ANNEX 4

Plan of action on public health, innovation and intellectual property[1]

[A62/16 Add.1 – 26 March 2009]

1. The Sixty-first World Health Assembly adopted the global strategy[2] and the agreed parts of the plan of action on public health, innovation and intellectual property in resolution WHA61.21. That resolution requested the Director-General, inter alia, to finalize the outstanding components of the plan of action, including time frames and estimated funding needs, and submit the final plan for consideration by the Sixty-second World Health Assembly through the Executive Board. The Board at its 124th session took note of the Secretariat's report on the global strategy and plan of action.[3]

2. The Secretariat has undertaken further work to propose time frames for the specific actions in the plan of action.

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[A62/16 Add.2 – 7 May 2009]

1. Resolution WHA61.21 requested the Director-General, inter alia, to finalize the outstanding components of the plan of action, including progress indicators, and submit them for consideration to the Sixty-second World Health Assembly. A set of progress indicators was presented to the Executive Board at its 124th session and, based on comments received,[3] a revised set [was presented in document A62/16 Add.2].

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[A62/16 Add.3 – 18 May 2009]

As a result of informal consultations among Member States in order to reach agreement on the open paragraphs on stakeholders in the plan of action,[4] [the final proposals for the remaining specific actions were presented in document A62/16 Add.3].

[The progress indicators are set out by element below. The time frames and finalized paragraphs on stakeholders have been incorporated into the finalized plan of action which is also reproduced below.]

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[1] See resolution WHA62.16.

[2] See resolution WHA61.21, Annex.

[3] Document EB124/2009/REC/2, summary record of the tenth meeting.

[4] Document A62/16, paragraph 12.

PROGRESS INDICATORS

INDICATORS BY ELEMENT

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 which 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.

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.

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 products[1] and technologies

number of countries with a national traditional medicines policy that includes research and development.

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.

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.

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

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

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.

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 strategy[1] over the reporting period.

Element 8. Establishing monitoring and reporting systems

Indicators

regular reporting on progress towards the implementation of the strategy[2]

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.

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.

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

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

PLAN OF ACTION

Explanatory notes

* **Stakeholder(s)**

Lead stakeholders are indicated by bold typeface.

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

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

Other international intergovernmental organizations, both global and regional, means that 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 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 regional organizations.

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

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 1. Prioritizing research and development needs			
(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries	(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific 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 and public–private partnerships)	2008–2015
	(c) include research and development needs on health systems in a prioritized strategy	Governments; WHO; other relevant stakeholders (including academia, national research institutions, and public–private partnerships)	2008–2015
	(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for 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 to address public health needs, 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, and public–private partnerships)	2008–2015

(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples	(a) set research priorities in traditional medicine	**Governments;** WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; national research institutions; public–private partnerships; and concerned communities)	2008–2015
	(b) support developing countries to build their capacity in research and development in traditional medicine	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including academia, relevant health-related industries, national research institutions, public–private partnerships)	2008–2015
	(c) promote international cooperation and the ethical conduct of research	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders	2008–2015
	(d) support South–South cooperation in information exchange and research activities	**Governments; WHO;** other international intergovernmental organizations; regional organizations; other relevant stakeholders	2008–2015
	(e) support early-stage drug research and development in traditional medicine systems in developing countries	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders	2008–2015
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 2. Promoting research and development			
(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area	(a) promote cooperation between private and public sectors on research and development	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders	2008–2015
	(b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding	**Governments; regional organizations; WHO** (technical assistance); other relevant stakeholders	2008–2015
	(c) support governments in establishing health-related innovation in developing countries	**Governments; regional organizations; WHO** (technical assistance); other relevant stakeholders	2008–2015
(2.2) promoting upstream research and product development in developing countries	(a) support discovery science, including, where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders	2008–2015
	(b) promote and improve accessibility to compound	**Governments; WHO;** other international	2008–2015

	libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries	intergovernmental organizations; other relevant stakeholders	
	(c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international – that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools	**Governments; WHO;** other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	2008–2015
	(d) support basic and applied scientific research on Type II and Type III diseases and on the specific 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 and development partners)	2008–2015
(2.3) improving cooperation, participation and coordination of health and biomedical research and	(a) stimulate and improve global cooperation and coordination in research and development, in order to	**Governments; WHO;** other international intergovernmental organizations; other	2008–2015

development	optimize resources	relevant stakeholders	
	(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities	**Governments; WHO;** other relevant stakeholders	2008–2015
	(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical 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 and research institutions)	2008–2015
	(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries	**Governments; WHO;** other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health-related industries)	2008–2015

	(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms	**Governments;** WHO; other international intergovernmental organizations; other relevant stakeholders (including academia and national research institutions)	2008–2015
	(e) consider, where appropriate, use of a "research exception" to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights	**Governments**	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
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 3. Building and improving innovative capacity			
(3.1) building capacity of developing countries to meet research and development needs for health products	(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health	**Governments;** other international intergovernmental organizations; other relevant stakeholders (including development partners)	2008–2015
	(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries	**Governments;** other international intergovernmental organizations; other relevant stakeholders (including research and development groups, relevant health-related industries and development partners)	2008–2015
	(c) strengthen health surveillance and information systems	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including nongovernmental organizations, research institutions, academia)	2008–2015
(3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation	(a) establish and strengthen regulatory capacity in developing countries	**Governments; WHO;** other relevant stakeholders (including national and regional regulatory agencies)	2008–2015
	(b) strengthen human resources in research and development in developing countries through long-term national capacity-building plans	**Governments;** other international intergovernmental organizations; other relevant stakeholders (including development partners;	2008–2015

		international and national research institutions)	
	(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 and ILO); other relevant stakeholders	2008–2015
	(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations	**Governments**	2008–2015
(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries	(a) develop successful health innovation models in developing innovative capacity	**Governments;** WHO; other international intergovernmental organizations (including WIPO, OECD and UNCTAD); other relevant stakeholders (including academia; research institutions; health-related industries and developmental partners)	2008–2015
	(b) intensify North–South and South–South partnerships and networks to support capacity building	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries)	2008–2015
	(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries	**Governments;** WHO; other relevant stakeholders (including academia and research institutions)	2008–2015
(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments	(a) establish and strengthen national and regional policies to develop, support 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	**Governments; WHO;** other international intergovernmental organizations; other	2008–2015

	the research necessary to establish such standards	relevant stakeholders (including national and regional regulatory agencies; international and national research institutions; development partners; concerned communities)	
	(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; relevant health-related industries; concerned communities)	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
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 4. Transfer of technology			
(4.1) promoting transfer of technology and the production of health products in developing countries	(a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development,	**Governments;** WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD, UNIDO); other relevant stakeholders (including	2008–2015

	particularly in developing countries	international and national research institutions; relevant health-related industries)	
	(b) promote transfer of technology and production of health products in developing countries through investment and capacity building	**Governments; WHO;** other intergovernmental organizations; other relevant stakeholders (including **health-related industries**)	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 the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights	**Governments**	2008–2015
	(d) promote the necessary training to increase absorptive capacity for technology transfer	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including research institutions)	2008–2015
(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies	(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders	2008–2015

	devices	(including international and national research institutions; relevant health-related industries, nongovernmental organizations; academia)	
	(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific 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
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 5. Application and Management of intellectual property to contribute to innovation and promote public health			
(5.1) support information sharing and capacity building in the application and management of intellectual property with respect to health-related innovation and the promotion of public health in developing countries	(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the 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

	(c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents	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; nongovernmental 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 TRIPS agreement	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, and UNCTAD)	2008–2015
(5.2) providing as appropriate, upon request, in	(a) consider, whenever necessary, adapting national	**Governments;** WHO; other international	2008–2015

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 TRIPS agreement, in order to promote access to pharmaceutical products	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	intergovernmental organizations (including WIPO, WTO and UNCTAD)	
	(b) take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States	**Governments;** WHO; other international intergovernmental organizations (including WIPO, WTO and UNCTAD)	2008–2015
	(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	**Governments**	2008–2015
	(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to facilitate through export access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	**Governments**	2008–2015
	(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate, legislative and other measures to help prevent misappropriation of such traditional knowledge	**Governments;** WHO; other international intergovernmental organizations (including WIPO, WTO, UNEP/Secretariat of the Convention on Biological Diversity); other relevant stakeholders (including **concerned communities**)	2008–2015
(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases	(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; development partners; charitable foundations; relevant health-related industries; nongovernmental	2008–2015

		organizations)	
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 6. Improving delivery and access			
(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system	(a) invest in developing health-delivery infrastructure and encourage financing of health products	**Governments;** WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, private sector and relevant health-related industries)	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[1]	**Governments;** WHO; other international intergovernmental organizations (including WTO); other relevant stakeholders	2008–2015
	(c) prioritize health care in national agendas	**Governments**	2008–2015
	(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines	**Governments; WHO**	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

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

(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices	(a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards	**Governments; WHO;** other relevant stakeholders (including national and regional regulatory agencies and development partners)	2008–2015
	(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings	**Governments; WHO;** other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; nongovernmental organizations, development partners and charitable foundations)	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 pre-qualification programme	Governments; **WHO;** other international intergovernmental organizations; other relevant stakeholders (including development partners)	2008–2015
	(e) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals	**Governments; WHO;** other relevant stakeholders (including national and regional regulatory agencies, regional bodies and development partners)	2008–2015
	(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 medicines evaluation and approval	**Governments; WHO;** other relevant stakeholders (including national and regional regulatory agencies, international and national research institutions, regional bodies and development partners)	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 which 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 and 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; further support WHO's ongoing work on pharmaceutical pricing	**Governments**	2008–2015
	(f) consider, where necessary, and provided that they are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products	**Governments**	2008–2015

	(g) increase information among policy makers, users, doctors and pharmacists regarding generic products	**Governments;** WHO other relevant stakeholders (including nongovernmental organizations and relevant health-related industry)	2008–2015
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 7. Promoting sustainable financing mechanisms			
(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 and relevant health-related industries)	2008–2015
	(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 (in= cluding relevant health-related	2008–2015

		industries, charitable foundations, development partners, nongovernmental organizations; academia; research institutions)	
Elements and sub-elements	**Specific actions**	**Stakeholder(s)***	**Time frame**
Element 8. Establishing monitoring and reporting systems			
(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action	(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action	Governments; **WHO**	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
	(c) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly	Governments; **WHO;** other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	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 and 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