

## Draft Plan of Action

### Chair's Text

Status 3 May 2008

Explanation by the Chair of the Drafting Group on the Plan of Action of the 'Stakeholder' Column in the attached table

**Discussed Text**

- White background indicates text discussed by the Drafting Group, with unbracketed text indicating consensus and bracketed text indicating that consensus has not been reached.
- Shaded background indicates text discussed by the Drafting Group where consensus was achieved. The Chair has standardized the sequence and nomenclature of the text in accordance with the format agreed by the Drafting Group.

**Text not discussed (Chair's proposal)**

- Black background indicates text which has been proposed by the Chair but has not been discussed by the Drafting Group and is therefore not consensus text.

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### \* **Stakeholder(s)**

Lead stakeholders are indicated by bold typeface.

Reference to **Governments** means WHO Member States<sup>1</sup> are urged to take action.

**WHO** means the Director General is requested to take action.

**Other International Intergovernmental Organizations**, both global and regional, means WHO Member States, or WHO as mandated by its Member States through this Plan of Action, invite these Organizations to take action. 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.

Member States are urged to raise appropriate issues in the governing bodies of the organizations.

**Other relevant stakeholders** means WHO Member States, or WHO 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; regional bodies; regional organizations. (consensus)

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<sup>1</sup> Where applicable, refers equally to regional economic integration organizations in their areas of competence and in accordance with WHA Resolution 59.24, para 3(2)

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Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
<b>Element 1. Prioritizing research and development needs</b>			
(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries (consensus)	(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 (consensus)	<b>WHO;</b> Governments; other relevant stakeholders	2008-2015
	(b) disseminate information on identified gaps, and evaluate their consequences on public health (consensus)	<b>WHO;</b> 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 (consensus)	<b>WHO;</b> Governments; other relevant stakeholders	2008-2015
(1.2) formulating explicit prioritised strategies for research and development at country and regional and inter-regional levels (consensus)	(a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments (consensus)	<b>Governments; regional organizations</b>	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 (consensus)	Governments; WHO; other relevant stakeholders (including academia, relevant health-related industries, national research institutions and public-private partnerships)	2008–2015

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	(c) include research and development needs on health systems in a prioritized strategy (consensus)	Governments; WHO; other relevant stakeholders (including academia, national research institutions, and public-private partnerships)	2008-2015
	(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for R&D to address public health needs (consensus)	<b>WHO</b> ; Governments; other International Intergovernmental Organizations; other relevant stakeholders (including private sector)	2008-2015
	(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability) (consensus)	<b>Governments</b> ; 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 (consensus)	(a) set research priorities in traditional medicine (consensus)	<b>Governments</b> ; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including academia, [relevant health-related industries]; national research institutions; public-	2008-2015

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		private partnerships; and concerned communities)	
	(b) support developing countries to build their capacity in research and development in traditional medicine (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including academia, relevant health-related industries, national research institutions, public-private partnerships)</b>	2008-2015
	(c) promote international cooperation and the ethical conduct of research (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders</b>	2008-2015
	(d) support South-South cooperation in information exchange and research activities (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; regional organizations; other relevant stakeholders</b>	2008-2015
	(e) support early-stage drug research and development in traditional medicine systems in developing countries (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders</b>	2008-2015
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 2. Promoting research and development</b>			
(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 (consensus)	a) promote cooperation between private and public sectors on research and development (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders</b>	2008–2015

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	(b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding (consensus)	<b>Governments; regional organizations; WHO</b> (technical assistance); other relevant stakeholders	2008–2015
	(c) support governments in establishing health-related innovation in developing countries (consensus)	<b>Governments; regional organizations; WHO</b> (technical assistance); other relevant stakeholders	2008-2015
(2.2) promoting upstream research and product development in developing countries (consensus)	(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products (consensus)	<b>Governments; WHO;</b> other international intergovernmental organizations; other relevant stakeholders	2008-2015
	(b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries (consensus)	<b>Governments; WHO;</b> other International Intergovernmental Organizations; other relevant stakeholders	2008-2015
	(c) identify incentives and barriers, including IP-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 (consensus)	<b>Governments; WHO;</b> other International Intergovernmental Organizations (including WIPO and WTO); other relevant stakeholders	2008-2015
	(d) support basic and applied scientific research on Type II and	<b>Governments; WHO;</b> other International	2008-2015

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	Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases (consensus)	Intergovernmental Organizations; other relevant stakeholders	
	(e) support early-stage drug research and development in developing countries (consensus)	<b>Governments</b> ; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including relevant health-related industries, academia, international and national research institutions; donor agencies; development partners; non-governmental 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 (consensus)	<b>Governments</b> ; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including relevant health-related industries; academia; development partners; charitable foundations; public-private partnerships; non-governmental 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	<b>Governments</b> ; [WHO/WHO]; other International Intergovernmental Organizations, other relevant stakeholders	

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

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	publications by universities, institutes and technical centres, especially in developing countries (consensus)	relevant stakeholders (including academia, research institutions, relevant health-related industries; nongovernmental organizations; publishers)	
	(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including academia and research institutions)</b>	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 (consensus)	<b>Governments; [WHO]/[WHO]; other International Intergovernmental Organizations (including WIPO and WTO); other relevant stakeholders (including relevant health-related industries)</b>	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 (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including academia and national research institutions)</b>	2008-2015

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	(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)	<b>Governments;</b> [WHO]; [other international intergovernmental organizations (including WTO and WIPO)]	
2.5 establishing and strengthening national and regional coordinating bodies on research and development (consensus)	(a) develop and coordinate a research and development agenda (consensus)	Governments; regional organizations; WHO; other relevant stakeholders	2008–2015
	(b) facilitate the dissemination and use of research and development outcomes (consensus)	Governments; regional organizations; WHO; other relevant stakeholders	2008-2015
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 3. Building and improving innovative capacity</b>			
(3.1) building capacity of developing countries to meet research and development needs for health products (consensus)	(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health (consensus)	<b>Governments;</b> 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 (consensus)	<b>Governments;</b> other International Intergovernmental Organizations; other relevant stakeholders (including research and development groups, relevant health-related	2008–2015

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		industries and development partners)	
	(c) strengthen health surveillance and information systems (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including non-governmental organizations, research institutions, academia)</b>	2008–2015
(3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation (consensus)	(a) establish and strengthen regulatory capacity in developing countries (consensus)	<b>Governments; WHO; other relevant stakeholders (including national and regional regulatory agencies)</b>	2008–2015
	(b) strengthen human resources in research and development in developing countries through long-term national capacity building plans (consensus)	<b>Governments; other International Intergovernmental Organizations; other relevant stakeholders (including development partners; international and national research institutions)</b>	2008–2015
	(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations (including IOM and ILO); other relevant stakeholders [(including Global Health Workforce Alliance)]</b>	2008–2015
	(d) urge Member States to establish	<b>Governments</b>	2008–2015

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	<p>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 (consensus)</p>	<p><b>[WHO; other International Intergovernmental Organizations (including IOM and ILO); other relevant stakeholders [(including [the Global Forum on Migration and Development] GHWA);]]</b>  Or  No stakeholders defined</p>	
<p>(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries (consensus)</p>	<p>(a) develop successful health innovation models in developing innovative capacity (consensus)</p>	<p><b>Governments; WHO; other International Intergovernmental Organizations (including WIPO, OECD and UNCTAD); other relevant stakeholders (including academia; research institutions; health related industries and developmental partners)</b></p>	<p>2008–2015</p>
	<p>(b) intensify North–South and South–South partnerships and networks to support capacity building (consensus)</p>	<p><b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries)</b></p>	<p>2008–2015</p>

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	(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries (consensus)	<b>Governments; WHO; other relevant stakeholders (including academia and research institutions)</b>	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 (consensus)	(a) establish and strengthen national and regional policies to develop, support, promote traditional medicine (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations [(including WIPO)]; other relevant stakeholders (including concerned communities)</b>	2008-2015
	(b) encourage and promote policies on innovation in the field of traditional medicine (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including international and national research institutions, concerned communities)</b>	
	(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including national and regional regulatory agencies; international and national research institutions; development partners)</b>	
	(d) encourage research on	<b>Governments; WHO; other</b>	

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	mechanisms for action and pharmacokinetics of traditional medicine (consensus)	International Intergovernmental Organizations; other relevant stakeholders (including academia; international and national research institution; relevant health-related industries)	
	(e) promote South-South collaboration in traditional medicine (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations [(including WIPO)]; other relevant stakeholders (including research institutions, regional bodies, academia)</b>	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 (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including national and regional regulatory agencies, relevant health-related industries)</b>	2008–2015
(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation (consensus)	(a) encourage the establishment of award schemes for health-related innovation (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including academia;</b>	

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		international and national research institution; development partners; charitable foundations)	
	(b) encourage recognition of innovation for purposes of career advancement for health researchers (consensus)	<b>Governments</b> ; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including academia; international and national research institution; development partners; charitable foundations)	
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 4. Transfer of technology</b>			
(4.1) promoting transfer of technology and the production of health products in developing countries (consensus)	(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 (consensus)	<b>Governments</b> ; WHO; other International Intergovernmental Organizations (including WTO, UNCTAD, UNIDO); other relevant stakeholders (including; international and national research institution; relevant health-related industries)	
	(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where	<b>Governments</b> ; WHO; other International Intergovernmental Organizations [(including WTO, WIPO and UNCTAD)]; other relevant stakeholders	2008–2015

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	appropriate (consensus)	(including [relevant health-related industries], or [relevant health-related industries]; academia; nongovernmental organizations; development partners; charitable foundations)	
(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development (consensus)	(a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry (consensus)	<b>Governments</b> ; WHO; other International Intergovernmental Organizations [(including WTO and 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 (consensus)	<b>Governments</b> ; 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	<b>Governments</b> ; WTO; [WHO or WHO]; [other	2008–2015

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	least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (consensus)	International Intergovernmental Organizations (including WIPO); other relevant stakeholders (including academia; research institutions; relevant health-related industries)]	
	(d) promote the necessary training to increase absorptive capacity for technology transfer (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations [(including WTO, WIPO, and UNCTAD)]; other relevant stakeholders (including research institutions)</b>	2008–2015
(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies (consensus)	(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 (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations (including WIPO); other relevant stakeholders (including international and national research institution; relevant health-related industries, nongovernmental organizations; academia)</b>	
	(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	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders</b>	

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	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 (consensus)		
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 5. Application and Management of intellectual property to contribute to innovation and promote public health (consensus)</b>			
(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 (consensus)	(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 (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations (including WIPO, WTO); other relevant stakeholders (including international and national research institutions and development partners)</b>	
	(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 (consensus)	<b>Governments; WHO; Other International Intergovernmental Organizations [including WIPO and WTO] Other relevant stakeholders (including academia; international and national research institutions; development agencies; nongovernmental organizations; relevant</b>	

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		health-related industries)	
	(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS Agreement (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations (including WIPO, WTO); other relevant stakeholders (including international and national research institutions and development partners)</b>	
	(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. (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations (including WIPO); other relevant stakeholders (including concerned communities)</b>	
	(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 (consensus)	<b>Governments</b>	

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	(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 (consensus)	<b>Governments; WHO; other International Intergovernmental Organizations (including WIPO and WTO)</b>	
(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 (consensus)	(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 (TRIPS agreement), including those recognized by the Doha Declaration on TRIPS agreement and Public Health and the WTO decision of 30 August 2003 (consensus)	<b>Governments; WHO; Other International Intergovernmental Organizations (including WIPO and WTO)</b>	
	(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 (consensus)	<b>Governments</b>	
	(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export,	<b>Governments</b>	

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	<p>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 (consensus)</p>		
	<p>(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge (consensus)</p>	<p><b>Governments; WHO; other International Intergovernmental Organizations (including WIPO, WTO, UNEP); other relevant stakeholders (including <b>concerned communities</b>)</b></p>	
<p>(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 (consensus)</p>	<p>(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 (consensus)</p>	<p><b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders (including international and national research institutions; development partners; charitable foundations; relevant health related industries)</b></p>	

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Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
<b>Element 6. Improving delivery and access (consensus)</b>			
(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system (consensus)	(a) invest in developing health-delivery infrastructure and encourage financing of health products (consensus)	<b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, private sector and relevant health-related industries)</b>	
	(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016 <sup>1</sup> (consensus)	<b>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders</b>	
	(c) prioritise health care in national agendas (consensus)	<b>Governments; [WHO; Other International Intergovernmental Organizations [including the World Bank, IMF and OECD]]</b>	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,	<b>Governments; WHO</b>	

<sup>1</sup> In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health

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	to develop strategies to promote rational use of medicines. (consensus)		
	(e) increase investment in human resource development in the health sector (consensus)	<b>Governments;</b> WHO; other International Intergovernmental Organizations [including the World Bank]; other relevant stakeholders (including development agencies; nongovernmental organizations; charitable foundations)	2008–2015
	(f) develop effective country poverty reduction strategies that contain clear health objectives (consensus)	<b>Governments;</b> other relevant stakeholders (including development partners)	2008–2015
	(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate (consensus)	<b>Governments; WHO;</b> other International Intergovernmental Organizations; other relevant stakeholders	
(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices (consensus)	(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 (consensus)	<b>Governments; WHO;</b> other relevant stakeholders (including <b>national and regional regulatory agencies</b> and development partners)	
	(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in	<b>Governments; WHO;</b> other International Intergovernmental Organizations (including	

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	high disease-burden settings (consensus)	UNICEF, GFATM); other relevant stakeholders (including international and national research institutions; nongovernmental organizations, development partners and charitable foundations)	
	(c) comply with good manufacturing practices for safety standards, efficacy and quality of health products (consensus)	<b>Governments; WHO;</b> other relevant stakeholders (including national regulatory bodies; relevant health-related industries; development partners)	2008–2015
	(d) strengthen the WHO pre-qualification programme (consensus)	<b>Governments; WHO,</b> other International Intergovernmental Organizations (including UNICEF); other relevant stakeholders (including national and regional regulatory agencies and development partners)	
	(f) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals (consensus)	<b>Governments; WHO;</b> other relevant stakeholders (including national and regional regulatory agencies, regional bodies and development partners)	

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	(g) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines (consensus)	<b>Governments; WHO;</b> other International Intergovernmental Organizations; other relevant stakeholders (including national and regional regulatory agencies)	
	(h) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval (consensus)	<b>Governments; WHO;</b> other relevant stakeholders (including national and regional regulatory agencies, international and national research institutions, regional bodies and development partners)	
(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs (consensus)	(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 TRIPS Agreement and instruments related	<b>Governments</b>	

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	to that agreement (consensus)		
	(b) frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements (consensus)	<b>Governments; WHO</b>	
	(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 (consensus)	<b>Governments</b>	
	(g) increase information among policy makers, users, doctors and pharmacists regarding generic products (consensus)	<b>Governments; WHO; other relevant stakeholders (including nongovernmental organizations and relevant health related industry)</b>	
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 7. Promoting sustainable financing mechanisms (consensus)</b>			
(7.1) endeavoring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries (consensus)	(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	<b>Governments; WHO; other International Intergovernmental Organizations; other relevant stakeholders</b>	

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	specific R&D needs of developing countries in relation to Type I diseases (consensus)		
	(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 WHA 58.34 (consensus)	<b>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)</b>	
	(c) create a database of possible sources of financing for R & D (consensus)	<b>Governments; WHO; other relevant stakeholders</b>	
(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 (consensus)	(a) document and disseminate best practices in public-private and product development partnerships (consensus)	Governments; <b>WHO</b> ; other relevant stakeholders (including research institutions, public-private and product development partnerships)	2008–2015
	(b) develop tools to periodically assess performance of public-private and product development partnerships (consensus)	Governments; <b>WHO</b> ; other relevant stakeholders (including research institutions; public-private and product development partnerships; charitable foundations)	2008–2009

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	(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries (consensus)	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
<b>Elements and sub-elements</b>	<b>Specific actions</b>	<b>Stakeholder(s)*</b>	<b>Time frame</b>
<b>Element 8. Establishing monitoring and reporting systems</b>			
(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action (consensus)	(a) establish systems to monitor performance and progress of the implementation of each element of the Global Strategy and Plan of Action (consensus)	Governments; <b>WHO</b>	From 2009
	(b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries (consensus)	Governments; <b>WHO</b>	[From 2009]
	(c) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report	<b>Governments; WHO; other International Intergovernmental Organizations (including WIPO and WTO); other relevant stakeholders</b>	

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	thereon to the Health Assembly (consensus)		
	(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices (consensus)	<b>Governments; WHO;</b> other International Intergovernmental Organizations (including WIPO and WTO); Other relevant stakeholders	
	(e) monitor and report on investment in research and development to address the health needs of developing countries (consensus)	<b>Governments; WHO;</b> other relevant stakeholders	

*A global responsibility for action*

1. Global responsibility for implementation of the strategy by 2015 will rest with a range of [actors] /**[stakeholders]**, including WHO's Member States, the WHO Secretariat, WIPO, WTO, national institutions, development partners, academia, pharmaceutical companies, public-private partnerships, charitable foundations and nongovernmental organizations. Together they can ensure that (i) the discovery and development of health products are promoted and funded in a sustainable manner in order to address the health needs of developing countries, and (ii) health products are accessible and affordable for people and governments in developing countries. Successful implementation will require concerted action.

2. Details of specific collaborative action on implementation are set out in the following draft plan of action, which provides a medium-term framework for stakeholders. It includes progress indicators.

3. The implementation of the plan of action will involve numerous stakeholders at national, regional and global levels. Therefore, realistic costing of the plan will require detailed information on the activities to be undertaken by each stakeholder and at which level. Costs will be reviewed after discussion and agreement on the range of specific actions during this second session of the Working Group. These estimates will include a costing for initial implementation in 2008 and 2009, and a preliminary cost estimate for full implementation. Costing assumptions and estimates for implementation from 2010 should be updated in the biennial review due at the end of 2009 on the basis of predefined monitoring and evaluation data.

(To move 4, 5, and 6 to the Committee of the Whole)

**4. [High prices of medicines contribute to inequitable access to treatment.**

**5. It is important to strengthen capacity of local public institutions and business in developing countries for participating in research and development efforts.**

**6. Efforts to develop new products will be of no value if they cannot be made available and accessible to those who need them. ]**

NOTE: Text for "A global responsibility for action" forwarded by Drafting Group B for consideration by the Plan of Action Drafting Group