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**PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY:
PROGRESS MADE IN THE INTER-GOVERNMENTAL WORKING GROUP
TO FACILITATE IMPLEMENTATION OF RESOLUTION WHA59.24**

Information Document

CONTENTS

| | Paragraphs |
|-------------------------|-------------------|
| BACKGROUND | 1–6 |
| PROGRESS TO DATE | 7–11 |
| CHALLENGES | 12 |
| FOLLOW-UP ACTIONS | 13–16 |

ANNEXES

| | Page |
|---|-------------|
| 1. Resolution WHA59.24 Public health, innovation, essential health research and intellectual property rights: Towards a global strategy and plan of action | 4 |
| 2. Resolution WHA60.30 Public health, innovation and intellectual property | 8 |

BACKGROUND

1. The African Region carries the heaviest burden of noncommunicable and communicable diseases, including HIV/AIDS, malaria and tuberculosis. Yet, more than 50% of the population in the Region lack regular access to essential medicines. One among other factors limiting access to medicines is high prices. Prices of patented medicines are particularly beyond the reach of the majority of the people in Africa. During the past decade, a growing international debate concerning the wider aspects of the relationship between intellectual property rights, innovation and public health has been taking place against a backdrop of poverty reduction and improving access to health care.

2. WHO has a long-standing mandate in the area of trade, intellectual property rights and access to medicines. Besides, WHO together with the African Union, regional economic communities and other UN agencies has been supporting countries to increase their awareness and build their capacities to effectively use public health safeguards that are contained under the Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization.

3. In 2004, WHO formed an independent commission to analyse the relationship between intellectual property rights, innovation and public health (WHO Commission on Intellectual Property Rights, Innovation and Public Health, CIPIH). The WHO Commission's report was published in April 2006, raising global awareness of problems around innovation and access to health products, especially in the developing world. The Commission concluded that intellectual property rights provide important incentives for the development of new medicines and medical technologies. However, intellectual property rights do not provide an effective incentive when patient populations are small or poor. The Commission made around sixty recommendations to foster innovation and improve access.

4. In May 2006, the Fifty-ninth World Health Assembly adopted Resolution WHA59.24 (Annex 1) requesting the Director-General to convene a meeting of an intergovernmental working group (IGWG) open to all interested Member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the WHO Commission on Intellectual Property Rights, Innovation and Public Health. In accordance with Resolution WHA59.24, the intergovernmental group would:

- (a) draw up a global strategy and plan of action aimed at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries;
- (b) 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 action;
- (c) submit the final global strategy and plan of action to the Sixty-first World Health Assembly in May 2008 through the Executive Board.

5. At its fifty-sixth session, the WHO Regional Committee for Africa discussed ways and means of facilitating implementation of Resolution WHA59.24. Noting the difficult negotiations due to conflicting interests, it was suggested that specific countries be designated to coordinate the regional participation in the open-ended working group established to develop the global strategy and plan of action.¹ Furthermore, during the Sixtieth World Health Assembly, the

¹ *The Fifty-sixth Session of the WHO Regional Committee for Africa, Addis Ababa, Federal Democratic Republic of Ethiopia, 28 August–1 September 2006, Final Report*, para 107, Brazzaville, World Health Organization, Regional Office for Africa, 2006.

Regional Director for Africa has expressed continued commitment to support the IGWG process in the African Region.

6. This information document is intended to provide background information about the IGWG process and to brief Member States about the progress made, major challenges encountered and follow-up actions needed to facilitate the work of the IGWG.

PROGRESS TO DATE

7. The IGWG held its first session in Geneva, 4 to 8 December 2006. Delegates from more than 100 Member States of the WHO, including 24 countries from the African Region, representatives of other international organizations, private sector, civil society and other interested stakeholders attended the first session. Member States and the Secretariat reported progress towards implementing aspects of Resolution WHA59.24. The key issues raised by Member States that will frame the strategy include fostering innovation and capacity building; supply of vaccines, medicines and diagnostic tools to developing countries; establishing an umbrella body under the auspices of WHO to guide research in the public domain; and establishing a financing mechanism to generate sustainable funding for research and development. The IGWG considered the draft global strategy and elements of a draft plan of action which included:

- (a) prioritizing research and development needs;
- (b) promoting research and development;
- (c) building and improving innovative capacity;
- (d) improving delivery and access;
- (e) ensuring sustainable financing mechanisms;
- (f) establishing monitoring and reporting systems;
- (g) transfer of technology;
- (h) management of intellectual property.

8. The outcomes of the first IGWG consultation towards implementing aspects of Resolution WHA59.24 were presented to the Executive Board in January 2007. Further to that, the Secretariat invited Member States to submit their inputs to the draft global strategy and plan of action. As of May 2007, the Secretariat received 21 submissions from Member States, including a submission² from Kenya endorsed by the 46 Member States of the African Region. The input received from Member States will form the basis of a revised working document which is expected to be made available by the end of July 2007 for subsequent negotiation during the second session of the IGWG in November 2007.

9. The Secretariat also invited Member States to submit proposals for experts and entities to assist the IGWG process in the different regions. Five countries (Kenya, Lesotho, Madagascar, Mauritius, South Africa) from the African Region have proposed 11 experts and institutes to the Secretariat. These proposals will be reviewed by the Bureau of IGWG for further consideration by the Director-General in accordance with the authority of Resolution WHA59.24 to invite such experts and entities. In addition, the Secretariat is continuing to implement CIPIH recommendations, specifically those addressed to WHO.

² Available at www.who.int/phi.

10. Furthermore, during the Sixtieth World Health Assembly, the Secretariat together with the Bureau of IGWG organized technical briefing sessions for Member States on progresses made towards implementing Resolution WHA59.24. Public health, innovation and intellectual property were discussed under agenda item 12.20. Resolution WHA60.30 (Annex 2) was adopted, urging Member States to support the IGWG process and the Secretariat to ensure support to the process, including support to regional consultative meetings.

11. To better inform and provide a forum to discuss issues of relevance to the Region, preparation for a regional consultation for Member States and stakeholders in the African Region started, and the consultation will take place during September 2007. Representatives from the African Union; government authorities, including ministries of health, trade and industry; and other concerned national and regional institutions will be invited to attend the regional consultation.

CHALLENGES

12. The IGWG has been confronted with lack of active participation of well-informed and prepared teams from all Member States of the African Region; it also lacks adequate resources to organize relevant briefings at regional and national levels to inform, prepare and engage Member State delegations. Another remaining challenge is ensuring multisectoral participation at national level, including civil society organizations, the pharmaceutical industry and academia, in both national and regional activities related to the IGWG.

FOLLOW-UP ACTIONS

13. WHO is to mobilize adequate resources and facilitate organization of technical consultation in the African Region, including relevant stakeholders, before the second session of the IGWG (5 to 10 November 2007) to adequately inform and prepare Member States on the IGWG process. The terms of reference for the participation of the Africa countries in the IGWG should include: (i) to provide guidance to the work of the WHO secretariat on public health, innovation and intellectual property; (ii) to review and comment on the IGWG process and other related work of the permanent secretariat; and (iii) to facilitate support from respective clusters and regional offices to the IGWG process and the permanent secretariat.

14. The African regional organizations dealing with intellectual property rights should contribute to the development and implementation of the global strategy and plan of action, taking into account the protection of innovations originating from Africa. Member States should fully utilize the TRIPS safeguards in order to increase access to innovative medicines to the most disadvantaged populations.

15. The IGWG will follow up finalization of the draft global strategy and plan of action for submission to the Sixty-first World Health Assembly in May 2008.

16. The Regional Committee is invited to review and provide orientations on this information document, "Public health, innovation and intellectual property: Progress made in the IGWG to facilitate implementation of Resolution WHA59.24".

ANNEX 1

FIFTY-NINTH WORLD HEALTH ASSEMBLY

WHA59.24

Agenda item 11.11

27 May 2006

WHA59.24 Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action

The Fifty-ninth World Health Assembly,

Recalling resolution WHA56.27, which requested the Director-General to establish 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;

Further recalling resolutions WHA52.19, WHA53.14, WHA54.10, and WHA57.14;

Having considered the report of the Commission on Intellectual Property Rights, Innovation and Public Health;¹

Conscious of the growing burden of diseases and conditions disproportionately affecting developing countries, particularly those affecting women and children, including an upsurge in noncommunicable diseases;

Considering the need to continue to develop safe and affordable new products² for such communicable diseases as AIDS, malaria and tuberculosis, and for other diseases or illnesses disproportionately affecting developing countries;

Conscious of the opportunities opened up by advances in biomedical science, and the need to harness them more effectively to develop new products, particularly in order to meet public health needs in developing countries;

Aware of the considerable progress that has been made in recent years 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;

Recognizing, however, that much more needs to be done in relation to the scale of avoidable suffering and mortality;

Concerned about the need for appropriate, effective and safe health tools for patients living in resource-poor settings;

Considering the urgency of developing new products to address emerging health threats such as multidrug-resistant tuberculosis, and other infectious diseases of particular relevance to developing countries;

¹ Public health, innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health. April 2006.

² The word "products" hereafter should be understood to include vaccines, diagnostics and medicines.

Aware of the need for additional funding for research and development for new vaccines, diagnostics and pharmaceuticals, including microbicides, for illnesses, including AIDS, that disproportionately affect developing countries;

Recognizing the importance of, and need for, public/private partnerships devoted to the development of new essential drugs and research tools, and aware of the need for governments to set a needs-based priority agenda for health, and to provide political support and sustainable sources of funding for such initiatives;

Recognizing the importance of public and private investment in the development of new medical technologies;

Considering that a number of developing countries have been strengthening their research and development capacity in new health technologies, and that their role will be increasingly critical, and recognizing the need for continued support for research in and by developing countries;

Noting that intellectual property rights are an important incentive for the development of new health-care products;

Noting, however, that this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain;

Noting that the Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the Agreement does not and should not prevent Members from taking measures to protect public health;

Further noting that the Declaration, while reiterating commitment to the Agreement on Trade Related Aspects of Intellectual Property Rights (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;

Taking into account Article 7 of the TRIPS agreement that 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”;

Stressing that 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”;

Concerned about the impact of high prices of medicines on access to treatment;

Aware of the need to promote new thinking on the mechanisms that support innovation;

Recognizing the importance of strengthening capacity of local public institutions and businesses in developing countries to contribute to, and participate in, research and development efforts;

Noting that the report of the Commission requests that WHO should prepare 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,

1. WELCOMES the report of the Commission on Intellectual Property Rights, Innovation and Public Health and expresses its appreciation to the Chair, Vice-Chair and Members of the Commission for their work;

2. URGES Member States:¹

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

(2) to consider the recommendations of the report and to 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;

(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;

(5) to ensure that the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health is included on the agendas of WHO's regional committees in 2006;

3. DECIDES:

(1) to establish, in accordance with Rule 42 of the Rules of Procedure of the World Health Assembly, an intergovernmental working group open to all interested Member States to 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 a strategy and plan of action aims at, inter alia, 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;

(2) that regional economic integration organizations constituted by sovereign States, Members of WHO, to which their Member States have transferred competence over matters governed by this resolution, including the competence to enter into international legally binding regulations, may participate, in accordance with Rule 55 of the Rules of Procedure of the World Health Assembly, in the work of the intergovernmental working group referred to under paragraph (1);

¹ Where applicable, also regional economic integration organizations.

(3) that the above-mentioned working group shall 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 action.

(4) that the working group shall submit the final global strategy and plan of action to the Sixty-first World Health Assembly through the Executive Board;

4. REQUESTS the Director-General:

(1) to convene immediately the intergovernmental working group and to allocate the necessary resources to it;

(2) to invite, as observers at the sessions of the intergovernmental working group, representatives of non-Member States, of liberation movements referred to in resolution WHA27.37, of organizations of the United Nations system, of intergovernmental organizations with which WHO has established effective relations, and of nongovernmental organizations in official relations with WHO, who shall attend the sessions of the working group in accordance with the relevant Rules of Procedure and resolutions of the Health Assembly;

(3) to invite experts and a limited number of concerned public and private entities to attend the sessions of the intergovernmental working group and to provide advice and expertise, as necessary, upon request of the Chair, taking into account the need to avoid conflicts of interest;

(4) to continue to issue public health-based research and development reports, identifying from a public health perspective, gaps and needs related to pharmaceuticals, and to report on them periodically;

(5) to continue 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 Commission's report, on the development of, and access to, health care products, and report thereon to the Health Assembly.

ANNEX 2

SIXTIETH WORLD HEALTH ASSEMBLY

WHA60.30

Agenda item 12.20 24

23 May 2007

REISSUED FOR TECHNICAL REASONS

Public health, innovation and intellectual property

The Sixtieth World Health Assembly,

Recalling resolution WHA59.24, creating an intergovernmental working group with the purpose of elaborating a draft global strategy and plan of action to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure, inter alia, 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;

Concerned that communicable diseases account for approximately 50% of the burden of disease in developing countries, and that access to medicines, vaccines and diagnostic kits is hampered by, inter alia, inadequate health-care systems, lack of resources and prices that are beyond the reach of many in the developing world;

Conscious of the growing burden of disease and conditions that disproportionately affect developing countries, particularly those affecting women and children, including an upsurge in noncommunicable diseases;

Noting that the Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the Agreement does not and should not prevent Members from taking measures to protect public health;

Noting that intellectual property rights are an important incentive for the development of new health-care products;

Welcoming with enthusiasm the commitment of the Director-General to the process spearheaded by the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property,

1. EXPRESSES appreciation to the Director-General for her commitment and encourages her to guide the process to draw up a global strategy and plan of action that will provide a medium-term framework for needs-driven essential health research and development;
2. URGES Member States to support fully and actively the Intergovernmental Working Group process and provide adequate resources to WHO;

3. REQUESTS the Director-General:

(1) to ensure technical and financial support to the Intergovernmental Working Group in order to facilitate completion of its tasks in time for its report to the Sixty-first World Health Assembly;

(2) to provide as appropriate, upon request, in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products,¹ and to implement the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments;

(3) to provide technical and financial support for regional consultative meetings in order to set regional priorities that will inform the work of the Intergovernmental Working Group;

(4) to encourage the development of proposals for health-needs driven research and development for discussion at the Intergovernmental Working Group that includes a range of incentive mechanisms including also addressing the linkage between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries;

(5) to prepare background documents on each of the eight proposed elements of the plan of action, as identified by the Intergovernmental Working Group, including:

- a matrix on ongoing activities and current gaps;
- a matrix on current proposals referring to key stakeholders;
- the financial implications of those proposals.

Eleventh plenary meeting, 23 May 2007
A60/VR/11

¹ The WTO General Council in its Decision of 30 August 2003 on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health decided that “pharmaceutical product” means any patented product, or products manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.