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

Report by the Secretariat

1. The Fifty-sixth World Health Assembly, in resolution WHA56.27, requested the Director-General to establish terms of reference for an appropriate time-limited body in order "to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries ...".

2. The duly established Commission on Intellectual Property Rights, Innovation and Public Health submitted its report[1] to the Fifty-ninth World Health Assembly, which, in resolution WHA59.24, decided to establish an intergovernmental working group that would submit to the Sixty-first World Health Assembly through the Executive Board a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission.

3. At the end of its first session (Geneva, 4–8 December 2006), the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property issued a document that recorded progress to date and contained the elements of a plan of action and a global strategy.[2] The Working Group agreed that Member States should be allowed additional time to review that document and provide additional comments and inputs. It requested the Secretariat to consider those inputs, in preparing the annexed draft global strategy and plan of action, as a basis for negotiation during its second session.

[1] Document CIPIH/2006/1.

[2] Document A/PHI/IGWG/1/5.

ANNEX

Draft global strategy on public health, innovation and intellectual property

The context

1. In resolution WHA59.24 the Health Assembly recognized the growing burden of diseases and conditions that disproportionately affect developing countries, and particularly women and children. Reducing the very high incidence of communicable diseases in those countries is an overriding priority. At the same time, it is important to ensure that the increasing prevalence of noncommunicable diseases in those countries is recognized and addressed.

2. Governments, the pharmaceutical industry, charitable foundations and nongovernmental organizations have made progress in recent years by funding initiatives to develop new products against diseases affecting developing countries and to increase access to existing products. However, these initiatives have proved inadequate to surmount the challenges. Much more must be done in relation to the scale of avoidable suffering and mortality.

3. Advances in biomedical science have provided opportunities to develop new, affordable health products, and in particular to meet public health needs in developing countries. These opportunities must be harnessed more effectively and more urgently.

The aim

4. The aim of the proposed global strategy on public health, innovation and intellectual property is to provide a medium-term framework for an enhanced and sustainable basis for needs-driven, essential research and development relevant to diseases that disproportionately affect developing countries.

5. The global strategy, designed to promote innovation, build capacity and improve access, will:

- establish a research and development agenda that covers the health needs of developing countries
- propose mechanisms to carry out the above research and development agenda, including increasing worldwide capacity for research and development, particularly in developing countries, into diseases affecting those countries
- secure financing for the activities resulting from the research and development agenda, including exploring innovative financial mechanisms
- seek to increase the availability, accessibility and uptake of health products (in particular, medicines, vaccines and diagnostics) in developing countries.

The focus

6. The focus of the strategy will be on diseases or conditions of significant public health importance in developing countries for which an adequate treatment for use in resource-poor settings is not available – either because no treatment exists or because, where treatments exist, they are inappropriate for use in countries with poor delivery systems, or unaffordable. The Commission

highlighted the need to focus on Type II and Type III diseases and the needs of developing countries in relation to Type I diseases.[1]

7. The eight elements agreed by the Intergovernmental Working Group at its first meeting provide the organizing principle for the plan of action.[2]

The elements

Element 1. Prioritizing research and development needs

8. Health research and development policies in developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the needs of developing countries in relation to Type I diseases need to be identified urgently. A better understanding of disease determinants is essential to drive sustainable research and development on new and existing products.

9. The actions to be taken to prioritize research and development needs are as follows:

(1.1) identifying gaps in research on diseases that disproportionately affect developing countries

(a) develop methodologies to identify gaps in research on Type II and Type III diseases and on developing countries' needs in relation to Type I diseases

(b) provide an assessment of identified gaps.

(1.2) facilitating upstream research on new and existing products for diseases that disproportionately affect developing countries

(a) *improve accessibility to compound libraries for identification of compounds with potential activity against the above-mentioned diseases, by means including public–private collaboration*

(b) provide technical support to developing countries in order to create libraries of new compounds at both national and regional levels.

[1] The Commission's definitions of Type I, Type II and Type III diseases, and the specific diseases on which this draft strategy focuses, are as follows: *Type I diseases* are incident in both rich and poor countries, with large numbers of vulnerable populations in each. The strategy will focus on the following Type I diseases, increasingly prevalent in developing countries: diabetes, cardiovascular disease and cancer. *Type II diseases* are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. For the purposes of the strategy, the focus is on HIV/AIDS and tuberculosis. *Type III diseases* are those that are overwhelmingly or exclusively incident in developing countries. For the purposes of the strategy, the focus is on the nine neglected infectious diseases that disproportionately affect poor and marginalized populations prioritized by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases: Chagas disease, dengue and dengue haemorrhagic fever, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, schistosomiasis and human African trypanosomiasis.

[2] Document A/PHI/IGWG/1/5.

(1.3) coordinating research activities between developed and developing countries

(a) coordinate international efforts in research and development in order to optimize resources

(b) support developing countries in building technological capacity.

(c) promote the active participation of developing countries in the innovation process.

(1.4) formulating explicit prioritized strategies for research and development at country level

(*a) developing countries to set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments*

(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products to combat diseases in developing countries (including Type I diseases)

(c) include research and development needs for traditional medicines in a prioritized strategy.

Element 2. Promoting research and development

10. This element covers both the discovery and development aspects of the innovation cycle. The range of measures to promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases needs to be substantially enhanced. Greater investment, in both developed and developing countries, is required. In this context, developing countries should consider the appropriate level of investment necessary to strengthen research and research capacity.[1]

11. The actions to be taken to promote research and development are as follows:

(2.1) increasing funding for research and development that focuses on the health needs of developing countries

(a) developed countries to devote a larger proportion of their health research and development budgets to the health needs of developing countries.

(2.2) supporting governments in improving national health research programmes and facilitating better coordination of stakeholders in this area

(a) promote cooperation between private and public sectors on research and development

[1] Participants in the High-Level Ministerial Meeting on Health Research for Disease Control and Development (Accra, 15–17 June 2006) committed themselves to meeting the recommendation by the Commission for Health Research for Development in 1990 that developing countries should invest at least 2% of the national health budget on research and on research capacity strengthening.

(b) provide support for national health research programmes in developing countries through political action and long-term funding

(c) develop and implement systems for supporting health-related innovation in developing countries (including intellectual property management).

(2.3) promoting upstream research and product development in developing countries

(a) promote discovery science, including through open-source methods, in order to develop a sustainable portfolio of new products

(b) promote access to drug leads identified through the screening of compound libraries

(c) promote basic and applied scientific research on Type II and Type III diseases

(d) promote early-stage drug research and development in developing countries

(e) developing countries to consider legislation that is compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights relating to research exemptions

(f) promote public funding for clinical trials and other mechanisms for stimulating local innovation

(2.4) improving global coordination and financing of medical research and development

(a) improve global coordination and financing, using systematic reviews and needs assessment

(b) set up a forum, or enhance existing ones, in order to improve the coordination of research and development activities and sharing of information

(c) support further discussion of a medical research and development treaty.

Element 3. Building and improving innovative capacity

12. There is a need to frame and support effective policies that promote the development of capacities in developing countries related to health innovation. Key areas for investment are capacities relating to science and technology, clinical trials, regulation, intellectual property and traditional medicine.

13. The agenda for this element covers the following:

(3.1) building capacity of developing countries to meet research and development needs for new health products

(a) support investment by developing countries in human resources and knowledge bases, especially in tertiary education

(b) support existing and new research and development groups in developing countries.

(3.2) framing and supporting effective policies that promote the development of capacities for health innovation

(a) strengthen product regulatory capacity in developing countries

(b) strengthen human resources in research and development in developing countries through a long-term plan for human resources

(c) address appropriate training and retention of researchers and health professionals, including issues relating to migration.

(3.3) providing support for innovation capacity building in developing countries, including in areas such as science and technology, regulation, clinical trials, the transfer of technology, traditional medicine and intellectual property

(a) document and disseminate best practices in innovation

(b) promote successful models in developing innovative capacity

(c) intensify North–South and South–South partnerships and networks to support capacity building.

(3.4) developing and implementing policies that will promote innovation based on traditional medicine

(a) develop and promote traditional medicine within an evidence-based framework

(b) promote documentation of traditional knowledge and natural genetics resources

(c) encourage developing countries to ensure high standards of safety and efficacy for traditional medicines

(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicines.

Element 4. Transfer of technology

14. North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

15. The actions to be taken in relation to this element are as follows:

(4.1) promoting transfer of technology and the production of health products in developing countries

(a) devise a mechanism, or make better use of existing ones, to facilitate transfer of technology and technical support

(b) promote transfer of technology and production of health products in developing countries through investment and capacity building.

(4.2) supporting improved collaboration and coordination of technology transfer

(a) encourage North–South and South–South collaboration, and collaboration between institutions in developing countries and the pharmaceutical industry

(b) support technology transfer related to research and development on natural products

(c) facilitate local and regional networks for collaboration on research and development

(d) promote compliance with obligations under Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights.

(4.3) developing mechanisms to manage intellectual property in order to promote transfer of and access to key technologies

(a) promote patent pools of upstream and downstream technologies

(b) develop other effective and sustainable mechanisms to promote innovation of products for priority diseases in developing countries

(c) examine best practices in areas such as competition, transparency and proper remuneration for patent holders.

Element 5. Management of intellectual property

16. Intellectual property is a vital concept in ensuring that development of new health products continues. However, complementary, alternative and/or additional incentive schemes for research and development, especially on Type II and Type III diseases and the special needs of developing countries in respect of Type I diseases, need to be explored and implemented. There is a crucial need to strengthen capacities in developing countries to manage intellectual property.

17. The actions to be taken in relation to this element are as follows:

(5.1) supporting information sharing and capacity building in the management of intellectual property

(a) promote national and/or regional institutional frameworks in order to build capacity and manage intellectual property

(b) compile and maintain national databases on patent status of relevant health-related products and promote exchange of information between relevant government departments

(c) WHO and WIPO to improve dissemination of relevant information and existing databases at international level

(d) WHO, in collaboration with WIPO and WTO, to strengthen education and training in the management of intellectual property.

(5.2) upon request, providing support for application of the flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights

(a) promote legislation to apply flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements, by means including the dissemination of best practices

(b) promote bilateral trade agreements that do not incorporate "TRIPS-plus" protection in ways that might reduce access to medicines in developing countries

(c) encourage trade agreements that take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (as recognized by the Doha Declaration on the TRIPS Agreement and Public Health).

(5.3) exploring and promoting complementary incentive schemes for research and development

(a) explore and implement complementary incentive schemes for research and development that separate the incentives for innovation from the prices of health-care products (for example, the prize fund model)

(b) expand the advance-market commitment approach

(c) assess the impact of data-exclusivity regulations

(d) examine measures to comply with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights for the protection of undisclosed test data against unfair commercial use.

Element 6. Improving delivery and access

18. Support for health systems is vital for the success of the strategy, as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products.

Mechanisms to regulate the safety, quality and efficacy of medicines and other health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a well-functioning health system.

19. International and bilateral agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries. The impact of such actions on innovation needs to be monitored.

20. The actions to be taken to improve delivery and access are as follows:

(6.1) encouraging governments to invest in the health-delivery infrastructure

(a) invest in developing health-delivery infrastructure and ensure financing of health products

(b) develop effective and sustainable mechanisms in least-developed countries in order to increase access to existing medicines, making full use of the transitional period until 2016[1]

(c) prioritize health care in national agendas.

(6.2) instituting mechanisms to regulate the quality, safety and efficacy of medicines and other health products

(a) strengthen capacity to monitor the quality, safety and efficacy of health products, and accelerate the regulatory approval of products with potential utility

(b) conduct operational studies to maximize the value and use of new products in high disease-burden settings with inadequate health services

(c) implement national and international disease-control policies that are based on evidence that use of new and existing products has an impact

(d) encourage compliance with good manufacturing practices in developing countries

(e) minimize the public health consequences of counterfeit and substandard products.

(6.3) promoting competition and ensuring that pricing of medicines is consistent with public health policies

(a) support the production and introduction of generic versions of essential medicines in developing countries, including national legislation to encourage generic entry on patent expiry

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

(b) frame policies emphasizing essential medicines at affordable prices

(c) remove tariffs and taxes on health-care products and monitor their supply and distribution chain

(d) take necessary legislative steps in countries with manufacturing and export capacity to allow compulsory licensing for export consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health

(e) encourage pharmaceutical companies to adopt transparent and consistent pricing policies, aiming to reduce prices for developing countries

(f) monitor pricing policies and strengthen WHO's work on pharmaceutical pricing.

Element 7. Ensuring sustainable financing mechanisms

21. In recent years donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional donor financing has also been secured for research and development activities relevant for the control and treatment of the diseases covered by this strategy. Nonetheless, further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries. The most serious gaps in donor financing for health products and research and development covered by this strategy need to be identified and analysed.

22. It is important to expand current initiatives, thereby contributing to a flow of resources into innovation and implementation, including public–private partnerships, initiatives by foundations, advance-market commitment mechanisms, and the International Finance Facility for Immunization.

23. The actions to be taken to ensure sustainable financing mechanisms are as follows:

(7.1) securing additional and sustainable financing for research and development in order to address the health needs of developing countries

(a) develop and implement a resource mobilization plan

(b) assess the utility of existing funding mechanisms, or a new global funding mechanism, in order to increase global coordination and sustainable funding of medical research and development

(c) use current and new financing initiatives (such as advance-market commitment schemes) to accelerate the progress of health-care products from development to delivery

(7.2) facilitating the expansion of activities in order to develop and deliver affordable products

(a) document and disseminate best practices in expanding public–private partnerships

(b) develop tools to assess performance of public–private partnerships

(c) support public–private partnerships and other research and development initiatives in developing countries in expanding their activities.

(7.3) increasing resources for research organizations in developing countries

(a) channel additional funds to research organizations in both the private and public sector of developing countries.

Element 8. Establishing monitoring and reporting systems

24. Systems should be established to monitor performance and progress of this strategy. Such performance and progress will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the strategy will be undertaken every four years.

25. Steps to be taken will include:

(8.1) measuring performance and progress towards objectives contained in the plan of action

(a) establish systems to monitor performance and report to WHO's governing bodies on progress every two years, with effect from end-2009.

(8.2) monitoring the impact of intellectual property rights and other factors on innovation and access to medicines and other health-care products

(a) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health-care products in developing countries

(b) monitor the impact of intellectual property rights and other factors on innovation and access to health-care products

(c) monitor investment in research and development to address the health needs of developing countries.

A global responsibility for action

26. Global responsibility for implementation of the strategy by 2015 will rest with a range of actors, 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.

27. 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.

28. 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.

Draft plan of action on public health, innovation and intellectual property

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
Element 1. Prioritizing research and development needs				
1.1 Identify gaps in research on diseases that disproportionately affect developing countries	*(a) Develop methodologies to identify gaps in research on Type II and Type III diseases and on developing countries' needs in relation to Type I diseases*	Governments; international and national research institutions; academia; **WHO**; pharmaceutical industry; public–private partnerships; nongovernmental organizations	2008	(i) Identification of existing methodologies completed (ii) Links with other ongoing work established (iii) Methodologies for gap analysis agreed (iv) Ongoing processes with multiple stakeholder engagement identified/developed (v) Specific methods for working with affected communities in order to elicit their research priorities developed
	(b) Provide an assessment of identified gaps	Governments; international and national research institutions; academia; **WHO**; pharmaceutical industry; public–private partnerships; nongovernmental organizations	Initial output 2009 with regular follow-up	(i) Gap analysis completed and publicized (ii) Plans for future periodic updates in place

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
1.2 Facilitate upstream research on new and existing products for diseases that disproportionately affect developing countries	*(a) Improve accessibility to compound libraries for identification of compounds with potential activity against the above-mentioned diseases, including through public–private collaboration*	Governments; **pharmaceutical industry**; international and national research institutions; academia; public–private partnerships; **WHO**	2008–2015	(i) No. of accessible databases facilitating information exchange on innovation for product development (ii) No. of agreements reported by companies or institutions, including academic institutions, to allow access to compound libraries for public-interest research Baseline 2008: xx Target 2010: yy Target 2015: zz (iii) Assessment of value in order to establish a global publicly-accessible compound library completed
	(b) Provide technical support to developing countries in order to create libraries of new compounds at both national and regional levels	Governments; pharmaceutical industry; national research institutions; WHO; academia; public–private partnerships	2008–2015	(i) No. of technical-support providers identified (ii) No. of countries supported and accessing technical support (iii) No. of countries generating technology platforms (e.g. creation of compound libraries) (iv) No. of regional centres of excellence established

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
1.3 Coordinate research activities between developed and developing countries	*(a) Coordinate international efforts in research and development in order to optimize resources*	Governments; **WHO**; other United Nations organizations; development partners; public–private partnerships; nongovernmental organizations; pharmaceutical industry; academia; research institutions	2008–2015	(i) Qualitative assessments (opinions of stakeholders) of increased coordination and harmonization of international efforts made (ii) Quantitative assessments (listed activities and examples) of increased coordination and harmonization of international efforts made (iii) No. of joint evaluation studies conducted on country and international coordination efforts, including assessment of impact of studies on policy and programme management
	(b) Support developing countries in building technological capacity[1]	Governments; development partners; pharmaceutical industry; **WHO**; other United Nations organizations; charitable foundations	2008–2015	(i) Amount of resources made available by donors, and national governments Baseline 2008: xx Target 2010: yy Target 2015: zz (ii) No. of new country-level efforts initiated (or similar indicator)

[1] Building technological capacity in countries is also covered in element 3.

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(c) Promote the active participation of developing countries in the innovation process	Governments; development partners; pharmaceutical industry; United Nations organizations; international and national research institutions; academia	2008–2015	(i) No. of developing countries with capacity for innovation (defined as successful participation in discovery and development of health products) Baseline 2008: xx Target 2010: yy Target 2015: zz (ii) No. of innovative health products and technologies emerging from developing countries Baseline 2008: xx Target 2015: zz (iii) No. of patents generated within developing countries
1.4 Formulate explicit prioritized strategies for research and development at country level	*(a) Developing countries to set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments*	**Governments**; international and national research institutions; academia; WHO; other United Nations organizations; public–private partnerships	2008–2015	(i) No. of countries with established research priorities and best practice mechanisms in place for maintaining and updating them and contributing to global priority setting Baseline 2008: xx Target 2010: yy Target 2015: zz (ii) No. of policy-dissemination efforts undertaken to ensure that priorities are reflected in budgets
	(b) Conduct research appropriate for resource-poor settings and research on technologically appropriate products to combat diseases in	Governments; WHO; academia; pharmaceutical industry; national research institutions; public–private partnerships	2008–2015	(i) Research needs established for countries (including national contributions to regional and global efforts)

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	developing countries (including Type I diseases)			(ii) Research priorities agreed (iii) No. of agreed research priorities where research is under way Baseline 2008: xx Target 2010: yy Target 2015: zz
	(c) Include research and development needs for traditional medicines in a prioritized strategy[1]	**Governments**; pharmaceutical industry; WHO; other United Nations organizations; academia; research institutions	2008–2015	(i) No. of countries including traditional medicine within their prioritization process and in their national plans (ii) Quantitative assessment made of innovation-driven activities related to traditional medicines
Element 2. Promoting research and development				
2.1 Increase funding for research and development that focuses on the health needs of developing countries	*(a) Developed countries to devote a larger proportion of their health research and development budgets to the health needs of developing countries*	**Governments of developed countries**; development partners	2009–2015	(i) Percentage increase in health research and development budget of developed countries devoted to health needs of developing countries Baseline 2009: xx Target 2015: y% increase (ii) Percentage increase in national research budgets allocated to health research Baseline 2009: xx Target 2015: y% increase

[1] Issues relating to traditional medicines are also covered in sub-element 3.4 below.

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
2.2 Support governments in improving national health research programmes and facilitating better coordination of stakeholders in this area	*(a) Promote cooperation between private and public sectors on research and development*	Governments; pharmaceutical industry; **WHO**; other United Nations organizations; academia; research institutions; public–private partnerships	2008–2015	(i) Enabling environment established by government, including policy frameworks and incentives (ii) Examples of public–private sector collaboration documented and disseminated
	(b) Provide support for national health research programmes in developing countries through political action and long-term funding	**Governments**; national research institutions; WHO; development partners	2008–2015	(i) Increase in external funding for national health research programmes Baseline 2008: xx Target 2015: yy (ii) Increase in national funding for national health research programmes Baseline 2008: xx Target 2015: yy
	(c) Develop and implement systems for supporting health-related innovation in developing countries (including intellectual property management)	**Governments**; research institutions; academia; WHO; WIPO; WTO; pharmaceutical industry; development partners	2008–2015	(i) No. of countries with appropriate management and monitoring system Baseline 2008: xx Target 2015: yy (ii) No. of countries with intellectual property management capabilities to support research institutions Baseline 2008: xx Target 2015: yy (iii) No. of countries with national, publicly transparent information systems to publicize ongoing

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
				research efforts Baseline 2008: xx Target 2015: yy
2.3 Promote upstream research and product development in developing countries	*(a) Promote discovery science, including through open-source methods, in order to develop a sustainable portfolio of new products*	Pharmaceutical industry; academia; international and national research institutions; **WHO**; other United Nations organizations; donor agencies; development partners	2008–2015	(i) No. of pharmaceutical companies participating in existing network and partnership activities Baseline 2008: xx Target 2015: yy (ii) No. of novel leads for medicines, diagnostics and vaccines for neglected diseases to which developing countries have significantly contributed
	(b) Promote access to drug leads identified through the screening of compound libraries	Pharmaceutical industry; academia; international and national research institutions; **WHO**; development partners	2008–2015	(i) Required target profiles for new medicines, diagnostics and vaccines for Type II and Type III diseases defined and accessible (ii) Increased investment in the establishment of new drug-screening tools for Type II and Type III diseases Baseline 2008: xx Target 2015: yy (iii) No. of countries with drug screening fully integrated into the product innovation cycle

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(c) Promote basic and applied scientific research on Type II and Type III diseases	**Governments**; pharmaceutical industry; WHO; academia; research institutions; public–private partnerships	2008–2015	(i) No. of patents held by developing country research and academic institutions (ii) No. of operational collaborative North–South and South–South projects Baseline 2008: xx Target 2015: yy (iii) No. of applications of basic research translated into innovative practices (iv) No. of publications on Type II and Type III diseases with first authors from developing countries (v) No. of developing country researchers being trained in relevant fields
	(d) Promote early-stage drug research and development in developing countries	**Governments**; national research institutions; WHO; academia; pharmaceutical industry	2008–2015	(i) No. of significant research and development activities initiated in developing countries Baseline 2008: xx Target 2015: yy (ii) Increased clinical trial capacities with best practices and data management capabilities in developing countries (iii) No. of quality-assured systems and regulatory systems established in developing countries or regions

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(e) Developing countries to consider legislation that is compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights relating to research exemptions	**Governments**; WIPO; WTO; WHO	2008–2012	No. of countries with TRIPS-compliant legislation relating to research exemptions Baseline 2008: xx Target 2012: yy
	(f) Promote public funding for clinical trials and other mechanisms for stimulating local innovation	**Governments**; pharmaceutical industry; academia; United Nations organizations; development partners	2008–2015	(i) No. of countries supporting product development through funding or through legislative support (ii) No. of new clinical trial sites funded and implemented in developing countries Baseline 2008: xx Target 2015: yy
2.4 Improve global coordination and financing of medical research and development	*(a) Improve global coordination and financing, using systematic reviews and needs assessment*[1]	Governments; pharmaceutical industry; international and national research institutions; academia; public–private partnerships; nongovernmental organizations; **WHO**; other United Nations organizations; development partners; charitable foundations	2008–2015	(i) No. of partnered coordination instruments, such as databases for information exchange (ii) No. of public–private partnerships engaged in health research (iii) Qualitative assessments (opinions of stakeholders) made of increased coordination and harmonization of international efforts (iv) Quantitative assessments (listed activities and examples) made of increased

[1] Ensuring sustainable financing mechanisms is dealt with in element 7 below.

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
				coordination and harmonization of international efforts (v) Indicators (ii) and (iii) with focus on assessment of developing country opinion and quantitative examples (vi) Best practices in promoting research and development in resource poor settings documented
	(b) Set up a forum, or enhance existing ones, in order to improve the coordination of research and development activities and sharing of information	Governments; pharmaceutical industry; international and national research institutions; academia; public–private partnerships; nongovernmental organizations; **WHO**; other United Nations organizations; development partners; charitable foundations	2008–2015	(i) No. of regular stakeholder forums held (ii) Implementation and progress monitored, with production of biennial reports (iii) No. of mechanisms in place to facilitate interaction and coordination between public–private partnerships (iv) No. of qualitative assessments made of effectiveness of these forums in order to demonstrate better information sharing and coordination
	(c) Support further discussion of a medical research and development treaty	Governments; **WHO**; other United Nations organizations; academia; pharmaceutical industry; public–private partnerships; nongovernmental organizations	2008–2010	(i) Analysis and feasibility review of proposal undertaken (ii) Meeting of experts and other stakeholders convened to explore feasibility of research and

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
				development treaty with consensus conclusions
Element 3. Building and improving innovative capacity				
3.1 Build capacity of developing countries to meet research and development needs for new health products	*(a) Support investment by developing countries in human resources and knowledge bases, especially in tertiary education*	**Developing country governments**; development partners; pharmaceutical industry; United Nations organizations	2008–2015	(i) No. of health-related degree courses provided (ii) No. of higher degrees awarded by developing country institutions Baseline 2008: xx Target 2015: yy
	(b) Support existing and new research and development groups in developing countries	**Governments**; United Nations organizations; research and development groups; pharmaceutical industry; development partners	2008–2015	No. of existing and new product research and development-related activities in developing countries supported
3.2 Frame and support effective policies that promote the development of capacities for health innovation	*(a) Strengthen product regulatory capacity in developing countries*	**Governments**; WHO; national and regional regulatory agencies	2008–2015	(i) No. of developing countries able to undertake quality assurance and product regulation to international standards Baseline 2008: xx Target 2015: yy (ii) No. of collaborative projects between developed- and developing-country regulatory agencies Baseline 2008: xx Target 2015: yy

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(b) Strengthen human resources in research and development in developing countries through a long-term plan for human resources	**Governments**; United Nations organizations; development partners; international and national research institutions	2008–2015	(i) No. of developing countries with a long-term human resources plan to promote innovation for health Baseline 2008: xx Target 2015: yy (ii) Increased rate of trained researchers employed and working in their fields (national-level data) Baseline 2008: xx Target 2015: yy
	(c) Address appropriate training and retention of researchers and health professionals, including issues relating to migration	**Governments**; development partners; academia; WHO; other United Nations organizations	2008–2015	(i) No. of countries with appropriate training policies and capacity Baseline 2008: xx Target 2015: yy (ii) No. of researchers and health professionals trained and active in developing countries Target 2010: xx Target 2015: yy (iii) No. of countries with appropriate retention policies and incentives Baseline 2008: xx Target 2015: yy (iv) No. of countries with measurable reduction in loss of researchers and health professionals, for all reasons and due to migration Baseline 2008: xx Target 2015: yy

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
3.3 Provide support for innovation capacity building in developing countries, including in areas such as science and technology, regulation, clinical trials, the transfer of technology, traditional medicine and intellectual property	*(a) Document and disseminate best practices in innovation*	**WHO in collaboration with WIPO**; other United Nations organizations; international and national research institutions; academia; nongovernmental organizations	2008–2015	Publication(s) produced and disseminated
	(b) Promote successful models in developing innovative capacity	**WHO in collaboration with WIPO**; other United Nations organizations; academia; research institutions; pharmaceutical industry	2008–2015	(i) Models disseminated through various channels, including open-access databases, scientific literature, media (ii) Evidence on use of models to alter national policy produced
	(c) Intensify North–South and South–South partnerships and networks to support capacity building	Governments; academia; research institutions; **WHO**; other United Nations organizations; pharmaceutical industry	2008–2015	No. of North–South and South–South collaborative networks established or strengthened Baseline 2008: xx Target 2015: yy
3.4 Develop and implement policies that will promote innovation based on traditional medicine	*(a) Develop and promote traditional medicine within an evidence-based framework*	Governments; **WHO**; other United Nations organizations; pharmaceutical industry; academia; research institutions	2008–2015	(i) Appropriate framework agreed for assessing traditional medicines (ii) Examples of innovation derived from indigenous knowledge
	(b) Promote documentation of traditional knowledge and natural genetics resources	Governments; **WHO**; WIPO; pharmaceutical industry; academia	2008–2015	(i) Database in place to document available and new information (ii) Information on traditional knowledge and natural genetics resources widely disseminated

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(c) Encourage developing countries to ensure high standards of safety and efficacy for traditional medicines	**Governments**; WHO; other United Nations organizations; regulatory agencies; pharmaceutical industry	2008–2015	(i) Regulatory guidelines for monitoring safety and efficacy developed (ii) No. of countries in which regulatory guidelines implemented Baseline 2008: xx Target 2015: yy (iii) No. of countries in which local biodiversity regulations for natural products implemented Baseline 2008: xx Target 2015: yy
	(d) Encourage research on mechanisms for action and pharmacokinetics of traditional medicines	Governments; WHO; other United Nations organizations; national research institutions; academia; pharmaceutical industry	2008–2015	(i) No. of entities in developing countries evaluating mechanisms of action of traditional remedies Baseline 2008: xx Target 2015: yy (ii) No. of publications on such research for which first author is from a developing country institution

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
Element 4. Transfer of technology				
4.1 Promote transfer of technology and production of health products in developing countries	*(a) Devise a mechanism, or make better use of existing ones, to facilitate transfer of technology and technical support*	Governments; international and national research institutions; academia; pharmaceutical industry; WHO; UNCTAD; public–private partnerships	2008–2015	(i) Review of needs and options completed; best practices identified and disseminated (ii) Implementation of best practices monitored
	(b) Promote transfer of technology and production of health products in developing countries through investment and capacity building	Governments; academia; UNCTAD; other United Nations organizations; nongovernmental organizations; development partners; charitable foundations; pharmaceutical industry	2008–2015	(i) Percentage increase in investment in technology transfer (a) by developed countries and (b) by developing countries Baseline 2008: xx Target 2015: y% increase (ii) Increase in capacity building for technology transfer
4.2 Support improved collaboration and coordination of technology transfer	*(a) Encourage North–South and South–South collaboration, and collaboration between institutions in developing countries and the pharmaceutical industry*	Governments; pharmaceutical industry; international and national research institutions; academia; **WHO**; other United Nations organizations; nongovernmental organizations; development partners	2008–2015	(i) No. of products transferred/licensed through North–South, South–South and South–North collaborative projects Baseline 2008: xx Target 2015: yy (ii) No. of products transferred from pharmaceutical industry to academia and vice versa Baseline 2008: xx Target 2015: yy (iii) No. of effective local public–private partnerships established in developing countries Baseline 2008: xx Target 2015: yy

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(b) Support technology transfer related to research and development on natural products	Governments; pharmaceutical industry; academia; research institutions; United Nations organizations; nongovernmental organizations	2008–2015	(i) No. of countries and institutions supported to implement technology transfer/licensing for natural products Baseline 2008: xx Target 2015: yy
	(c) Facilitate local and regional networks for collaboration on research and development	**Governments**; pharmaceutical industry; national research institutions; academia; **WHO**; other United Nations organizations; nongovernmental organizations	2008–2015	(i) No. of local and regional networks established (ii) No. of product research and development projects implemented through these networks
	(d) Promote compliance with obligations under Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights	**Governments**; WTO; WIPO; WHO; academia; research institutions; pharmaceutical industry	2008–2015	(i) Gaps in local research and development and manufacturing capacity in least-developed countries identified (ii) North–South collaborative projects in place to close identified gaps
4.3 Develop mechanisms to manage intellectual property in order to promote transfer of and access to key technologies	*(a) Promote patent pools of upstream and downstream technologies*	Governments; pharmaceutical industry; academia; research institutions; WIPO; WHO; other United Nations organizations; nongovernmental organizations	2008–2015	(i) Meeting convened to review and discuss patent pool models with consensus conclusions (ii) Evaluations made of new patent pools and their effectiveness
	(b) Develop other effective and sustainable mechanisms to promote innovation of products for priority diseases in developing countries	**Governments**; pharmaceutical industry; academia; research institutions; public–private partnerships;	2008–2015	New mechanisms to promote innovation of products and management of intellectual property in developing

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
		United Nations organizations		countries documented and disseminated
	(c) Examine best practices in areas such as competition, transparency and proper remuneration for patent holders	Governments; pharmaceutical industry; academia; research institutions; **WHO**; other United Nations organizations; nongovernmental organizations	2008–2010	Best practices documented and disseminated
Element 5. Management of intellectual property				
5.1 Support information sharing and capacity building in the management of intellectual property	*(a) Promote national and/or regional institutional frameworks in order to build capacity and manage intellectual property*	**Governments**; pharmaceutical industry; academia; research institutions; United Nations organizations; nongovernmental organizations; WIPO; WHO; WTO	2008–2012	No. of national and/or regional institutional frameworks established for capacity building and management of intellectual property
	(b) Compile and maintain national databases on patent status of relevant health-related products and promote exchange of information between relevant government departments	**Governments**; national patent offices, technology transfer offices and national regulatory authorities; pharmaceutical industry; academia; nongovernmental organizations; WIPO; WHO; other United Nations organizations	2008–2012	(i) No. of national databases on patent status established and used Baseline 2008: xx Target 2012: yy (ii) Mechanisms for exchange of information between national regulatory agencies and patent offices in developing countries established and/or strengthened
	(c) WHO and WIPO to improve dissemination of relevant information and existing databases at international level	Governments; **WIPO**; **WHO**; national patent offices, technology transfer offices and national regulatory	2008–2012	(i) No. of new open-access databases established Baseline 2008: xx Target 2012: yy

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
		authorities; pharmaceutical industry; academia; research institutions; nongovernmental organizations; other United Nations organizations		(ii) No. of existing databases made accessible globally Baseline 2008: xx Target 2012: yy
	(d) WHO, in collaboration with WIPO and WTO, to strengthen education and training in the management of intellectual property	Governments; **WHO**; **WIPO**; **WTO**; national patent and technology transfer offices; pharmaceutical industry; academia; research institutions; nongovernmental organizations; other United Nations organizations; development partners	2008–2012	No. of training sessions held in the area of management of intellectual property
5.2 Upon request, provide support for application of the flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights	*(a) Promote legislation to apply flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements, by means including the dissemination of best practices*	**Governments**; WTO; WIPO; WHO; development partners; nongovernmental organizations	2008–2015	(i) Documentation and dissemination of best practices and practical guidelines for national legislation relating to the Agreement on Trade-Related Aspects of Intellectual Property Rights (ii) No. of national governments that have introduced or enacted legislation that includes the flexibilities contained in, and consistent with, the Agreement on Trade-Related Aspects of Intellectual Property Rights

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
				(iii) No. of countries reviewing national policy/legislation against set criteria and internationally agreed standards to highlight gaps
	(b) Promote bilateral trade agreements that do not incorporate "TRIPS-plus" protection in ways that might reduce access to medicines in developing countries	**Governments**	2008–2015	No. of developed countries not incorporating TRIPS-plus protection in bilateral trade agreements with developing countries Baseline 2008: xx Target 2015: yy
	(c) Encourage trade agreements that take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (as recognized by the Doha Declaration on the TRIPS Agreement and Public Health)	**Governments**; WTO; WIPO; WHO; development partners; nongovernmental organizations	2008–2015	No. of trade agreements that contain flexibilities provided for in the TRIPS agreement Baseline 2008: xx Target 2015: yy
5.3 Explore and promote complementary incentive schemes for research and development	*(a) Explore and implement complementary incentive schemes for research and development that separate the incentives for innovation from the prices of health-care products (for example, the prize fund model)*	**Governments**; WHO; other United Nations organizations; nongovernmental organizations; charitable foundations	2008–2015	(i) Meeting convened to review and discuss complementary incentive models with consensus conclusions (ii) No. of pilot models implemented
	(b) Expand the advance-market commitment approach	**Governments**; WHO; other United Nations organizations; nongovernmental organizations	2008–2010	(i) Review documentation of existing advance-market commitment model, including proposals for scaling up

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
				(ii) Number, capitalization, and evidence of use of advance-market commitments
	(c) Assess the impact of data-exclusivity regulations	Governments; WHO; other United Nations organizations; nongovernmental organizations; pharmaceutical industry	2008–2015	Comparative studies undertaken on data-exclusivity arrangements, market entry of generics, and newly marketed products
	(d) Examine measures to comply with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights for the protection of undisclosed test data against unfair commercial use	Governments; WHO; WTO; other United Nations organizations; nongovernmental organizations; academia; research institutions; pharmaceutical industry	2008–2010	Study undertaken, and results published and disseminated
Element 6. Improving delivery and access				
6.1 Encourage governments to invest in the health-delivery infrastructure	*(a) Invest in developing health-delivery infrastructure and ensure financing of health products*	**Governments**; development partners; United Nations organizations; nongovernmental organizations; charitable foundations	2008–2015	(i) No. of developing countries that have increased (as a share of national health budgets) investment in health delivery infrastructure countries Baseline 2008: xx Target 2015: yy (ii) No. of developing countries that have increased investment in financing health products Baseline 2008: xx Target 2015: yy

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(b) Develop effective and sustainable mechanisms in least-developed countries in order to increase access to existing medicines, making full use of the transitional period until 2016[1]	**Governments**; development partners; other United Nations organizations; nongovernmental organizations	2008–2015	No. of least-developed countries that have adopted a national policy with clear objectives and strategies on access to medicines Baseline 2008: xx Target 2015: yy
	(c) Prioritize health care in national agendas	**Governments**; WHO; other United Nations organizations	2008–2015	(i) No. of countries with increased percentage of national budget allocated to health care Baseline 2008: xx Target 2015: yy (ii) No. of developing countries that have developed national strategic plans to counter major public health problems Baseline 2008: xx Target 2015: yy (iii) Percentage of country poverty reduction strategy papers that contain health objectives, and nature of these
6.2 Institute mechanisms to regulate the quality, safety and efficacy of medicines and other health products	*(a) Strengthen capacity to monitor the quality, safety and efficacy of health products, and accelerate the regulatory approval of products with potential utility*	**Governments**; WHO; other United Nations organizations; national regulatory bodies; pharmaceutical industry; nongovernmental organizations	2008–2015	No. of developing countries with strengthened medicines regulatory capacity, including that required to assess new products and monitor product safety Baseline 2008: xx Target 2015: yy

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

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(b) Conduct operational studies to maximize the value and use of new products in high disease-burden settings with inadequate health services	Governments; international and national research institutions; academia; **WHO**; other United Nations organizations; pharmaceutical industry; charitable foundations	2008–2015	(i) No. of operational studies on new products initiated (ii) No. of new products assessed in high disease-burden settings
	(c) Implement national and international disease-control policies that are based on evidence that use of new and existing products has an impact	**Governments**; WHO; other United Nations organizations; international and national research institutions	2008–2015	No. of national, regional and international disease prevention and control policies implemented, based on operational studies
	(d) Encourage compliance with good manufacturing practices in developing countries	**Governments**; national regulatory bodies; pharmaceutical industry; **WHO**; development partners	2008–2015	(i) No. of countries supported for national reviews of technical capacities for good manufacturing practices (ii) No. of WHO prequalified manufacturers in each developing country Baseline 2008: xx Target 2015: yy
	(e) Minimize the public health consequences of counterfeit and substandard products	**Governments**; WTO; WHO; WIPO; other United Nations organizations; nongovernmental organizations; pharmaceutical industry	2008–2015	No. of countries with appropriate legislation against counterfeiting and with effective enforcement strategies Baseline 2008: xx Target 2015: yy

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
6.3 Promote competition and ensure that pricing of medicines is consistent with public health policies	*(a) Support the production and introduction of generic versions of essential medicines in developing countries, including national legislation to encourage generic entry on patent expiry*	**Governments**; regulatory bodies; pharmaceutical industry; WHO; other United Nations organizations	2008–2015	No. of new generics produced and introduced in developing countries Baseline 2008: xx Target 2015: yy
	(b) Frame policies emphasizing essential medicines at affordable prices	**Governments**; WHO; development partners	2008–2015	No. of developing countries that have a medicines policy based on the essential medicines concept
	(c) Remove tariffs and taxes on health-care products and monitor their supply and distribution chain	**Governments**; WHO; WTO	2008–2015	(i) No. of countries removing tariffs and taxes on health-care products (ii) No. of countries with district health centres experiencing stock-outs with a frequency greater than xx days per month
	(d) Take necessary legislative steps in countries with manufacturing and export capacity to allow compulsory licensing for export consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health	**Governments**; WHO; WTO; development partners	2008–2015	No. of developing countries with manufacturing capacity that have enacted legislation that allows for compulsory licensing of medicines for export to developing countries declaring a public health emergency Baseline 2008: xx Target 2015: yy

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(e) Encourage pharmaceutical companies to adopt transparent and consistent pricing policies, aiming to reduce prices for developing countries	**Governments**; pharmaceutical industry; WHO; other United Nations organizations; nongovernmental organizations	2008–2015	No. of companies that have adopted transparent and consistent pricing policies Baseline 2008: xx Target 2015: yy
	(f) Monitor pricing policies and strengthen WHO's work on pharmaceutical pricing	**Governments**; **WHO**; pharmaceutical industry	2008–2015	(i) No. of countries undertaking regular medicine price surveys Baseline 2008: xx Target 2015: yy (ii) No. of countries regularly monitoring availability and affordability of medicines Baseline 2008: xx Target 2015: yy
Element 7. Ensuring sustainable financing mechanisms				
7.1 Secure additional and sustainable financing for research and development in order to address the health needs of developing countries	*(a) Develop and implement a resource mobilization plan*	Governments; **WHO**; other United Nations organizations; development partners; charitable foundations	2008–2015	(i) Budget targets established with broad consensus from resource contributors, national governments and variety of sectors (ii) Global resource mobilization plan implemented and monitored

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
	(b) Assess the utility of existing funding mechanisms, or a new global funding mechanism, in order to increase global coordination and sustainable funding of medical research and development	Governments; **WHO**; other United Nations organizations; nongovernmental organizations; development partners	2008–2015	(i) Needs and options reviewed (ii) Funding mechanism(s) agreed and implemented (iii) Implementation monitored
	(c) Use current and new financing initiatives, (such as advance-market commitment schemes) to accelerate the progress of health-care products from development to delivery	**Governments**; WHO; other United Nations organizations; pharmaceutical industry; public–private partnerships; development partners; charitable foundations	2008–2015	No. of new health-care products accelerated through development to delivery by new financing initiatives
7.2 Facilitate the expansion of activities to develop and deliver affordable products	*(a) Document and disseminate best practices in expanding public–private partnerships*	Governments; **WHO**; public–private partnerships; nongovernmental organizations; charitable foundations	2008–2009	Documentation of experiences and best practices widely disseminated
	(b) Develop tools to assess performance of public–private partnerships	Governments; **WHO**; other United Nations organizations; public–private partnerships; development partners; academia; research institutions; pharmaceutical industry; charitable foundations; nongovernmental organizations	2008–2009	Indicators to assess performance developed, tested and used
	(c) Support public–private partnerships and other research and development initiatives in developing countries in expanding their activities	Governments; WHO; other United Nations organizations; pharmaceutical industry; charitable foundations;	2008–2015	(i) Increased funding of existing public–private partnerships Baseline 2008: xx Target 2010: yy Target 2015: zz

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
		development partners; nongovernmental organizations; academia; research institutions		(ii) No. of new public–private partnerships established Baseline 2008: xx Target 2015: zz
7.3 Increase resources for research organizations in developing countries	*(a) Channel additional funds to research organizations in both the private and public sector of developing countries*	Governments; development partners; other United Nations organizations; charitable foundations; academia; research institutions	2008–2015	Increased funding to research organizations in developing countries Baseline 2008: xx Target 2010: yy Target 2015: zz
Element 8. Establishing monitoring and reporting systems				
8.1 Measure performance and progress towards objectives contained in the plan of action	*(a) Establish systems to monitor performance and report to WHO's governing bodies on progress every two years, with effect from end-2009*	**WHO**	2008–2015	(i) Monitoring and reporting system established (ii) Progress reports every two years
8.2 Monitor the impact of intellectual property rights and other factors on innovation and access to medicines and other health-care products	*(a) Monitor and report periodically to WHO's governing bodies on the gaps and needs related to health-care products in developing countries*	Governments; **WHO**; national research institutions; academia; pharmaceutical industry; public–private partnerships; charitable foundations; development partners	From 2009	(i) Initial gap analysis to be completed by 2009 (see sub-element 1.1) (ii) Updated monitoring reports to be published in 2012 and 2018 to have an impact on subsequent WHO medium-term strategic plans
	(b) Monitor the impact of intellectual property rights and other factors on innovation and access to health-care products	Governments; **WHO**; WIPO; WTO; academia; research institutions; pharmaceutical industry; development partners; nongovernmental organizations	2008–2015	(i) Patent status of essential medicines determined (ii) A public-health perspective for examination of pharmaceutical patents determined

Elements and sub-elements	Specific actions	Stakeholders*	Time frame	Progress indicators
				(iii) Methodology developed, then impact of trade agreements assessed on regular basis
	(c) Monitor investment in research and development to address the health needs of developing countries	Governments; pharmaceutical industry; **WHO**; public–private partnerships; nongovernmental organizations; development partners; charitable foundations; academia; research institutions	2008–2015	Increased overall investment in research and development to address the health needs of developing countries Baseline 2008: xx Target 2015: yy

***** Entries in this column provide non-exclusive lists of potential stakeholders who implement and/or provide technical assistance, or offer policy guidance. Where appropriate, **bold** type face is used to indicate possible lead stakeholders for a specific action.

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