Report

Planning Meeting with Regional Advisers on Medicines for the Implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (26-27 August 2009)

The Planning Meeting was held 26-27 August 2009 at WHO Headquarters. The Executive Director of the Director-General's Office, Dr. Anne-Marie Worning, in her opening remarks, highlighted the complexities associated with the negotiations and now the implementation of the global strategy and plan of action on public health, innovation and intellectual property (GSPOA) and its increasing importance and far-reaching implications. Relationships with other organizations and agencies that are important partners in the implementation of the GSPOA have to be intensified. Funding is needed to keep and expand activities to an acceptable level. There is also a need for the distribution of labour and responsibilities among the key players. The economic crisis and limited financial resources require WHO to prioritize work and to concentrate on concrete and tangible activities. The development of work-plans for 2010/2011 on headquarter, regional and country level is in progress and composite work-plans that define roles and attribute responsibilities to all have to be compiled.

The meeting was chaired by the new Director of Public Health, Innovation and Intellectual Property (PHI). The Regional Advisers on Medicines of AMRO, EMRO, EURO, and WPRO, officials from the Special Programme for Research and Training in Tropical Diseases (TDR), Research Policy and Cooperation (RPC), Essential Medicines and Pharmaceutical Policies (EMP), UNITAID, Members of PHI and advisers to PHI attended the meeting. AFRO participated through a teleconference for part of the meeting.

The purpose of the meeting was to agree on key components of the implementation plan of the GSPOA and to consider approaches on how coordination and collaboration can be achieved with stakeholders identified in the GSPOA. The **objectives** set for the meeting were to:

- Provide an update on quick-start actions and report on activities that are not necessarily routine business of WHO
- Propose mechanisms for collaboration in the implementation of GSPOA and ways of engaging various stakeholders in its implementation
- Develop an organization-wide implementation strategy particularly where WHO is a lead stakeholder
- Hold a discussion on a monitoring and evaluation framework in line with element 8

The **expected outcomes** of the meeting were to:

- Identify what WHO does best and how to leverage actions outside the sphere of influence of WHO
- Discuss the distribution of labour and definition of responsibilities between different levels of the organization
- Define implementation mechanisms that can link with other sectors and stakeholders
- Link the GSPOA with other initiatives that would promote harmonization and alignment (WHO-led, non-WHO-led, HQ, regional and country level actions)
- To solicit proposals for advocacy and promotion of the GSPOA
- Explore possible funding sources and mobilization of resources for the implementation of the GSPOA

The implementation of the strategy is a great challenge. For instance, multiple stakeholders are (jointly) responsible for implementation, but there is a lack of clarity on how activities will be coordinated, particularly where WHO is not the lead stakeholder. Some stakeholders have been proactive in the implementation of the strategy and this level of enthusiasm has to be maintained. The coordination of activities could be more efficiently managed. Another challenge is to make sure that activities are implemented and coordinated even where WHO is not a lead stakeholder, however it is not clear how this can be reported upon. Ways of working that will optimize the use of the limited resources and maximize effectiveness have to be sought. There is a need for a communication framework together with materials and a media package, to address the

current shortcomings in the dissemination of the GSPOA at various levels within and outside WHO. At national level there is a need for coordination mechanisms and coherence of activities.

The report on the quick start programme which was initiated based on WHA Resolution 61.21 was distributed. Beyond the quick-start programme, the mapping of activities undertaken by WHO departments was recommended. This mapping would take into account ongoing work and new initiatives.

Presentations in relation to Elements 1-3, 4 and 5

Elements 1-3: Promoting research and prioritization

The GSPOA is a major driver for the TDR strategy and has presented an enhanced opportunity for leveraging resources. For effective implementation of the GSPOA, an additional 30% of TDR budget would be needed. A number of activities are currently under way including an initiative in Africa, the African Network for Drugs and Diagnostics Discovery and Innovation (ANDI) which is being developed as a sustainable platform for promoting and building capacity for product R&D innovation. It will be governed and managed from within Africa and will enable institutions to collaborate cost-effectively across the continent. Similar types of initiatives are discussed in other regions.

Work leading up to WHA 62 had estimated that about 147 billion dollars were needed globally to implement the research based component of the whole GSPOA and this translated to 25-30 billion per year. There is value in developing a top level business plan for the implementation of the GSPOA that would demonstrate how different components of the elements link together, the contributions and activities of different stakeholders and how funds would be utilized for the various activities. This would not only ensure coherence, but would be a common document used for fund raising and advocacy.

The WHO Health Research Strategy is underpinned by principles of quality, impact and inclusiveness. There is a direct link between the GSPOA and the WHO Health Research Strategy. A framework for priority setting has been developed which would be of use for the GSPOA. An opportunity for building networks, strengthening countries' health research systems exists, however this would require coordination which is currently a huge challenge. WHO has many tools that can be used within the framework of the GSPOA, even though a good set of communications tools is needed. These could be developed at HQ and disseminated backed up with case studies. M&E could be a good opportunity for collection of data to report on the GSPOA.

Ethics are a cross cutting issue, and there is a lot of fragmentation in-house. There is a need for working more collaboratively within the organization. Mapping of activities within and outside the organization can bring more coherence. At the global level, WHO has a role in supporting the development of norms and standards for research ethics. An opportunity exists for building networks, and strengthening national ethics committees as part of the implementation of GSPOA.

Participants also discussed the proposal for regional platforms to facilitate research and whether this could be a useful approach to foster research.

Traditional Medicine (TRM)

A quick-start program is underway and a number of ongoing activities were reported. TRM is an important area for both developing and developed countries alike.

Element 4 and 5: Transfer of technology and management and application of IP

PHI is currently working on a EC-funded project on transfer of technology (ToT) and local production, with other partners, namely UNCTAD and ICTSD. ToT is a cross-cutting issue that is largely driven outside WHO. The usefulness of involving UNIDO in the project was highlighted because of UNIDO's role in local production. The regions required information on the process for the selection of case studies and countries.

Collaboration with other international intergovernmental organizations

The main organizations that are specifically mentioned in the GSPOA are WIPO, WTO and UNCTAD. There were suggestions for inclusion of other agencies like UNESCO and UNIDO. There is a need to define the scope of activities, partners, attuned to regions and countries, define approaches to working together at respective levels and ways of coordinating efforts between the different organizations. A framework was under development on collaborating mechanisms, which will be finalized following further inputs.

A presentation on current ongoing work of PHI in the field of health, intellectual property and trade was shared with the participants. There is a need for an implementation plan for the actions of the GSPOA that relate to health, intellectual property and trade, that are directed to WHO. Activities will have to be coordinated between WHO headquarters and regions.

UNITAID patent pool

A presentation on patent pools was shared with the participants that reported on the progress made thus far. Time lines and a full implementation plan will be presented to the UNITAID board in December 2009. Establishment of an entity that will provide administration of the pool should take place in 2010. The successful collaboration with the regional and country offices in relation to the effort to reach out to the generic industry in developing countries was highlighted. Overall, there seems to be a cultural change in industry from companies investing in exclusive technology to sharing technologies. A number of technical questions regarding the specific features of the planned patent pool were raised.

Element 8: Monitoring and Evaluation

For M&E there is not a single one size fits all model. The presentation outlined some thoughts about the evaluation of the GSPOA. The mandate to report stems from paragraph 10 of resolution WHA61.21 and element 8. The WHA 62 also adopted a list of 32 indicators which have to be refined further. These were distributed by elements

objectives, sources, methods for collection, methods for interpretation and analysis.

Regarding the monitoring and evaluation, participants pointed out the need to come up with a baseline/starting point and the need to define upfront the purpose of the evaluation process. A template for reporting by regions would have to be developed, and endorsed by the regions.

WHO's role was discussed and the following issues were identified as key in the implementation of the strategy (not in prioritized order):

- Convening power
- Advocacy role
- Use and generation of evidence
- Technical assistance
- Standard setting
- Act as facilitator

Regional presentations

Some of the regions have already begun work and presented their implementation activities. Many of these activities are part of on-going work that is now captured and presented under the GSPOA. All regions emphasized the need for resources at regional level, because no additional resources have become available for regional implementation. The Regions are at different levels in term of progress and there are different needs and interests. Participants thus emphasized and agreed that implementation will differ from region to region and from country to country. Implementation therefore has to recognize regional specificity and activities can be quite different in scope, scale and focus. The areas covered include innovative products and delivery, research activities, networks, priority setting, research to support implementation and scale-up, research strategy, M&E framework, regional platforms and coordination of activities. Some regions are considering the creation of regional advisory groups for regional implementation of the strategy. Issues raised by nearly all regions were the need for better coordination, mobilization of additional resources, and improved external and internal communication.

AMRO

The presentation demonstrated how the global mandate had been translated to regional level. The strategic approach that was being followed by the region and which could serve as a guide for other regional processes was presented. The region has countries that were active during the negotiations and that also had an added advantage in their resource base and technical capacity. Key issues for implementation were mainly on the need for the establishment of mechanisms for communication between regions and headquarters, and the need for the mapping of implementation activities. The key focus was the identification of missing activities related to innovation and incorporation of new technologies.

EMRO

The presentation provided an overview on how implementation of GSPOA has been initiated in the region and what activities have been planned. In EMRO EMP has joined hands with RPC and both units are developing a regional implementation plan for the GSPOA as a joint responsibility. Overall, countries of the EMRO region were less active in the negotiation process than other regions, a matter that might have contributed to the implementation process in the region. Thus, it is important to involve all the countries in the implementation with varying objectives.

The following points were highlighted:

- the urgent need for resource mobilization to support implementation in the region
- the need for a reporting template for the regional offices
- clarification of the roles and responsibilities between HQ and RO
- the need to improve internal and external communication on the GSPOA in a simple and effective way, including communication between HQ and RO
- the need for facilitate inter-regional collaboration and meetings between PHI and regional focal points
- the need to enhance the opportunity to use the upcoming RC meeting to promote GSPOA

WPRO

As a quick start, the two broad themes are on innovation and access. There is a need for facilitation of dialogue between different sectors. The mapping of activities as well as the development of national plans will be undertaken. There was one country which had established a health forum (China). Intersectoral dialogue and interregional activities were being planned. The current Asia-specific network, which is supported by TDR, needs to be strengthened. In the area of access and intellectual property, selected Pacific Islands Countries (PICs) including Fiji, Papua New Guinea, Samoa, Solomon Islands, Tonga and Vanuatu as well as Lao PDR and the Maldives attended the Informal Inter-country Consultation on Public Health and Intellectual Property Rights for selected Pacific Island Countries (25-27 March 2009). Technical supports are also provided for countries to undertake a national consultation involving different sectors on public health and intellectual property. Consultation and coordination with regard to different programs which are involved in research will be undertaken, especially in promoting research and innovation, to explore feasible options for implementation of the GSPOA.

EURO

The region is large and diverse with several of the transitional countries having access challenges. The EU, Switzerland and Norway were very active during the IGWG, and are now actively contributing resources to the HQ Secretariat. There is a need for recognition of interregional specificity and regional specificity. Within EURO the Medicines programme is currently the only one implementing the GSPOA. The European Advisory Committee on Health Research was discontinued, but is currently being reconstituted, and the CD department with the TDR focal point are fully occupied with the pandemic influenza issues. Currently there is no additional funding for the GSPOA in EURO. Advocacy work at the level of the EU is essential and a number of related activities that can be linked to the GSPOA are underway e.g. WHO/EURO country support on strengthening regulation, or the innovative medicines initiative by the EU.

AFRO

The Regional Committee has tabled the GSPOA on the agenda with an outline of activities that are relevant to the African region. This will further assist with the

refinement of the plan and identification of partners and stakeholders. Two institutions have been evaluated with respect to TRM with specific reference to R&D. ANDI has been a main activity jointly planned with HQ, and its status is currently under discussion. Local production has been discussed with AU Health Ministers. In AFRO better collaboration is needed between the medicines department and RPC to achieve coherence. A number of workshops on intellectual property and public health have been held, and this has been a joint collaboration between HQ and the regional office.

Briefing on Expert Working Group on R&D financing

A brief report was provided by Elil Renganathan on the work of the expert working group on R&D financing (EWG). All the regional advisors received the recent documents produced by the EWG for comments.

Main issues highlighted for implementation

Some general issues were highlighted which are key to the implementation of the strategy. The most important are the following:

1. Communication of GSPOA was considered a problem that needed immediate attention. A communication framework is proposed which will cover different levels and target audience.

   (a) Communication within WHO

   - Information materials and a media pack on the GSPOA and WHO department (in the short term some communication materials need to be developed and disseminated e.g. a brochure about GSPOA. A short documentary film can also be an idea to be explored).
   - Communication to regions via regional offices and regional governance structures.
   - Administration lines of communication to establish responsible department/focal points is urgently needed. This would require a letter to all RDs from the office of the Director-General.

   (b) Communication outside WHO

Social marketing for advocacy of the GSPOA is necessary to promote knowledge of GSPOA which is currently limited. A media pack should be developed soon.

2. A mechanism across the whole organization is needed to raise and allocate resources for the implementation of the GSPOA. A comprehensive and innovative fundraising approach is needed that covers both HQ and the Regional Offices.
3. Development of a top level business plan for the GSPOA and objectives that are visible within the WHO mid-term strategic plan.
4. A coordination mechanism needs to be established for the implementation of the GSPOA.
5. An objective way of allocating tasks between HQ and the Regional Offices should be initiated.
6. Internal consultation within WHO should be conducted to map the resources and actions available for the implementation of GSPOA. The original matrix developed on ongoing work and new activities can be considered for this purpose.
7. The relationship between the GSPOA and the WHO Research Strategy should be mapped to avoid overlap and duplication of effort.
8. The need for collaboration and partnership with other relevant organizations was emphasized.
9. Interregional collaboration and sharing of information should be promoted.
10. Technology transfer and local production are key areas of focus that should involve regional counterparts.
11. Working with partners and other stakeholders and reporting on non-WHO led activities was key and a system for this line of reporting should be established.
12. The implementation of the strategy will need coordination and collaboration on all levels, including the national level. Countries that have already initiated national implementation such as Switzerland and France might serve as examples for how to manage national implementation.
13. Mechanisms for institutionalisation of the GSPOA are required and regional offices should develop the implementation infrastructure. PAHO/AMRO has a framework that can be considered.

14. A guidance is needed for how to incorporate the implementation plan in biennial planning process of the organization at all levels of the organization.

In view of implementation of the GSPOA, the meeting recommended prioritization of issues. The following issues are grouped into short, medium and long term.

Issues	**Priority**	**Stakeholder**
Communication framework	Short term	HQ
Development of business plan	Short term	HQ
Communication to regional offices for appointment of focal points	Short term	HQ
Proposal of structure for coordination	Short term	HQ, RO
Inventory of what is happening under each element	Short to medium term	HQ, RO
Division of labour across three levels of the organization	Short term	HQ, RO
M & E framework and refinement of indicators	Short term	HQ
Development of a template for reporting from regional offices	Short to medium term	HQ, RO
Collection of baseline data	Medium term	HQ
Fundraising	Short to medium term	HQ/RO
Advocacy	Short-long term	HQ and RO