Implementation, monitoring and evaluation for GSPOA

WHO Department of Public Health, Innovation and Intellectual Property

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PHI document on implementation, monitoring and evaluation of the Global Strategy and plan of action on public health, innovation and intellectual property

OBJECTIVE OF THIS DOCUMENT

This document aims to give an outline of the Department of Public Health, Innovation and Intellectual Property (PHI) approach for the implementation, monitoring and evaluation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) across all level of WHO and for its facilitation in countries.

The document gives an overview of the work being undertaken by PHI to mainstream the implementation activities inside WHO and the work planned for the facilitation of the implementation of the GSPOA at country level, together with the work done and planned for the development of the monitoring and evaluation framework to date.

The work undertaken for the implementation of element 8 - Establishing monitoring and reporting systems, is more extensively developed in the following pages. The document focuses in particular on the outline of the reporting mechanism to be set up by WHO and the overall monitoring and evaluation (M&E) system that will facilitate this process.

INTRODUCTION

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) was adopted by the World Health Assembly Member States to promote new thinking on innovation and access to medicines, which would encourage needs-driven research rather than purely market-driven research to target diseases that disproportionately affect people in developing countries. It was envisaged that by promoting and fostering such new thinking WHO would play a more strategic and central role in the relationship between public health and innovation and intellectual property.

The eight key-elements of the GSPOA are the following:

(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 IP to contribute to innovation and to promote public health
(6) Improving delivery and access
(7) Promoting sustainable financing mechanisms
(8) Establishing monitoring and reporting systems.

The GSPOA covers broad areas of research and development (R&D), including the use and dissemination of R&D knowledge, as well as it is concerned with methods to leverage funds for health R&D. It is inspired by WHO's guiding and proposing role on research for health, helping member States to develop national health R&D plans, to harmonize national legislation, to enhance innovation capacities and to better use all the flexibilities that international legislation on intellectual property offers.
DEVELOPMENT OF GSPOA IMPLEMENTATION, MONITORING AND EVALUATION STRATEGY FOR WHO

During discussions to understand the most effective way to implement the Global Strategy PHI, in collaboration with relevant stakeholders, developed and initiated parallel processes as follow:

- one aiming at mainstreaming implementation activities inside WHO, with identification of lead department that oversees the implementation of each element of the strategy and guarantee the flow of information. PHI maintains the coordinating role

- one to facilitate a regional development of implementation plan, with country specific mechanisms and inclusion of locally-developed M&E systems

- the third to build the reporting system at central level (HQ) and develop an M&E system that will pull information from and provide feedback to country systems and other relevant stakeholders.

Two approaches have been adopted to facilitate the implementation of the GSPOA:

1) A SHORT-TERM APPROACH: this approach aims at reporting on the overall implementation of the strategy, to highlight activities’ outcome on the existing situation. Meanwhile, pro-actively promoting the implementation of the strategy at country level

2) A LONG-TERM APPROACH: this approach concentrates on consolidation of work under-going and implementation of monitoring and evaluation systems that derive from country experiences and that relies on centralized information-sharing points, managed at HQ level.

Both these two approaches rely on funds that needs to be made available for the establishment of implementation mechanisms at global and country level as well as for the M&E.

Short term approach

For the first approach, PHI is developing an implementation proposal to be shared and refined with regions and member states that can help define a framework to achieve the aim of the global strategy, using current experiences that are under-going mainly in some regions¹.

¹ For example, PAHO is developing an Platform for Innovation and Access for Health (see link http://new.paho.org/hq/index2.php?option=com_content&do_pdf=1&id=2168 ), and the Africa Union together with the Council on Research for Health and New Partnership for Africa’s Development (NEPAD) developed a grid to design strategies at country level for pharmaceutical innovation. (See Strengthening Pharmaceutical Innovation in Africa - Designing strategies for national pharmaceutical innovation: choices
M&E for GSPOA

For immediate monitoring PHI developed a background document for discussion that set the basis for the preparation of the first progress report to the 2012 World Health Assembly and that gives a outline of a proposed web-based platform for information sharing that will create the link between the two mentioned approaches (short and long term). The discussion document reflects the comments provided by WHO staff, the informal advisory group on M&E for GSPOA\(^2\), and other external implementing stakeholders.

In the background document for discussion around the monitoring and evaluation setting up, each element has a lead WHO Department that is in charge of the following activities:

- involve the relevant stakeholders that implement specific action of the strategy and coordinate the various inputs,

- identify information need for reporting and its data sources

- develop methodologies for collection and analysis of data

- develop the analysis and provide inputs to the 2012 Progress Report regarding the element of the report under its responsibility.

This multiple-partner system, under PHI overall coordination, will allow progresses in the setting up of the M&E system, meanwhile providing on-going reports over such a complex and wide-breadth subject as the one of the global strategy.

The 2012 Report to the World Health Assembly will be developed around the approved progress indicators, establishing baselines and providing an analysis of the progress made in the implementation of each element, when possible through the indicators, but mainly focusing on the spirit of each element. The Report will provide Member States with relevant information to inform the discussion of how to proceed to realize the goals of the Strategy, identifying gaps to be filled in terms of specific actions needed and data to be collected.

**Long term approach**

The role of PHI in the long term is both to facilitate the initiatives of WHO Departments in the implementation of the strategy and to assist Member States in the implementation of the strategy at country level. This stems from the fact that the majority of the specific actions and sub-actions have member states as the lead stakeholders, and that the strategy requires country-ownership in the driving process.

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2 ToR of the group, list of members
That is the reason for the emphasis that this implementation framework set on the country implementation mechanisms.

When those mechanisms will be developed and endorsed at country level, and the corresponding monitoring systems will be operational, the reporting mechanism at central level should derive data from the latter.

PHI is engaging in facilitating the setting-up of these mechanisms, using this framework as a basis for discussion with Regions, Countries and other stakeholders.

**STAKEHOLDER RESPONSIBILITIES**

The eight elements and 108 corresponding actions defined in the GSPOA are or will be implemented by several stakeholders\(^3\). These stakeholders include: WHO Member States, Non-Governmental Organizations, Pharmaceutical Industry, academia, civil society organizations, WIPO, WTO, UNCTAD, UNIDO and WHO. Success in implementing the Strategy will require strong coordination and joint efforts, as well as on-going and timely reporting. This monitoring and evaluation framework reflects this consideration and takes into account the involvement of all the listed stakeholders.

When mechanisms for the implementation of the global strategy will be available at country and/or regional levels, together with the specific monitoring and reporting systems locally developed, this framework will be modified accordingly to reflect the specific indicators and targets set and endorsed.

However, to ensure ownership and identification of all the stakeholders, this framework will be presented and refined in consultation with the major contributor for the implementation of the GSPOA.

**OBJECTIVE OF THE M&E FRAMEWORK**

The aim of this exercise is to conceptualize the system required in Element 8 of the Global Strategy and to develop a mechanism that allows to understand the progress made by the stakeholders in the implementation of the specific actions of the global strategy and to give policy makers the possibility to evaluate the positive or negative long-term change produced by the strategy on relevant issues like innovation and access to health products, resource mobilization and enhancement of needs-driven essential health research and development relevant to diseases that disproportionally affects developing countries.

At present, the following proposal has been commented by WHO, WIPO and the Council on Research for Health staff and it will need to be shared with other partners and

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\(^3\) http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf
GUIDING PRINCIPLES FOR M&E SYSTEM

The framework and the system for the monitoring and evaluation of the implementation of the GSPOA build upon the following guiding principles:

1- HARMONIZATION AND NO DUPLICATION - avoid duplication of activities at all level of the system and stimulate the endorsement by all the stakeholders of a synergistic reporting system

2- EFFICIENCY - efficiently utilize all data sources already used by WHO and the other stakeholders

3- QUALITY - ensure the quality of the data through WHO Departments' and other stakeholders' control

4- GRASS ROOT LEVEL DATA - privilege tools to collect data at country level, ensuring the same data are used for R&D development when appropriate.

5- AGREED DEFINITIONS - work within the indicators approved by the World Health Assembly and improve the monitoring system by agreeing on the definition of each term of the indicators

6- CONTINUOUS EVALUATION - Improve the quality of the reporting system on an ongoing basis (pilot the implementation of the system and integrate the lessons learned thereby)

7- SUSTAINABILITY - develop the system to ensure sustainability in maintenance and functioning over time. Make available information and communication technology and tools that are user-friendly in order to meet future requirements and latest developments.

8- REALTIME UP-DATING - ensure collection and availability of up-to-date documents and information. Existing documents and information are up-dated immediately and automatically when their original source is up-dated.

This system relies on M&E systems in place at country/regional level. The work on country M&E for the GSPOA should generate the information needed for global monitoring, distributing the reporting burden among stakeholders.

These principles stem, in particular, from the Bamako Global Ministerial Forum on Research for Health in November 2008, during which Ministers agreed that WHO ensures that the architecture, governance and implementation of its research activities are in unison with the Strategy on Research for Health and the GSPOA on public health, innovation, and intellectual property.
**Progress Indicators**

The first set of indicators to monitor the progress of the GSPOA was approved by the World Health Assembly in 2009. However, the Assembly took "note of the need periodically to review and refine them" and added that "where the indicators are quantitative, the Secretariat shall provide complementary information on the implementation of the specific actions".

Having the first set of indicators adopted, in August 2009 PHI established an internal working group to coordinate next steps for the development of the GSPOA M&E. However, since most of the indicators refer to the number of countries that realized or developed specific activities, policies or plans, PHI is setting up a reporting system that allows to investigate the qualitative information related to those activities, policies or plans, in the belief that this exercise is useful if it can be used by Member States and development agencies to have a comprehensive picture of what is needed to enhance innovation, strengthen capacities, improve access and mobilize financial resources.

**Current WHO monitoring systems**

As a first step to develop the framework and outline the system, data sources were mapped for all the departments and units in WHO that have any information relevant for the implementation of the GSPOA. Available data sources were tracked and analyzed. As an example, the exercise that was conducted inside WHO had the aim to verify the potentiality of the existing reporting systems. It demonstrated that the WHO Medium Term Strategic Plan (MTSP) represents a source of information for the purpose of GSPOA reporting, being the work-plan of the entire Organization, originating from clear and comprehensive strategic objectives, counting on a set of progress indicators and relying on a consolidated reporting system. Data are collected from Regional Offices and the headquarters via facilitators, which are designated at unit/department/cluster level.

The Global Strategy adds a set of activities to the MTSP that had not initially been integrated or covered by MTSP Indicators. The following figure represent the intersections among WHO core activities (in red WHO), the activities already planned and linked to the GSPOA (purple - I), a new set of activities that will be included in the future WHO work-plans but that currently are not covered by MTSP (blue - II) and the GSPOA activities who's lead stakeholder is not WHO (Members States, Academia, other intergovernmental international organizations etc., in green - III).

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7 WHO Medium-Term Strategic Plan (2006) and 2008-2013 (Amended) – Available at: http://apps.who.int/gb/e/e_amtsp3.html
8 http://apps.who.int/gb/e/e_amtsp.html
During the tracking exercise conducted inside WHO, another monitoring and reporting system was analysed and it will have strong links with the M&E system for the GSPOA. This monitoring and reporting system is the one that will be set up for the WHO Strategy on Research for Health. This strategy will be discussed and approved during the 63rd World Health Assembly; it relates to the management and organization of research activities within WHO, following three guiding principles (quality, impact, and inclusiveness) and proposing five goals that pertain to the organization priorities, capacity, standards, and translation of research. The Strategy addresses WHO activities on R&D, promotes good research practice, informs WHO agenda on R&D, enhances WHO role in capacity building at country level for R&D and for knowledge management, ultimately supporting the development of robust national research systems. The Strategy defines output indicators that can be matched with the indicators of the GSPOA. The efforts for the collection of data related to common indicators will be shared between PHI and RPC.

For the purposes of GSPOA M&E, the use of the MTSP information is highly recommended, as it reflects WHO mainstream activities.
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health) are at present not covered by WHO work-plan (MTSP). Considering that these two elements strongly involve other leading stakeholders like Governments, health-related industries, WIPO, WTO, UNCTAD and concerned communities, coordinating activities and interactions with them in order to identify indicators and to establish a reporting system are important.

Among these interaction, a major step was taken by WHO Director General addressing her colleagues at WTO and WIPO through a document on "Collaboration between WHO, WIPO and WTO with regard to public health and intellectual property" where the basis for a structured consultative process was set out and in which WIPO and WTO recognized GSPOA implementation activities as one of their priority.

**Data sources and reporting systems external to WHO**

Several external partners, such as the Global Forum for Health Research and the Council on Health Research for Development, are participating in the process of collecting and collating data for the purpose of monitoring.

As a means for establishing coordination relationships among the many stakeholders to facilitate the collection of data and further definition of a comprehensive reporting system PHI is currently establishing more formal consultative and informative forums, coalitions and networks that involve all these stakeholders.

The wide variety of the sources of data is one of the strengths of this system but also represent a major challenge for the accountability of the system itself. For this reason, the system will integrate processes that ensure the reliability of the sources and guarantee the grounding of the information provided. In fact, the final aim of this monitoring exercise is to provide policy makers with reliable information built on evidence and relevant for the decision making process.

For some of the information to be collected PHI is engaging relevant partners and stakeholders to set up specific initiatives for the confrontation on those data.

**Current needs and future steps**

For the development of a complete monitoring system targets for the expected results and a timeframe for each indicator is needed, giving a possible progression of expected results in time, so that progress reports on the implementation can have a comparison base to show possible gaps between expected intermediate results and real achievements.

The development of the monitoring and evaluation system will be revised and guided by the Advisory Group. In fact, the described system still has gaps that need to be filled. However,

Given the novelty of this exercise, PHI proposes to test/pilot it addressing either a single element or a set of indicators or an implementing region or a group of activities so that it will become clear what is missing and how PHI can address these gaps. Moreover, since a wide variety of initiatives to implement the strategy and to collect data for purpose of monitoring are still in their developing stage, PHI is not able to provide a comprehensive definition of all the aspect of this system, also because possibilities of new contributors, new sources of data and information etc. are still being discovered at present. Therefore,
the proposed system will need continuous refinement to incorporate all the initiatives set up for the GSPOA.

However, ahead of the coming WHA, PHI hosted the first meeting of the informal advisory group of experts, meanwhile starting the procedure for its formal constitution. PHI will provide a budgeted plan to realize the M&E system in its full potential.

**Proposed M&E platform**

The GSPOA involves many actors, mainly Governments and other international organizations, and requires the possibility to manage and make available an enormous/huge quantity of data and information that comes from a wide variety of sources. This implies having a powerful technology base to be able to contain all the information and be accessible to all the interested parties. Given the wide sources of information (Member States, International Intergovernmental Agencies, Academia, NGOs etc.), to monitor the progress of the activities carried out under the GSPOA the use of technology is highly recommended and probably the only way to reach as many interested parties as possible. PHI therefore suggests that an internet platform is set up under WHO domain. This platform should have the following characteristics:

- membership to access the platform should be controlled by WHO
- feeding of the platform should be left directly to the Member States via their accredited institutions
- the uploading process should happen through a defined tool set up to meet the countries' reporting needs and combined with the existing reporting instruments, and accompanied by clear guidelines and instructions
- a big share of the information should be automatically retrieved from those existing reporting systems (linking directly with the source databases).

The concept of a web-platform is useful mainly for the following reasons:

- responsibility for uploaded information in the hands of countries, that can choose what to share with WHO and that double-check the pre-filled parts coming from existing databases in use inside and outside WHO;
- respect of national autonomy, since the relevance of the additional information provided for monitoring purposes is evaluated by the country itself;
- possibility to be expanded to contain more information, generated through the various forums set up for implementation of specific aspects of the global strategy;
- possibility to question the DB according to the needs of the authorized user;
- possibility to be linked to other DB on line and up-date it as soon as the primary source is up-dated;
Moreover, this platform allows the creation of country profiles that can be compiled taking into consideration information contained in data sources at present not linked together.

Monitoring progress depends on input, process and output indicators and hence is reliant on routinely collected data from Member States and relevant institutions: the aim of this platform is to collect validated data and to link together various information coming from different sources. Its innovative aspect is the capacity to link information that will be analysed under a “cause-effect lens”, and to harmonize data and information giving a comprehensive picture of the health research and development (in terms of funding and financing, human resources, technology, centres, legislation, policies, priorities etc.) at global, regional and national level.

PHI recognizes however that, given the wide spectrum of actions stated in the global strategy, the number of implementers and the initiatives that were already existent when the global strategy came into force, it's very difficult to state direct casual links between activities and changes in the specific area observed. Mainly, in fact, it is implied that the observed (or expected) changes cannot be produced by the set of activities of the strategy alone, but will be the result of a combination of various factors playing together on the R&D scene.

The platform should link to external databases that are created and populated by other implementers (NGOs, Academia, etc.), and be a repository for relevant documentation that will be produced during the implementation of the strategy. The content of the platform will be accessed by WHO only to produce and publish reports directed to the World Health Assembly and for the other reporting relevant to inform decision making process at all level. As for the WHO reporting system for the GSPOA implementation, the same principle will be applied to the up-loading/feeding process from countries (avoiding duplication of activities, efficient utilization of existing data sources, extension of existing tools to collect data).

At present, PHI in collaboration with the Council on Health Research for Development (COHRED), has developed a trial presentation of the web-based platform, to show preliminary results and work in progress and to give a sense of the possibility that this web-based platform has to harmonize the activities of different partners and give a comprehensive outline of the implementation and monitoring process of the global strategy.

LINK TO BASELINE FOR TRIPS (DORA) AND TECH TRANSFER REPORT

ANTICIPATED CHALLENGES FOR M&E IMPLEMENTATION

The initial analysis of the implementation requirements for the monitoring and evaluation of the GSPOA raises the following issues:
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- tracking of information requires major efforts given the large number of implementers. Regions and Countries are key in this, and country capacity constraints may be encountered in the process

- some of the actions contained in the strategy and in the plan are in general term, the implementation plan is again in quite general terms, and indications of objectives and outputs is missing

- the logic model structure needs to be developed: inputs (financial, human and material resources)-process (activities)-outputs (products and services)-outcomes (short- and medium-term effects of outputs)-impact (long term change produced directly or indirectly)

- difficulty to clearly state direct attribution (in terms of inputs-processes and outputs), mainly contribution to global results/impact

- difficulties in data availability

- financial constraint: costing of the M&E system to give the clear idea of the scale of the operation (surveys, adaptation of existing reporting tools, regular consultation with relevant stakeholders, team of evaluators for the 2012 exercise, technology platform and links to relevant external databases).