World Health Organization

INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY
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Review of recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health

Report by the Secretariat

1. The Commission on Intellectual Property Rights, Innovation and Public Health was established pursuant to resolution WHA56.27, which was adopted by the Fifty-sixth World Health Assembly in May 2003. The Health Assembly requested the Director-General "to establish the terms of reference for 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, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries, and to submit a progress report to the Fifty-seventh World Health Assembly and a final report with concrete proposals to the Executive Board at its 115th session" (subsequently deferred to the 117th session).[1]

2. In its report,[2] the Commission concluded that intellectual property rights provide important incentives for the development of new medicines and medical technologies. Those rights, however, do not provide an effective incentive when patients are either small in number or poor. The Fifty-ninth World Health Assembly, in resolution WHA59.24 on "public health, innovation, essential health research and intellectual property rights towards a global strategy and plan of action", welcomed the Commission's report, which concluded with some 60 recommendations. The Health Assembly urged Member States to take determined action to emphasize priorities in research and development addressed to the needs of patients, especially those in resource-poor settings. It also urged Member States to harness collaborative research and development initiatives involving disease-endemic countries. In addition, the Health Assembly decided to establish an intergovernmental working group, which would draw up a global strategy and plan of action in order to provide a framework based on the Commission's recommendations, with a focus on research and development relevant to diseases that disproportionately affect developing countries.

[1] Decision WHA57(9).

[2] Document CIPIH/2006/1.

RECOMMENDATIONS OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH

3. The recommendations were grouped in five categories, and are attached at the annex.

4. **Discovery.** With regard to the discovery of new health-care products, the Commission reviewed the science and economic and policy choices facing countries, in particular the scientific, institutional and financial issues arising in the process between basic research and identification of a lead compound. The Commission sought to determine what are the gaps in this process for diseases principally affecting developing countries, and what policy measures might be appropriate to fill those gaps. It concluded that it is in the interest of all countries to promote health research that addresses the health needs of developing countries and to set specific and measurable targets in this regard.

5. **Development.** The most expensive part of the process is development: taking the candidate product through all the required stages of pre-clinical and clinical research and the regulatory process. The Commission recognized the increasing attention being given to the drug development and regulatory process, but stressed the strengthening of clinical trials and regulatory frameworks in all countries. It also recognized the role of new players and private-public partnerships. It examined the range of activities, from optimization of a lead compound through to regulatory review of the safety, efficacy and quality of a new product, and identified several key issues that need careful consideration.

6. **Delivery.** Successful efforts to develop new products will be of no value if they cannot be made available and accessible to those who need them. The Commission examined the factors affecting the introduction of new and existing products into developing countries, including health delivery systems, regulation, pricing, intellectual property and policies to promote competition.

7. **Fostering innovation in developing countries.** The Commission observed that lessons can be learnt from those countries that have made significant progress in developing innovative capacity for health research. It also affirmed the significant contribution the most scientifically and technologically advanced developing countries were making to biomedical research and development. It recognized the massive indigenous resource in developing countries in the form of traditional medicine, better use of which could be made through wider availability and application of knowledge to accelerate development of new treatments. The Commission's recommendations focused on building capacity in developing countries in the fields of science and technology, regulation, clinical trials, the transfer of technology and traditional medicine, as well as intellectual property.

8. **The way forward.** In order to support a sustainable global effort, the Commission defined the important role and responsibilities for WHO as the lead international agency for public health.

ANNEX

RECOMMENDATIONS OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH[1]

Discovery

1. Governments of developed countries should reflect adequately this objective in their research policies. In particular, they should seek to define explicit strategies for research and development and devote a growing proportion of their total funding for research and development in health to the needs of developing countries, with an emphasis on upstream and applied research.

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. Governments and donors should pay attention to upstream research that enables and supports the acquisition of new knowledge and technologies that will facilitate the development of new products, including drugs, vaccines and diagnostic tests to tackle the health problems of developing countries. Attention should also be paid to the current inadequacy of the research tools available in these fields of research. These include techniques to understand new pathways to discovery, better ways to use bioinformatics, more suitable animal models and other disease-specific technologies.

4. Given the health needs of people in developing countries, it is important to seek innovative ways of combating diseases that are prevalent in both rich and poor countries, as well as those diseases of which a substantial proportion of cases occur in poor countries and those that are overwhelmingly or exclusively found in developing countries. Governments and donors need to assign higher priority to combating the rapidly growing impact of the first category of disease in developing countries, and, through innovation, to finding affordable and technologically appropriate means for their diagnosis, prevention and treatment.

5. Actions should be taken by WHO to find ways to make compound libraries more accessible in order that potential compounds for use against diseases affecting developing countries may be identified.

6. WHO should bring together academics, small and large pharmaceutical and biotechnology companies, governments in the form of aid donors or medical research councils, foundations, public-private partnerships and patient and civil society groups in a standing forum to enable more organized sharing of information and greater coordination between the various players.

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

[1] From document CIPIH/2006/1, chapter 6.

8. 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 with respect to diseases that disproportionately affect developing countries.

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

10. Countries should provide in their legislation powers to use compulsory licensing, in accordance with the TRIPS agreement, 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.

11. 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 that meets their industrial or export objectives and that could contribute to improved public health in other countries.

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

Development

13. Governments and the appropriate national authorities and donors should assign a higher priority to research on the development of new animal models, biomarkers, surrogate end-points and new models for assessing safety and efficacy, which would increase the efficiency of product development. They should also work with their counterparts in developing countries to formulate a mechanism for helping to identify research priorities in this area for diseases that are incident in both poor and rich countries but with a substantial proportion of the cases in poor countries and those that are overwhelmingly or exclusively incident in the developing countries, and provide funding for this research and development.

14. In order to enhance the sustainability of public-private partnerships:

- current donors should sustain and increase their funding for research and development into the health problems of developing countries

- more donors, particularly governments, should contribute to increase funding and to help to protect public-private partnerships and other research and development sponsors from changes in policy by any major donor

- funding bodies should commit funds over longer time frames

- 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, 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 executing research and trials.

15. WHO should initiate a process to devise mechanisms that ensure the sustainability and effectiveness of public-private partnerships by attracting new donors, both governments and from among the private sector, and also to promote wider participation of research institutions from developing countries. However, governments cannot passively rely on what these partnerships could eventually deliver; there is a need for a stronger commitment on their part for an articulated and sustainable effort to address the research gaps identified in the report of the Commission on Intellectual Property Rights, Innovation and Public Health.[1]

16. Further efforts should be made to strengthen the clinical trials and regulatory infrastructure in developing countries, in particular in sub-Saharan Africa, including the improvement of ethical review standards. WHO has a role to play, in collaboration with interested parties, in an exploration of new initiatives that might be undertaken to achieve this goal.

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

18. Recognizing the need for an international mechanism to increase global coordination and funding of medical research and development, the sponsors of the treaty proposal on medical research and development should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision.

19. Practical initiatives that would motivate more scientists to contribute to this field through "open source" methods should be supported.

Delivery

20. Governments need to invest appropriately in the health-delivery infrastructure, and in financing the purchase of medicines and vaccines through insurance or other means, if existing and new products are to be made available to those in need of them. Political commitment is a prerequisite for bringing about a sustained improvement in the delivery infrastructure and health outcomes. Health systems research to inform policy-making and improve delivery is also important. The integration of traditional medicine networks with formal health services should be encouraged.

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

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

[1] Document CIPIH/2006/1.

23. Governments have an important responsibility to put in place mechanisms to regulate the quality, safety and efficacy of medicines and other products. As a starting point, adherence to good manufacturing practices and effective supply-chain management can ensure product quality and will also curb the circulation of counterfeit products.

24. Policies for biomedical innovation must take account of the fact that health systems in many developing countries remain resource-constrained. Policies must emphasize affordable innovations adapted to the realities of health-care delivery in developing countries, and covering appropriate technologies for the diagnosis, prevention and treatment of both communicable and noncommunicable diseases. Mechanisms for promoting such adaptive research in a systematic way must be improved.

25. All companies should adopt transparent and consistent pricing policies, and should work towards reducing prices on a more consistent basis 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 vast numbers of poor patients live.

26. For noncommunicable diseases, governments and companies should consider how treatments, which are widely available in developed countries, can be made more accessible for patients in developing countries.

27. Continuing consideration needs to be given to the prices of treatments for communicable diseases, particularly of second-line medicines for HIV/AIDS treatment.

28. Governments of low- and middle-income countries where there are both rich and poor patients should formulate their funding and price regulation with a view to providing access for poor people.

29. Governments need to prioritize health care in their national agendas and, given the possibility to determine prices that patents confer, should adopt measures to promote competition and ensure that pricing of medicines is consistent with their public health policies. Access to medicines cannot depend solely on the decisions of private companies; it is also a government responsibility.

30. Corporate donation programmes can be of great value in several fields in collaboration with the actions of governments and nongovernmental organizations. However, tackling health needs in developing countries requires more structured and sustainable actions by governments and other parties that stimulate accessibility to products, while generating new treatments and products adapted to the needs of developing countries.

31. Governments should remove any tariffs and taxes on health-care products, where appropriate, in the context of policies to enhance access to medicines. They should also monitor carefully the supply and distribution chain to minimize costs that could adversely influence the prices of medicines.

32. The Doha Declaration on the TRIPS Agreement and Public Health clarifies the right of governments to use compulsory licensing as a means of resolving tensions that may arise between public health and intellectual property, and to determine the grounds for using it. Developing countries should provide in their legislation for the use of compulsory licensing provisions, consistent with the TRIPS agreement, as one means to facilitate access to cheaper medicines through import or local production.

33. Developed and other countries with manufacturing and export capacity should take the necessary legislative steps to allow compulsory licensing for export consistent with the TRIPS agreement.

34. The decision on "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" of the General Council of WTO agreed on 30 August 2003[1] for countries with inadequate manufacturing capacity has not yet been used by any importing country. Its effectiveness needs to be kept under review and appropriate changes considered to achieve a workable solution, if necessary.

35. 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 with technology transfer activities.

36. Developing country governments should make available full and reliable information on patents granted. WHO, in cooperation with WIPO and others, should continue to pursue the establishment of a database of information about patents, in order to remove potential barriers to availability and access resulting from uncertainty about the patent status of a given product in a country.

37. Developed countries and the WTO should take action to 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.

38. The restriction of parallel imports by developed countries is likely to be beneficial for affordability in developing countries. Developing countries should retain the possibilities to benefit from differential pricing, and the ability to seek and parallel import lower priced medicines.

39. Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS agreement, would benefit public health, weighing the positive effects against the negative effects. A public-health justification should be required for data protection rules going beyond what is required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, developing countries should not impose restrictions on the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into the TRIPS agreement.

40. In bilateral trade negotiations, it is important that governments ensure that ministries of health be properly represented in the negotiation, 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.

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

[1] WT/L/540 and Corr.1.

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

43. 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 generics, 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.

44. 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 pro-competitive measures available under intellectual property law.

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

46. Governments should take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria and, if appropriate, consider changes to national patent legislation.

Fostering innovation in developing countries

47. A prerequisite for developing innovative capacity is investment in the human resources and the knowledge base, especially the development of tertiary education. Governments must make this investment, and donors should support them.

48. 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 collaborations which will help build capacity in developing countries.

49. WHO, WIPO and other concerned organizations should work together to strengthen education and training on the management of intellectual property in the biomedical field, fully taking into account the needs of recipient countries and their public-health policies.

50. 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.

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

52. Developing countries need to assign a higher priority to improving the regulation of medical products. Developed countries, and their regulatory institutions, should provide greater financial and technical assistance to help attain the minimum set of regulatory standards needed to ensure that good quality products are available for use. This assistance should also support infrastructure developments within a country, to ensure that good manufacturing practice and supply chain management standards are implemented and sustained.

53. The process of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use currently lacks immediate relevance to the needs of many developing countries, but those countries should maintain their participation in the process. In the meantime, developing country governments and regulatory institutions should give support to regional initiatives, tailored to the current capacities of their member countries, which offer more scope for lifting standards over time, exploiting comparative advantages, avoiding duplication, sharing information and facilities, and promoting appropriate standardization without erecting barriers to competition.

54. WHO has an important role to play, in collaboration with interested parties, in helping to strengthen the clinical trials and regulatory infrastructure in developing countries, in particular in sub-Saharan Africa, including the improvement of ethical review standards.

55. Apart from the European & Developing Countries Clinical Trial Partnership, donors together with medical research councils, foundations and nongovernmental organizations, need to offer more help to developing countries in strengthening clinical trials and regulatory infrastructure.

56. 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 the 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.

57. All countries should consider how best to fulfil the objectives of the Convention on Biological Diversity. This could be, for instance, through the establishment of appropriate national regimes for prospecting for genetic resources and for their subsequent utilization and commercialisation; contractual agreements; the disclosure of information in the patent application of the geographical source of genetic resources from which the invention is derived and other means.

The way forward

58. WHO should develop a global plan of action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries.

59. 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 as well as access to medicines and other health-care products in developing countries.

60. WHO should consider these recommendations in consultation with others, and recommend how these could be taken forward in each region and country.

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