World Health Organization
REGIONAL OFFICE FOR Africa

AFR/RC59/6
2 September 2009

REGIONAL COMMITTEE FOR AFRICA **ORIGINAL: ENGLISH**

Fifty-ninth session
Kigali, Republic of Rwanda, 31 August–4 September 2009

Provisional agenda item 8.4

PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY: REGIONAL PERSPECTIVE TO IMPLEMENT THE GLOBAL STRATEGY AND PLAN OF ACTION

CONTENTS

BACKGROUND

1. The impact of intellectual property rules and practices on access to health products for poor people in developing countries has been a subject of international debate. The Fifty-second World Health Assembly (WHA) through Resolution WHA52.19 mandated the World Health Organization (WHO) to cooperate with its Member States, at their request, and with international organizations in monitoring and analysing pharmaceutical and public health implications of relevant international agreements, including trade agreements, to protect public health and promote access to health products.[1]

2. The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was reaffirmed by the Doha Ministerial Declaration on TRIPS and Public Health,[2] provides opportunities for Member States to use public health safeguards to improve access to medicines. Based on WHO assessment, to-date, 15 countries in the African Region have amended their national policies and legislation to be compliant with TRIPS.

3. Consistent with the provisions of the TRIPS Agreement, some Member States, for example Kenya, South Africa, Zambia and Zimbabwe, have been attempting to make use of public health safeguards to improve access to essential medicines. However, the majority of Member States are yet to amend their national policies and laws to take full advantage of public health safeguards.

4. Because of the relevance and complexity of the subject, the Fifty-sixth World Health Assembly, through Resolution WHA56.27, established the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). The Commission studied the relationship between intellectual property rights (IPRs), innovation, and public health. It also addressed appropriate funding and incentive mechanisms for the development of new medicines and other health products for diseases that disproportionately affect developing countries.

5. The CIPIH submitted its report to the Fifty-ninth World Health Assembly which established the intergovernmental working group (IGWG), by Resolution WHA59.24, to draw up a global strategy and plan of action for public health, innovation and intellectual property rights (GSPOA). The global strategy and plan aim to promote new thinking on innovation and access to medicines. Based on the recommendations of the CIPIH report, the GSPOA provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases disproportionately affecting developing countries, proposing clear objectives and priorities, and estimating the necessary funding for research and development.

6. The Sixty-first World Health Assembly, through Resolution WHA61.21, adopted the global strategy and the agreed parts of the plan of action.[3] The Resolution requests the Director-General to undertake a number of immediate and medium-term actions, including finalization of the outstanding components of the plan of action. The Resolution also urges Member States to implement, support and consider providing adequate resources for implementation of the global strategy and plan of action (2008 to 2015). The Secretariat has finalized the outstanding components of the plan of action

---

[1] WHO, World Health Assembly Resolution WHA52.19, Revised drug strategy. In: Fifty-second World Health Assembly, Geneva, 24 May 1999. Geneva, World Health Organization.

[2] http://www.who.int/medicines/areas/policy/doha_declaration/en/print.html; accessed 16 February 2009.

[3] WHO, World Health Assembly Resolution WHA61.21, Global Strategy and Plan of Action on public health, innovation and intellectual property. In: Sixty-first World Health Assembly, Geneva, 24 May 2008. Geneva, World Health Organization.

and presented a progress report[4] to the One-hundred-and-twenty-fourth session of the Executive Board (EB124). The Sixty-second World Health Assembly adopted the final plan of action in respect of specific actions, stakeholders and time frame.

7. The global strategy and plan of action have eight elements: (i) prioritizing research and development needs; (ii) promoting research and development; (iii) building and improving innovative capacity; (iv) transfer of technology; (v) application and management of intellectual property to contribute to innovation and promote public health; (vi) improving delivery and access; (vii) promoting sustainable financing mechanisms; and (viii) establishing monitoring and reporting systems. Member States need guidance to better understand these complex and technical elements and to effectively implement the proposed specific actions.

8. At its fifty-eighth session, the WHO Regional Committee for Africa reviewed an additional information document on the IGWG[5] and Member States decided to include public health, innovation and intellectual property on the agenda of subsequent sessions of the Regional Committee and to follow up implementation of the global strategy and plan of action. Member States further underscored the need to ensure synergy in the implementation of previous related resolutions and decisions, including the Algiers Declaration on Research for Health and the African Pharmaceutical Manufacturing Plan.[6] At the One-hundred-and-twenty-fourth session of the Executive Board, Member States reiterated the Regional Committee decision and the need to monitor access to medicines.

9. The purpose of this document is to highlight the regional perspective and provide guidance to Member States on how to implement the global strategy and plan of action for public health.

ISSUES AND CHALLENGES

10. Implementation of agreed parts of the specific actions in the global strategy and plan of action at country level has been slow, mainly because adoption was fairly recently, in May 2008. Most countries have not established national platforms to adequately inform policy-makers, coordinate stakeholders, or identify and initiate priority actions. Limited resources and inadequate capacities of most national authorities have also contributed to slow implementation. The shortage of skilled human resources in the area of intellectual property could hinder implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) including compliance with the TRIPS agreement and subsequent decisions to protect public health.

11. Developing countries account for four-fifths of the world's population and carry the heaviest disease burden; however, the development of medicines is almost entirely profit-driven, with the result that investment in health-related research and development has nearly come to a standstill.[7] Furthermore, the pharmaceutical research and development companies lack sufficient markets and financial incentives to invest in research and development aimed at diseases that disproportionately

---

[4] EB124/16, Public Health, Innovation, and Intellectual Property: Global Strategy and plan of action, Report by the Secretariat.

[5] WHO, Intergovernmental working group on public health, innovation and intellectual property and follow-up of Resolution WHA61.21, paper prepared for the Fifty-eighth session of the WHO Regional Committee for Africa, Yaounde, Republic of Cameroon, 1–5 September 2008 (AFR/RC58/22).

[6] WHO, *Fifty-eighth Session of the WHO Regional Committee for Africa, Yaounde, Republic of Cameroon, 1–5 September 2008, Final report*, Brazzaville, World Health Organization, Regional Office for Africa, 2008 (AFR/RC58/20).

[7] Trouiller P et al, Drug development for neglected diseases: a deficient market and a public health policy failure, *The Lancet* 2188: 359, 2002.

affect the African Region.

12. WHO estimates that 80% of the population living in rural areas in developing countries depend on traditional medicine for their health care needs.[8] However, the quantity and quality of safety and efficacy data to support the use of traditional medicine are insufficient. Where they exist, implementation of policies and enforcement of regulations are inadequate. Member States in the Region lack adequate capacities for research, development and innovation in regard to health products, including those based on traditional medicine. Identification of research gaps and elaboration of specific research needs for health products remain limited.

13. Research initiatives are largely carried out without a needs-driven research agenda and due consideration given to public health priorities. Although promising innovations have been developed in Africa and for the continent's specific diseases, not many investments are being made in product development and delivery.[9]

14. The TRIPS Agreement encourages transfer of technology to strengthen capacities in developing countries for production of essential medicines and research and development for other health products. However, transfer of technology has been very slow and in some cases nonexistent. This could be attributed to unfavourable socioeconomic development, slow advancement in science and technology, and inadequately developed infrastructure, particularly in the least developed countries of the Region.

15. The effect of stringent intellectual property protection in the pharmaceutical market is contentious.[10] As part of the free-trade agreements, additional restrictions (TRIPS-plus standards) are imposed on developing countries. TRIPS-plus standards hinder developing countries' efforts to improve access to affordable health products. Policy-makers and stakeholders require clear understanding about issues related to application and management of IPRs. However, inadequate human resource capacities, mainly in the area of intellectual property, coupled with limited hands-on experience in many countries hamper effective use of public health safeguards to improve access to affordable health products.

16. Although traditional medicine is extensively practised in the Region, only a few countries such as Cameroon, Ghana, Nigeria, South Africa and Uganda and a couple of regional organizations are dealing with IPRs and have developed mechanisms for the protection of traditional medical knowledge and access to biological resources. The lack of adequate measures to protect and preserve such traditional knowledge as well as the national resources necessary for its sustainable use have contributed to the slow pace of discovery of active ingredients in traditional medicine that could be used for research and development of health products.

17. For most developing countries, the domestic industry is small, usually focused on generic production and traditional medicines. These countries consequently have to pay high prices for imported medicine and are affected by intellectual property rights, especially TRIPS and TRIPS-plus

---

[8] WHO, Promoting the role of traditional medicine in health systems: a strategy for the African Region, paper prepared for the Fiftieth session of the WHO Regional Committee for Africa, Ouagadougou, Republic of Burkina Faso, 28 August–2 September 2000 (AFR/RC50/9).

[9] NEPAD, *Science, technology and innovation: public health in Africa*, Addis Ababa, New Partnership for Africa's Development, February 2009.

[10] www.the lancet.com, Vol 373 Feb 21, 2009; Trade, TRIPS and pharmaceuticals (accessed 3 March 2009).

standards.[11] Public health and supply systems in many countries of the Region are weak. Cost of health products, mainly medicines, are paid for out-of-pocket and contribute to catastrophic expenditures. Regulatory mechanisms to ensure the quality, safety and efficacy of health products are inadequate.

18. The different types of health research institutions in the Region vary according to major funding sources for their research activities. The most notable sources of funding for health research activities are ministries of health, education, science and technology; non-profit institutions; external agencies; and individual health institutions.[12] To fulfill the recommendations of the Commission on Health Research for Development, African governments have committed to allocate at least 2% of national health expenditures and at least 5% of external aid for health projects and programmes to research and research capacity building, and to invest more in research aimed at improving health systems. However, most countries of the African Region fail to reach the target of 2%.[13]

PROPOSED ACTIONS

19. In line with the *Strategic orientations for WHO action in the African Region, 2005-2009*, as well as previous related decisions and resolutions, the WHO Regional Office for Africa will, in collaboration with headquarters, regional economic communities and other relevant stakeholders, support Member States to disseminate information and intensify communication strategies to increase awareness and involvement of all stakeholders and communities, organize briefing seminars and build national capacity to implement the global strategy and plan of action. WHO and partners will support countries to implement the GSPOA through building institutional and production capacities, and promoting intergovernmental working groups. Under the eight elements of the strategy, Member States will undertake actions as described below.

20. **Prioritize and promote research and development.** This will involve mapping ongoing research initiatives and identifying gaps and opportunities to strengthen the development of health products; strengthening national health information systems; and developing evidence-based research agendas to prioritize public health needs for development of health products. Further actions include ensuring synergy in the implementation of previous resolutions and decisions related to the global strategy and plan of action, including the Algiers Declaration on Research for Health, the African Pharmaceutical Manufacturing Plan, Ouagadougou Declaration on Primary Health Care and Health Systems in Africa, and the Bamako call to action on research for health; and strengthening and establishing national and regional networks of researchers and research institutes to promote information-sharing on research initiatives, results and innovations.

21. **Build and improve innovative capacity.** There will be need to strengthen health research systems, research and development, and innovative capacities for health products with particular emphasis on traditional medicine; implement national and regional initiatives to harmonize policies and regulations that could improve innovative research capacities for health products; and establish and strengthen centres of excellence for research and development of health products, including traditional

[11] www.the lancet.com, Vol 373 Feb 21, 2009; Trade, TRIPS and pharmaceuticals (accessed 3 March 2009).

[12] WHO, *The African Regional Health Report 2008: Narrowing the knowledge gap to improve Africa's Health* (forthcoming), Brazzaville, World Health Organization, Regional Office for Africa.

[13] WHO, *The African Regional Health Report 2008: Narrowing the knowledge gap to improve Africa's Health* (forthcoming), Brazzaville, World Health Organization, Regional Office for Africa.

medicines, with up-to-date clinical laboratory infrastructure, information and management systems, human resource development plans, and linkages with regional and international scientific bodies.

22. **Apply and manage intellectual property to contribute to innovation and promote public health.** A clear understanding among policy-makers and stakeholders on the application and management of intellectual property issues should be created. Continuous education and training of appropriate national personnel should be conducted. Particular emphasis should be put on the application and management of the TRIPS Agreement from a public health perspective. Intercountry collaboration in the sharing of hands-on experience in how to make effective use of public health safeguards should be strengthened. Policies, laws and regulations must be formulated and updated to become TRIPS-compliant and thus in line with national, regional or international decisions to improve access to health products. Furthermore, relevant tools and guidelines for the protection and preservation of traditional medical knowledge should be adapted and used, and access to biological resources should be enhanced.

23. **Strengthen collaboration with regional, international organizations and relevant stakeholders**. There will be need to forge and strengthen collaboration with regional, international organizations and relevant stakeholders, including ministries of health, trade and industry, in order to establish national and regional coordination mechanisms. The impact of trade agreements on access to health products should be monitored. Stringent free-trade agreements, including TRIPS-plus standards, which negatively impact on access to affordable health products should be systematically discouraged. Regional cooperation on issues related to intellectual property, research and development of health products including traditional medicine should be strengthened.

24. **Enhance technology transfer.** Technology transfer should be enhanced in the Region by creating a favourable policy and regulatory environment to facilitate industrial and economic development; investing more in science and technology and developing infrastructure to strengthen capacities for production of essential medicines; promoting technology transfer and research into other health products; and strengthening collaboration among countries and relevant organizations within and outside the African Region. Countries should link up with the African Union Commission and the Regional Economic Communities to pursue ongoing efforts for the development of traditional medicine and local production of essential medicines.

25. **Improve delivery and access.** Delivery and access to health products should be improved by implementing national policies and regulations to strengthen health and medicine supply systems; monitoring the prices of health products using standard methodologies; regulating prices to ensure availability and affordability of health products; developing and implementing appropriate strategies to promote competition in the pharmaceutical market; and establishing and strengthening regulatory capacities to ensure the quality, safety, efficacy and appropriate use of health products, including traditional medicines. Considering the current limited medicine regulatory capacities and consequent circulation of substandard health products in many African countries, the use of existing regional quality control laboratory facilities should be maximized, initiatives to harmonize medicine policies and regulations should be strengthened and, as appropriate, regional or subregional centres should be established for quality assurance of medicines. In order to induce the necessary changes and momentum to move the GSPOA forward, countries should establish, among others, a core group of persons with requisite knowledge and skills in intellectual property and phamarceuticals.

26. **Promote sustainable financing mechanisms.** This will involve providing adequate resources for implementing the global strategy and plan of action with the overall aim of improving access to health products; and undertaking advocacy as well as collaboration with national and regional alliances to mobilize adequate and sustainable financing to strengthen health research systems, health products research and development initiatives.

27. **Establish monitoring and reporting systems.** Implementation of the global strategy and plan of action should be monitored using the progress indicators in accordance with World Health Assembly Resolution WHA61.21.

28. The Regional Committee for Africa adopted this document and endorsed the proposed actions.