

Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property



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Introduction

This publication is intended to be a reader-friendly and consolidated version of documents relevant to the global strategy and plan of action on public health, innovation and intellectual property (now abbreviated to GSPA-PHI). In it the reader will find in one place for the first time the original documents as agreed by Member States, along with the finalized, agreed list of stakeholders, time frames and progress indicators. It also includes the relevant World Health Assembly resolutions – WHA61.21 and WHA62.16 – as annexes.

Careful attention has been paid to preserve the original integrity of the text and only typographical or obvious grammatical errors have been corrected.

Overview

In 2006, the Commission on Intellectual Property Rights, Innovation and Public Health completed its report and the Member States of the World Health Organization implemented the main recommendation by establishing an intergovernmental working group to draft a global strategy and plan of action on public health, innovation and intellectual property. In 2008, following a two-year negotiation process, the Sixty-first WHO World Health Assembly debated the output of the intergovernmental working group and subsequently the global strategy and plan of action on public health, innovation and intellectual property was adopted in resolution WHA61.21.

The aim of the strategy is to promote new thinking on innovation and access to medicines and to secure an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases that disproportionately affect developing countries. The strategy comprises eight elements, 25 sub-elements and 108 specific actions. These elements and actions are designed to: set, prioritize and promote research; foster and build innovation capacity; promote technology transfer and local production of medical products; promote the management and application of intellectual property rights to improve public health; improve access to medical products; mobilize resources for research and development relevant to this area and monitor and evaluate the progress in all these areas.

In the following year, 2009, resolution WHA62.16 finalized the list of stakeholders responsible for the implementation of each element and sub-element, established progress indicators for each element and proposed time frames in which the actions specified in the GSPA-PHI should be accomplished. Resolution WHA62.16 also noted

estimated funding needs for the completion of each element but did not endorse or adopt these figures.

This publication consolidates in one volume the document that was adopted as an annex to WHA 61.21 and all changes adopted subsequently in WHA 62.16.

Even though some progress has been made in the past few years, the basis for alleviating the burden of diseases that disproportionately affect poor populations has to continue to be strengthened. The GSPA-PHI represents an international consensus on a strategy and actions to be taken to address these challenges. It is hoped that GSPA-PHI in its present form is more accessible to all those who are interested in seeing development and delivery of essential health technologies to all those who need them the most.

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

Consolidated version

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, 4800 million people live in developing countries, representing 80% of the world population. Of this number, 2700 million, 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 products¹ 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 delinking 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.

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.

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.
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 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, affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of World Trade Organization (WTO) Members to protect public health and, in particular, to promote access to medicines for all.
9. Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights 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 from, inter alia, 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 and, based on the recommendations of the report of the Commission on Intellectual Property Rights, Innovation and Public Health, provide a medium-term framework for 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.

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 research and development priorities at the national, regional and international levels;
 - (b) promote research and development focusing on Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases;³
 - (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 research and development 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 research and development;
 - (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 research and development 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. WHO's Constitution states that "the objective of WHO shall be the attainment by all peoples of the highest possible level of health". Accordingly, 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

3 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 report of the Commission on Intellectual Property Rights, Innovation and Public Health: *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.

Health Assembly resolutions), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations. In this context, WHO, including its regional and, when appropriate, country offices, needs to strengthen its institutional competencies and relevant programmes 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.
17. The promotion of technological innovation and the transfer of technology should be pursued by all States and supported by intellectual property rights.
18. Intellectual property rights do not and should not prevent Member States from taking measures to protect public health.
19. International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health.
20. The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health.
21. Research and development of developed countries should better reflect the health needs of developing countries.
22. 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:
 - (a) developed in an ethical manner
 - (b) available in sufficient quantities
 - (c) effective, safe and of good quality
 - (d) affordable and accessible
 - (e) used in a rational way.
23. 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.
24. 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

25. 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 research and development 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.
26. 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 research and development 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 interregional 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 research and development to address public health needs;*
 - (e) *increase overall research and development efforts on diseases that disproportionately affect developing countries, leading to the development of quality products that address public health needs, and that are 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

27. 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.
28. 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 access 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 research and development 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 forums 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 research and development, including, inter alia, an essential health and biomedical research and development 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 centres, especially in developing countries;*

- (b) *promote public access to the results of government-funded research by strongly encouraging all investigators funded by governments to 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

29. There is a need to frame, 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.
30. 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, taking into account the relevant provisions of relevant international instruments:
- (a) *establish and strengthen national and regional policies to develop, support and 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

31. 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 Agreement on Trade-Related Aspects of Intellectual Property Rights 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.
32. 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 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 research and development needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights 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

33. 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 research and development 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 Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement, which provide flexibilities to take measures to protect public health.
34. 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 Agreement on Trade-Related Aspects of Intellectual Property Rights and other WTO instruments related to that agreement and meets the specific research and development 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 that 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 Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights;*
 - (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 coordinate effectively work relating to intellectual property and public health among the secretariats and governing bodies of relevant regional and international organizations in order 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 Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights, 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 the 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, including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health 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 to 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 delinking 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 that disproportionately affect developing countries.*

Element 6. Improving delivery and access

35. 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.
36. 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 Agreement on Trade-Related Aspects of Intellectual Property Rights 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.
37. 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;⁴*
 - (c) prioritize health care in national agendas;*
 - (d) encourage health authorities to improve domestic management capacities in order to improve delivery of 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;*
 - (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:

⁴ In line with the extension, provided to least developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

- (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 settings with a high disease burden;*
 - (c) *comply with good manufacturing practices for safety standards, efficacy and quality of health products;*
 - (d) *strengthen the WHO prequalification programme;*
 - (e) *where appropriate, initiate programmed actions on regional and subregional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals;*
 - (f) *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;*
 - (g) *support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for evaluation and approval of medicines.*
- (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 that 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, and 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 that 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

38. 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.
39. It is important to make maximum use of, and complement as appropriate, feasible current initiatives, thereby contributing to a flow of resources into innovation and implementation.
40. 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 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;*
 - (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 resolution WHA58.34;*

- (c) *create a database of possible sources of financing for research and development.*
- (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 for periodic assessment of 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

41. 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.
42. 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.*

Plan of action

Explanatory notes

Stakeholder(s)

Lead stakeholders are indicated by **bold** typeface.

Reference to **governments** means that WHO Member States⁵ 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 the 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 the 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 organizations.

Key to organizations abbreviated:

ILO	International Labour Organization
IOM	International Organization for Migration
OECD	Organisation for Economic Co-operation and Development
UNCTAD	United Nations Conference on Trade and Development
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

⁵ Where applicable, also regional economic integration organizations.

Element 1

Prioritizing research and development needs

Indicators:

- analysis of research and development gaps, including the public health consequences of these gaps in developing countries, completed and a report on this analysis produced, published and disseminated
- number of developing countries with national health-related research and development capacity-building plans that prioritize research and development based on identified public health needs and research and development gaps
- number of consensus reports published on global research needs and priorities for a disease or type of intervention.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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 research and development 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 interregional 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, 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, 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 research and development to address public health needs	WHO ; governments; other international intergovernmental organizations; other relevant stakeholders (including private sector)	2008–2015
	(e) increase overall research and development efforts on diseases that disproportionately affect developing countries, leading to the development of quality products that address public health needs, and that are 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, public–private partnerships)	2008–2015

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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, 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

Element 2 Promoting research and development

Indicators:

- number of countries whose national strategic plans for the health workforce and related professionals include a research and development component
- number of new or strengthened national, regional and global coordination initiatives on health-related research and development, including between public and private entities
- number of new or strengthened initiatives aimed at providing efficient and affordable access to publications and information such as research knowledge, results and technology
- number of new or strengthened initiatives aimed at enhancing capacities to analyse and manage clinical trial data
- proportion of peer-reviewed publications where the main author's institution is in a developing country.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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, WTO); other relevant stakeholders	2008–2015
	(d) support basic and applied scientific research on Type II and Type III diseases and on the specific research and development 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 institutions, relevant health-related industries, development partners)	2008–2015

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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 forums 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 research and development, including, inter alia, an essential health and biomedical research and development treaty	governments; 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 publications by universities, institutes and technical centres, especially in developing countries	governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries, nongovernmental organizations, publishers)	2008–2015
	(b) promote public access to the results of government-funded research by strongly encouraging all investigators funded by governments to 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, 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

Sub-elements	Specific actions	Stakeholder(s)	Time frame
	(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, 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	2008–2015
(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

Element 3 Building and improving innovative capacity

Indicators:

- number of new and existing research centres in developing countries strengthened through comprehensive institutional development and support
- proportion of developing countries in which national health research systems meet international standards
- number of countries whose national regulatory authorities have been assessed, supported and accredited
- number of new or updated global quality and ethical standards, reference preparations, guidelines and tools for promoting the quality and effective regulation of health products⁶ and technologies
- number of countries with a national traditional medicines policy that includes research and development.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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

⁶ The term “health products” hereafter should be understood to include vaccines, diagnostics and medicines in accordance with resolution WHA59.24.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
	(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 IOM, 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, 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, research institutions)	2008–2015

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities, taking into account the relevant provisions of relevant international instruments	(a) establish and strengthen national and regional policies to develop, support and 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)	2008–2015
	(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)	2008–2015
	(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)	2008–2015
	(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; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including academia, international and national research institutions, development partners, charitable foundations)	2008–2015
	(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)	2008–2015

Element 4

Transfer of technology

Indicators:

- number of national, regional and global coordination and collaboration initiatives aimed at increasing and facilitating transfer of health-related technology, including between public and private entities
- number of countries with technology transfer strategies that include health-related technologies and relevant capacity-building components.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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)	2008–2015
	(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)	2008–2015
	(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 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

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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 institutions, relevant health-related industries, nongovernmental organizations, academia)	2008–2015
	(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 research and development needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights 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)	2008–2015

Element 5

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

Indicators:

- number of countries engaged in initiatives to strengthen capacities to manage and apply intellectual property rights to contribute to innovation and promote public health
- number of countries promoting and supporting efforts to strengthen capacities in the management and application of intellectual property rights in a manner oriented to public health needs and priorities of developing countries
- number of countries integrating flexibilities for protection of public health of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights into national legislation
- number and type of initiatives between secretariats and governing bodies of relevant regional and international organizations aimed at coordinating work relating to intellectual property and public health.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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 Agreement on Trade-Related Aspects of Intellectual Property Rights and other WTO instruments related to that Agreement and meets the specific research and development 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)	2008–2015
	(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; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)	2008–2015

Sub-elements	Specific actions	Stakeholder(s)	Time frame
	(c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases that 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	governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)	2008–2015
	(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, non-governmental organizations, relevant health-related industries)	2008–2015
	(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 Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights	governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)	2008–2015
	(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	governments; concerned communities	2008–2015
	(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	2008–2015
	(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 in order to facilitate dialogue and dissemination of information to countries	governments ; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD)	2008–2015

Sub-elements	Specific actions	Stakeholder(s)	Time frame
<p>(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 Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights, in order to promote access to pharmaceutical products</p>	<p>(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 the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003</p>	<p>governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD)</p>	<p>2008–2015</p>
	<p>(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</p>	<p>governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD)</p>	<p>2008–2015</p>
	<p>(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003</p>	<p>governments</p>	<p>2008–2015</p>
	<p>(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</p>	<p>governments</p>	<p>2008–2015</p>
	<p>(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 to prevent misappropriation of such traditional knowledge</p>	<p>governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNEP/Secretariat of the Convention on Biological Diversity); other relevant stakeholders (including concerned communities)</p>	<p>2008–2015</p>

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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 delinking 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 that disproportionately affect developing countries	governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions, development partners, charitable foundations, relevant health-related industries, nongovernmental organizations)	2008–2015

Element 6 Improving delivery and access

Indicators:

- number of countries formulating and implementing official national policies on access, quality and use of essential medical products and technologies
- number of countries designing or strengthening comprehensive national procurement and supply systems
- number of priority health products and diagnostic tools that have been assessed and prequalified for procurement by the United Nations
- number of countries possessing and implementing national or regional strategic plans for the health workforce and related professionals, including policies and management practices on incentives, regulation and retention
- number of countries that have an adequate number of qualified or trained health-related regulatory professionals and the specific areas of specialization where gaps exist.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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, relevant health-related industries)	2008–2015
	(b) develop effective and sustainable mechanisms in least developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016 ⁷	governments; WHO; other international intergovernmental organizations (including WTO); other relevant stakeholders	2008–2015
	(c) prioritize health care in national agendas	governments	2008–2015

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

Sub-elements	Specific actions	Stakeholder(s)	Time frame
	(d) encourage health authorities to improve domestic management capacities in order to improve delivery of 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	2008–2015
	(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
	(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate	governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015
(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, development partners)	2008–2015
	(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in settings with a high disease burden	governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions, nongovernmental organizations, development partners, charitable foundations)	2008–2015
	(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 prequalification programme	governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners)	2008–2015
	(e) where appropriate, initiate programmed actions on regional and subregional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals	governments; WHO; other relevant stakeholders (including national and regional regulatory agencies, regional bodies, development partners)	2008–2015

Sub-elements	Specific actions	Stakeholder(s)	Time frame
	(f) 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)	2008–2015
	(g) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for evaluation and approval of medicines	governments; WHO; other relevant stakeholders (including national and regional regulatory agencies, international and national research institutions, regional bodies, development partners)	2008–2015
(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 that are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement	governments	2008–2015
	(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, WIPO); other relevant stakeholders	2008–2015
	(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	2008–2015
	(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)	2008–2015
	(e) consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products, and further support WHO’s ongoing work on pharmaceutical pricing	governments	2008–2015

Sub-elements	Specific actions	Stakeholder(s)	Time frame
	(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 that unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products	governments	2008–2015
	(g) increase information among policy-makers, users, doctors and pharmacists regarding generic products	governments; WHO; other relevant stakeholders (including nongovernmental organizations, relevant health-related industries)	2008–2015

Element 7

Promoting sustainable financing mechanisms

Indicators:

- submission of report of expert working group on research and development and financing
- number of new or strengthened sustainable financing initiatives, including public–private initiatives
- increase in sustainable health-related research and development funding relevant to the strategy⁸ over the reporting period.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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 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	governments; WHO ; other international intergovernmental organizations; other relevant stakeholders	2008–2010
	(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 resolution WHA58.34	governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, international and national research institutions, academia, private sector, relevant health-related industries)	2008–2015

⁸ Baselines and guidance to be provided by the expert working group on research and development and financing, established in accordance with resolution WHA61.21.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
	(c) create a database of possible sources of financing for research and development	governments; WHO ; other relevant stakeholders	2008–2015
(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 for periodic assessment of 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

Element 8

Establishing monitoring and reporting systems

Indicators:

- regular reporting on progress towards the implementation of the strategy⁹
- number of new or strengthened sustainable initiatives at national, regional and global levels, including those by nongovernmental stakeholders, to promote the implementation of the strategy
- submission of reports on the respective issues addressed in element 8 of the strategy.

Sub-elements	Specific actions	Stakeholder(s)	Time frame
(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	2009–2015
	(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	2009–2015

⁹ A qualitative assessment measuring progress on the objectives of the strategy is to be included as a key component in the comprehensive four-year evaluation required by paragraph 41 of the global strategy.

	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	governments; WHO ; other international intergovernmental organizations (including WIPO, WTO); other relevant stakeholders	2009–2015
	(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, WTO); other relevant stakeholders	2009–2015
	(e) monitor and report on investment in research and development to address the health needs of developing countries	governments; WHO ; other relevant stakeholders	2009–2015

All elements

Additional overarching strategic indicators:

- number of new and improved health products receiving internationally recognized approval for use, including information on the nature and novelty of these products
- number of new and improved interventions and implementation strategies whose effectiveness has been determined and the evidence made available to appropriate institutions for policy decisions.

ANNEX 1

WHA61.21

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;¹⁰

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 Rights, 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, 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 action¹¹ on public health, innovation and intellectual property, attached to this resolution;
2. URGES Member States:¹²
 - (1) to implement the specific actions recommended in the global strategy and plan of action on public health, innovation and intellectual property;
 - (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;

¹⁰ Document A61/9.

¹¹ On the specific actions and stakeholder components.

¹² Where applicable, also regional economic integration organizations.

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, WHA54.10, WHA56.30 and WHA57.14 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 time frames, 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 the World Intellectual Property Organization, the World Trade Organization and the United Nations Conference on Trade and Development, 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 2

WHA62.16

Global strategy and plan of action on public health, innovation and intellectual property¹³

The Sixty-second World Health Assembly,

Recalling resolution WHA61.21 on the global strategy and plan of action on public health, innovation and intellectual property, and noting the information provided by the Secretariat;¹⁴

Welcoming the reference in the report by the Secretariat to the implementation of the African Network for Drugs and Diagnostics Innovations, which supports and promotes African-led health product innovation for the discovery, development and delivery of medicines and diagnostics for neglected tropical diseases, and reiterates the need to fast-track activities to reach neglected people who are sick and suffering from neglected tropical diseases,

1. DECIDES:

(1) to incorporate into the plan of action the additional agreed stakeholders as outlined in document A62/16 Add.3; deleting “interested” before “governments” for specific action 2.3(c);

(2) to incorporate into the plan of action the proposed time frames outlined in document A62/16 Add.1;

2. ADOPTS the final plan of action, as amended in paragraph 1, in respect of specific actions, stakeholders and time frames;¹⁵

3. NOTES the estimated funding needs related to the plan of action;¹⁶

4. ACCEPTS the proposed progress indicators,¹⁷ taking note of the need periodically to review and refine them; where the indicators are quantitative, the Secretariat shall provide complementary information on the implementation of the specific actions;

13 See Annex 5 for the financial and administrative implications for the Secretariat of the resolution.

14 Documents A62/16, A62/16 Add.1, A62/16 Add.2 and A62/16 Add.3.

15 See Annex 4.

16 Document A62/16 Add.1.

17 Document A62/16 Add.2.

5. REQUESTS the Director-General to provide significantly increased support for greater efficiency and effectiveness in the implementation of the global strategy and plan of action on public health, innovation and intellectual property and prioritize concrete actions in the area of capacity building and access;
6. FURTHER REQUESTS the Director-General, in addition to continued monitoring, to conduct an overall programme review of the global strategy and plan of action in 2014 on its achievements, remaining challenges and recommendations on the way forward to the Health Assembly in 2015 through the Executive Board.

(Eighth plenary meeting, 22 May 2009 – Committee B, second report)



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