Monitoring and evaluation framework
for the Global Strategy and Plan of Action
on Public Health, Innovation
and Intellectual Property

Draft for discussion

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Table of contents

ABOUT THIS DOCUMENT ............................................................................................................................. 3

BACKGROUND .................................................................................................................................................. 3


The three levels of implementation for the Global Strategy ........................................................................ 4

MONITORING AND EVALUATION FRAMEWORK STRUCTURE ................................................................ 4

Aim and objectives of the M&E framework ................................................................................................. 4

Result-Based Management and monitoring approach ................................................................................. 4

The logic model ............................................................................................................................................. 6

IMPLEMENTATION OF THE FRAMEWORK ................................................................................................. 12

Implementation approaches for element 8 “Establishing monitoring and reporting systems” .................. 12

Work-plan for M&E framework development and implementation ............................................................... 13

1) Strategy implementation arrangements at regional/country level and corresponding national M&E systems ........................................................................................................................................................................ 16

2) 2012 and 2014 Progress Reports .............................................................................................................. 18

3) Web-based platform for the M&E of GSPA-PHI ..................................................................................... 18

4) Programme revision and comprehensive evaluation (2014-2015) ......................................................... 19

LEARNING BY DOING .................................................................................................................................. 20

ANTICIPATED CHALLENGES ..................................................................................................................... 21

Annex 1 .......................................................................................................................................................... 23

Annex 2 .......................................................................................................................................................... 25

Annex 3 .......................................................................................................................................................... 27
ABOUT THIS DOCUMENT

This document gives an overview of the monitoring and evaluation framework for the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) developed by the Department of Public Health, Innovation and Intellectual Property (PHI). This document explains also how PHI will implement the monitoring and evaluation plan, focusing in particular on the outline of the reporting mechanism to be set up by WHO.

One of the element of the GSPA-PHI (Element 8) states that: “Systems should be established to monitor performance and progress of the Strategy. A progress report will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the strategy will be undertaken after four years.”

Additionally, action (8.1) establishes that measuring performance and progress towards objectives contained in the GSPOA should include the following activities and priority issues:

a) Establish systems to monitor performance and progress of the implementation of each element of the GSPOA.

This document illustrates the development of the implementation of action 8.1 a).

BACKGROUND

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

Lack of innovation and access to existing health products, including diagnostics, vaccines and medicines, remains one of the most serious global health problems. Although considerable progress in terms of global access to health products has been made in recent years, including with regard to the prevention, diagnosis and treatment of diseases, developing countries nevertheless often remain excluded from the benefits of modern science and access is hindered by a variety of complex and intertwined factors, including among many other high medicine prices, lack of financing of R&D of relevant diseases, unfavourable trade agreements, low innovative capacity in some countries, weaknesses in drug procurement and supply management and weak health systems.

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property was approved by WHO Member States in 2008 and offers a holistic approach to this complex issue. It aims to stimulate new thinking on access to medicines and innovation.

The GSPA-PHI proposes objectives and priorities for setting the R&D needs-based agenda, for promoting innovation and associated skills in countries, for sharing existing knowledge through technology transfer initiatives and the management and application of intellectual property rights according to pro-public health criteria, to improve access to medicines as well as to mobilize resources.

Responsibility for implementation is scattered among a large number of diverse stakeholders, including governments, academia, civil society organizations, international intergovernmental organizations and the private sector.

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1 2010, 2012 and 2014
2 2012
The breath of the strategy is vast and challenging and the WHO Department of Public Health, Innovation and Intellectual Property (PHI) is required to set up a performance monitoring system in order to provide member states and the other stakeholders with regular up-dates on the results achieved and evidence on the future needs for their interventions.

**The three levels of implementation for the Global Strategy**

The implementation plan for the Global Strategy represents the way GSPA-PHI intends to engage itself and the relevant stakeholders in the realization of the objectives of the GSPA-PHI. According to the plan Member States are the key stakeholders that are to take forward many of the specific actions specified in the GSPA while it is the role of the WHO to provide them with technical assistance and evidence to inform their decision-making process.

The plan has been developed, together with the global stakeholders and experts in each specific field covered by the elements of the strategy, with a view to providing a clear vision of the process that WHO is setting up to implement the strategy. Finalization of this implementation plan, however, cannot be completed without involving the six WHO regional offices and Member States.

This means that the implementation plan will take place at three levels: a) at the global level, where activities are carried out in collaboration with global partners and where WHO, given its role and convening power, will assume a primary role in taking the activities forward; b) at the regional level, where initiatives will be developed that engage the regions; c) at the national level, where ownership and endorsement is assured and the gap in the country's capacities to innovation in health is addressed.

**MONITORING AND EVALUATION FRAMEWORK STRUCTURE**

**Aim and objectives of the M&E framework**

The aim of the monitoring and evaluation framework is as follow:

- To create evidence for informed decision making for Member States, mainly at policy level, and to provide information for accountability and performance improvement.

The objectives are:

- To develop a mechanism that allows for an understanding and monitoring of the progress made by stakeholders in the implementation of specific actions of the global strategy
- To help countries to build their own M&E system that can be used to measure countries' progress
- To give policy makers the possibility to evaluate long-term changes produced by the strategy on relevant issues, such as innovation and access to health products, sustainable resource mobilization for health research and enhancement of needs-driven essential health research relevant to diseases that disproportionally affects developing countries.

**Result-Based Management and monitoring approach**

In the “Programme for Reform”, presented by the former United Nation (UN) Secretary General to the UN General Assembly in 1997, Kofi Annan proposed that the UN placed greater emphasis on results in its planning, budgeting and reporting “with the aim of shifting the United Nations
programme budget from a system of input accounting to results-based accountability...”. The focus of planning, budgeting, reporting and oversight thereby shifted from how things are done to what is accomplished. Since then, the notion of Result-Based Management (RBM) became a central aspect within the UN system and a global trend among international organizations. The principles of “managing for results” was especially highlighted in the 2005 Paris Declaration on Aid Effectiveness and reaffirmed in the Accra Agenda for Action in 2008 as part of the efforts to work together in a participatory approach to strengthen countries’ capacity to reach agreed development objectives and to promote accountability of all major stakeholders in the pursuit of results.

From an institutional point of view, the basic purposes of RBM systems are to generate and use performance information for:

1. accountability reporting to external stakeholders,
2. learning and improving performance and
3. decision-making.

The same 2 milestones in the field of international cooperation (Paris Declaration and Accra Agenda) state the importance of country ownership in development policies and programmes, reinforcing the idea that developing countries' institutions and systems (i.e. public financial management, procurement, audit, monitoring and evaluation, social and environmental assessment) should be strengthened in order to be able to rely on them for the programmes' successful implementation.

In addition, the Accra agenda for Action reaffirms the importance of development policies designed at country level and country-led monitoring and evaluation.\(^1\)

The Global Strategy is the perfect frame in which the principles of RBM can be implemented: in fact, to maximize relevance, the RBM approach must be applied, without exceptions, to all organizational levels. Each is expected to define anticipated results for its own work, which in an aggregative manner contribute to the achievement of the overall or high-level expected outcomes for the programme/strategy/policy as a whole, irrespective of the scale, volume or complexity involved.

Given the three levels of implementation of the global strategy (national, regional and global), the strong accent that WHO Member States have put on the expected results of this multi-sectoral policy, and the need for coordinated actions, following the principles and methods of the RBM facilitates the attainments of the best results.

Evidence-based policy making, defined in 1999 by P.T. Davies as an approach that "helps people make well informed decisions about policies, programmes, and projects by putting the best available evidence at the hart of policy development and implementation", has been gaining importance over the past years among institutions like national and local governments and international intergovernamental organizations.

The use of strong evidence in policy making has been demonstrated also with the work of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). The global strategy is the product of negotiations among Member States that were informed by the evidence generated by various studies commissioned for the preparation of the report of the CIPIH. Thanks to this report, the response to the complex issue of innovation and public health has been holistic,
based on the principle of inter-sectoral action and cooperation\(^1\), as introduced in the International Conference on Primary Health Care in Alma-Ata, Kazakhstan, in 1978.

**The logic model**

Having decided to adopt the principles of the result-based management to design the monitoring and reporting framework, the priority is to define clearly the results' chain\(^2\), in order to be able to identify the objectives of the future actions and plan activities to reach them.

The overall GSPOA-PHI M&E system is a sum of monitoring and evaluation sub-systems that are or will be present in WHO and other organizations. In fact, the implementation of the global strategy has been mainstreamed inside the organizations and relies on well-established and successful programmes that take care of the single aspects of the strategy, providing also detailed information and data to measure progress.

Relying on the monitoring and reporting systems set up by these relevant departments, PHI developed the one for GSPA-PHI concentrating its efforts on the establishment of reporting tools at national level to capture the missing information and to aggregate the existing one and on mechanisms for a deep analysis and timely reporting to the Member States.

The M&E framework is composed of 2 parts:

1) one that will help to monitor from a global perspective the development in terms of access and innovation as the aim of the global strategy suggests. This second part, given the broad scope of the strategy and the multiple organizations and institutions contributing to its aim, will be used by PHI to monitor the evolution of the situation in terms of short and long term outcomes regardless of the actions that initiated the process, while setting up a mechanism to allow implementers and stakeholders to report on their activities in order to be able to link inputs/actions to the outcomes observed and

2) one dedicated to the tracking and monitoring of WHO, and PHI in particular, achievements in implementing the global strategy following the logic of a results plan or chain of results, from activities to outputs that will produce middle/intermediate changes and final outcomes (as represented in figure 1).

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\(1\) Stern, 1990; Spassof, 1992; Walker, 1992; Evans & Vega, 2006; Health Promotion International Volume 9, Issue 3, Pp. 143-144

\(2\) The purpose of the results chain is to build a logical relationship between the expected results at different programmatic levels, it is built on the principle of aggregation of results, which implies that the aggregation of results at one level should make it possible to achieve the expected result of the higher level.
The framework is based on output and outcome indicators and tries to identify longer term changes (or impact) that the strategy will produce, linking them to impact indicators that will be defined over time. The output indicators derive from the implementation plan for each element that PHI developed, together with, among others, the Council on Health Research for Development (COHRED) and the Special Programme for Research and Training on Tropical Diseases (TDR).

The World Health Assembly approved in 2009 thirty-two progress indicators, that have been classified during the framework development as output or outcome indicators.

The M&E framework has three main components:

1. The results’ chain
2. The planning, monitoring and evaluation cycle (management cycle)
3. The M&E plan

1. The result chain
The overall strategy result chain is represented in the following picture:\footnote{To simplify the reading, actions and output has been omitted, but are included in the section dedicated to each short-term outcome or element.}

![Figure 2: the results chain](image)

The results chain takes into consideration **8 expected results** (or short-term outcomes) defined by...
the policy-setters during the development of the plan of action:

(a) element 1 - to provide an assessment of the public health needs of developing countries with respect to diseases that disproportionately affect developing countries and identify their R&D priorities at the national, regional and international levels (prioritizing R&D needs)

(b) element 2 - to promote R&D focusing on Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases (promoting research and development)

(c) element 3 - to build and improve innovative capacity for research and development, particularly in developing countries (building and improving innovative capacity)

(d) element 4 - to improve, promote and accelerate transfer of technology between developed and developing countries as well as among developing countries (transfer of technology)

(e) element 5 - to encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, possible incentive schemes for R&D (application and management of intellectual property to contribute to innovation and promote public health)

(f) element 6 - to improve delivery of and access to all health products and medical devices by effectively overcoming barriers to access (improving delivery and access)

(g) element 7 - to secure and enhance sustainable financing mechanisms for R&D and to develop and deliver health products and medical devices to address the health needs of developing countries (promoting sustainable financing mechanisms)

(h) element 8 - to develop mechanisms to monitor and evaluate the implementation of the strategy and plan of action, including reporting systems (establishing monitoring and reporting systems).

The idea at the basis of the strategy is that in order to improve innovation for and access to health products and technologies there are "intermediate results" to be achieved, such as innovation promoted, capacity built, access improved and resources mobilized. However, these results can be achieved only if research and development (R&D) needs are prioritized (element 1), health R&D is promoted (element 2), innovative capacity at country level is built (element 3), knowledge is shared through technology transfer (element 4), IP is applied and managed to promote public health (element 5), supply and delivery systems are improved (element 6), sustainable financing mechanisms are secured (element7) and planning and reporting are aligned at national and international levels (element 8).

However, 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 is difficult to state direct causal links between activities and changes observed in the specific area (attributions). Mainly, in fact, the observed (or expected) changes will be the result of a combination of various factors playing together on the health R&D scene (contributions). Having thus clearly defined the aim of the strategy and the milestones that lead the way to a successful implementation, the definition of implementation activities, needed resources, procedures and timetable by governments, WHO and the other stakeholders will be done with a backward process (from expected results to activities and inputs, in order to design the logic model pictured before).
2. The management cycle

The picture below illustrates an adaptation of the result-based management cycle to illustrate the steps that each implementing stakeholder should take in order to develop and implement effective action plans.

**2. Planning, monitoring and evaluation cycle**

or management cycle

Figure 3

**Planning**

This virtuous circle starts with the planning process during which decision/policy makers draft their policies and plans according to the evidence available and the defined expected results. The result chain is defined, identifying clearly the deliverables and intended changes (targets). In the same process is included the definition of the monitoring and evaluation system, including M&E work-plan, indicators, measurement and progress review, reporting and capacities needed.

**Implementation**

The implementation phase is based on the plans and is monitored progressively, according to targets and progress indicators.

**Monitoring and Reporting**

Reporting is done according to the M&E work-plan that defines the audience, the content, the format and the frequency.
**Evaluation and Learning**

The plan should include also self-evaluation and independent evaluation, their results being indispensable to improve and adjust the initial plans. In fact, creating the right environment to share experience, disseminate and discuss progress, results and issues and to incorporate feedbacks in the relevant phase of the implementation, is conducive to overall learning and improvement.

3. **The M&E plan**

Considering the links in terms of outcomes and impact, the M&E plan can be represented as follow:

![Figure 4](image)

**Implementation**

Stakeholders will implement their action plans according to their timing and procedures, in order to produce the outputs identified and will make sure that these induce the changes envisaged in the short and long term course.

**Monitoring and reporting**

Each expected result (output, outcome and longer term change or impact) generated by actions that governments, international intergovernmental organizations and all the other stakeholders...
will carry out, will be measured using the **progress indicators** that were approved by the World Health Assembly in 2009\(^1\) (annex 1). These indicators cover the short-term outcome level (but some has been classified as output indicators) and are designed to give a picture of the overall implementation of the strategy. Each stakeholder will be responsible for the reporting of the activities and initiatives carried out, in order to allow WHO to fulfill its reporting obligation as stated by the WHO Member States.

PHI, in consultation with the relevant stakeholders, will develop and make available user-friendly reporting tools to facilitate the stakeholders’ duties.

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"\(^2\). The refinement of the indicators has already started, involving the current implementers of the actions to whom the specific indicator pertains.

**Measurement**

During the definition of the implementation plan for WHO and the corresponding M&E framework, other output indicators were identified. WHO is responsible for measuring and reporting according to the indicators and the timeline, as explicated in the lower part of the graph above. Given the nature of the reporting required by the Member States (progress in the implementation of the global strategy, whose stakeholders are governments, international intergovernmental organizations, NGOs, pharmaceutical industry, academia etc.) information needs to be made available to PHI in order for WHO to be able to analyse it and compile the reports.

The timeframe set for the global strategy limits the need and effectiveness of impact assessment, however PHI will develop new thinking on how to measure access and innovation starting from the two indicators currently used as a proxy:

1) Access to medicines index from **MDG Target 8.E**: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries, indicator 8.13 Proportion of population with access to affordable essential drugs on a sustainable basis

2) Nr of new chemical entities (NCE) for type II and III diseases and specific type I diseases affecting DC.

As mentioned before, PHI has already set up a process to refine the indicators, through internal consultations. The draft list of the new or modified indicators will be shared with the GSPA-PHI stakeholders in order to reach consensus on it. However, for each of the progress (outputs) and outcome indicators (including those approved by the WHA in 2009) the following information is provided to complete the framework:

- target
- baseline source
- indicators measurement: when and who
- source of verification (responsibility)

The **baseline** for most of the indicators will be set with the surveys that will be published in the 2012 progress report. For those indicators that have a corresponding WHO Medium Term

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\(^1\) A62_16Add2. http://apps.who.int/gb/e/e_wha62.html

Strategic Plan\(^1\) (MTSP) Indicator, the responsible departments will provide the data and background/complementary information (see annex 2).

For the **measurement of the targets through the indicators** PHI will follow the same methodology applied to the collection of the baselines, even if after the 2012 progress report the reporting system from countries should be ready to allow collection of data in a more structured way and with an increased number of data sources. The major deadline for indicators measurement is set for 2012 and 2014. WHO departments are responsible for the collection and analysis of data used to up-date the progress in the implementation.

The **source** (or means) of verification is represented by the process or document or tool that can be used to determine the quality of the information provided through the indicator.

The example of the detailed indicators' matrix for an element of the strategy can be found in annex 3 (output and outcome level).

**IMPLEMENTATION OF THE FRAMEWORK**

*Implementation approaches for element 8 "Establishing monitoring and reporting systems"*

The monitoring and reporting system is a combination of current existing efforts and new mechanisms to pull information together, and it requires joint actions among the stakeholders and a step-by-step process that leverages on the on-going positive experiences.

Two approaches have been adopted to facilitate the implementation of element 8 of the global strategy, namely the establishment of monitoring and reporting systems:

1) **A SHORT TERM APPROACH:** this approach aims at reporting on the initial steps of the implementation, mainly the preparatory work that has been undertaken to facilitate the roll-out of the programme. The short-term approach has its major output in the 2012 Progress Report, that is due to Member States in 2012.

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

The role of PHI in the long term is both to assist Member States in the implementation of the strategy at country level and to facilitate the initiatives of WHO Departments in the implementation of the strategy. This stems from the fact that the majority of the specific actions and sub-actions have WHO Member States as the lead stakeholders, and that the strategy requires country-ownership in the driving process. The major outputs of this approach will be the finalization of implementation plans and corresponding M&E systems at country level and a web-based M&E platform to be used as a management and reporting tool both at national and global level.

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\(^1\) WHO Medium-Term Strategic Plan (2006) and 2008-2013 (Amended) – Available at: http://apps.who.int/gb/e/e_amtsp3.html
Work-plan for M&E framework development and implementation

The following figure gives highlights of the M&E framework development process.

Figure 5 - Process to develop the M&E framework

The proposed work-plan for the refinement and implementation of the M&E framework for GSPOA is shown in the table below.
<table>
<thead>
<tr>
<th>Activity</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informal consultative group work</td>
<td>April</td>
<td>May</td>
<td>June</td>
<td>July</td>
<td>August</td>
<td>Sept</td>
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<tr>
<td>Refinement of indicators</td>
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<td>Formal consultative group appoint</td>
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<td>Finalize M&amp;E framework</td>
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<tr>
<td>Develop M&amp;E plan</td>
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<td>Consult regional/country focal pts</td>
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<tr>
<td>Support country M&amp;E mechanisms</td>
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<tr>
<td>Develop web-based M&amp;E platform Mock-up</td>
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<tr>
<td>Develop data dictionary/standards</td>
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<tr>
<td>Data collection tools &amp; instruments</td>
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<tr>
<td>Commission research for baseline</td>
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<td>Stakeholders consultations</td>
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<tr>
<td>Develop up-loading tools for the platform (through regional/country consultations)</td>
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<tr>
<td>Develop web-based M&amp;E platform</td>
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<tr>
<td>Populate data platform</td>
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<tr>
<td>Advocacy</td>
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<tr>
<td>Source sustainable funding</td>
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<tr>
<td>Ongoing monitoring /feedback</td>
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<td>Evaluation report to WHA</td>
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<tr>
<td>Report to WHA every 2 years</td>
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</table>
The efforts for the M&E implementation are strongly conditioned by the reporting requirements. In fact, according to WHA Resolutions 61.21 and 62.16, and to the plan of action included in the annex of WHA 62.16, the requirements of the global strategy in terms of reporting and evaluation are represented in the figure below and fall directly under PHI’s responsibility. (Reporting on progress (WHA 61.21): every two years (2010-2012-2014); Comprehensive evaluation of the strategy: after four years (2012); Overall programme review (WHA 62.16): in 2015).

Monitoring requirements

![Monitoring requirements diagram]

However, in order to provide Member States with relevant and consistent information, PHI is engaging in the facilitation of the strategy implementation at country level. In fact, as explained throughout this document, the M&E framework relies on national data made available according to the country M&E framework developed together with the national implementation plan.

The activities that PHI has planned for the implementation of element 8 are:

1. development of strategy implementation arrangement at national and regional level
2. preparation and distribution of 2012 and 2014 Progress Reports
3. development of a web-based platform for M&E for GSPA-PHI
4. revision and comprehensive evaluation of the strategy in 2014-2015.
1) Strategy implementation arrangements at regional/country level and corresponding national M&E systems

The main objective of the global strategy is to boost innovation for diseases that disproportionately affect developing countries and to raise the access to health products and technologies in these countries.

Interventions work when there is a full involvement of the recipient countries in the design, planning and implementation of the interventions\(^\text{10}\).

The approach to fully implement the global strategy is to engage national governments in the development of national strategy and plan of action for public health, innovation and intellectual property (NSPA-PHI).

The 7 steps towards a NSPA-PHI could be summarized in the following:

1) assess country situation
2) set up a task force at government level to steer and oversee the process; seek alliances outside the country to create synergies when needed
3) develop an implementation plan/national plan of action
4) communicate the government intentions' to the interested institutions
5) integrate the national M&E system in order to include the information needed to track the progress of the implementation
6) assess periodically the country's progress
7) share the results (accountability, improvement, motivation, fund-raising)

PHI interest is to engage national governments and regions in the development of implementation plans tailored on the specific needs of the country. In order to do so, PHI is finalizing a country assessment tool to map the current innovation system and access situation at national level, the existence of an enabling environment and the gaps to be filled in order for the country to achieve its results. Given the multi-sectoral approach that the strategy requires, a strong commitment from the national political and economic institutions is a pre-requisite.

In parallel, PHI will assist the country to design a monitoring and evaluation framework for the national strategy, that responds to the needs and capacity of the country and that builds on the existing system and knowledge and that complements the expertise at the national level with that at regional and global levels.

PHI will develop a monitoring and evaluation web-based platform (see further down in this document) as a long-term solution for the collection of data on relevant issues of the global strategy. The platform will serve as a tracking system and a tool to systematize the flow of information from Member States and other stakeholders. In the long run, countries' strengthened capacity to collect, systematize and analyse information regarding the specific topics of GSPA-PHI will enable them to exploit the potentials of the web-based platform, which in turns also assures the tool's sustainability.

\(^{10}\) Moving from policies to results by developing national capacities for country-led monitoring and evaluation systems, M. Segone in From Policies to results. Developing capacities for country monitoring and evaluation systems, VV.AA. Unicef (2010)
The international literature provides indications on norms and standards and best practices on evaluation systems, but this is not the case for the setting up of sustainable, cost-effective and participative monitoring practices, that provide the basis for learning from evidence and adjustment of policies.\footnote{McKay, K. (2007) \textit{How to Build M&E Systems to Support Better Government}, Washington, World Bank}

The importance and implications of national contexts in developing monitoring and evaluation systems supports the idea developed by PHI to tailor the M&E framework and data collection and reporting tools/systems to countries' capacities and needs.

PHI will work in close collaboration with country institutions and organizations (government departments, regulatory authority, academia, NGOs, evaluation societies and other professional associations etc.) using its convening power to involve the expertise of the WHO departments to implement specific aspects of the strategy and those of external stakeholders that have a pro-active role in the implementation of the strategy and in the collection of data.

The process will start with a desk review regarding the availability of data, as well as the existence of collecting mechanisms, expertise to develop and implement M&E plans, supportive technologies, interactions among relevant institutions and organizations etc. The assessment will provide information to identify gaps in the system and empowerment needs to enable the implementation of a monitoring and evaluation plan for GSPA-PHI. It will also inform the development of the tool that helps to bridge the gaps and to develop the expertise for M&E for the global strategy (training courses/workshops design and roll-out, framework design, M&E plan, definition of needed partnerships and networks etc).

The country will benefit from WHO's assistance in the development of its own monitoring and evaluation plan for GSPA-PHI, enhancing its capacities to network and synergize national resources and knowledge and complementing it with international and regional expertise and experiences.

Over time, the strengthened M&E system will be the source of information to inform and guide the national policy, providing evidence on the various aspects of the determinants of access to health products and innovation systems. Its link to the web-based M&E platform will ensure that the two systems (national and global) will complement each other in terms of the exchange of information.

Various countries are already engaged in different ways in the implementation of the global strategy and PHI will work with them to:

- finalize and test the country assessment tool
- finalize and test the checklist "7 steps to a NSPA-PHI: an actionable national strategy" (listed above), that has been drafted to help countries to start the planning process for the implementation of the strategy
- develop the \textit{national strategy and plan of action} or implementation plan, defining the inter-sectoral policies and the interventions to be carried out
• design the monitoring framework, according to national capacities and existing systems.
More countries to be engaged in the implementation process can be identified through consultations with global players like COHRED, WHO regions and country offices, NGOs and other international intergovernmental organizations.

2) 2012 and 2014 Progress Reports
The global strategy requires WHO to report on the progress of the implementation of the specific actions. The first Report in 2012 will provide Member States with relevant information to inform the discussion on how to proceed to realize the goals of the Strategy, identifying gaps in the implementation phase providing the basis to correct the approach and giving the opportunity for more effective policies and actions. The report will be developed around the approved progress indicators, establishing baselines and providing an analysis of the progress made in the implementation of each element, focusing on their spirit. The report will be a combination of case studies, country surveys and literature reviews. It will be a joint effort between PHI and stakeholder departments in WHO (namely, among others, the Departments of Essential Medicines and Policies, Traditional Medicine, and the Special Programme on Tropical Diseases Research). The 2014 Progress Report represents a major challenge, given that it will influence the debate about future commitments of Member States and possible new solutions following the 2015 overall programme review. The comprehensive evaluation of the strategy should be part of this report, given that the initial results of some activities could already be available and a first assessment of the effectiveness of the strategy could be relevant. More information on this aspect is contained in point 4 below.
According to PHI implementation plan, the setting up of monitoring and evaluation systems at country level and the availability of a web-based platform for M&E should allow an easier collection of data and information.

3) Web-based platform for the M&E of GSPA-PHI
The GSPA-PHI involves many actors, mainly Governments and other international organizations, and requires the possibility to manage and make available an considerable quantity of data and information that come 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 range of sources to obtain information (Member States, International Intergovernmental Agencies, Academia, NGOs etc.) and 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 in a timely manner. Monitoring progress depends on input, process and output indicators and hence has to rely on routinely collected data from Member States and relevant institutions.
PHI has therefore developed the idea of a web-based platform to be used as a tool to facilitate implementation and to provide information for the monitoring and reporting, collecting validated data and linking together various information coming from different sources. This platform has the following characteristics:

- membership to access the platform is controlled by WHO
- feeding of the platform is left directly to the Member States via their accredited institutions
- the up-loading process is happening through defined tools 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 is automatically retrieved from those existing reporting systems (linking directly with their data sources).

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

- responsibility for the content of uploaded information rests in the hands of countries, that can choose what to share with 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 database according to the needs of the authorized user;
- possibility to be linked to other database on line and to up-date it as soon as the primary source is up-dated.

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 innovation for and access to health products and technologies in developing countries.

The platform will be linked 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 data that Member States will choose to share and that will be up-loaded in 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 GSPA implementation, the up-loading/feeding process from countries will follow various good practices and principles with the aim to avoid duplication of activities, efficient use of existing data sources and extend the existing tools to collect data.

**4) Programme revision and comprehensive evaluation (2014-2015)**

Usually, WHO Member States call for periodic independent evaluations of WHO policies, programs, projects and operations. The results of evaluations and revisions contribute
to better informed decision-making, foster an environment of learning by doing and promote greater accountability for performance.

An evaluation is recommended to ascertain results to date for use in determining optimal projects for the strategy continuation. Value added from this evaluation is expected to be achieved through lessons learned and the development of more efficient and effective implementation plans, but also highlighting the gaps in the current implementation process (involvement and ownership at government level, funds, coordination arrangements, dissemination of on-going initiatives to create synergies with others, etc.).

The plan of action for element 8 point 43 (establishing monitoring and reporting systems in annex to Resolution WHA61.21) states that a comprehensive evaluation of the strategy will be undertaken in 2012. To evaluate such a strategy, given its broad scope and various areas of interest, a dedicated process will be established that will involve the leading stakeholders (WHO, WTO, WIPO, Unctad, governments and NGOs actively implementing the strategy) and evaluators from the implementing countries. In fact, the idea is to apply the principles of the country-led evaluations, where the countries lead and own the design, establishment and management of their own M&E system for GSPA.

As an initial thinking on the first strategy implementation evaluation, the research questions to be answered could be:

1. is the strategy well-known by the Member States?
2. are there the potentials for the strategy to be effective in its aim?
3. what are the main aspects of the strategy to be highlighted in order for the results to be achieved?
4. is the environment conducive to the expected results?

However, the definition of an implementable plan for the strategy has required a long process and currently implementation plans at country level do not yet exist for the majority of countries. This implies that a comprehensive evaluation of the implementation process at global and country level after four years could be incomplete and any further effort in this regard could furthermore be resource consuming. Probably, Member States could be interviewed during the 2011 WHA to give their opinion on the usefulness of such an exercise.

**LEARNING BY DOING**

The development of the monitoring and evaluation system has been done in consultation with other WHO M&E experts. Given the novelty of this exercise, PHI will consult countries and regions for their endorsement and will then test/pilot it in those countries where the implementation process is part of the national agenda, in order to clarify potential deficiencies and address possible gaps.

As part of the M&E framework for element 8 - Establishing monitoring and reporting systems, PHI defined progress and outcome indicators that reflect the willingness to use
monitoring and evaluation as a learning tool, in order to achieve the overall results, as shown in the picture below.

The framework at element level

Figure 7

ANTICIPATED CHALLENGES

The initial analysis of the implementation requirements for the monitoring and evaluation of the GSPOA raises the following issues and opportunities:

- *Keep the momentum alive*
  Governments’ interest on this issue is demonstrated by the two years-long intense negotiation that led to the approval of the GSPA PHI resolution. But the momentum of those years needs to be kept alive. In fact, to address the lack of innovation for health products for developing countries and the access to those products by their population, the solution can be found at global and local level. Global solution can be thought, developed, implemented and improved by WHO and its partner agencies (WTO, WIPO, Unctad, etc.). But for solution at national level the issue of innovation and access for developing countries needs to be on the national political agenda. And this requires an intense campaign by WHO to raise attention, awareness and commitment. In fact, to develop a M&E for the national implementation is necessary a sustained country involvement, since
national data needs to be derived and built at the country level, and its quality and timeliness has to be ensured.

- **Remove constrains**
  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.

- **Demonstrate cause-effect links**
  It is difficulty to link specific actions and observed changes (attribution in terms of inputs-processes, outputs and outcomes), mainly in fact the actions set up to implement the strategy are contributions to global results/impact.

- **Establish standards**
  Currently is very difficult to have data available for analysis and reporting and to aggregate those available given the lack of standards, for example in the field of research and research financing.

- **Mobilize resources**
  Costing of the M&E system showed the relevant resources that are needed (surveys, adaptation of existing reporting tools, regular consultation with relevant stakeholders, team of evaluators for the external independent evaluation, technology platform and links to relevant external databases). Synergize with existing mechanisms for collection of data and information and encourage investments in national monitoring and evaluation systems will allow better results in terms of monitoring and evaluation of the implementation of the strategy.
Annex 1  
*Progress Indicators approved by the 2009 World Health Assembly*

The code of the indicator indicates:

OP: Output indicator  
OC: outcome indicator  
OSI: overarching strategic indicator (as defined by the WHA2009, Res. 62.16 add.1)  
Number: the corresponding element of the Global Strategy

<table>
<thead>
<tr>
<th>GSPOA Indicators</th>
<th>GSPOA Indicator Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>OP1.a</td>
<td>Report of analysis of research and development gaps, including the public health consequences of these gaps in developing countries, completed and a report on this analysis produced, published and disseminated</td>
</tr>
<tr>
<td>OC1.b</td>
<td>Number of developing countries with national health-related research and development capacity-building plans which prioritize research and development based on identified public health needs and research and development gaps</td>
</tr>
<tr>
<td>OC1.c</td>
<td>No. of consensus reports on global research needs and priorities for a disease /type of intervention</td>
</tr>
<tr>
<td>OC2.a</td>
<td>No. of countries whose national strategic plans for the health workforce and related professionals include a research and development component</td>
</tr>
<tr>
<td>OC2.b</td>
<td>No. of new or strengthened initiatives (national, regional and global) on health related research and development, including between public and private entities</td>
</tr>
<tr>
<td>OC2.c</td>
<td>No. of new or strengthened initiatives aimed at providing efficient and affordable access to publications and information such as research knowledge, results and technology</td>
</tr>
<tr>
<td>OC2.d</td>
<td>No. of new or strengthened initiatives aimed at enhancing capacities to analyze and manage clinical trial data</td>
</tr>
<tr>
<td>OC2.e</td>
<td>Proportion of peer-reviewed publications where the main author’s institution is in developing countries</td>
</tr>
<tr>
<td>OC3.a</td>
<td>No. of new and existing research centres in developing countries strengthened through comprehensive institutional development and support</td>
</tr>
<tr>
<td>OC3.b</td>
<td>Proportion of developing countries in which national health research systems meet international standards</td>
</tr>
<tr>
<td>OP3.c</td>
<td>No. of countries whose national regulatory authorities have been assessed, supported and accredited</td>
</tr>
<tr>
<td>OP3d</td>
<td>No. of new/updated global quality, ethical standards, reference preparations, guidelines and tools for promoting the quality and effective regulation of health products (incl. vaccines, diagnostics, and medicines) and technologies</td>
</tr>
<tr>
<td>OC3.e</td>
<td>No. of countries with a national traditional medicines policy that includes research and development</td>
</tr>
<tr>
<td>OC4.a</td>
<td>No. of national, regional and global coordination and collaboration initiatives aimed at increasing and transfer of health-related technology, including between public and private entities</td>
</tr>
<tr>
<td>GSPOA Indicators</td>
<td>GSPOA Indicator Details</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>OC4.b</td>
<td>No. of countries with technology transfer strategies that include health-related technologies and relevant capacity-building components</td>
</tr>
<tr>
<td>OC5.b</td>
<td>No. of countries promoting and supporting efforts to strengthen capacities in the management and application of intellectual property rights in a manner oriented to public health needs and priorities of developing countries</td>
</tr>
<tr>
<td>OC5.c</td>
<td>No of countries integrating flexibilities for protection of public health of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)</td>
</tr>
<tr>
<td>OC6.a</td>
<td>No. of countries formulating and implementing official national policies on access, quality and use of essential medical products and technologies</td>
</tr>
<tr>
<td>OC6.b</td>
<td>No. of countries designing or strengthening comprehensive national procurement and supply systems</td>
</tr>
<tr>
<td>OC6.c</td>
<td>No of priority health products and diagnostic tools that have been assessed and prequalified for procurement by the UN</td>
</tr>
<tr>
<td>OC6.d</td>
<td>No. of countries possessing and implementing national or regional strategic plans for the health workforce and related professionals, including policies and management practices on incentives, regulation and retention</td>
</tr>
<tr>
<td>OC6.e</td>
<td>No. of countries that have an adequate number of qualified or trained health-related regulatory professionals and the specific areas of specialization where gaps exist</td>
</tr>
<tr>
<td>OP7.a</td>
<td>Submission of report of expert working group on research and development and financing</td>
</tr>
<tr>
<td>OC7.b</td>
<td>No. of new or strengthened sustainable financing initiatives including public-private initiatives</td>
</tr>
<tr>
<td>OC7.c</td>
<td>Increase in sustainable health-related research and development funding relevant to the strategy over the reporting period</td>
</tr>
<tr>
<td>OP8.a</td>
<td>Regular reporting on progress towards the implementation of the strategy</td>
</tr>
<tr>
<td>OC8.b</td>
<td>No. of new/strengthened sustainable initiatives at national, regional and global levels, including those by non-governmental stakeholders, to promote the implementation of the strategy</td>
</tr>
<tr>
<td>OP8.c</td>
<td>Submission of reports on the respective issues addressed in E8 of the strategy</td>
</tr>
<tr>
<td>OSI-OC1</td>
<td>No. of new and improved health products receiving internationally recognized approval for use, including information on the nature and novelty of these products</td>
</tr>
<tr>
<td>OSI-OC2</td>
<td>No. of new and improved interventions and implementation strategies whose effectiveness has been determined and the evidence made available to appropriate institutions for policy decisions</td>
</tr>
</tbody>
</table>
## Annex 2
### Matching of GSPOA indicators with MTSP OWERs indicators

<table>
<thead>
<tr>
<th>GSPOA Indicators</th>
<th>GSPOA Indicator Details</th>
<th>2009 Current MTSP indicators (amended version)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OC2.a</td>
<td>No. of countries whose national strategic plans for the health workforce and related professionals include a research and development component</td>
<td>OWER10.8 Health workforce information and knowledge base strengthened, and country capacities for policy analysis, planning, implementation, information-sharing and research built up</td>
</tr>
<tr>
<td>OC2.c</td>
<td>No. of new or strengthened initiatives aimed at providing efficient and affordable access to publications and information such as research knowledge, results and technology</td>
<td>MTSP10.5.1 Proportion of countries for which high quality profiles with core health statistics are available from its open-access databases (reworded)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MTSP10.7.2 Number of Member States with access to electronic international scientific journals and knowledge archives in health sciences as assessed by the WHO Global Observatory for eHealth biannual survey</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MTSP12.4.2 Number of pages in languages other than English available on WHO country and regional offices’ and headquarters’ web sites</td>
</tr>
<tr>
<td>OC2.e</td>
<td>Proportion of peer-reviewed publications where the main author’s institution is in developing countries</td>
<td>MTSP1.5.2 Proportion of peer-reviewed publications based on WHO-supported research where the main author’s institution is in a developing country</td>
</tr>
<tr>
<td>OC3.a</td>
<td>No. of new and existing research centers in developing countries strengthened through comprehensive institutional development and support</td>
<td>MTSP4.2.1 Number of research centers that have received an initial grant for comprehensive institutional development and support</td>
</tr>
<tr>
<td>OC3.b</td>
<td>Proportion of developing countries in which national health research systems meet international standards</td>
<td>MTSP10.6.1 Proportion of low- and middle-income countries in which national health-research systems meet internationally agreed minimum standards</td>
</tr>
<tr>
<td>OP3.c</td>
<td>No. of countries whose national regulatory authorities have been assessed, supported and accredited</td>
<td>MTSP11.2.4 Number of Member States for which the functionality of the national regulatory authorities has been assessed or supported</td>
</tr>
<tr>
<td>GSPOA Indicators</td>
<td>GSPOA Indicator Details</td>
<td>2009 Current MTSP indicators (amended version)</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>OC6.b</td>
<td>No. of countries designing or strengthening comprehensive national procurement and supply systems</td>
<td>MTSP11.1.2 Number of Member States receiving support to design or strengthen comprehensive national procurement or supply systems</td>
</tr>
<tr>
<td>OC6.c</td>
<td>No. of priority health products and diagnostic tools that have been assessed and prequalified for procurement by the UN</td>
<td>MTSP11.2.3 Number of priority medicines, vaccines, diagnostic tools and items of equipment that are prequalified for United Nations procurement</td>
</tr>
<tr>
<td>OC6.d</td>
<td>No. of countries possessing and implementing national or regional strategic plans for the health workforce and related professionals, including policies and management practices on incentives, regulation and retention</td>
<td>OWER10.8 Health workforce information and knowledge base strengthened, and country capacities for policy analysis, planning, implementation, information-sharing and research built up</td>
</tr>
<tr>
<td>OC7.c</td>
<td>Increase in sustainable health-related research and development funding relevant to the strategy over the reporting period</td>
<td>MTSP10.6.2 Number of Member States complying with the recommendation to dedicate at least 2% of their health budget to research (Commission on Health Research for Development, 1990)</td>
</tr>
<tr>
<td>OSI-OC1</td>
<td>No. of new and improved health products receiving internationally recognized approval for use, including information on the nature and novelty of these products</td>
<td>MTSP11.2.2 Number of assigned International Nonproprietary (generic) Names for medical products (information partially derived from this indicator)</td>
</tr>
</tbody>
</table>
Annex 3
OUTLINE of expected results framework and indicators matrix - example Element 1, specific action 1.1.a, output level only

Element: (1) Prioritizing research and development needs

**Sub-element:** (1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries

**Specific action:** 1.1 (a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries’ specific R&D needs in relation to Type I diseases

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### IMPLEMENTATION ACTIVITIES

| a1_1 | Creation of a group to undertake the mapping of global R&D with a view to identify gaps |
| a1_2 | Comprehensive literature reviews of previous such exercises at global level and production of a synthesis paper |
| a1_3 | Undertaking new mapping exercise with a view to:  
1. Compare the results with the previous studies and identify state of gaps in the current R&D  
2. Develop a methodology which can be adopted at regional and national level |

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### INDICATOR MEASUREMENT

<table>
<thead>
<tr>
<th>OUTPUT</th>
<th>Indic. code</th>
<th>PROGRESS INDICATOR</th>
<th>TARGET</th>
<th>BASELINE SOURCE</th>
<th>WHO</th>
<th>WHEN</th>
<th>source of verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>op1_1</td>
<td>A Synthesis paper about the <strong>previous mapping exercises</strong> at global level</td>
<td>OP1.a</td>
<td>Report of analysis of <strong>research and development gaps</strong>, including the <strong>public health consequences</strong> of these gaps in developing countries, completed and a report on this analysis <strong>produced, published and disseminated</strong> (OP1.a)</td>
<td>one report and methodology developed by 2012</td>
<td>NA</td>
<td>PHI</td>
<td>2012</td>
</tr>
<tr>
<td>op1_2</td>
<td><strong>New mapping of current R&amp;D</strong> at global level and gaps therein in comparison to previous such exercises</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>op1_3</td>
<td><strong>A methodology</strong> to undertake such <strong>mapping exercise at global level</strong> in future which is adaptable at regional and national level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
OUTLINE of expected results framework and indicators matrix - example Element 1, **outcome** level

**Element:** (1) Prioritizing research and development needs

**Sub-Element:** (1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries

**Sub-Element:** (1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels

<table>
<thead>
<tr>
<th>INDICATOR MEASUREMENT</th>
<th>OUTCOME INDICATORS (PHI revision of progress indicators approved by WHA)</th>
<th>TARGET</th>
<th>BASELINE SOURCE</th>
<th>WHO</th>
<th>WHEN</th>
<th>source of verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>OC1.b</td>
<td>N. OF DEVELOPING COUNTRIES THAT HAVE SET NATIONAL HEALTH RESEARCH PRIORITIES BASED ON IDENTIFIED NEEDS AND R&amp;D GAPS</td>
<td>having the maximum possible number of countries that undertook a priority setting exercise for national R&amp;D</td>
<td>literature review, new country surveys</td>
<td>PHI and COHRED</td>
<td>Publication of 2012 Progress Report</td>
<td>2012 progress report reviewed by internal WHO staff and external partners. Clearance procedure for submission to WHO governing bodies</td>
</tr>
<tr>
<td>OC1.c</td>
<td>N. OF CONSENSUS REPORTS ON GLOBAL RESEARCH PRIORITIES FOR A DISEASE OR TYPE OF INTERVENTION</td>
<td>providing stakeholders with a collection of useful reference document on global priority setting exercises</td>
<td>literature review, online search</td>
<td>PHI</td>
<td>Publication of 2012 Progress Report</td>
<td>2012 progress report reviewed by internal WHO staff and external partners. Clearance procedure for submission to WHO governing bodies</td>
</tr>
</tbody>
</table>