SIXTY-FIRST WORLD HEALTH ASSEMBLY **WHA61.21**

Agenda item 11.6 **24 May 2008**

Global strategy and plan of action on public health, innovation and intellectual property

The Sixty-first World Health Assembly,

Having considered the report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property;[1]

Recalling the establishment pursuant to resolution WHA59.24 of an intergovernmental working group 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 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;

Recalling resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14 and WHA54.10 and WHA57.14 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation and public health, WHA58.34 on the Ministerial Summit on Health Research, WHA59.26 on international trade and health; and WHA60.30 on public health, innovation and intellectual property;

Welcoming the progress made by the Intergovernmental Working Group in elaborating the global strategy and the identification of the stakeholders in the plan of action,

1. ADOPTS the global strategy and the agreed parts of the plan of action[2] on public health, innovation and intellectual property, attached to this resolution;

2. URGES Member States:[3]

(1) to implement the specific actions recommended in the global strategy and plan of action on public health, innovation and intellectual property;

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[1] Document A61/9.

[2] On the specific actions and stakeholder components.

[3] Where applicable, also regional economic integration organizations.

(2) to support actively the wide implementation of the global strategy and plan of action on public health, innovation and intellectual property, and to consider providing adequate resources for its implementation;

3. CALLS UPON relevant international organizations and other relevant stakeholders to give priority within their respective mandates and programmes to implementing the global strategy and plan of action on public health, innovation and intellectual property;

4. REQUESTS the Director-General in implementing the global strategy and agreed parts of the plan of action without prejudice to the existing mandates:

(1) to provide support for Member States, upon request, in implementing the global strategy and plan of action on public health, innovation and intellectual property and in monitoring and evaluating its implementation;

(2) to support effective promotion and implementation of the global strategy and plan of action on public health, innovation and intellectual property;

(3) to continue to implement the mandates contained in resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14 and WHA54.10, WHA57.14 and WHA56.30 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation and public health, WHA59.26 on international trade and health, and WHA60.30 on public health, innovation and intellectual property, as well as WHA55.11 on health and sustainable development, WHA55.14 on ensuring accessibility of essential medicines, and WHA60.18 on malaria, including proposal for establishment of World Malaria Day;

(4) to finalize urgently the outstanding components of the plan of action, concerning timeframes, progress indicators and estimated funding needs, and to submit the final plan of action including the open paragraphs on stakeholders for consideration by the Sixty-second World Health Assembly through the Executive Board;

(5) to coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD, to effectively implement the global strategy and plan of action;

(6) notwithstanding the request in subparagraph (4) above, to prepare a quick start programme with adequate budget provision and begin immediately to implement the elements of the global strategy and plan of action on public health, innovation and intellectual property that fall under the responsibility of WHO;

(7) to establish urgently a results-oriented and time-limited expert working group to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases, and open to consideration of proposals from Member States, and to submit a progress report to the Sixty-second World Health Assembly and the final report to the Sixty-third World Health Assembly through the Executive Board;

(8) to reflect, as appropriate, the global strategy and plan of action on public health, innovation and intellectual property in the further development of WHO's research strategy;

(9) to include adequate resources in the forthcoming proposed programme budgets for effective implementation of the global strategy and plan of action on public health, innovation and intellectual property;

(10) to monitor performance and progress in implementing the global strategy and plan of action on public health, innovation and intellectual property, and to report progress to the Sixty-third World Health Assembly through the Executive Board, and subsequently every two years, until the fulfilment of the time frame, to the Health Assembly, through the Executive Board.

ANNEX

Global strategy on public health, innovation and intellectual property

The context

1. In resolution WHA59.24 the Health Assembly recognized the growing burden of diseases and conditions that disproportionately affect developing countries, and particularly women and children. Reducing the very high incidence of communicable diseases in those countries is an overriding priority. At the same time, it is important for WHO Member States and the WHO Secretariat to recognize and better address the increasing prevalence of noncommunicable diseases in those countries.

2. Currently, 4.8 billion people live in developing countries, representing 80% of the world population. Of this number, 2.7 billion, representing 43% of the world population, live on less than US$ 2 a day. Communicable diseases account for 50% of the developing countries' burden of disease. Furthermore, poverty, among other factors, directly affects the acquisition of health products[1] and medical devices, especially in developing countries.

3. Member States,[2] the pharmaceutical industry, charitable foundations and nongovernmental organizations have taken initiatives in recent years to develop new products against diseases affecting developing countries and to increase access to existing health products and medical devices. However, these initiatives are not sufficient to surmount the challenges of meeting the goal of ensuring access and innovation for needed health products and medical devices. More efforts should be made to avoid suffering and reduce preventable mortality and to meet the health-related Millennium Development Goals and to implement States' obligations and commitments arising under applicable international human rights instruments with provisions relevant to health.

4. Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods 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. Advances in biomedical science have provided opportunities to develop new, affordable, safe and effective health products and medical devices, particularly those that meet public health needs. Urgent efforts should be made to make these advances more affordable, accessible and widely available in developing countries.

[1] The term "health products" hereafter should be understood to include vaccines, diagnostics and medicines in accordance with resolution WHA59.24.

[2] Where applicable, also regional economic integration organizations.

6. The Report of the Commission on Intellectual Property Rights, Innovation and Public Health provides an analysis of the problems and makes recommendations that form a basis of future actions.

7. Intellectual property rights are an important incentive for the development of new health-care products. 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.

8. 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. 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.

9. Article 7 of the TRIPS agreement states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation into 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".

10. 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".

11. The price of medicines is one of the factors that can impede access to treatment.

12. International intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities. These countries may benefit, inter alia, from technical assistance.

The aim

13. The global strategy on public health, innovation and intellectual property aims to promote new thinking on innovation and access to medicines, as well as, based on the recommendations of the CIPIH report, provide a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area.

14. The elements of the global strategy, which are designed to promote innovation, build capacity, improve access and mobilize resources, will:

(a) provide an assessment of the public health needs of developing countries with respect to diseases that disproportionately affect developing countries and identify their R&D priorities at the national, regional and international levels

(b) promote R&D focusing on Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases[1]

(c) build and improve innovative capacity for research and development, particularly in developing countries

(d) improve, promote and accelerate transfer of technology between developed and developing countries as well as among developing countries

(e) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, possible incentive schemes for R&D

(f) improve delivery of and access to all health products and medical devices by effectively overcoming barriers to access

(g) secure and enhance sustainable financing mechanisms for R&D and to develop and deliver health products and medical devices to address the health needs of developing countries

(h) develop mechanisms to monitor and evaluate the implementation of the strategy and plan of action, including reporting systems.

The principles

15. The WHO Constitution states that "the objective of WHO shall be the attainment by all peoples of the highest possible level of health". Accordingly, the WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandates (including those contained in relevant WHA resolutions), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations. In this context, the WHO, including the regional and, when appropriate, country offices, need to strengthen its institutional competencies and relevant programs in order to play its role in implementing this global strategy with its plan of action.

16. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

[1] For the purposes of this strategy, the definitions of Type I, II and III diseases, are as referred to by the Commission on Macroeconomics and Health and as further elaborated in the CIPIH report: *Type I diseases* are incident in both rich and poor countries, with large numbers of vulnerable populations in each. *Type II diseases* are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. *Type III diseases* are those that are overwhelmingly or exclusively incident in developing countries. The prevalence of diseases and thereby their categorization in the typology can evolve over time.

17. *(Deleted)*

18. *(Deleted)*

19. The promotion of technological innovation and the transfer of technology should be pursued by all states and supported by intellectual property rights.

20. Intellectual property rights do not and should not prevent Member States from taking measures to protect public health.

21. International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health.

22. The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health.

23. Research and development of developed countries should better reflect the health needs of developing countries.

24. The global strategy and the plan of action should promote the development of health products and medical devices needed by Member States, especially developing countries, that are:

(i) developed in an ethical manner

(ii) available in sufficient quantities

(iii) effective, safe and of good quality

(iv) affordable and accessible

(v) used in a rational way.

25. Intellectual property rights are an important incentive in the development of new health care products. However, 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.

26. Several factors contribute to the price of health products and medical devices, and public policies should address these factors to increase their affordability and accessibility. Among others, competition and reduction or elimination of import tariffs on these products and devices can contribute to the reduction of prices. Countries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices.

The elements

Element 1. Prioritizing research and development needs

27. Health research and development policies of developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases need to be identified

urgently. A better understanding of the developing countries' health needs, and their determinants is essential to drive sustainable research and development on new and existing products.

28. The actions to be taken to prioritize research and development needs are as follows:

(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries

(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific R&D needs in relation to Type I diseases

(b) disseminate information on identified gaps, and evaluate their consequences on public health

(c) provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs.

(1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels

(*a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments*

(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries

(c) include research and development needs on health systems in a prioritized strategy

(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for R&D to address public health need

(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability).

(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples

(a) set research priorities in traditional medicine

(b) support developing countries to build their capacity in research and development in traditional medicine

(c) promote international cooperation and the ethical conduct of research

(d) support South-South cooperation in information exchange and research activities

(e) support early-stage drug research and development in traditional medicine systems in developing countries.

Element 2. Promoting research and development

29. There are many determinants of innovation capacity. Political, economic and social institutions in each country should participate in the development of health research policy, taking into consideration their own realities and needs. The range of measures to promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases needs to be substantially enhanced. Greater investment, in both developed and developing countries, is essential.

30. The actions to be taken to promote research and development are as follows:

(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area

(a) promote cooperation between private and public sectors on research and development

(b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding

(c) support governments in establishing health-related innovation in developing countries.

(2.2) promoting upstream research and product development in developing countries

(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products

(b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries

(c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international – that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools

(d) support basic and applied scientific research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases

(e) support early-stage drug research and development in developing countries

(f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries

(g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries.

(2.3) improving cooperation, participation and coordination of health and biomedical research and development

(a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources

(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities

(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty

(d) support active participation of developing countries in building technological capacity

(e) promote the active participation of developing countries in the innovation process.

(2.4) Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries

(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centers, especially in developing countries

(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts

(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries

(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms

(e) consider, where appropriate, use of a "research exception" to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights.

(2.5) Establishing and strengthening national and regional coordinating bodies on research and development

(a) develop and coordinate a research and development agenda

(b) facilitate the dissemination and use of research and development outcomes.

Element 3. Building and improving innovative capacity

31. There is a need to frame and develop and support effective policies that promote the development of capacities in developing countries related to health innovation. Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property and traditional medicine.

32. The actions to be taken to build and improve innovative capacity are as follows:

(3.1) building capacity of developing countries to meet research and development needs for health products

(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health

(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries

(c) strengthen health surveillance and information systems.

(3.2) Framing, developing and supporting effective policies that promote the development of capacities for health innovation

(a) establish and strengthen regulatory capacity in developing countries

(b) strengthen human resources in research and development in developing countries through long-term national capacity building plans

(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries

(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations.

(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries

(a) develop successful health innovation models in developing innovative capacity

(b) intensify North–South and South–South partnerships and networks to support capacity building

(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries.

(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments

(a) establish and strengthen national and regional policies to develop, support, promote traditional medicine

(b) encourage and promote policies on innovation in the field of traditional medicine

(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards

(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine

(e) promote South-South collaboration in traditional medicine

(f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation.

(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation

(a) encourage the establishment of award schemes for health-related innovation

(b) encourage recognition of innovation for purposes of career advancement for health researchers.

Element 4. Transfer of technology

33. North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. Article 7 of the TRIPS Agreement states that the protection and the enforcement of intellectual property rights should contribute to the promotion of technological innovation and 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 the balance of rights and obligations.

34. The actions to be taken in relation to this element are as follows:

(4.1) promoting transfer of technology and the production of health products in developing countries

(a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries

(b) promote transfer of technology and production of health products in developing countries through investment and capacity building

(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate.

(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development

(a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry

(b) facilitate local and regional networks for collaboration on research and development and transfer of technology

(c) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights

(d) promote the necessary training to increase absorptive capacity for technology transfer.

(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies

(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices

(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

Element 5. Application and management of intellectual property to contribute to innovation and promote public health

35. The international regimes on intellectual property aim, inter alia, to provide incentives for the development of new health products. However, incentive schemes for research and development, especially on Type II and Type III diseases and the specific R&D needs of developing countries in respect of Type I diseases, need to be explored and implemented, where appropriate. There is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the TRIPS Agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

36. The actions to be taken in relation to this element are as follows:

(5.1) supporting information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries

(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries

(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries

(c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.

(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs

(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement

(f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including, where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries

(g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs

(h) strengthen efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries.

(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products

(a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003

(b) take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States

(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003

(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003

(e) *encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge.*

(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases

(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through

the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries

(b) (Deleted)

(c) (Deleted)

(d) (Deleted)

(e) (Deleted)

Element 6. Improving delivery and access

37. Support for and strengthening of health systems is vital for the success of the strategy, as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products. Mechanisms to regulate the safety, quality and efficacy of medicines and other health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a well-functioning health system.

38. International agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements, including those contained in the TRIPS agreement and recognized by the Doha Declaration on the TRIPS Agreement and Public Health that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries. The impact of such actions on innovation needs to be monitored.

39. The actions to be taken to improve delivery and access are as follows:

(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system

(a) *invest in developing health-delivery infrastructure and encourage financing of health products*

(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016[1]

(c) prioritize health care in national agendas

(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality,

[1] In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines

(e) increase investment in human resource development in the health sector

(f) develop effective country poverty reduction strategies that contain clear health objectives

(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate.

(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices

(a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards

(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings

(c) comply with good manufacturing practices for safety standards, efficacy and quality of health products

(d) strengthen the WHO pre-qualification programme

(e) (Deleted)

(f) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals

(g) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines

(h) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval.

(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs

(a) support the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a "regulatory exception" or "Bolar"-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement

(b) frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements

(c) consider where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access

(d) encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law

(e) consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO's ongoing work on pharmaceutical pricing

(f) Consider, where necessary, and provided that they are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products

(g) increase information among policy makers, users, doctors and pharmacists regarding generic products.

Element 7. Promoting sustainable financing mechanisms

40. In recent years donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional financing has also been secured for research and development activities relevant for the control and treatment of the diseases covered by this strategy. Nonetheless, further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries. The most serious gaps in financing for health products and research and development covered by this strategy need to be identified and analysed.

41. It is important to make maximum use of and complement as appropriate and feasible current initiatives, thereby contributing to a flow of resources into innovation and implementation.

42. The actions to be taken to promote sustainable financing mechanisms are as follows:

(7.1) endeavouring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries

(a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and

innovative sources of financing to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases

(b) consider channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness as recommended by the resolution WHA58.34

(c) create a database of possible sources of financing for R & D.

(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices

(a) document and disseminate best practices in public-private and product development partnerships

(b) develop tools to periodically assess performance of public-private and product development partnerships

(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries.

Element 8. Establishing monitoring and reporting systems

43. Systems should be established to monitor performance and progress of this strategy. A progress report will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the strategy will be undertaken after four years.

44. Steps to be taken will include:

(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action

(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action

(b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries

(c) 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 report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly

(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices

(e) monitor and report on investment in research and development to address the health needs of developing countries.

Appendix

Plan of Action

Explanatory notes

* **Stakeholder(s)**

Lead stakeholders are indicated by bold typeface.

Reference to **Governments** means that WHO Member States[1] are urged to take action.

WHO means that the Director-General is requested to take action.

Other international intergovernmental organizations, both global and regional**,** means that WHO Member States, or WHO Secretariat as mandated by Member States through this plan of action, invite these organizations to take action. Member States are urged to raise appropriate issues in the governing bodies of the organizations. The Director-General is requested to bring this global strategy and plan of action to the attention of all relevant international organizations and invite them to consider the relevant provisions of this global strategy and plan of action.

Other relevant stakeholders means that WHO Member States, or WHO Secretariat as mandated by its Member States through this plan of action, invite these relevant actors to take action. These include inter alia, as appropriate, international and national research institutions; academia; national and regional regulatory agencies; relevant health-related industries, including both public and private; public–private partnerships; public-private and product development partnerships; nongovernmental organizations; concerned communities; development partners; charitable foundations; publishers; research and development groups; and regional bodies; and regional organizations.

[1] Where applicable, also regional economic integration organizations.

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 1. Prioritizing research and development needs			
(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries	(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific R&D needs in relation to Type I diseases	**WHO;** Governments; other relevant stakeholders	2008-2015
	(b) disseminate information on identified gaps, and evaluate their consequences on public health	**WHO;** Governments; other relevant stakeholders	2008-2015
	(c) provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs	**WHO;** Governments; other relevant stakeholders	2008-2015
(1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels	(a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments	**Governments; regional organizations**	2008–2015
	(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries	Governments; WHO; other relevant stakeholders (including academia, relevant health-related industries, national research institutions and public–private partnerships)	2008–2015
	(c) include research and development needs on health systems in a prioritized strategy	Governments; WHO; other relevant stakeholders (including academia, national research institutions, and public–private partnerships)	2008-2015

	(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for R&D to address public health needs	**WHO**; Governments; other international intergovernmental organizations; other relevant stakeholders (including private sector)	2008-2015
	(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability)	**Governments**; WHO; other relevant stakeholders (including academia, relevant health related industries, national research institutions, and public–private partnerships)	2008-2015
(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples	(a) set research priorities in traditional medicine	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; national research institutions; public–private partnerships; and concerned communities)	2008-2015
	(b) support developing countries to build their capacity in research and development in traditional medicine	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including academia, relevant health-related industries, national research institutions, public–private partnerships)	2008-2015
	(c) promote international cooperation and the ethical conduct of research	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015

	(d) support South-South cooperation in information exchange and research activities	**Governments; WHO**; other international intergovernmental organizations; regional organizations; other relevant stakeholders	2008-2015
	(e) support early-stage drug research and development in traditional medicine systems in developing countries	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 2. Promoting research and development			
(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area	a) promote cooperation between private and public sectors on research and development	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008–2015
	(b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding	**Governments**; **regional organizations; WHO** (technical assistance); other relevant stakeholders	2008–2015
	(c) support governments in establishing health-related innovation in developing countries	**Governments**; **regional organizations**; **WHO** (technical assistance); other relevant stakeholders	2008-2015
(2.2) promoting upstream research and product development in developing countries	(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015
	(b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015

	(c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international - that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools	**Governments; WHO;** other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	2008-2015
	(d) support basic and applied scientific research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008-2015
	(e) support early-stage drug research and development in developing countries	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, academia, international and national research institutions; donor agencies; development partners; nongovernmental organizations)	2008–2015
	(f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries; academia; development partners; charitable foundations; public-private partnerships; nongovernmental organizations)	2008–2015

	(g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries	**Governments**; WHO; other international intergovernmental organizations, other relevant stakeholders (including; academia, international and national research institution; relevant health-related industries and development partners)	
(2.3) improving cooperation, participation and coordination of health and biomedical research and development	(a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources	**Governments; WHO**; other international intergovernmental organizations; other relevant stakeholders	2008–2015
	(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities	**Governments; WHO**; other relevant stakeholders	2008–2015
	(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty	**Interested Governments;** [WHO]; **other relevant stakeholders (including nongovernmental organizations)**	[2008–2010]
	(d) support active participation of developing countries in building technological capacity	**Governments; WHO**; other relevant stakeholders	2008-2015
	(e) promote the active participation of developing countries in the innovation process	**Governments; WHO;** other relevant stakeholders	2008-2015
(2.4) promoting greater access to knowledge and technology relevant to meet public health needs of developing countries	(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders	2008-2015

	publications by universities, institutes and technical centres, especially in developing countries	(including academia, research institutions, relevant health-related industries; nongovernmental organizations; publishers)	
	(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including academia and research institutions)	2008-2015
	(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries	**Governments; WHO**; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health-related industries)	2008-2015
	(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms	**Governments;** WHO; other international intergovernmental organizations; other relevant stakeholders (including academia and national research institutions)	2008-2015
	(e) consider, where appropriate, use of a “research exception” to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights	**Governments**	

2.5 establishing and strengthening national and regional coordinating bodies on research and development	(a) develop and coordinate a research and development agenda	Governments; regional organizations; WHO; other relevant stakeholders	2008–2015
	(b) facilitate the dissemination and use of research and development outcomes	Governments; regional organizations; WHO; other relevant stakeholders	2008-2015
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 3. Building and improving innovative capacity			
(3.1) building capacity of developing countries to meet research and development needs for health products	(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health	**Governments**; other international intergovernmental organizations; other relevant stakeholders (including development partners)	2008–2015
	(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries	**Governments**; other international intergovernmental organizations; other relevant stakeholders (including research and development groups, relevant health-related industries and development partners)	2008–2015
	(c) strengthen health surveillance and information systems	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including nongovernmental organizations, research institutions, academia)	2008–2015
(3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation	(a) establish and strengthen regulatory capacity in developing countries	**Governments; WHO;** other relevant stakeholders (including national and regional regulatory agencies)	2008–2015

	(b) strengthen human resources in research and development in developing countries through long-term national capacity building plans	**Governments**; other international intergovernmental organizations; other relevant stakeholders (including development partners; international and national research institutions)	2008–2015
	(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries	**Governments; WHO**; other international intergovernmental organizations (including International Organization for Migration and ILO); other relevant stakeholders	2008–2015
	(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations	**Governments**	2008–2015
(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries	(a) develop successful health innovation models in developing innovative capacity	**Governments;** WHO; other international intergovernmental organizations (including WIPO, OECD and UNCTAD); other relevant stakeholders (including academia; research institutions; health related industries and developmental partners)	2008–2015

	(b) intensify North–South and South–South partnerships and networks to support capacity building	Governments; WHO; other International intergovernmental organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries)	2008–2015
	(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries	**Governments;** WHO; other relevant stakeholders (including academia and research institutions)	2008–2015
(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments	(a) establish and strengthen national and regional policies to develop, support, promote traditional medicine	**Governments;** WHO; other international intergovernmental organizations; other relevant stakeholders (including concerned communities)	2008-2015
	(b) encourage and promote policies on innovation in the field of traditional medicine	**Governments;** WHO**;** other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions, **concerned communities**)	
	(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies; international and national research institutions; development partners; concerned communities)	

	(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; relevant health-related industries; concerned communities)	
	(e) promote South-South collaboration in traditional medicine	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including research institutions, regional bodies, academia)	2008–2015
	(f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies, relevant health-related industries)	2008–2015

(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation	(a) encourage the establishment of award schemes for health-related innovation	**Governments**; [WHO]/[~~WHO~~]/[**WHO]**; other international intergovernmental organizations [(including WIPO)]; other relevant stakeholders (including academia; international and national research institutions; development partners; charitable foundations)	
	(b) encourage recognition of innovation for purposes of career advancement for health researchers	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; development partners; charitable foundations)	
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 4. Transfer of technology			
(4.1) promoting transfer of technology and the production of health products in developing countries	(a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries	**Governments**; WHO; other international intergovernmental organizations (including WTO, UNCTAD, UNIDO, WIPO); other relevant stakeholders (including; international and national research institutions; relevant health-related industries)	
	(b) promote transfer of technology and production of health products in developing countries through investment and capacity building	**Governments; WHO;** other intergovernmental organizations; other relevant stakeholders (including **health-related industries**)	

	(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate	**Governments**; WHO; other international intergovernmental organizations;other relevant stakeholders (including **relevant health-related industries;** academia; nongovernmental organizations; development partners; charitable foundations)	2008–2015
(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development	(a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry	**Governments**; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health-related industries; international and national research institutions; academia; nongovernmental organizations; development partners)	2008–2015
	(b) facilitate local and regional networks for collaboration on research and development and transfer of technology	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, national research institutions, academia; nongovernmental organizations)	2008–2015
	(c) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights	**Governments**	2008–2015

	(d) promote the necessary training to increase absorptive capacity for technology transfer	**Governments**; **WHO**; other international intergovernmental organizations; other relevant stakeholders (including research institutions)	2008–2015
(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies	(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institution; relevant health-related industries, nongovernmental organizations; academia)	
	(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health	**Governments;** WHO**;** other international intergovernmental organizations (including WIPO, WTO); other relevant stakeholders (including health-related industries)	

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 5. Application and Management of intellectual property to contribute to innovation and promote public health			
(5.1) support information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries	(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries	[**Governments; WHO;** other international intergovernmental organizations (including **WIPO, WTO, UNCTAD**); other relevant stakeholders (including international and national research institutions and development partners)] [**Governments;** WHO**;** other international intergovernmental organizations (including WIPO**,** WTO**,** UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)]	
	(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries	**Governments; WHO/**[WHO]**;** other international intergovernmental organizations (including [**WIPO]/[**WIPO]**, [WTO]/**[WTO]**, UNCTAD;** other relevant stakeholders (including international and national research institutions and development partners)	
	(c) Facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-	[Governments]/[**Governments**]; [WHO]/[**WHO**]; other international intergovernmental organizations (including [WIPO]/[**WIPO**], [WTO]/[**WTO**], [UNCTAD]; other relevant stakeholders (including	

	related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.	international and national research institutions and development partners)]	
	(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs	**Governments**; WHO; Other international intergovernmental organizations; Other relevant stakeholders (including academia; international and national research institutions; development agencies; nongovernmental organizations; relevant health-related industries)	
	(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement	Governments; [**WHO]/**[WHO]**;** other international intergovernmental organizations (including [WIPO]/[**WIPO]**, [WTO]/**[WTO],** [UNCTAD]/**[UNCTAD]**); other relevant stakeholders (including international and national research institutions and development partners)	
	(f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including,	**Governments;** [WHO; other international intergovernmental organizations; other relevant stakeholders (including] **concerned communities**)	

	where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries		
	(g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs	**Governments**	
	(h) strengthen efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries	**Governments;** WHO; other international intergovernmental organizations (including WIPO, WTO, and UNCTAD)	
(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products	(a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	**Governments;** WHO; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)	

	(b)Take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States	**Governments;** [WHO; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)]	
	(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003	**Governments**	
	(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	**Governments**	

	(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge	**Governments;** WHO**;** other international intergovernmental organizations (including WIPO, WTO, UNEP/Secretariat of the Convention on Biological Diversity); other relevant stakeholders (including **concerned communities**)	
(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases	(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries	**[Governments**; [WHO]/[**WHO**]; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; development partners; charitable foundations; relevant health related industries; nongovernmental organizations)]	
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 6. Improving delivery and access			
(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system	(a) invest in developing health-delivery infrastructure and encourage financing of health products	**Governments;** WHO**;** other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, private sector and relevant health-related industries)	

	(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016[1]	**Governments;** WHO**;** other international intergovernmental organizations (including WTO); other relevant stakeholders	
	(c) prioritize health care in national agendas	**Governments**	2008–2015
	(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines	**Governments; WHO**	
	(e) increase investment in human resource development in the health sector	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners; nongovernmental organizations; charitable foundations)	2008–2015
	(f) develop effective country poverty reduction strategies that contain clear health objectives	**Governments;** other relevant stakeholders (including development partners)	2008–2015

[1] In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

	(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders	
(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices	(a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards	**Governments; WHO;** other relevant stakeholders (including national and regional regulatory agencies and development partners)	
	(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; nongovernmental organizations, development partners and charitable foundations)	
	(c) comply with good manufacturing practices for safety standards, efficacy and quality of health products	**Governments; WHO;** other relevant stakeholders (including national regulatory bodies; relevant health-related industries; development partners	2008–2015
	(d) strengthen the WHO pre-qualification programme	Governments; **WHO**, other international intergovernmental organizations; other relevant stakeholders (including development partners)	

	(f) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals	**Governments;** [**WHO**]/[WHO]; other relevant stakeholders (including national and regional regulatory agencies, regional bodies and development partners)	
	(g) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies)	
	(h) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval	**Governments; WHO;** other relevant stakeholders (including national and regional regulatory agencies, international and national research institutions, regional bodies and development partners)	
(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs	(a) support the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a “regulatory exception” or	**Governments**	

	"Bolar"-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement		
	(b) frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements	**Governments;** WHO; other international intergovernmental organizations (including WTO and WIPO); other relevant stakeholders	
	(c) consider where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access	**Governments**	
	(d) encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law	**Governments**; WHO; other international intergovernmental organizations; other relevant stakeholders (including **relevant health-related industries)**	
	(e) consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO's ongoing work on pharmaceutical pricing	**Governments**	

	(f) Consider, where necessary, and provided that they are consistent with the provisions of the Agreement on TRIPS, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products	**Governments**	
	(g) increase information among policy makers, users, doctors and pharmacists regarding generic products	**Governments;** WHO other relevant stakeholders (including nongovernmental organizations and relevant health related industry)	
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 7. Promoting sustainable financing mechanisms			
(7.1) endeavoring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries	(a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases	Governments; **WHO;** other international intergovernmental organizations; other relevant stakeholders	
	(b) consider channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to	**Governments;** WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations,	

	maximize its effectiveness as recommended by the resolution WHA58.34	international and national research institutions, academia, private sector and relevant health-related industries)	
	(c) create a database of possible sources of financing for R & D	**Governments; WHO;** other relevant stakeholders	
(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices	(a) document and disseminate best practices in public-private and product development partnerships	Governments; **WHO;** other relevant stakeholders (including research institutions, public-private and product development partnerships)	2008–2015
	(b) develop tools to periodically assess performance of public-private and product development partnerships	Governments; **WHO;** other relevant stakeholders (including research institutions; public-private and product development partnerships; charitable foundations)	2008–2009
	(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, charitable foundations, development partners, nongovernmental organizations; academia; research institutions)	2008–2015
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 8. Establishing monitoring and reporting systems			
(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action	(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action	Governments; **WHO**	From 2009

	(b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries	Governments; **WHO**	[From 2009]
	(c) 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 report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly	Governments; **WHO;** other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	
	(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices	**Governments; WHO;** other international intergovernmental organizations (including WIPO and WTO); Other relevant stakeholders	
	(e) monitor and report on investment in research and development to address the health needs of developing countries	Governments; **WHO;** other relevant stakeholders	

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