

Progress reports

F. Public health, innovation and intellectual property: towards a global strategy and plan of action

Areas for early implementation

Report by the Secretariat

1. By resolution WHA59.24 the Health Assembly decided that the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property should report to the Sixtieth World Health Assembly through the Executive Board on progress made in drawing up a global strategy and plan of action, giving particular attention to potential areas for early implementation. Although time did not permit the Working Group to discuss the matter at its first session, suggestions made by some Member States of possible areas for early implementation, 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 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.

¹ See document A/PHI/IGWG/1/2, Annex.

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.

8. Developing countries need to consider in their legislation the form of research exemption that might be appropriate in their own circumstances 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 organizations 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 are 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 to 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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