

3 May 2008

Draft Plan of Action

Chair's Text

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

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.]

* **Stakeholder(s)**

Lead stakeholders are indicated by bold typeface.

Reference to **Governments** means WHO Member States¹ 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 strategy and Plan of Action to the attention of all relevant international organizations inviting them to consider the relevant provisions of this 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 pharmaceutical companies, both innovator and generic, biotechnology companies, vaccine companies and medical device companies)] [including both public and private]; public-private partnerships, *public-private and product development partnerships*, nongovernmental organizations, concerned communities, development partners, *donor agencies, development agencies*, charitable foundations, *private sector, publishers, research and development groups, regional bodies, regional organizations*²

[DRAFTING NOTE: FULL LIST OF RELEVANT STAKEHOLDERS TO BE COMPLETED]/

¹ [Where appropriate refers equally to regional economic integration organizations in their areas of competence and in accordance with WHA Resolution 59.24 , operational paragraph 3(2)]

² *Note: regional organizations are referred to here and elsewhere in the action plan. Identification and assignment of specific roles for regional entities will be done during further development of the plan.

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

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
		institutions, and public-private partnerships)	
	(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)	WHO ; Governments; Other International Intergovernmental Organizations; Other relevant stakeholders (including private sector)	2008-2015
	(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability). (consensus)	Governments ; WHO; Other relevant stakeholders (including academia, relevant health related industries, national research institutions, and public-private partnerships)	2008-2015
(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples (consensus)	(a) set research priorities in traditional medicine (consensus)	Governments ; WHO; Other International Intergovernmental Organizations; Other relevant stakeholders (including academia, [relevant health-related industries]; national research institutions; public-private partnerships; and concerned communities);	2008-2015
	(b) supporting developing countries to build their capacity in research and development in traditional medicine (consensus)	Governments ; WHO; Other International Intergovernmental Organizations; Other	2008-2015

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
		relevant stakeholders (including academia, relevant health-related industries, national research institutions, public-private partnerships); Governments; WHO; Other International Intergovernmental Organizations; Other relevant stakeholders;	2008-2015
	(c) promote international cooperation and the ethical conduct of research; (consensus)	Governments; WHO; Other International Intergovernmental Organizations; Other relevant stakeholders;	2008-2015
	(d) support South-South cooperation in information exchange and research activities (consensus)	Governments; WHO; Other International Intergovernmental Organizations; regional organizations; Other relevant stakeholders	2008-2015
	(e) support early-stage drug research and development in traditional medicine systems in developing countries. (consensus)	Governments; WHO; Other International Intergovernmental Organizations; Other relevant stakeholders;	2008-2015
Element 2. Promoting research and development (2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area (consensus)	a) promote cooperation between private and public sectors on research and development (consensus) b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding (consensus) c) support governments in establishing health-related innovation	Governments; WHO; Other International Intergovernmental Organizations; Other relevant stakeholders Governments; regional organizations; WHO (technical assistance); Other relevant stakeholders Governments; regional Organizations; WHO	2008-2015

