate in their own circumstances in order to foster health-related research and innovation.

9. Countries should provide in their legislation powers to use flexibilities allowed under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), where this power might be useful as one of the means available to promote, inter alia, research that is directly relevant to the specific health problems of developing countries.

10. Developing countries should ensure that their universities and public research institutions maintain research priorities in line with their public-health needs and public-policy goals, in particular the need for innovative research of benefit to the health problems of their populations. This should not exclude support of health-related research which meets their industrial or export objectives and that could contribute to improved public health in other countries.

11. Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to output of research and development that is relevant to the health concerns of developing countries, and to products derived therefrom, are facilitated through appropriate licensing policies and practices.

Development

12. In order to enhance the sustainability of public–private partnerships the following actions should be considered:

- current donors should sustain and increase their funding for research and development in the health problems of developing countries;
- more donors, particularly governments, should contribute to increasing funding and protecting public–private partnerships and other research and development sponsors from changes in policy by any major donor;
- financing bodies should commit funds over longer timeframes;
- public–private partnerships need to continue to demonstrate that they are using their money wisely, that they have transparent and efficient mechanisms for accountability, that they coordinate and collaborate among each other, and that they continue regularly to monitor and evaluate their activities;
- the pharmaceutical industry should continue to cooperate with public–private partnerships and increase contributions to their activities;
- research institutions in developing countries should be increasingly involved in conducting research and trials.

13. Further efforts should be made to strengthen the clinical trials and regulatory infrastructure in developing countries, in particular in sub-Saharan Africa, including improvement of ethical-review standards. WHO, in collaboration with interested parties, should help explore new initiatives for achieving this goal.

14. Governments should continue to develop forms of advance-purchase schemes that may contribute to moving later-stage vaccines, medicines and diagnostics as quickly as possible through development to delivery.

15. Support should be provided for practical initiatives that would motivate more scientists to contribute to development through "open-source" methods.

Delivery

16. Developing countries should create incentives designed to train health-care workers and retain them in employment.

17. Developed countries should provide support for developing countries' efforts to improve health-care delivery systems, inter alia, by increasing the supply of their own trained health-care workers.

18. All companies should adopt transparent and consistent pricing policies, and should work towards regularly reducing prices for low- and lower middle-income developing countries. Products, whether originator's or generic, should be priced equitably, not just in sub-Saharan Africa and least developed countries, but also in low- and lower middle-income countries where there is a vast number of poor patients.

19. Continuing consideration needs to be given to the price of treatments for communicable diseases, particularly of second-line drugs for treatment of HIV/AIDS.

20. Governments of low- and middle-income countries where there are both rich and poor patients should finance delivery of health services and regulate prices with a view to providing access for poor people.

21. In their efforts to prioritize health care, governments should adopt measures to promote competition and ensure that pricing of medicines is consistent with their public health policies. Access to medicines cannot depend on the decisions of private companies alone; it is also a responsibility of government.

22. Companies should adopt patent and enforcement policies that facilitate greater access to medicines needed in developing countries. In low-income developing countries, they should avoid filing patents, or enforcing them in ways that might inhibit access. Companies are also encouraged to grant voluntary licences in developing countries, where this will facilitate greater access to medicines, and to accompany this measure with transfer of technology.

23. Developed countries and WTO should ensure compliance with the provisions of Article 66.2 of the TRIPS agreement, and to operationalize the transfer of technology for pharmaceutical production in accordance with paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

24. Governments should ensure that ministries of health are properly represented in bilateral trade negotiations, and that the provisions in the texts respect the principles of the Doha Declaration. Partners should consider carefully any trade-offs they may make in negotiation.

25. Governments and concerned international organizations should promote new purchasing mechanisms in order to stimulate the supply of affordable new products, and to enhance the number of suppliers in order to provide a more competitive environment.

26. Developing countries should adopt or effectively implement competition policies and apply measures allowed under the TRIPS agreement that favour competition in order to prevent or remedy anti-competitive practices related to use of medicinal patents.

27. Countries should provide in national legislation for measures to encourage generic entry on patent expiry, such as the "early working" exception, and more generally policies that support greater competition between generic products, whether branded or not, as an effective way to enhance access by improving affordability. Restrictions should not be placed on the use of generic names.

28. Developing countries should adopt or effectively implement competition policies in order to prevent or remedy anti-competitive practices related to the use of medicinal patents, including the use of measures that favour competition available under intellectual property law.

29. Bilateral trade agreements should not seek to incorporate "TRIPS-plus" protection in ways that may reduce access to medicines in developing countries.

30. Governments should avoid barriers to legitimate competition by drawing up guidelines for patent examiners on proper application of patentability criteria and, if appropriate, consider changes to national patent legislation.

Fostering innovation in developing countries

31. The formation of effective networks, nationally and internationally, between institutions in developing countries and developed countries, both formal and informal, is an important element in building innovative capacity. Developed and developing countries should seek to intensify collaboration that will help build capacity in developing countries.

32. Developed countries, and pharmaceutical companies (including generic producers), should take measures to promote the transfer of technology and local production of pharmaceuticals in developing countries, wherever this makes economic sense and promotes the availability, accessibility, affordability and security of supply of needed products.

33. Developed countries should comply with their obligations under article 66.2 of the TRIPS agreement and paragraph 7 of the Doha Declaration.

34. Digital libraries of traditional medical knowledge should be incorporated into the minimum search documentation lists of patent offices to ensure that the data contained within them will be considered during the processing of patent applications. Holders of traditional knowledge should play a crucial role in deciding whether such knowledge is included in any databases and should also benefit from any commercial exploitation of the information.

The way forward

35. WHO should continue to monitor, from a public health perspective, the impact of intellectual property rights and other factors on development of new products and on access to medicines and other health-care products in developing countries.

Others

36. Member States could consider voluntary reporting on their implementation of the recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health, and the mapping of existing gaps and opportunities for action in the areas identified above.

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