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

Report by the Secretariat

This document adds a column to the matrix in the annex contained in document A/PHI/IGWG/2/2. It provides details of ongoing activities in relation to the eight elements of the draft strategy and plan of action on public health, innovation and intellectual property, as requested by resolution WHA60.30.

Elements and sub-elements	Specific actions	Ongoing activities
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*	Work has already been done in the context of: • the Global Forum for Health Research's work on mapping global health research and the financing of health research; • consultations between the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases and disease control programmes, national health organizations and research centres/experts to identify needs in relation to diseases, establish research priorities and obtain feedback on product target profiles; and • the methodology for prioritizing medicine needs for Europe and the world that was described in a WHO report issued in 2004[1] Although its main focus is not the current state of research and development, the study on priorities for global disease control does also deal with this issue.[2] In addition, the Bill & Melinda Gates Foundation has addressed selected priorities in its Grand Challenges in Global Health initiative. In addition to neglected diseases, there are also assessments related to other disease areas. In particular these have focused on the lack of commercial research and development on subjects arousing major health concerns, such as antibiotics and infectious diseases, due to insufficient profit margins.
	(b) Provide an assessment of identified gaps	Several agencies including WHO, and various public–private partnerships, have identified gaps in translational research for Type II and Type III diseases as well as the need to establish a publicly accessible compound library for these diseases. WHO, through the Special Programme, is analysing the feasibility of a public chemical library for Type III diseases. WHO's project on priority medicines for Europe and the world has identified therapeutic gaps that require concerted research and development.

[1] Accessible online at http://mednet3.who.int/prioritymeds/report/index.htm

[2] Jamison DT et al., eds. *Disease control priorities in developing countries*, 2nd ed. New York, Oxford University Press, World Bank, 2006.

Elements and sub-elements	Specific actions	Ongoing activities
		The Global Forum for Health Research, the Ministerial Summit on Health Research (Mexico City, 16–20 November 2004) and other related work have highlighted the need to respond to the relative lack of research on health services and systems.
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*	The screening of compound libraries for use in research and development on tropical and/or neglected diseases has gained momentum recently, based on voluntary arrangements with the corporate sector. Several current activities are described below. • In the context of the United States' National Institutes of Health Roadmap for medical research, an initiative has been created to develop molecular libraries in order to facilitate the identification of drug targets and screening of compounds, to focus on structural biology, and to promote the development of bioinformatics, computational biology and nanomedicine. • Screening activities of the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases are being supported by compound libraries from industry, Special Programme's Medicinal Chemistry Network, and the National Institutes of Health Roadmap initiative. WHO collaborates with industry to ensure that compound libraries are available for screening for activity against parasitic diseases, particularly in countries where such diseases are endemic. A network of compound screening centres is being expanded to include more developing countries, and a drug-target portfolio network is creating a database of prioritized drug targets across a range of parasites, capitalizing on research on their genomes; this latter network is being extended to diagnostics and vaccines. A global screening platform for parasitic diseases using free computer power is under way. WHO continues to complement public-private collaboration in this domain, and provides support for open source research through academic networks.

Elements and sub-elements	Specific actions	Ongoing activities
		• There is a large amount of private sector activity concerning compound libraries. A review of efforts in facilitating upstream research and development and discovery has been provided online by the Special Programme.[1] Individual companies engage with international organizations and/or nongovernmental organizations in various ways through initiatives involving public–private partnerships. Access to compound libraries is likely to require specific negotiation and is thus found more often in specific public–private partnerships and product development partnerships. • WIPO has been active in the area of chemical libraries and traditional knowledge. It maintains the "Health Heritage" traditional knowledge database, which is a digital library originally compiled by the Council of Scientific and Industrial Research of India.
	(b) Provide technical support to developing countries in order to create libraries of new compounds at both national and regional levels	Capacity-building activities in this area are limited and fragmented. Some public–private partnerships are involved (e.g. the Drugs for Neglected Diseases initiative).
1.3 Coordinate research activities between developed and developing countries	*(a) Coordinate international efforts in research and development in order to optimize resources*	There are currently no global institutionalized efforts consistently directed at coordination of health research and development, other than those undertaken by the Global Forum for Health Research, and work done in the context of global joint United Nations research programmes and activities. Some coordination is in practice exercised through discovery and development networks but these do not necessarily span initiatives. The Global HIV Vaccine Enterprise is an example of an alliance of independent organizations around the world dedicated to accelerating the development of a preventive HIV vaccine.
	(b) Support developing countries in building technological capacity[2]	The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical diseases provides support for exploitation of biodiversity and for screening facilities for neglected tropical diseases. The private sector has established some research and development institutions in developing countries.

[1] Accessible at http://www.who.int/tdr/cd_publications/pdf/discovery_strat.pdf.

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

Elements and sub-elements	Specific actions	Ongoing activities
	(c) Promote the active participation of developing countries in the innovation process	Particular efforts focus on publicly-funded international research cooperation programmes (e.g. the European Union's INCO-DC programme) and on the role of private foundations and their support for cooperation with developing countries and for scholars in such countries. Through the Special Programme, WHO has been active in implementing "North" and "South" innovation of products.
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*	It is unclear how many developing countries have explicit, prioritized strategies for health research and development at country level, although specific programmes for particular diseases and groups of diseases, do exist (e.g. HIV/AIDS, malaria, tuberculosis and neglected diseases). The Special Programme has sponsored disease-specific working groups with input from developing countries to define needs and opportunities.
	(b) Conduct research appropriate for resource-poor settings and research on technologically appropriate products to combat diseases in developing countries (including Type I diseases)	Public–private partnerships are active in this area.[1] The Special Programme provides ongoing consultation and support for the development of natural product initiatives; it also sponsors clinical research development activities, assuring good clinical practice and high ethical standards within resource-poor settings.
	(c) Include research and development needs for traditional medicines in a prioritized strategy[2]	The WHO traditional medicine strategy 2002–2005 included a focus on strengthening research methodologies, and on increasing the quality, quantity and accessibility of clinical evidence to support claims for the effectiveness of traditional medicine and complementary/alternative medicine.[3]

[1] Such partnerships and partnership activities include the Medicine for Malaria Venture, the Drugs for Neglected Diseases initiative, the Global Alliance for TB Drug Development, the Foundation for Innovative New Diagnostics and the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases.

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

[3] Accessible online at http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf.

Elements and sub-elements	Specific actions	Ongoing activities
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*	
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*	Public–private partnerships, the Special Programme and individual institutions are active in promoting cooperation. New networks and partnerships with industry and public institutions in the "North" and the "South" are showing promise.
	(b) Provide support for national health research programmes in developing countries through political action and long-term funding	Current funding for health research and development is mostly based on northern institutional or individual funders with relatively few southern governments investing substantially. Through ministerial forums, such as the High-Level Ministerial Meeting on Health Research for Disease Control and Development (Accra, 15–17 June 2006), WHO is encouraging governments, particularly in developing countries, to dedicate a percentage of their budget to health research. For example, the High-Level Ministerial Meeting on Health Research in Africa (Abuja, 8–10 March 2006) committed governments to striving to allocate for health research at least 2% of their national health budget and to mobilize further resources in support of such research from national and international sources. Promoting the empowerment of developing countries, enabling them to take a broader role in research and development in the area of tropical diseases, is a core element of the Special Programme's new strategy. The Global Forum for Health Research has also been active in promoting further investment in health research.
	(c) Develop and implement systems for supporting health-related innovation in developing countries (including intellectual property management)	There are South-South and North-South research and development activities in developing countries, for example through bodies such as the Universities Allied for Essential Medicines, and the Technology Managers for Global Health.

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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*	Current activities in promoting upstream research and development have been discussed in the context of OECD's work and have also been on the agendas of nongovernmental organizations and initiatives. In the field of global health, the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases has been active in innovative drug discovery activities, involving networks and partnerships with academia and industry in the developed and developing countries; the Special Programme has also been involved in multisectoral integration, involving the health, education and industrial sectors.
	(b) Promote access to drug leads identified through the screening of compound libraries	The Special Programme's innovative drug discovery activities involve networks and partnerships with academia and industry in developed and developing countries.
	(c) Promote basic and applied scientific research on Type II and Type III diseases	WHO collaborates with academia and industry in developing and developed countries in order to create career development programmes in pharmaceutical research and development. The Special Programme supports capacity-building efforts, through its "North" and "South" networks and partnerships for drug discovery. There are South-South and North-South networks in genomics, bioinformatics, and elaboration of portfolios of drug and diagnostic targets.
	(d) Promote early-stage drug research and development in developing countries	Policies governing health and development aid have not focused sharply on promoting early-stage drug research in developing countries. In some developing countries a lack of regulatory and institutional capacity has also hindered further cooperation in this field. The Special Programme supports capacity-building efforts, through its "North" and "South" networks and partnerships in drug discovery. There are South-South and North-South networks in genomics, bioinformatics, and elaboration of portfolios of drug and diagnostic targets.

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	(e) Developing countries to consider legislation that is compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights relating to research exemptions	WHO provides technical support in response to requests from Member States; nongovernmental organizations also provide support. An UNCTAD project has provided information on the use of exceptions to patent rights in developing countries.[1] In practice, many developing countries already have research exemption as part of their legislation; however, it is not certain that the full scope of legislation is being utilized in either developing or developed countries. A dispute settlement case ("Bolar exception") has clarified interpretation on the issue and WTO provides information on exceptions in its web pages.[2]
	(f) Promote public funding for clinical trials and other mechanisms for stimulating local innovation	Some funding is provided through the European and Developing Countries Clinical Trials Partnership Programme, the United States' National Institutes of Health and other institutes of health, public–private partnerships and the Special Programme. Generally, there has been no major promotion of public funding for clinical trials.
2.4 Improve global coordination and financing of medical research and development	*(a) Improve global coordination and financing, using systematic reviews and needs assessment*[3]	The main forum for global health research is the Global Forum for Health Research. WHO's activities and those of the Global Forum have been closely linked and joint ministerial summits have been organized. OECD has a role in promoting science and technology and its "Noordwijk Medicines Agenda" is supportive of the Intergovernmental Working Group process and medium-term plan of action. The principal global forum for science and technology continues to be provided by UNESCO, but other agencies, such as OECD, have also been active in the field. The main actors in the area of development policies are aid agencies and international financial institutions such as the World Bank and IMF.

[1] Accessible online at http://www.unctad.org/en/docs/iteipc200612_en.pdf

[2] Accessible at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

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

Elements and sub-elements	Specific actions	Ongoing activities
	(b) Set up a forum, or enhance existing ones, in order to improve the coordination of research and development activities and sharing of information	A wide range of WHO programmes are involved. The Special Programme has a new stewardship and empowerment role. By convening high-level meetings, such as the series of conferences on health research development, WHO is promoting twin objectives: the use of health-research findings in policy-making; and policy implementation as a partnership between policy-makers, civil society and researchers. It also promotes the Evidence-Informed Policy Network initiative. WHO has developed a drug discovery platform based on networks and partnerships between academia, industry and developing-country institutions in order to mobilize efforts and funding in this area. WHO is also promoting interaction between organizations and companies in order to bring about, or enhance, synergies in the development of innovative vaccines. WHO also supports open access to scientific literature in developing countries and further development of a knowledge platform for neglected infectious diseases, to be initiated in 2007. The Organization provides financial and technical support to the Global Forum for Health Research, whose work aims to reduce inequalities in health research and health research funding. The Drugs for Neglected Diseases initiative, in collaboration with WHO is developing active regional networks of scientists involved in research on new drugs for neglected diseases. The initiative has recently launched its first medicine, which is going to be made available patent-free in developing countries. WHO is also collaborating with the Global Alliance for TB Drug Development, a public–private partnership for improved, affordable anti-tuberculosis drugs. WHO continues to collaborate with the European Union Research Directorate on research and development initiatives in following up the Priority Medicines for Europe and the World Project; the Organization is in the process of establishing a WHO collaborating centre in the Netherlands that will also work on pharmaceutical innovation policies.
	(c) Support further discussion of a medical research and development treaty	Existing work on a global research and development treaty is mostly based on contributions from nongovernmental organizations, think tanks and academia. A draft treaty has been prepared by the Consumer Project on Technology.[1] The possibility of negotiations being initiated that might

[1] Accessible online at http://www.cptech.org/workingdrafts/rndtreaty4.pdf.

Elements and sub-elements	Specific actions	Ongoing activities
		ultimately produce a multilateral treaty has been examined in the online journal, *Globalization and Health* with respect to safety and cost-effectiveness of pharmaceuticals and medical devices.[1]
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*	Capacity-building activities are being undertaken by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, the European and Developing Countries Clinical Trials Partnership Programme and the United States' National Institutes of Health. The Special Programme provides support for master's degree and PhD programmes in research training in pharmaceutical sciences. OECD countries offer bilateral aid agreements. Activities also take place in the context of capacity building for science and technology. International agencies involved include UNESCO, UNCTAD, UNIDO, the United Nations University and OECD.
	(b) Support existing and new research and development groups in developing countries	The Special Programme provides support through specific product development activities that engage local regulatory organizations in guiding the research and development process. It facilitates the active participation of developing countries in discussions with regulatory authorities in the "North". WHO provides country support for good manufacturing practice. Generally, support to research institutions and groups in developing countries has been part of development cooperation efforts. UNCTAD is also involved with cooperation issues concerning science and technology.

[1] Accessible online at http://www.globalizationandhealth.com/content/2/1/5.

Elements and sub-elements	Specific actions	Ongoing activities
3.2 Frame and support effective policies that promote the development of capacities for health innovation	*(a) Strengthen product regulatory capacity in developing countries*	Working in coordination with WHO, the European Medicines Agency and individual regulatory authorities in the European Union have set up a mechanism to provide a scientific assessment of products destined for a third country. They have also been asked to contribute – in coordination with WHO – to capacity-building activities for national regulatory authorities in developing countries through partnerships, scientific or technical support, or financing. WHO has played a long-term part in bringing together regulators through the annual International Conference of Drug Regulatory Authorities. Aiming to ensure that good-quality pharmaceuticals are available, WHO sets norms and standards, develops guidelines and advises Member States on issues related to quality assurance of medicines in national and international markets. WHO helps countries to build national regulatory capacity through networking, training and information sharing, and provides technical assistance to drug regulatory agencies in developing countries, often with the support of the World Bank, and bilateral donors. The WHO Regional Office for Europe provides technical support to the drug regulatory authorities of the United States' National Institutes of Health (and their network, DRUGNET), and to those of the south-eastern European countries. There are other WHO initiatives, such as the Developing Countries' Vaccine Regulators Network, which involves nine national regulatory authorities across five continents. In some cases, cooperation at a regional level has proved more effective than international efforts in strengthening regulatory capacity at the national level. Regional associations of regulators include ASEAN, the Andean Community, the Gulf Cooperation Council, MERCOSUR and the Southern African Development Community.
	(b) Strengthen human resources in research and development in developing countries through a long-term plan for human resources	Human resources and health, and migration, are at the core of various global initiatives and activities (e.g. the Global Health Workforce Alliance, hosted in WHO). *The world health report 2006* focused on human resources.[1]

[1] *The world health report 2006: Working together for health.* Geneva, World Health Organization, 2006.

Elements and sub-elements	Specific actions	Ongoing activities
	(c) Address appropriate training and retention of researchers and health professionals, including issues relating to migration	
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*	The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases undertakes activities to document and disseminate good practices. OECD has been working on best practice guidelines with respect to biological centres and is also working more broadly on innovation and capacity building. The Commission on Intellectual Property Rights, Innovation and Public Health has commissioned background studies on developing country needs' in relation to regulation and clinical trials, including ethical issues. The general aim of sub-element 3.3. is also promoted by other organizations such as UNESCO, WIPO UNCTAD and the United Nations University.
	(b) Promote successful models in developing innovative capacity	Falling under the same sub-element as 3.3 (a) above, this specification is also promoted by other organizations such as UNESCO, WIPO, and UNCTAD. The European Union has a clinical trials partnerships initiative, the European and Developing Countries Clinical Trials Partnership Programme, which was recently evaluated.[1] The Special Programme and public–private partnerships play a role in this context,[2] (e.g. the Special Programme's work on ethical capacity building). A seven-country study has focused on the issue in relation to biotechnology.

[1] Report accessible online at http://ec.europa.eu/research/health/poverty-diseases/doc/final_ier_report_12july2007_en.pdf.

[2] Accessible online at http://www.utoronto.ca/jcb/home/documents/Conclusions.pdf.

Elements and sub-elements	Specific actions	Ongoing activities
	(c) Intensify North–South and South–South partnerships and networks to support capacity building	North–South partnerships include those promoted by medical research councils in the developed world (for example, the Swiss Tropical Institute and the Wellcome Trust promote several collaborative research networks in countries such as Gambia, Thailand, Uganda and United Republic of Tanzania). A number of WHO programmes are providing support for partnerships. In addition, the Special Programme supports North-South networks and partnerships in drug discovery and diagnostics development. WHO has set up the secretariat of the International Clinical Trials Registry Platform, which has started to identify and map clinical trials registers across the world. The platform has established a network of such registers and identified opportunities to develop new ones. WHO also contributes to the work of the European and Developing Countries Clinical Trials Partnership Programme, which provides guidance on prequalification of medicines for developing countries, and works with regional groups to strengthen capacity for conducting clinical trials. WHO is a member of a network funded by the European Commission, Networking for Ethics on Biomedical Research in Africa, whose strategy includes strengthening the capacity and harmonizing the regulation of health research involving human participants. WHO has also contributed to a number of training activities, regional consultations and conferences in order to strengthen ethical review of research. The Organization participates in the steering committee of the Global Forum on Bioethics in Research and serves as secretariat for the Global Summit of National Bioethics Commissions. South–South networks include the Technology Network for HIV/AIDS, whose purpose is to support research and South–South technology transfer in respect of antiretroviral drugs and drug formulations, and the development of an HIV vaccine; and the Developing Countries Vaccine Manufacturers Association, which aims to provide developing countries with a consistent and sustainable supply of high-quality vaccines at an affordable price.
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*	In South Africa, where a majority of the population consults traditional healers, the Government has adopted the Traditional Health Practitioners Bill, which recognizes and regulates the practice of the country's traditional healers. In India, a network of over 30 research laboratories, industries, universities and institutes of traditional medicine are working on 20 diseases.

Elements and sub-elements	Specific actions	Ongoing activities
		WHO has implemented a programme on traditional medicines, and the following agencies and bodies have been involved in international work for the protection of traditional knowledge and medicines: WIPO, WTO, UNCTAD, UNEP, the United Nations University and the Secretariat of the Convention on Biological Diversity. A paper on the issue was developed for WHO's Commission on Macroeconomics and Health, drawing attention to protection of indigenous traditional medicines. This issue had also been taken up earlier by the report of the Commission on Intellectual Property Rights, established by the Government of the United Kingdom of Great Britain and Northern Ireland. The South Centre, an intergovernmental organization of developing countries, has also worked on traditional medicines-related issues.
	(b) Promote documentation of traditional knowledge and natural genetics resources	WHO supports countries in establishing digital libraries of traditional medical knowledge in accordance with the WHO traditional medicine strategy. Activities are also continuing with respect to plant and animal genetic resources through the FAO-established Commission on Genetic Resources for Food and Agriculture. WIPO is involved with intellectual property rights, hosting the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The Convention on Biological Diversity also deals with natural genetic resources, and includes provisions on access and benefit sharing. OECD is working on intellectual property rights, technology transfer and genetic resources.
	(c) Encourage developing countries to ensure high standards of safety and efficacy for traditional medicines	See 3.2 (a) in relation to the strengthening of regulatory activities. WHO's traditional medicines programme also provides support in this area.
	(d) Encourage research on mechanisms for action and pharmacokinetics of traditional medicines	

Elements and sub-elements	Specific actions	Ongoing activities
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*	Current activities related to the Agreement on Trade-Related Aspects of Intellectual Property Rights' and commitments to international technology transfer activities are dealt with in the context of WTO's TRIPS Council. UNESCO is working on various aspects of technology transfer and exchange as part of its work on science, technology and higher education. UNIDO is active in the same area, having published a manual on technology transfer negotiations.[1] UNCTAD and OECD have both worked on technology transfer issues and UNCTAD has initiated the Transfer of Technology and Intellectual Property Rights initiative, which also deals with matters concerning pharmaceuticals. The World Bank, too, has conducted studies and analysis on technology transfer. In addition to its work on technology transfer, WTO provides training on the matter in collaboration with WIPO. The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases undertakes activities on capacity utilization for research and development in respect of specific products in the developing countries.
	(b) Promote transfer of technology and production of health products in developing countries through investment and capacity building	The Special Programme has provided a legal framework to regulate cooperation with companies in the "North" on product-related research and development, ensuring transfer of technology and rights (through non-exclusive licensing agreements). The Special Programme's screening facilities in the "North" have been transferred to the "South". Work has been carried out both nationally and internationally in the context of the Global Forum for Health Research. Analysis on encouraging technology transfer and on new trends in technology transfer has also been provided by the joint programme between UNCTAD and the International Centre for Trade and Sustainable Development.

[1] *Manual on technology transfer negotiations*. Vienna, United Nations Industrial Development Organization, 1996.

Elements and sub-elements	Specific actions	Ongoing activities
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*	See 2.3 (d) and 3.3 (c). The promotion of collaboration between the pharmaceutical industry and institutions in developing countries takes place mostly in the context of public–private partnerships and product development partnerships or of networks based on these. The Special Programme is encouraging product development with clinical activities by researchers in the "South", following technologies and processes established in the "North" (e.g. data collection, transmission). There are examples of industry-supported research and development centres.
	(b) Support technology transfer related to research and development on natural products	
	(c) Facilitate local and regional networks for collaboration on research and development	The Special Programme has networks for clinical research in Latin America for research and development for products against Chagas disease.
	(d) Promote compliance with obligations under Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights	WTO, in the context of the TRIPS Council, follows up implementation of Article 66.2.
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*	**Upstream technologies** WHO programmes providing support include those working on vaccine research and control of neglected tropical diseases. WHO encourages pooling of publicly funded research to promote innovation for developing countries. In addition, work under the aegis of the Medicines for Malaria Venture includes the synthetic peroxide project and the project on 8-aminoquinolines for malaria, in which information is shared for use in control of leishmaniasis. WHO has launched an initiative to facilitate discovery of new drugs and diagnostics for helminth infections and has provided support for exploration of the patent-pool model for a vaccine against severe acute respiratory syndrome. Patent pools have also been proposed for HIV/AIDS research.

Elements and sub-elements	Specific actions	Ongoing activities
		Downstream technologies The WHO medicines strategy guides the support provided to Member States with regard to intellectual property rights and trade agreements. The Organization has commissioned a study on patent claims for pharmaceutical products in order to assess the practices of patent offices and generate information for improving the work of patent offices.
	(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	Guidelines have been produced by the United States' National Institutes of Health in order to encourage good patenting and licensing practices. WHO has worked in these areas as part of its work on medicines, in relation to technical cooperation, health needs and access to pharmaceuticals. WHO has issued remuneration guidelines for the use of patents on medical technologies, as well as a guide on compulsory licensing.
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*	Technical assistance being provided – when requested by countries – by WHO, WIPO and WTO on safeguards available under the Agreement on Trade-Related Aspects of Intellectual Property Rights, and access to medicines. WHO provides direct support to countries to facilitate the review of national policy and legal frameworks. Such country support is focused on developing patent legislation that is sensitive to public health, and on incorporating the flexibilities contained in the Agreement into domestic legislation. In response to resolution WHA59.26, on international trade and health, WHO is scaling up its work in this area by developing a diagnostic tool and companion workbook in trade and health, which will guide national policy-makers in developing national policies and strategies related to trade and health; structuring their requests for capacity building in relation to activities concerning trade and health.

Elements and sub-elements	Specific actions	Ongoing activities
		The diagnostic tool and workbook project builds on work continuing within WHO and in selected countries aimed at improving understanding of, and action on, trade and health issues.
	(b) Compile and maintain national databases on patent status of relevant health-related products and promote exchange of information between relevant government departments	The United States Food and Drug Administration maintains a database on patent status, which is linked with regulatory approval. Many other countries, including European Union countries, do not have a system for linking patenting status and approval. Information on patent status is generally maintained by patent offices and it is unclear whether databases are to be maintained by patent offices or by the health administration. Consolidating the link between regulatory approval of pharmaceuticals and patent status is also part of the additional commitments in trade agreements, known as "TRIPS-plus".
	(c) WHO and WIPO to improve dissemination of relevant information and existing databases at international level	Joint work and information sharing on the part of WHO and WIPO with respect to databases on patent status is continuing.
	(d) WHO, in collaboration with WIPO and WTO, to strengthen education and training in the management of intellectual property	WHO, WIPO and WTO have all contributed to organizing education and training in the management of intellectual property. In 2005 and 2006, WHO organized and facilitated a series of regional and national training workshops for developing country policy-makers, with a focus on enhancing the capacity of trade negotiators, policy-makers and institutions to understand and monitor the impact of trade agreements, and to improve negotiating skills.
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*	Resolution WHA56.27 urged Member States to adapt "national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)". Resolution WHA57.14 urged Member States as a matter of priority "to 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" and "to take into account in bilateral trade agreements the flexibilities contained in the Agreement … and recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001)".

Elements and sub-elements	Specific actions	Ongoing activities
		Technical assistance is provided by WHO, when requested by countries, in line with Resolution WHA60.30, which requested the Director-General "to provide as appropriate, upon request, in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products, and to implement the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments". WHO continues to identify key issues related to implementation of the Agreement and the Doha Declaration; and to develop technical and policy guidance in the form of technical publications and briefing documents, in consultation with various experts and relevant international organizations. United States National Institute of Health have introduced draft "best practices" guidelines on the patenting and licensing of genetic inventions funded by National Institutes' grants. On licensing, they have provided a more extensive set of principles supporting non-exclusive licensing as a general rule. UNCTAD has a joint programme with the International Centre for Trade and Sustainable Development, with a focus on intellectual property-related matters. South Centre has provided several publications on applying flexibilities in developing countries.
	(b) Promote bilateral trade agreements that do not incorporate "TRIPS-plus" protection in ways that might reduce access to medicines in developing countries	Bilateral treaties have become more important in comparison with multilateral agreements; as part of these, governments have approved higher levels of protection of intellectual property rights than is required in the context of the Agreement on Trade-Related Aspects of Intellectual Property Rights. This has been the focus of debate and campaigning by nongovernmental organizations.[1] An UNCTAD/International Centre for Trade and Sustainable Development web site provides background information on issues involving intellectual property rights[2], including those raised in relation to various bilateral treaties. Background papers of the Commission of Intellectual Property Rights, Innovation and Public Health dealt with bilateral TRIPS-plus issues, and South Centre has focused on the area in relation to investment treaties.

[1] See, for example, the briefing paper accessible online at http://www.oxfam.org/en/files/bp102_jordan_us_fta.pdf/.

[2] See http://www.iprsonline.org/.

Elements and sub-elements	Specific actions	Ongoing activities
		The report submitted in 2005 to the United Nations Commission on Human Rights (now the Human Rights Council) by the Commission's Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health has also drawn attention to health aspects of bilateral treaties as part of country missions.[1]
	(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)	See 5.2(a). In 2005 and 2006, WHO organized and facilitated a series of regional and national training workshops for developing country policy-makers, with a focus on enhancing the capacity of trade negotiators, policy-makers and institutions to understand and monitor the impact of trade agreements, and to improve negotiating skills.
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)*	Mechanisms such as prize funds have been promoted in Member States' submissions as well as those of nongovernmental organizations and academia.[2] The OECD Noordwijk Medicines Agenda, supporting the Intergovernmental Working Group process, is likely to explore some complementary incentive schemes. The separation of incentives from prices of health-care products responds to resolution WHA60.30. Examples of schemes include, the Grand Challenges in Global Health initiative – involving the Bill & Melinda Gates Foundation, the Foundation for the National Institutes of Health, the Wellcome Trust and the Canadian Institutes of Health Research – which offers grants to attract investigators to tackle key health-related research questions. On InnoCentive's web site "seeker" companies and scientists interact in a marketplace. Companies post specific problems, and offer rewards for a solution. For example, in the summer of 2007 a 'seeker' was offering US$ 60 000 for a simple, rapid diagnostic test for tuberculosis.

[1] Document E/CN.4/2005/51/Add.3.

[2] See article at http://www.bmj.com/cgi/content/full/333/7582/1279.

Elements and sub-elements	Specific actions	Ongoing activities
	(b) Expand the advance-market commitment approach	The first pilot advance market commitment - for a vaccine to prevent pneumococcal disease – was launched in February 2007. The first payments are expected to begin in 2010, and last for nine or 10 years. The GAVI Alliance hosts the Secretariat of the initiative on advance market commitments for vaccine and provides programmatic functions; the World Bank provides the relevant administrative and financial functions. Advance market commitments have also been part of OECD's approach, and the Noordwijk Medicines Agenda calls for the model to be explored.
	(c) Assess the impact of data-exclusivity regulations	The WHO Regional Office for the Western Pacific has provided a briefing paper on data exclusivity.[1]
	(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	There are different interpretations of the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights concerning the protection of undisclosed test data against unfair commercial use, and whether countries may decide themselves what is the appropriate level of protection for this purpose (and, if so, on what basis). Nongovernmental organizations have been campaigning on the matter and have issued policy proposals.
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*	Technical and financial support are being provided by WHO and many international partners and institutions. A new International Health Partnership, launched in September 2007, aims to improve the way that international agencies, donors and poor countries develop and implement health plans together in order to create and improve health services for poor people. The Global Fund to Fight AIDS, Tuberculosis and Malaria provides finance to countries for prevention and treatment programmes so that country priorities are incorporated into health systems' strengthening. The GAVI Alliance makes funding for health system strengthening available in parallel with support for immunization services.

[1] Accessible online at http://www.wpro.who.int/NR/rdonlyres/47A06511-2522-4C9A-97FF-B76C9D1971B2/0/BriefingNote2DataexclusivityMarch2006.pdf.

Elements and sub-elements	Specific actions	Ongoing activities
	(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]	Technical support is being provided by WHO and many international partners. WHO is in the process of publishing a guide for the application and granting of compulsory licences and for the for the authorization of use by government of pharmaceutical patents. The guide will deal with the special situation of least developed countries, as provided for in paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, which allows least developed countries a transition period until 2016, during which it will not be necessary for them to provide for, or enforce, patent rights and exclusive marketing rights in relation to pharmaceutical products.
	(c) Prioritize health care in national agendas	This is a country-led activity. However, WHO provides technical support to countries, as prioritizing health care in national agendas is already part of longer-term efforts. *The world health report 2007* highlights global interdependence in health security.[2]
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*	See 3.2 (a) Working in coordination with WHO, the European Medicines Agency and individual regulatory authorities in the European Union have set up a mechanism to provide a scientific assessment of products destined for a third country. Under this mechanism, it would be the responsibility of developing countries to make their own risk–benefit and market authorization decisions. They have also been asked to provide support – in coordination with WHO – for capacity building of national regulatory authorities in developing countries through partnerships, scientific or technical assistance, or financing. WHO has played a long-term part in bringing together regulators through the annual International Conference of Drug Regulatory Authorities. Aiming to ensure that good-quality pharmaceuticals are available, WHO sets norms and standards, develops guidelines and advises Member States on issues related to quality assurance of medicines in national and international markets. WHO supports countries in building national regulatory capacity through networking, training and information sharing, and provides continuing technical support to drug regulatory agencies in developing countries, often in collaboration with the World Bank, and bilateral donors. The WHO

[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.

[2] *The world health report 2007. A safer future: global public health security in the 21st century*. Geneva, World Health Organization, 2007.

Elements and sub-elements	Specific actions	Ongoing activities
		Regional Office for Europe provides technical support to the drug regulatory authorities of the United States' National Institutes of Health (and their network, DRUGNET), and to those of the south-eastern European countries. There are other WHO initiatives, such as the Developing Countries' Vaccine Regulators Network, which involves nine national regulatory authorities across five continents. A range of WHO programmes are involved; including those working in areas such as research policy and cooperation; vaccine research; tropical diseases; medicines policy and standards; and essential drugs and traditional medicine. In some cases, cooperation at a regional level has proved more effective than international efforts in strengthening regulatory capacity at the national level. Regional associations of regulators include ASEAN, the Andean Community, the Gulf Cooperation Council, MERCOSUR and the Southern African Development Community. The acceleration of regulatory approval has been used by the United States Food and Drug Administration for priority medicines.
	(b) Conduct operational studies to maximize the value and use of new products in high disease-burden settings with inadequate health services	Empirical evaluation of relevance, impact and appropriate use of new products is part of the research activities of the UNICEF/UNDP/World Bank/WHO Special Programme.
	(c) Implement national and international disease-control policies that are based on evidence that use of new and existing products has an impact	Technical support is provided by WHO. The Special Programme undertakes implementation research (e.g. concerning the use of bednets and antimalarial drugs).
	(d) Encourage compliance with good manufacturing practices in developing countries	WHO plays a central role in the United Nations agencies' prequalification programme, together with UNICEF and UNAIDS, and provides technical support at headquarters and regional levels. The Organization uses various means to foster good manufacturing practices, including training workshops and inspections. The Pharmaceutical Inspection Cooperation Scheme has also been operating since 1998 and comprises 31 participating authorities.

Elements and sub-elements	Specific actions	Ongoing activities
	(e) Minimize the public health consequences of counterfeit and substandard products	In 2006 WHO created a global coalition of stakeholders, the International Medical Products Anti-Counterfeiting Taskforce, in order to seek global solutions to this global challenge and raise awareness of the dangers of counterfeit medical products. OECD has a project on counterfeiting. The G8 countries took counterfeiting and innovation as areas of concern of their 33rd summit (Heiligendam, Germany, 6–8 June 2007).
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*	Enacting national legislation is a country-led activity. WHO gives technical support to countries in developing their generic medicines policies
	(b) Frame policies emphasizing essential medicines at affordable prices	This is a country-led activity. WHO provides technical support to countries in the development and implementation of their pricing policies and regulations. WHO – in collaboration with other organizations, namely, UNICEF, Management Sciences for Health and the International Trade Center – makes available information about medicine prices, including those used against HIV/AIDS. The WHO/Health Action International project on medicine prices, makes available information about the prices of medicines in the public and private sectors. It has conducted national medicine prices surveys in about 50 countries.
	(c) Remove tariffs and taxes on health-care products and monitor their supply and distribution chain	

Elements and sub-elements	Specific actions	Ongoing activities
	(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	This is a country-led activity. Technical support is provided by WHO, which is in the process of publishing a guide for the application and granting of compulsory licences and for the authorization of use by governments of pharmaceutical patents. Since 2003, several developed countries (including Canada, Netherlands, Norway and Switzerland), together with the European Union, have moved to change their respective legislations in order to permit their producers to act as exporters under the compulsory licence regime agreed in WTO. India's legislation enacted in 2005 also implemented the waiver. WTO's web site has specific pages on the use of the mechanism known as "the paragraph 6 system". To date, one importing country has made a notification (Rwanda, in July 2007). No notifications have been made by exporting countries. The number of countries that have accepted the amendment of the Agreement on Trade-Related Aspects of Intellectual Property Rights currently stands at 10 out of 151, representing 6.6% of the membership of WTO, against the target of 67% headed for the amendment to take effect.
	(e) Encourage pharmaceutical companies to adopt transparent and consistent pricing policies, aiming to reduce prices for developing countries	This is a private sector led activity, but national governments need to lay down requirements in their respective legislations. The Medicines Transparency Alliance an initiative to address these issues alongside other pharmaceuticals-related matters is being set up, with a first stakeholder meeting hosted in 2007 by the Department for International Development of the United Kingdom of Great Britain and Northern Ireland. Since 2002, the European Commission initiative on differential pricing on voluntary basis has encouraged companies to use tiered pricing; however, this has not yet attracted substantial support from within the pharmaceutical industry.
	(f) Monitor pricing policies and strengthen WHO's work on pharmaceutical pricing	WHO has done initial work on pricing of pharmaceuticals and comparison of prices between countries. The WHO/Health Action International project on medicine prices has conducted national medicine prices surveys in the public and private sectors in around 50 countries. In line with resolution WHA54.11, WHO is improving countries' access to price information. OECD has compiled data on pricing in its member countries.

Elements and sub-elements	Specific actions	Ongoing activities
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*	
	(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	There are a number of funding sources, including the following: individual countries; the private sector; the not-for-profit sector, especially foundations and public–private partnerships; and innovative financing mechanisms like the Grand Challenges in Global Health initiative (launched in 2003 by the Bill & Melinda Gates Foundation), the International Finance Facility for Immunization (launched in 2005), and the initiative on advance market commitments (launched in 2007).
	(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	See 5.3 (b)

Elements and sub-elements	Specific actions	Ongoing activities
7.2 Facilitate the expansion of activities to develop and deliver affordable products	*(a) Document and disseminate best practices in expanding public–private partnerships*	In recent years a considerable number of documents have been produced on the subject of public–private partnerships, including in relation to general organizational and governance issues. The High-Level Forum on the Health MDGs produced the Best Practice Principles for Global Health Partnership Activities at Country Level. Some studies make specific recommendations on policies to support public–private partnerships for research and development, for example the London School of Economics and Political Science/Wellcome Trust study, "The New Landscape of Neglected Disease Drug Development". The UNICEF/UNDP/World Bank/WHO Special Programme on Research and Training in Tropical Diseases has produced publications on innovation in tropical diseases and developing countries.
	(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	Activities are undertaken in a number of WHO programmes, including those working in the following areas: tuberculosis, HIV/AIDS, malaria, medicines policy, and essential drugs and traditional medicine. Some of the available drugs for tropical diseases have been developed through public-private partnerships involving or established by WHO. Through the Special Programme, WHO has supported the establishment of public–private partnerships for the development of existing products, such as the Medicines for Malaria Venture and the Foundation for Innovative New Diagnostics, and is supporting the discovery of new drug and diagnostic leads to feed into portfolios of public–private partnerships. WHO is providing evidence to inform policy at the end of the product development process. Working through the Special Programme and with the Foundation for Innovative New Diagnostics, WHO has supported the publication of several guidelines for diagnostics testing and evaluation and has recently presented an analysis of the market for tuberculosis diagnostics.[1] WHO is providing guidance on prequalification of medicines for developing countries.

[1] *Diagnostics for tuberculosis: global demand and market potential.* WHO, Geneva, 2006.

Elements and sub-elements	Specific actions	Ongoing activities
		WHO supports the investment of public–private partnerships and investing in tropical diseases by working to develop mechanisms that enhance purchase of and access to products in support of the Millennium Development Goals, namely: the Global Fund to Fight AIDS, Tuberculosis and Malaria, the GAVI Fund and the International Drug Purchase Facility.
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*	In 2003 developed and developing governments collectively contributed 59% of overall funds for all research for health in low-income and middle-income countries; pharmaceutical companies contributed 32%, and the private not-for-profit sector 9%. On data reported, in 2003 only Argentina and Brazil met the target, proposed in 1999 by the Commission on Health Research for Development, for expenditures on health research and development to total at least 2% of national health expenditures. Research focused specifically on neglected diseases relies more heavily on the contribution of public-private partnerships. OECD's Noordwijk Medicines Agenda, issued in 2007, called for action to improve predictability and transparency of funding, including official development assistance.
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*	
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*	

Elements and sub-elements	Specific actions	Ongoing activities
	(b) Monitor the impact of intellectual property rights and other factors on innovation and access to health-care products	In 2006 resolution WHA59.24, making reference to the Commission on Intellectual Property Rights, Innovation and Public Health, requested the Director-General "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 Commission's report, on the development of, and access to, health care products, and to report thereon to the Health Assembly." Monitoring and analysis activities include those described below. • **Determining the patent status of essential medicines.** A joint pilot project involving WIPO, the European Patent Office and national patent offices is under way with the aim of to analysing the extent of patent protection for essential medicines in developing countries. • **Determining a public-health perspective for examination of pharmaceutical patents.** WHO has commissioned a study on patent claims for pharmaceutical products with a view to assessing the practices of patent offices. • **Assessing the impact of trade agreements.** In partnership with the World Bank Institute and the International Centre for Trade and Sustainable Development, WHO organized an expert consultation on developing a methodology to assess the impact of TRIPS-plus provisions affecting the prices of medicines (Geneva, 2006). Following its organization of a technical workshop to examine the relationship between vaccines and intellectual property rights in developing countries (Geneva, April 2004), WHO is conducting field studies in order to assess the impact of intellectual property rights on the development of innovative vaccines by local manufacturers in Brazil and India. Capacity-building projects are under way in Africa, Asia and Latin America.
	(c) Monitor investment in research and development to address the health needs of developing countries	There is currently no comprehensive monitoring beyond that performed by the Global Forum for Health Research. The Stop TB Partnership monitors investment in tuberculosis-related research and development, and the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases monitors very neglected infectious diseases that disproportionately affect poor and marginalized populations.

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