

Public health, innovation and intellectual property: global strategy and plan of action

Proposed time frames and estimated funding needs

1. The Sixty-first World Health Assembly adopted the global strategy 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.
2. The Secretariat has undertaken further work to propose time frames for the specific actions in the plan of action, and has also carried out a costing exercise to estimate funding needs for the implementation of the plan. Where appropriate, this exercise has been guided by the work performed in costing other WHO plans of action. Details of the proposed time frames and estimated funding needs are annexed.
3. The funding estimates are presented for each element of the global strategy and plan of action. This report also presents the expected outcomes if the funding were available for implementation, and explains the methods and major assumptions used in estimating the funding requirements.

Funding requirements

4. Table 1 presents, by element, the funding required from 2009 to 2015 to carry out the activities associated with each specific action at two levels: national and international.¹

¹ Values may not sum as expected because of rounding.

Table 1. Cost by element (excludes research and development) (million US\$)

Elements	National level activities	Global/regional level activities	Total
1. Prioritizing research and development needs	93	354	447
2. Promoting research and development	354	137	490
3. Building and improving innovative capacity	366	43	409
4. Transfer of technology	35	15	50
5. Application and management of intellectual property	89	46	136
6. Improving delivery and access	298	216	514
7. Promoting sustainable financing mechanisms	included in cost of support units	4	4
8. Establishing monitoring and reporting systems		15	15
Total elements 1–8	1 234	830	2 064

The figures provided above represent the costs of establishing the system needed in order to develop and implement the eight elements at national and international levels, with national-level costs constituting 60% of the US\$ 2000 million required. The figures cover activities to facilitate coordination, advocacy, development of norms and standards, information sharing, agenda setting, policy making and regulatory functions.

5. However, it is less easy to estimate the subsequent costs of undertaking the subsequent research and development, innovation and technology transfer actions required for implementing the elements identified in Table 1, and the relevant figures are presented separately in Table 2.

Table 2. Research and development, innovation and technology transfer (million US\$)

Subtotals	National level activities	Global/regional level activities	Total
Subtotal research and development	98 225	32 742	130 966
Subtotal education of research and development workers	6 249	0	6 249
Subtotal research and development infrastructure	6 806	2 876	9 683
Subtotal support units	191	64	255
Total	111 471	35 682	147 154

If the two tables are considered together, the costs of strengthening the system for implementing the eight elements would be about US\$ 2000 million, while the costs of undertaking the research and development, innovation and technology transfer, including education of workers and building of infrastructure, might be as high as US\$ 147 000 million. The grand total for implementing the global

strategy and plan of action costed here for all Member States from 2009 to 2015 is of the order of US\$ 149 000 million, averaging US\$ 21 000 million per year. These costs are additional to those currently being borne (see paragraph 8 below).

Expected outcomes

6. Should this funding be made available by 2015 a total of about 530 000 research and development workers will have been trained, and there will be new and improved research infrastructure, 10 public access compound libraries, some 35 new health products (vaccines, diagnostics and medicines), extensive national research under way on diseases or conditions of importance in each country, strengthened regulatory capacity, political will supportive of innovation and access, and an improved environment for global sharing of information and technology transfer.

Methodology and major assumptions

7. The aim of the costing exercise was to provide an estimate for the additional funding needed to implement the global strategy and plan of action over the medium term (2009–2015). Where possible, the costing used an ingredients approach, in which the quantities of activities deployed in respect of each specific action were identified separately from their associated cost in order to ensure transparency. The relevant figures were obtained from experts within WHO and beyond, and from documents available in-house or on the Internet. The following costs were included: supplemental salaries, meetings, travel, and other operating costs. The assumptions underlying the costing of the major areas of expenditure are provided in Table 3 below.

Table 3. Costings assumptions for major areas of expenditure

Subtotal	Percentage of costs	Assumptions
Research and Development	91	Indicative targets for African Union and European Union spending on research and development as a percentage of gross domestic product (1% to 3%). It was assumed that 20% of this was for health.
Education of Research and Development workers	4	Targets were set based on existing numbers of research and development workers in high- and middle-income countries of whom 20% were assumed to be working for health.

The assumption was made that activities for those two areas of expenditure would reach their targets by 2015 and earlier years were scaled using a sigmoid curve. Inflation is not factored into the costing. A technical document detailing the costing is available on request.

Funding requirements for the global strategy and plan of action in the global context

8. Currently, about US\$ 160 000 million per year is spent globally on health research and development, of which only about 3% is directed at diseases that disproportionately affect developing countries. The cost of US\$ 147 000 million over seven years for the global strategy and plan of action will mean that, over the same period, 12% of the expected global total of research and development spending will now be used against these diseases.

ANNEX

Plan of Action on Public Health, Innovation and Intellectual Property

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries			
(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific R&D needs in relation to Type I diseases	WHO; Governments; other relevant stakeholders	2008–2015	13 631 210 plus share of subtotal on support unit costs
(b) disseminate information on identified gaps, and evaluate their consequences on public health	WHO; Governments; other relevant stakeholders	2008–2015	Included in 1.1(c) plus share of subtotal on support unit costs
(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	408 952 863 plus share of subtotal on support unit costs
(1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels			
(a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments	Governments; regional organizations	2008–2015	Included in 1.1(c) plus share of subtotal on support unit costs
(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	Included in subtotal on R&D plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	Included in 1.1(c) and 1.2(b) plus share of subtotal on support unit costs
(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for R&D to address public health needs	WHO; Governments; other international intergovernmental organizations; other relevant stakeholders (including private sector)	2008–2015	Included in 1.1(c) plus share of subtotal on support unit costs
(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability)	Governments; WHO; other relevant stakeholders (including academia, relevant health-related industries, national research institutions, and public-private partnerships)	2008–2015	Included in subtotal on education of R&D workers plus share of subtotal on support unit costs
(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	Included in 1.1(c) plus share of subtotal on support unit costs
(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	Included in subtotal on education of R&D workers plus share of subtotal on support unit costs
(c) promote international cooperation and the ethical conduct of research	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015	24 095 640 plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(d) support South–South cooperation in information exchange and research activities	Governments; WHO; other international intergovernmental organizations; regional organizations; other relevant stakeholders	2008–2015	Included in 2.2(f) and 2.3(b) and 2.4 plus share of subtotal on support unit costs
(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	Included in subtotal on R&D plus share of subtotal on support unit costs
(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	Included in subtotal on support unit costs
(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	35 642 670 plus share of subtotal on support unit costs
(c) support governments in establishing health-related innovation in developing countries	Governments; regional organizations; WHO (technical assistance); other relevant stakeholders	2008–2015	45 069 570 plus share of subtotal on support unit costs
(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	Included in 2.2(b)
(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	59 000 000 plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	70 508 930 plus share of subtotal on support unit costs
(d) support basic and applied scientific research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015	Included in subtotal on R&D plus share of subtotal on support unit costs
(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	Included in subtotal on R&D plus share of subtotal on support unit costs
(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	210 886 095 plus share of subtotals on education of R&D workers and support unit costs
(g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries	Governments; WHO; other international intergovernmental organizations, other relevant stakeholders (including: academia; international and national research institution; relevant health-related industries and development partners)	2008–2015	Included in 2.2(b), 2.4 plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	Included in 1.1(c) plus share of subtotal on support unit costs
(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	4 878 400 plus share of subtotal on support unit costs
(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty	Interested Governments; [WHO]; other relevant stakeholders (including nongovernmental organizations)	2008–2010	1 980 870 plus share of subtotal on support unit costs
(d) support active participation of developing countries in building technological capacity	Governments; WHO; other relevant stakeholders	2008–2015	Included in subtotal on education of R&D workers and element 4 plus share of subtotal on support unit costs
(e) promote the active participation of developing countries in the innovation process	Governments; WHO; other relevant stakeholders	2008–2015	Included in subtotal on support unit costs
(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	42 210 000 plus share of subtotal on support unit costs
(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia and research institutions)	2008–2015	Included in 2.4(a) plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	Included in 2.2.(b) plus share of subtotal on support unit costs
(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	19 958 800 plus share of subtotal on support unit costs
(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 (consensus)	Governments	2008–2015	Included in 5.2.(a) plus share of subtotal on support unit costs
(2.5) establishing and strengthening national and regional supporting bodies on research and development			
(a) develop and coordinate a research and development agenda	Governments; regional organizations; WHO; other relevant stakeholders	2008–2015	Included in 1.1(c) plus share of subtotal on support unit costs
(b) facilitate the dissemination and use of research and development outcomes	Governments; regional organizations; WHO; other relevant stakeholders	2008–2015	Included in share of subtotal on support unit costs
(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	Included in subtotal on education of R&D workers plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	Included in subtotal on education of R&D workers plus share of subtotal on support unit costs
(c) strengthen health surveillance and information systems	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including nongovernmental organizations, research institutions, academia)	2008–2015	Not included in these estimates. These would ordinarily be part of the costs of health system strengthening
(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	Included in 6.2(a) plus share of subtotal on support unit costs
(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	Included in 2.1(b) plus share of subtotals on education of R&D workers and support unit costs
(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries	Governments; WHO; other international intergovernmental organizations (including International Organization for Migration and ILO); other relevant stakeholders	2008–2015	Not included in these estimates. These would ordinarily be part of the costs of health system strengthening
(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	Not included in these estimates. These would ordinarily be part of the costs of health system strengthening

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	1 442 050 Included in subtotal on education of R&D workers plus share of subtotal on support unit costs
(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	Included in 1.3, 2.3(b) and 3.3(b) and 3.4(e) plus share of subtotal on support unit costs
(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	235 208 873 plus share of subtotal on support unit costs
(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments			
(a) establish and strengthen national and regional policies to develop, support, promote traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including concerned communities)	2008–2015	25 776 175 plus share of subtotal on support unit costs
(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	Included in 2.1(c) plus share of subtotal on support unit costs
(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	17 697 714 plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	14 942 918 plus share of subtotal on support unit costs
(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	21 875 482 plus share of subtotal on support unit costs
(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	71 749 170 plus share of subtotal on support unit costs
(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	Included in 3.5(b) plus share of subtotal on support unit costs
(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	20 204 100 plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	13 988 290 plus share of subtotal on support unit costs
(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	23 049 000 plus share of subtotals on R&D, education of R&D workers and support unit costs
(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	Included in 4.1 (b) plus share of subtotals on education of R&D workers and support unit costs
(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	Included in 4.1 (b) plus share of costs in support unit
(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	Included in 4.1 (b) plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	Included in 4.1(b) plus share of costs in support unit
(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	12 135 200 plus share of subtotal on support unit costs
(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies			
(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institution; relevant health-related industries, nongovernmental organizations; academia)	2008–2015	1 000 000 plus share of subtotal on support unit costs
(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO); other relevant stakeholders (including health-related industries)	2008–2015	Included in 4.1 plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(5.1) supporting information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries			
(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries	[Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)] [Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)]	2008–2015	46 649 752 plus share of subtotal on support unit costs
(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries	Governments; WHO/[WHO]; other international intergovernmental organizations (including WIPO/[WIPO], WTO/[WTO], UNCTAD; other relevant stakeholders (including international and national research institutions and development partners)	2008–2015	13 708 184 plus share of subtotal on support unit costs
(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]/[Governments]; [WHO]/[WHO]; other international intergovernmental organizations (including WIPO/[WIPO], [WTO]/[WTO], [UNCTAD]; other relevant stakeholders (including international and national research institutions and development partners)]	2008–2015	17 629 960 plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
<p>(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</p>	<p>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; development agencies; nongovernmental organizations; relevant health-related industries)</p>	<p>2008–2015</p>	<p>Included in 5.1(a) and (b) plus share of subtotal on support unit costs</p>
<p>(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS Agreement</p>	<p>Governments; [WHO]/[WHO]; other international intergovernmental organizations (including [WIPO]/[WIPO], [WTO]/[WTO], [UNCTAD]/[UNCTAD]); other relevant stakeholders (including international and national research institutions and development partners</p>	<p>2008–2015</p>	<p>Included in 5.1(a) and (b) plus share of subtotal on support unit costs</p>
<p>(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</p>	<p>Governments; [WHO]; other international intergovernmental organizations; other relevant stakeholders (including concerned communities)</p>	<p>2008–2015</p>	<p>14 177 000 plus share of subtotal on support unit costs</p>
<p>(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</p>	<p>Governments</p>	<p>2008–2015</p>	<p>Included in share of costs of support unit</p>
<p>(h) strengthen efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries</p>	<p>Governments; WHO; other international intergovernmental organizations (including WIPO, WTO and UNCTAD)</p>	<p>2008–2015</p>	<p>2 561 160 plus share of subtotal on support unit costs</p>

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products			
(a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO and UNCTAD)	2008–2015	31 832 650 plus share of subtotal on support unit costs
(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	Included in 5.1 (a) plus share of subtotal on support unit costs
(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003	Governments	2008–2015	Included in 5.1 (a) plus share of subtotal on support unit costs
(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	Governments	2008–2015	9 006 050 plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003			
(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge	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	Included in 5.1(f) plus share of subtotal on support unit costs
(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases			
(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries	[Governments; [WHO]/[WHO]; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; development partners; charitable foundations; relevant health-related industries; nongovernmental organizations)]	2008–2015	Included in 2.2(c) plus share of subtotal on support unit costs
(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	Not included in these estimates. These would ordinarily be part of the costs of health system strengthening

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	20 259 620 plus share of subtotal on support unit costs
(c) prioritize health care in national agendas	Governments	2008–2015	Not included in these estimates. These would ordinarily be part of the costs of health system strengthening
(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	129 393 638 plus share of subtotal on support unit costs
(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	Not included in these estimates. These would ordinarily be part of the costs of health system strengthening
(f) develop effective country poverty reduction strategies that contain clear health objectives	Governments; other relevant stakeholders (including development partners)	2008–2015	Not included in these estimates. These would ordinarily be part of the costs of health system strengthening
(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015	12 205 845 plus share of subtotal on support unit costs

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

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	18 511 690 plus share of subtotal on support unit costs
(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	Included in subtotal on R&D plus share of subtotal on support unit costs
(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	8 944 000 plus share of subtotal on support unit costs
(d) strengthen the WHO pre-qualification programme	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners)	2008–2015	87 319 559 plus share of subtotal on support unit costs
(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]/[WHO]; other relevant stakeholders (including national and regional regulatory agencies, regional bodies and development partners)	2008–2015	92 277 138 plus share of subtotal on support unit costs
(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	Included in 1.3(c), 2.2(f) and 3.3(c) plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	35 261 197 plus share of subtotal on support unit costs
(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	19 642 175 plus share of subtotal on support unit costs
(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	32 416 275 plus share of subtotal on support unit costs
(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	49 817 950 plus share of subtotal on support unit costs
(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	Included in subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	Included in subtotal on support unit costs
(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	Included in 5.1(a) plus share of subtotal on support unit costs
(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	7 760 000 plus share of subtotal on support unit costs
(7.1) endeavouring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries			
(a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases	Governments; WHO ; other international intergovernmental organizations; other relevant stakeholders	2008–2010	2 000 000 plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(b) consider channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness as recommended by the resolution WHA58.34	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	Included in subtotal of R&D plus share of subtotal on support unit costs
(c) create a database of possible sources of financing for R&D	Governments; WHO; other relevant stakeholders	2008–2015	Included in subtotal of support unit costs
(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	1 250 000 plus share of subtotal on support unit costs
(b) develop tools to periodically assess performance of public–private and product development partnerships	Governments; WHO; other relevant stakeholders (including research institutions; public–private and product development partnerships; charitable foundations)	2008–2009	350 000 plus share of subtotal on support unit costs
(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	Included in subtotal of R&D plus share of subtotal on support unit costs

Specific actions	Stakeholders	Time frame	Estimated funding needs in US dollars
(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	1 014 560 plus share of costs of support unit
(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	Included in 1.1(c) plus share of subtotal on support unit costs
(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	9 146 720 plus share of subtotal on support unit costs
(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	Included in 8.1(c) plus share of subtotal on support unit costs
(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	5 250 000 plus share of subtotal on support unit costs