Perspective

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Sri Lanka's national assessment on innovation and intellectual property for access to medical products

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ABSTRACT

In 2008, the *Global strategy and plan of action on public health, innovation and intellectual property* (GSPA-PHI) was launched by the World Health Organization, to stimulate fresh thinking on innovation in, and access to, medicines and to build sustainable research on diseases disproportionately affecting low- and middle-income countries. As part of the activities of the GSPA-PHI, Sri Lanka has been the first country to date to assess the national environment for medical technology and innovation. This year-long, multistakeholder, participative analysis facilitated identification of clear and implementable policy recommendations, for the government to increase its effectiveness in promoting innovation in health products through institutional development, investment and coordination among all areas relevant to public health. The assessment also highlighted areas for priority action, including closing the technology gap in development of health products, facilitating technology transfer, and building the health-research and allied workforces. The Sri Lankan experience will inform the ongoing independent external evaluation of the GSPA-PHI worldwide. The assessment process coincided with the passing of the *National Medicines Regulatory Authority Act* in 2015. In addition, there is growing recognition that regional cooperation will be critical to improving access to medical products in the future. Sri Lanka is therefore actively promoting cooperation to establish a regional regulatory affairs network. Lessons learnt from the Sri Lankan assessment may also benefit other countries embarking on a national GSPA-PHI assessment.

Key words: access to medical products, innovation, intellectual property, Sri Lanka

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BACKGROUND

For the diseases that disproportionally affect low- and middle-income countries (LMICs), there is an urgent need to promote access to new and existing medicines and to develop new diagnostics and vaccines. Renewed focus on this vital task in the past two decades has seen fresh thinking and creative new approaches to pharmaceutical research. For example, World Health Organization (WHO) Member States, the for-profit sector, charitable foundations and nongovernmental organizations have undertaken partnering initiatives to develop new products for diseases that disproportionately affect LMICs. Some of these partnerships, such as the TB Alliance and Medicines for Malaria Venture, are financed by public agencies and private foundations, and have partnered with research institutes and private pharmaceutical companies to develop faster-acting, novel treatments. Recognition that the challenge is not only the inability to purchase existing medical products but also the lack of products that are specifically designed for resource-limited settings, has stimulated non-profit donors to focus on research projects that are not commercially attractive to the for-profit sector.[1]

These non-traditional approaches to pharmaceutical research and development (R&D) have largely been motivated in response to controversy in recent years over the appropriate roles of innovation and intellectual property in global health. Entrenched positions have been taken on both sides of the debate: on one side, defenders of patents for new medical products argue that this protection is essential if the pharmaceutical industry is to invest in future R&D; on the other side, civil-society groups cite the human rights of people in LMICs both to access essential medicines and to benefit from innovations in medical science.[2] As observed in *The world health report 2013: research for universal health coverage*: "Both free knowledge (as a public good) and highly restricted

knowledge (limited by its proprietary nature) can be obstacles to improving health; the former may discourage innovation and the latter may limit access to the products of innovation".[3]

Globally, balance between these two opposing forces has been sought through a series of activities, including multistakeholder initiatives convened by WHO. In 2004, the independent Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was set up by WHO to examine these issues in response to the 2003 World Health Assembly resolution WHA56.27 on intellectual property rights, innovation and public health.[4] The comprehensive analysis done by CIPIH had a particular focus on funding and incentive mechanisms for the creation of new medicines, vaccines and diagnostic tests to tackle diseases that disproportionately affect LMICs.[5] The CIPIH report in 2006 made key recommendations aimed at fostering innovation and improving access to drugs.[6]

Responding to this changing R&D landscape, WHO established a Department of Public Health, Innovation and Intellectual Property in 2006, to address the resources needed for LMICs; assess the impact of innovation and intellectual property on access to medicines; explore innovative funding mechanisms for R&D; and provide evidence-based policy-making recommendations.[2]

GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

Following extensive consultation on the CIPIH recommendations, an intergovernmental working group negotiated the *Global strategy and plan of action on public health, innovation and intellectual property* (GSPA-PHI),[7] which was launched in 2008. The aims of the GSPA-PHI are (i) to stimulate fresh thinking on innovation and access to medicines; and (ii) to secure an enhanced and sustainable basis for needs-driven essential health R&D relevant to diseases that disproportionately affect LMICs. The strategy is broad and comprises eight elements, 25 sub-elements and 108 specific actions. These elements and actions are designed to set, prioritize and promote research; foster and build innovation capacity; promote technology transfer and local production of medical products; promote the management and application of intellectual property rights to improve public health; improve access to medical products; mobilize resources for R&D relevant to this area; and monitor and evaluate the progress in all these areas.

A key theme of the strategy was that Member States should be responsible for a large portion of the 108 action points. To facilitate these activities at the national level, the WHO Department of Public Health, Innovation and Intellectual Property developed a questionnaire-based tool to enable systematic assessment of a Member State's environment in relation to medical technology and innovation.[8] Use of this tool allows benchmarking and identification of strengths and weaknesses in implementing the GSPA-PHI, and highlights where the Member State and other stakeholders, including WHO, need to focus attention and assistance. The assessment tool also allows identification of clear and implementable policy recommendations for governments to increase their effectiveness in promoting innovation within their countries, through institutional development, and investment in and coordination of areas relevant to health innovation.

The tool had been pilot-tested by the WHO Department of Public Health, Innovation and Intellectual Property in Kenya and employed by the United Republic of Tanzania. In the WHO South-East Asia Region, Sri Lanka took the lead for this assessment. Prior to the national assessment, Sri Lanka had been actively involved in the GSPA-PHI processes at regional and global levels. To date, the Sri Lankan assessment is the only report published by a ministry of health. This account of the participative processes used and lessons learnt may benefit other WHO Member States embarking on a national GSPA-PHI assessment.

THE PROCESS OF GSPA-PHI ASSESSMENT IN SRI LANKA

To lead the national assessment, the Ministry of Health, Nutrition and Indigenous Medicine nominated a focal point in February 2014, which was supported by a working group of WHO representatives and external experts. The multistage process of assessment was highly collaborative and efforts were made to include the widest range of stakeholders, such as from government, industry and academia. In brief, a list of potential stakeholder institutions was researched and members of the working group visited the institutions in person to explain the assessment tool and facilitate data collection. A discussion paper was drafted for validation by the stakeholder institutions during a national consultative workshop. A second consultative workshop was organized to produce a final draft report of the national assessment, incorporating all submissions and comments provided by the stakeholder institutions. The final report was launched in Colombo in March 2015, with the participation of all stakeholders.[9]

The step-wise process of the assessment brought together representatives from diverse institutions nationwide and across a range of government ministries. The very broad remit of the GSPA-PHI necessitated engaging not only stakeholders relevant to core areas of the health sector, such as policy-making on medical-product regulation and health-workforce retention, but also those involved in critical ancillary areas, such as basic sciences research, trade and tariffs on medical products and the management of intellectual property rights. The assessment workshops were therefore unique opportunities to bring together disparate specialists to focus on the future needs of the country.

RESULTS OF THE GSPA-PHI ASSESSMENT IN SRI LANKA

With respect to health R&D, the assessment enabled detailed identification and description of all relevant policies and public and private infrastructure. Funding for health-related R&D and the institutions responsible for disbursement and monitoring

the utilization of such funds were also mapped. In addition, the current status of discovery science and clinical research, especially in relation to conducting clinical research, regulatory and ethics governance of clinical research, and measures for protection of intellectual property, were delineated.

The assessment report noted that the science and technology policy of Sri Lanka should be updated and that the scope of the policy should be broadened to include specific provisions for pharmaceutical products. Although several institutions promote R&D in general, and health R&D in particular, there is a clear need both to improve coordination of these efforts to support public health and to prioritize investment in health R&D.

Critical gaps in the country's ability to build relevant human capital were identified. For example, the *Human resources for health strategic plan 2009–2018* of the Ministry of Health, Nutrition and Indigenous Medicine does not include any capacity-building of the health workforce in R&D.[10] And, since the local pharmaceutical manufacturing industry is relatively small in Sri Lanka, expertise in industrial pharmacy, technology management and other related areas of pharmaceutical manufacturing is limited. The Sri Lanka Inventors Commission, under the purview of the Ministry of Technology and Research, has fostered collaboration between inventors and industry. With appropriate modifications, this mechanism could be extended to the public health services sector in Sri Lanka.

The assessment's benchmarking of pharmaceutical manufacturing capacity illustrated that current capacity to develop health products, particularly pharmaceuticals and related technologies, is weak and that major investments in the pharmaceutical sector are needed if public health objectives are to be achieved. International transfer of technology, local production policies, capacity and legislation, and industry's capacity for local production of existing products were examined in detail. The analysis highlighted a concerning technology gap in health products and a limited amount of technology transfer. There is no formal process for technology assessment in Sri Lanka at present. The expertise available to undertake such an exercise also appears to be limited. Rectification of this situation was identified as an urgent need. Additional points for future consideration included the preparation and implementation of a national pharmaceutical industry development plan, and investment to increase the viability of the local manufacturing industry. Sri Lanka's need for more trained human resources to manage good manufacturing practice requirements was also noted.

Regarding the impact of trade agreements on intellectual property and patents that are relevant to public health, the assessment showed that there is no coordination within or among different stakeholder ministries. Participants proposed establishment of a permanent mechanism to bring together the ministries of health and trade and commerce, together with the National Intellectual Property Office.

With respect to improved delivery and access to affordable, quality medicines, the assessment process pointed towards the need for a high-level mechanism to coordinate relevant activities between the ministries of health, industry and finance. Currently, medical supplies account for around 20% of the annual health budget and there are well-established procurement procedures for pharmaceuticals, surgical supplies and equipment. Nevertheless, periodic shortages of medicines occur at public facilities. The urgent need to establish good storage and good distribution practices to overcome shortcomings in the supply chain was highlighted.

The assessment also highlighted the value of indigenous knowledge, including traditional medicine, noting that more research should be promoted to strengthen the evidence base. Although several attempts have been made to protect traditional knowledge, there is still no legal framework in place. Anecdotal evidence suggests that large amounts of traditional knowledge, particularly related to medicinal use, are exploited and taken out of the country through illegal means.

CONCLUSION AND NEXT STEPS

The Sri Lankan GSPA-PHI assessment has been timely. The assessment process coincided with the passing of the *National Medicines Regulatory Authority Act* in 2015.[11] The establishment of a new drug regulatory authority gives an opportunity to place a regulatory framework in line with the GSPA-PHI. There is growing realization that cooperation among Member States in the region is becoming increasingly important, owing to the complexity of pharmaceuticals, biologicals, vaccines, diagnostics and medical devices; globalization; threats to supply chains; and rising public expectations. Access to medical products is currently greatly influenced by regulatory requirements at national and international levels. Sri Lanka is thus actively promoting cooperation at regional level, to establish a regional regulatory affairs network.

From the global perspective, WHO has commissioned an independent external evaluation of the implementation of the eight elements and 108 specific actions of the GSPA-PHI.[7] Covering 2008–2015, the global evaluation will document achievements, gaps and remaining challenges and make recommendations on the way forward. The evaluators will look at activities of global, regional and national stakeholders, including assessing implementation by national governments, the WHO Secretariat and other relevant institutions and organizations. The analysis will include a global electronic survey of Member States. The findings and recommendations of this evaluation will be made available to Member States on completion and also presented to the 140th session of the Executive Board in January 2017.[12,13]

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