



**Monitoring the implementation of the WHO  
Global Strategy and Plan of Action on Public  
Health, Innovation and Intellectual Property  
Rights**

**-A Pilot Monitoring Tool-**

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## Section 1: Introduction

This questionnaire has been developed jointly by Health Action International Africa (HAI Africa) and IQsensato. The tool is designed to monitor the implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Rights (GS). In its current draft form, it is being piloted in Ghana, Uganda, Zimbabwe, Rwanda and Kenya. The pilot process has already highlighted the need to prepare a short guide for each question, which will increase awareness of the type of information that is being collected.

Paragraph 4(1) of the preamble to World Health Assembly (WHA) Resolution WHA61.21 requests the WHO Director-General (DG) to support Member States in monitoring and evaluating the implementation of the global strategy and plan of action.<sup>1</sup> This tool may be regarded as complementary to the WHO's efforts in this area. There are seven parts to the tool (under section 3 in this document), corresponding to the first seven elements of the GS.

1. Prioritizing research and development needs
2. Promoting research and development
3. Building and improving innovative capacity
4. Transfer of technology
5. Application and management of Intellectual Property to contribute to innovation and promote public health
6. Improving delivery and access
7. Promoting sustainable financing mechanisms

**Section 2** of this document gives a brief overview of each issue and the monitoring intentions and needs.

**Section 3** contains the seven parts of the tool with their questions. Each part begins with guidance on who should be supplying the information and suggestions for where the information may be found.

Each part contains questions that policy makers should address with a view to mapping their national environments in terms of essential health innovation and access to lifesaving tools. This will also help them to establish how they intend to implement, or are already implementing, the WHO Global Strategy and Plan of Action. An indication of the actors in government who should be consulted relating to specific elements is also provided, but this is not an exhaustive list.

## Context

The preamble to WHA61.21 outlines the scope and method of implementation of the GS. For approximately 90 actions, **governments** are identified as lead stakeholders and principal responsibility lies with Member States to initiate actions that they have themselves negotiated. On the other hand, **WHO** is the lead stakeholder for 48 actions to date, including time frames, progress indicators and estimated funding needs. Additional actions are to be presented to the Sixty-second WHA in May 2009

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<sup>1</sup> WHO. 2008. Sixty-first World Health Assembly Resolution WHA61.21 Global strategy and plan of action on public health, innovation and intellectual property. [http://apps.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf)

for approval.<sup>2</sup> In addition, **intergovernmental organisations** have an important facilitating role, in particular where collective action is required and **civil society organisations (CSOs)** are recognised as relevant players for the enactment of the GS.

The WHO Secretariat is required to carry out monitoring. In relation to this, the WHO DG is called upon to report progress of implementation to the sixty-third WHA in 2010, and subsequently every two years.

Element 8 of the Global Strategy and Plan of Action (PoA) calls for monitoring of the following:

- gaps and needs related to health products and medical devices in developed and developing countries;
- the impact of intellectual property and other issues from a public health point of view; including the development of, and access, to health products;
- impact of incentive mechanisms on the innovation of, and access to, health products and medical devices;
- investment in research and development to address the health needs of developing countries.

## Section 2: Overview of the Global Strategy Elements

This section provides short introductions to each of the seven areas of the tool.

### 1. Prioritizing research and development needs

Innovation is strongly linked to research and development (R&D). Based on the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH)<sup>3</sup> analysis, the innovation process is seen as a cycle consisting of three major phases that feed into each other: discovery, development and delivery. Within this cycle, public health needs create a demand for a product of a particular kind, suited for the particular medical, practical or social context of the group in question, and this feeds into efforts to develop new and improved health tools. This is in contrast to innovation being seen as a linear process culminating in the launch of a new product.

#### Discovering needs

Innovation and R&D should both be responsive to needs. The 2006 CIPRH report stated clearly in the context of needs and innovation that “our remit is to cover the range of diseases and conditions that currently affect developing countries, from Type I to Type III,<sup>4</sup> taking account of those that will increase in importance in coming decades [...] The focus of innovation should not only be on particular diseases that

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<sup>2</sup> Sixty-second World Health Assembly A62.16, Provisional agenda item 12.11, Public health, innovation and intellectual property: global strategy and plan of action, Report by the Secretariat (and addenda). [http://apps.who.int/gb/e/e\\_wha62.html](http://apps.who.int/gb/e/e_wha62.html).

<sup>3</sup> Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH). <http://www.who.int/intellectualproperty/en/>

<sup>4</sup> Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable populations in each; Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries; Type III diseases are those that are overwhelmingly or exclusively incident in developing countries. (See CIPRH, 2006).

are mainly confined to developing countries, but also tackling the health problems of developing countries in the light of their circumstances”<sup>5</sup>.

Needs assessment is the first essential phase in the implementation exercise and it aims to:

- identify the health problems and their determinants;
- evaluate the health care system status and its potential deficiencies;
- measure the health research system in terms of available of resources for research.

Several different initiatives are currently in place to detect the needs of small and large companies in pharmaceuticals or biotechnology, or of governments in the form of aid donors or medical research councils, foundations and civil society groups. These often fragmented initiatives need to be coordinated with public health needs. Promoting more organized information sharing on current activities is a key step towards this and the entire process of needs assessment should be transparent, participatory, government-driven and inclusive of all stakeholders.

## Priority setting

Based on the information generated in the needs assessment phase and the criteria developed, an initial report of **priority needs** should be produced and made available at country level. This is also important for the development of a relevant innovation cycle.

Priority setting is a continuous and cyclical activity based on assessment of needs that involves an increasing number of people over time and builds on better and more accurate data as the process continues. Priority setting improves the use of financial and human resources, as well as focusing efforts where health needs are most demanding. It also helps to define the health problems of a country and a county’s capacity to solve those problems.

It is clear that, for each disease, different approaches to prevention, treatment or diagnosis may be needed. Even then, there will inevitably be different but equally legitimate views about priorities in each disease area. Prioritization processes in health research should encompass all factors that affect health – not only concentrating on biomedical and clinical research, but also on health systems research, macroeconomic policies, the impact of other sectors on health, etc.

## 2. Promoting research and development

There are many stages in the medical R&D process, i.e. basic research, discovery research (synthesis, biological testing, pharmacology screening), preclinical testing, development research (clinical test, Phase I–III), registration and post-marketing surveillance. At each of these stages, suitable partnerships with different R&D actors need to be established to facilitate R&D based on the gaps identified and the needs prioritised and to assure the emergence of a product to satisfy such needs.

R&D efforts should focus on the development of products that are:

- **adapted** to the needs of patients of all ages (with a special attention to women and children);
- **simple** (in terms of use, prescription and storage);

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<sup>5</sup> WHO. 2006. *Public health, innovation and intellectual property rights: report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health*. Geneva, pp. 13–15.  
<http://www.who.int/intellectualproperty/report/en/>

- **accessible** (in terms of availability and affordability);
- **of quality**.

R&D results should be disseminated as widely as possible through publications, presentations, the internet and other appropriate methods. All results will be beneficial for other researchers particularly where they can engage in additional or follow-on health research.

### 3. Building and improving innovative capacity

“Actions taken by regulatory authorities, or not taken by them, can facilitate or hinder product development and delivery”, as the CIPIH report highlights.<sup>6</sup> Policy interventions that seek viable, sustainable and long-term solutions need to be based on international support for mobilization of local resources in developing countries, with the aim of strengthening local absorptive capacity for knowledge and technology transfer. However, more focused strategies are needed to better link science and technology policies in developing countries to policies for health. Regulations play a critical role in the development of new medicines, vaccines and diagnostics, setting standards for research and providing a scientific evaluation of product safety, efficacy and quality.

The challenging reality is that regulatory capacity remains weak in most developing countries, particularly the capacity to regulate clinical trials. Yet, as the CIPIH report comments, “while trials can be conducted according to the rules of the developed country regulatory authorities such as the United States FDA, these are not necessarily the most appropriate or acceptable locally. For example, judgements about market approval should appropriately reflect local circumstances: there is an important distinction between scientific assessment [...] and coming to an informed judgement of a particular product, based on weighing the factual analysis of the risks and benefits in the light of local health needs”<sup>7</sup>.

The integrated monitoring of the efficacy/utility, safety/acceptability and relevance/policy of experimental interventions is an essential component for which WHO, local representatives and experts have to take responsibility. This should make clinical trials a tool for health improvements, and a real opportunity for populations. Strengthening the clinical trials and regulatory capacity in developing countries, including the improvement of ethical review standards, should be a main objective of interventions.

Fundamental steps to pave the way for an appropriate approach to the development of quality drugs for developing countries and cut R&D costs include:

- increasing trials capacity in developing and least developed countries;
- streamlining regulation;
- defining essential regulatory standards in relation to the needs of patients, the severity of the disease, and the availability of alternative treatments and vaccines.

### 4. Transfer of technology

‘Technology transfer’ is the process by which non-commercial and commercial technology is disseminated. This involves the communication of relevant knowledge. According to the UNCTAD draft International Code for the Transfer of Technology,<sup>8</sup> the concept of technology is defined as the

<sup>6</sup> CIPIH report, p. 79.

<sup>7</sup> CIPIH report, p. 80.

<sup>8</sup> UNCTAD. 1985. Draft international code of conduct on the transfer of technology. <http://stdev.unctad.org/compendium/documents/totcode%20.html>.

“systematic knowledge for the manufacture of a product, for the application of a process and for the rendering of a service”. Technology is therefore the knowledge that goes into the creation and provision of the product or service and is not the finished product or service as such. The World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement says that developed countries shall grant incentives to their institutions and enterprises to encourage the transfer of technologies to least developed countries (art. 66.2).

However, for many reasons, the transfer of technology to developing countries for manufacturing medicines (and particularly active ingredients) is today still scant or nonexistent.

It is important to remember that manufacturing pharmaceutical products entails many processes and there may be special challenges in developing local production, especially for smaller, less scientifically advanced countries. However, developing a local manufacturing capacity has many advantages, such as employment of local technicians and professionals and therefore skill retention, savings of foreign currency, ability to respond to emergencies and better knowledge of local conditions for storage and distribution.

North-South and South-South alliances and networks need to be supported to build and improve processes of technology transfer **to** and **between** developing countries in relation to essential health innovation. The success of technology transfer activities should be measured by the degree to which these facilitate access to essential health tools.

## **5. Application and management of intellectual property to contribute to innovation and promote public health**

Over the last few decades, the main mechanism to stimulate the development of new medicines has been via intellectual property rights (IPRs), especially patents. Under the IPR system, incentive is linked to sales and profit margins, which (during the time-limited 20-year monopoly period) should motivate the innovator to continue investing in medical research and development. The amount of profit depends on the profit margin and the sales volume.

However, if a few people need a particular drug, or if people who need the drug are too poor to pay for it, then sales will be low. This implies that IPR does not (and cannot be expected to) provide effective incentives for the development of new medicines for diseases that mainly or exclusively affect people in developing countries. Nor do they provide sufficient incentive for the development of medicines for orphan diseases.<sup>9</sup>

IPRs are a policy tool, whose objective is to favour innovation. In the face of their failure to fully achieve their objective, it is necessary to encourage positive change and identify both alternative mechanisms and innovative pathways to ensure the pro-health utilization of the current IP regimes and overcome some of the inherent limitations. Innovative approaches (such as sensible patenting and licensing strategies, or patent pools, to facilitate access to existing scientific knowledge) are considered to have considerable potential, although they suffer from a certain lack of evidence in the field of health.

Different proposals should not be seen as mutually exclusive; rather, they should be seen as a menu of policy options. Incentives that motivate the relevant actors to partner in the different stages of R&D will have to be explored. In some cases, where basic or discovery research is involved, a public grant may be the best way to facilitate R&D. In another case, institutions, including product development public-private partnerships (PDPs) or companies, may offer to conduct certain stages of R&D without any financial support. Reward systems such as ‘prize funds’, should also be considered and used where appropriate.

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<sup>9</sup> Orphan diseases are rare diseases that affect only a small number of people.

Whatever incentives are chosen, guidelines should be formulated for their selection and implementation and should place an emphasis on cost-effectiveness criteria, while avoiding the granting of monopoly rights as an incentive. Of course, governments have a crucial role in promoting the further implementation of these pathways, according to their needs and capabilities.

## 6. Improving delivery and access

Innovation has little impact if there is no access to the products. Support for health systems, including the investment in human resource development in the health sector, is vital to ensure delivery and access of medicines, as are the stimulation of competition and the adoption of appropriate pricing policies for health products. In addition, regulatory approval processes need to be seriously considered and streamlined in order to rapidly deliver lifesaving medicines to patients.

According to the spirit of the Declaration of Helsinki,<sup>10</sup> human experimentation can and must be seen as one of the most powerful tools to promote and assure the right to health to populations and individuals. The focus on drugs development, especially in the absence of the investment of public health actors, favour research and regulations that have little to do with unmet public health needs and human rights.

Regrettably, regulatory authorities have increasingly focused on methodological studies on drugs that are not necessarily lifesaving. This increasing distancing from essential health tools has distorted their approach towards bureaucracy, to the detriment of the people's interests. A more structural linkage has to be promoted between unmet public needs and lifesaving health tools. Regulatory authorities can play a huge role in terms of promoting access, identifying needs and eroding costs, both *a priori* and *a posteriori* of any R&D project.

Medical problems cannot have univocal answers, and essential standards have to be defined that can be applied according to a country's conditions, in order to suitably respond to specific needs. The risks and benefits of each drug or vaccine should be then assessed in relation to the patients' needs, the severity of the disease and the availability of alternative preventive/therapeutic options.

## 7. Promoting sustainable financing mechanisms

Financing is needed in all phases, but it is particularly crucial for the 'development' phase, which is significantly more expensive than the discovery phase. The CIPIH report has noted that more funding is a necessity and it has to be provided on a sustainable basis if R&D efforts are to be encouraged. The report endorsed strongly the "need for more resources if this research effort is to be sustained and the development of new arrangements that may facilitate the flow of new funds for a greater impact" and a "new approach which involves governments on a sustainable basis in the financing of health-related research relevant to developing countries". A number of recommendations on resource flow and coordination have been made in the past,<sup>11</sup> and have been reiterated as recently as 2005.<sup>12</sup> No specific outcomes have yet resulted from these negotiations.

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<sup>10</sup> World Medical Association. 1964. Declaration of Helsinki: ethical principles for medical research involving human subjects (amended 2008). <http://www.wma.net/e/policy/b3.htm>.

<sup>11</sup> The 1990 Commission on Health Research for Development, recommended that governments should spend 2% of their health budgets on what it called essential national health research, and that donor nations should invest 5% of their aid for health in developing countries in research and strengthening research capacity. <http://www.cohred.org/Assests/PDF/Papers/ComReports.pdf>.

<sup>12</sup> WHO. 2005. Fifty-eighth World Health Assembly Resolution WHA58.34 Ministerial Summit on Health Research. [http://apps.who.int/gb/ebwha/pdf\\_files/WHA58/WHA58\\_34-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_34-en.pdf).

## Section 3: Pilot Monitoring tool

### 1. Prioritizing research and development needs

The questions in this element are best answered by individuals responsible for matters relating to health and research. Such officials should be sought in the Ministry of Health, in Medical Research Institutes, in National Disease Control Programmes, in Drug Regulatory Authorities (DRAs), in academia (faculties of medicines and public health) and in traditional medicines institutes. Important information may be obtained by the WHO representation in the country, and/or other UN agencies, such as UNDP, UNICEF, etc.

#### 1.1. In mapping global research and development with a view to identifying gaps in R&D on diseases that disproportionately affect developing countries, ask the following questions:

- 1.1.1. What role does your government play in assessing health and biomedical needs, and how?
- 1.1.2. How regularly are public health needs assessed in your country?
- 1.1.3. Are research needs on health systems being included as part of an overall prioritized strategy?
- 1.1.4. Do you think that your government leadership is recognized in determining priorities for R&D to address public health needs? At which level (local level/ national level/ regional level)? What improvement would you see as being necessary?
- 1.1.5. Which stakeholders are involved in the definition of needs in health?
- 1.1.6. What are the potentials and the challenges/constraints involved in this assessment and prioritisation process?
- 1.1.7. What capacities have been identified at the national level and what resources gaps?
- 1.1.8. What information has been disseminated on any identified gaps?
- 1.1.9. Have the consequences of these gaps on public health been analyzed in your country, at the local and national level?
- 1.1.10. Is there any definition of needs in health pursued at regional level, or across countries in the area?
- 1.1.11. What health priority needs have been set so far in your country?
- 1.1.12. Does your government feel that the definition of the health needs in your country is affected by availability of donor funding? Can you measure the impact of this condition in your policy?
- 1.1.13. Do you exchange any experiences on your needs assessment process with other countries? If yes, when and how?

#### 1.2. In formulating explicit prioritized strategies for R&D at country and regional and inter-regional levels, ask the following questions:

- 1.2.1. Do you have currently a list of codified priorities related to your public health policy, based on appropriate and regular needs assessments?
- 1.2.2. What methodologies and mechanisms have been developed to define your R&D agenda?
- 1.2.3. What stakeholders are involved in the definition of health priorities in your country?
- 1.2.4. Is the private sector committed in assisting in the determination of priorities for R&D to address public health needs in your country? How is this commitment being expressed: at the local level? National level? Regional level?
- 1.2.5. Do you exchange any experiences on your priority setting process and methodologies with other countries? If yes, when and how?
- 1.2.6. What are the achievements so far? Do you notice any increase in research efforts leading to the development of quality, user friendly and accessible tools to address public health needs, as a result of the needs assessment and consequent definition of health priorities in your country?
- 1.2.7. If yes, what research approaches have been favoured and what policies adopted to achieve such a result?
- 1.2.8. If no, what R&D policies do your government intend to consider to follow up from the identification of needs, and to comply with the implementation requirements of the Global Strategy and the Plan of Action on Public Health, Innovation and IP?

**1.3. In encouraging R&D in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge (TK) and the rights of indigenous peoples, ask the following questions:**

- 1.3.1. Are there any specific health policies in your country that promote traditional medicine?
- 1.3.2. At what level are such policies implemented (community level, district level, national level)?
- 1.3.3. What research priorities in traditional medicines have been set in your country? In your region?
- 1.3.4. What national capacity have you developed in traditional medicine so far?
- 1.3.5. How do you project traditional medicine in your future plans for health, if at all?
- 1.3.6. Have you requested or are you receiving any support to build your capacity in R&D in traditional medicine? If you have requested support, from whom? If you are receiving support, from whom?
- 1.3.7. Is your country supporting any South-South cooperation efforts in information exchange and research activities in traditional medicines? How?
- 1.3.8. Have you requested, are you receiving or are you giving support to early-stage drug R&D in traditional medicine systems in your country? From whom and how?

## 2. Promoting research and development

The questions in this element are best answered by individuals responsible for health and research at the Ministry of Science/Innovation/Technology, Ministry of Health, Institutes of Technology, in the academic world, in DRAs, in Ministry of Foreign Affairs, Ministry of Finance. Important information may be obtained through the WHO and UNDP representation in the country, and/or other relevant UN agencies.

### 2.1. In supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area, ask the following questions:

- 2.1.1. Is research being conducted in your country that is appropriate for resource-poor settings and on technologically appropriate products for addressing public health needs to combat diseases?
- 2.1.2. Does your government have an established national health research programme?
- 2.1.3. If yes, what are its current opportunities and challenges?
- 2.1.4. If no, could you briefly explain the reasons why?
- 2.1.5. In view of the WHO GS and PoA, does your government intend to take any concrete measures to overcome these constraints? Which ones?
- 2.1.6. Do you think that your country does/can contribute to an essential innovation agenda in health? If yes, how?
- 2.1.7. Is there any national legislative framework favouring innovation in broad terms, and specifically health innovation, in your country?
- 2.1.8. Is your country promoting cooperation between private and public sectors on R&D?
- 2.1.9. What policy action supports your national health research programme, and what type of sustainable funding?
- 2.1.10. Are any international organizations involved in supporting your endeavours in essential health innovation? And how closely connected is your national health research programme to relevant international research networks?
- 2.1.11. Has your country requested or is it receiving support in establishing health-related innovation (including South-South and not only North-South)?

### 2.2. In promoting upstream R&D in developing countries, ask the following questions:

- 2.2.1. Is your country supporting discovery science?
- 2.2.2. Which approaches/policies have so far been adopted to promote discovery science in your country?
- 2.2.3. Which methodologies for discovery science referred to in the GS and PoA do you think would most adequately suit the research needs and realities in your country?
- 2.2.4. Has your government requested or received such support? If yes, from whom?

- 2.2.5. What efforts does your country intend to make to promote and use the identified appropriate methodologies for upstream innovation at the national level?
- 2.2.6. Which actors need to be involved in your country? (Universities and beyond).
- 2.2.7. Has your country identified incentives and barriers at different levels that might affect increased research on public health and suggested ways to facilitate access to research results and research tools?
- 2.2.8. Has your country requested or received any assistance to this end? If yes, from whom?

**2.3. In improving cooperation, participation and coordination of health and biomedical R&D, ask the following questions:**

- 2.3.1. What efforts is your country making towards stimulating and improving regional and global cooperation and coordination in health R&D?
- 2.3.2. What needs to be done, in order to improve the coordination and sharing of information on R&D activities?
- 2.3.3. Is your country open to considering further exploratory discussions on the utility of new instruments or mechanisms for essential health and biomedical R&D, including an essential health and biomedical R&D treaty?
- 2.3.4. Has your country requested or is it receiving support to actively participate in building technological capacity? If yes, from who? If no, why not?

**2.4. In promoting greater access to knowledge and technology relevant to meet public health needs of developing countries, ask the following questions?**

- 2.4.1. Is your country promoting public access to the results of government-funded research?
- 2.4.2. Is your country supporting or willing to support the creation of voluntary open databases and compound libraries?
- 2.4.3. Is your country encouraging the further development and dissemination of publicly or donor-funded medical inventions and know-how? If yes, how?
- 2.4.4. Has your country considered the use of a 'research exemption' to address public health needs consistent with the Agreement on Trade- Related Aspects of Intellectual Property Rights?

**2.5. In establishing and strengthening national and regional coordinating bodies on R&D, ask the following questions:**

- 2.5.1. Is your country involved in the development or coordination of a regional research agenda? If yes, through which regional organizations?
- 2.5.2. What are the current opportunities and obstacles in your region?

### 3. Building and improving innovative capacity

The questions in this element are best answered by individuals responsible for matters relating to health, education and research. Researchers will have to find these officials at the Ministry of Health, at the Ministry of Education, at the Ministry of Science/Innovation/Technology, Ministry of Foreign Affairs, Ministry of Industry. Additional information may be obtained through the national WHO representation, and/or other UN agencies such as UNESCO, UNDP, etc.

#### 3.1. In building capacity of developing countries to meet R&D needs for health products, ask the following questions:

- 3.1.1. Is your country supporting investment in human resources and knowledge bases, especially in education and training including in public health? If yes, how? If no, what are the constraints?
- 3.1.2. Is your country supporting existing and new R&D groups and institutions, including regional centres of excellence? If yes, how? If no, why not?
- 3.1.3. Is your country strengthening health surveillance and information systems? If yes, how? If no, why not?
- 3.1.4. Do you receive any external support – technical or financial - to pursue these efforts? If yes, from whom?
- 3.1.5. Is there any regional or cross-country initiative aimed to strengthen local capacities in the health domain?

#### 3.2. In framing, developing and supporting effective policies that promote the development of capacities for health innovation, ask the following questions:

- 3.2.1. What regulatory capacity does your country have, if any?
- 3.2.2. What are its major weaknesses, and potentials?
- 3.2.3. What is your country doing to develop and strengthen the capacity of its national regulatory authority to monitor the quality, safety and efficacy of health products?
- 3.2.4. Is your country pursuing a human resources strengthening policy in health? If yes, in which fields?
- 3.2.5. What national capacity building plans are currently in place?
- 3.2.6. Has your country developed any policies for retention of health professionals, including researchers? If yes, how? If no, why not?
- 3.2.7. Is your country establishing mechanisms to mitigate the adverse impact of the loss of its health personnel, particularly researchers, through migration (to the private sector, and especially abroad)?
- 3.2.8. What are your objectives in the short, medium and long term?
- 3.2.9. Do these mechanisms include support from receiving countries to strengthen your country's national health and research systems, in particular human resource development?

**3.3. In providing support for improving innovative capacity in accordance with the needs of developing countries, ask the following questions:**

- 3.3.1. Do you think that your country is developing successful models in shaping and upgrading its innovative capacity in health? If yes, can you explain how? If no, why not?
- 3.3.2. Does your country participate in or is it planning to participate in any efforts to intensify North–South and South–South partnerships and networks to support capacity building? If yes, how? If no, why not?
- 3.3.3. Is your country building capacity to conduct clinical trials and other mechanisms for stimulating local innovation, taking into account ethical standards and its needs? If yes, how? If no, why not?
- 3.3.4. Is your country establishing any mechanisms for ethical review in the R&D process, including clinical trials?
- 3.3.5. If your country has already established these mechanisms, what are the potentials and constraints?

**3.4. In supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments, ask the following questions:**

- 3.4.1. Are there any efforts to establish a traditional medicine policy at the regional level? If yes, how? If no, why not?
- 3.4.2. Is your country encouraging and promoting policies on innovation in the field of traditional medicine? If yes, how? If no, why not?
- 3.4.3. Is your country promoting standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards?
- 3.4.4. Is your country promoting South-South collaboration in traditional medicines? If yes, how? If no, why not?
- 3.4.5. Is your country collaborating with WHO in formulating and disseminating guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation? If yes, how? If no, why not?

**3.5. In developing and implementing possible incentive schemes for health-related innovation, where appropriate, ask the following questions:**

- 3.5.1. Have award schemes or incentive mechanisms for health-related innovation been set in place in your country? If yes, are these effective? If no, what are the obstacles?

## **4. Transfer of technology**

The questions in this element are best answered by individuals responsible for health research, trade and intellectual property administration – Ministry of Trade, Intellectual Property Offices – individuals responsible for international relations and cooperation at the Ministry of Foreign Affairs, and officials in the Ministry of Industry. Important information may also be obtained through interviewing people at the national WHO representation and officials from other relevant UN agencies, such as UNDP and UNCTAD, and also organisations such as WTO, if they have a country office.

**4.1. In promoting transfer of technology and the production of health products in developing countries, ask the following questions:**

- 4.1.1. Are there any technology transfer activities in your country in the health sector? If yes, can you elaborate?
- 4.1.2. Which actors are involved in the technology transfer process?
- 4.1.3. Does your government keep track of the technology transfer initiatives in place, and is it able to monitor their outcome and the actors involved?
- 4.1.4. Is your country promoting transfer of technology and production of health products through investment and capacity building? If no, why not?
- 4.1.5. Is your country making proper use of existing mechanisms or exploring possible new mechanisms to facilitate the transfer of technology and technical support to build and improve innovative capacity for health-related R&D? If yes, how?
- 4.1.6. Is your country receiving any assistance in promoting transfer of technology and production of health products? If yes, from where? If no, why not?

**4.2. In supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development, ask the following questions:**

- 4.2.1. Is your country encouraging North–South and South–South cooperation for technology transfers? If yes, in which ways? If no, why not?
- 4.2.2. Is your country encouraging collaboration between research institutions and the pharmaceutical industry? If yes, how? If no, why not?
- 4.2.3. Is your country facilitating local and regional networks for collaboration on R&D and transfer of technology? If yes, how? If no, why not?
- 4.2.4. Is your country promoting and encouraging technology transfer in a manner consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights? If yes, how? If no, why not?
- 4.2.5. Is your country promoting the necessary training to increase absorptive capacity for technology transfer? If yes, how? If no, why not?
- 4.2.6. Is your country developing possible new mechanisms to promote transfer of and access to key health-related technologies? If yes, which mechanisms are being explored?
- 4.2.7. What are some of the most important achievements in this field, if any, that you consider worth sharing for the purpose of the implementation of the GS and PoA?
- 4.2.8. What are your objectives as a government in the short, medium and long term, in the field of technology transfer?

## 5. Application and management of intellectual property to contribute to innovation and promote public health

Questions under this element are best answered by individuals responsible for matters relating to health research, procurement and intellectual property. These officials are to be found in specific departments at the Ministry of Health, Ministry of Trade, Ministry of Justice, Ministry of Industry, Ministry of Foreign Affairs, DRAs. Relevant information may also be obtained through the local WHO office, the local UNDP and WIPO office, the local WTO representatives, if any.

### 5.1. In support of information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries, ask the following questions:

- 5.1.1. What legislation is enforced in your country (if any) to regulate intellectual property rights? To what extent does this regulation impact on health related innovation and access to essential medicines in your country?
- 5.1.2. Has your country adapted or is it considering adapting national legislation in order to use to the full the flexibilities contained in the TRIPS Agreement, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003? If yes, how? If no, why not?
- 5.1.3. Is your country taking into account the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights? If yes, how? If no, why not?
- 5.1.4. Is your country taking into account in trade agreements, the flexibilities contained in the TRIPS Agreement and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003? If yes, how? If no, why not?
- 5.1.5. Is your country considering taking necessary measures with countries with manufacturing capacity to facilitate access to pharmaceutical products in a manner consistent with the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003? If yes, how? If no, why not?
- 5.1.6. Is your country encouraging finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge? If yes, how? If no, why not?
- 5.1.7. Is your country encouraging and supporting the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and that meets its specific R&D needs? If yes how? If no, why not?
- 5.1.8. Is your country stimulating collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions in order to promote information sharing relevant to public health needs? If yes, how? If no, why not?

- 5.1.9. Is your country strengthening education and training in the application and management of intellectual property from a public health perspective? If yes, how? If no, why not?
- 5.1.10. Is this education and training taking into account the provisions contained in the TRIPS Agreement, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement? If yes, how? If no, why not?
- 5.1.11. Is your country promoting active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs? If yes, how? If no, why not?

**5.2. In providing, as appropriate and upon request, in collaboration with other competent international organizations, technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the TRIPS Agreement, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products, ask the following questions:**

- 5.2.1. Is your country promoting and supporting, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries? If yes, how? If no, why not?
- 5.2.2. Is your country involved in strengthening efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries? If yes, how? If no, why not?

**5.3. In exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases, ask the following questions:**

- 5.3.1. Is your country exploring the promotion of incentive schemes for essential health R&D, so as to suitably respond to priority needs? How?
- 5.3.2. Which incentives are being considered, and what is the rationale of your options?

## **6. Improving delivery and access**

The questions under this element are best answered by those knowledgeable of matters relating to delivery of health services, most likely in the ministries responsible for health. Drug Regulatory Authorities are particularly relevant in this element, and so are officials at the Ministry of Trade, and cooperation departments in the Ministry of Foreign Affairs. Important information may also be obtained through interviews with the local representative of WHO, UNDP, UNICEF in the country, the profit and non-profit private sector, NGOs in the country.

**6.1. In encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system, ask the following questions:**

- 6.1.1. What poverty reduction strategies does your country implement, and do these contain clear health clauses and objectives? If yes, which ones?

- 6.1.2. Is your country prioritizing health care in national agendas?
- 6.1.3. Is your country investing in developing health-delivery infrastructure? If yes, how? If no, why not?
- 6.1.4. Is your country increasing investment in human resource development in the health sector? If yes, how? If no, why not?
- 6.1.5. Is your country encouraging financing of health products? If yes, how? If no, why not?
- 6.1.6. Is your country encouraging pooled procurement mechanisms for health products and medical devices, where appropriate? If yes, how? If no, why not?
- 6.1.7. Is your country developing effective and sustainable mechanisms in order to improve access to existing medicines, acknowledging the transitional period until 2016? [This question applies only to LDCs.]
- 6.1.8. Is your country encouraging health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines? If yes, how? If no, why not? Has your country requested or received assistance in this area?

**6.2. In establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices, ask the following questions:**

- 6.2.1. Is your country promoting operational research to maximize the appropriate use of new and existing products? If yes, how? If no, why not?
- 6.2.2. Is your country supporting regional networks and collaborative efforts to strengthen the regulatory infrastructure for drug marketing approval, including the ultimate goal of harmonization of processes employed by the regulatory authorities, and to promote in particular the implementation of clinical trials using appropriate standards for medicines evaluation and approval? If yes, how? If no, why not?
- 6.2.3. Is your country complying with good manufacturing practices for safety standards, efficacy and quality of health products? If yes, how? If no, why not?
- 6.2.4. Is your country involved in the strengthening of the WHO prequalification programme?
- 6.2.5. Is your country promoting ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines? If yes, how? If no, why not?

**6.3. In promoting competition to improve availability and affordability of health products consistent with public health policies and needs, ask the following questions:**

- 6.3.1. Is your country framing and implementing policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements? If yes, which ones (the production and introduction of generic versions of essential medicines; national legislation and/or policies including a 'regulatory exception' or Bolar-type provision, consistent with the TRIPS Agreement; the reduction or

elimination of import tariffs on health products and medical devices; the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access; differential pricing policies and pricing monitoring policies; etc.)? If no, why not?

- 6.3.2. Is your country supporting WHO's ongoing work on pharmaceutical pricing? If yes, how? If no, why not?
- 6.3.3. Is your country considering, where necessary, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products? If yes, how? If no, why not?
- 6.3.4. What is your country doing to increase information among policy makers, users, doctors and pharmacists regarding generic products?

## 7. Promoting sustainable financing mechanisms

The questions under this element are best answered by individuals in the Ministry of Health, Ministry of Science/Research/Technology, Ministry of Finance, and Ministry of Foreign Affairs.
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### 7.1. In endeavouring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries, ask the following questions:

- 7.1.1. Is your country considering channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector and promoting good financial management to maximize its effectiveness, as recommended by Resolution WHA58.34?
- 7.1.2. Would your government be willing to consider binding agreements to ensure public funding of essential health R&D and access to lifesaving health and biomedical instruments?
- 7.1.3. Has your government considered any innovative financing mechanisms to secure support to innovation and access to essential health tools? If yes, which ones? If no, why not?
- 7.1.4. Is your country involved in any way in the activity of the results-oriented and time-limited Expert Working Group under the auspices of WHO, as provided in the GS and PoA? If yes, how? If no, why not?
- 7.1.5. Is your country creating a database of possible sources of financing for R&D? If yes, how? If no, why not?

### 7.2. In facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices, ask the following questions:

- 7.2.1. Has your country been involved by the WHO in documentation and dissemination of best practices in public-private and product development partnerships? Have you requested for involvement? If yes, why? If no, why not?
- 7.2.2. Has your country been involved by the WHO in development of tools to periodically assess performance of public-private and product development partnerships? Have you requested for involvement? If yes, why? If no, why not?

- 7.2.3. Is your country supporting public-private and product development partnerships and other appropriate R&D initiatives? If yes, how? If no, why not?
- 7.2.4. What is your country expecting from the Expert Working Group set up at the end of 2008 as part of the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA 61.21)?