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# **Comprehensive Evaluation of the Implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property**

Corporate evaluation commissioned  
by the WHO Evaluation Office

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Report by Capra International Inc.

Evaluation Team: Gunter Rochow (Team Leader), Dr. Ágnes Czimbalmos (Co-Team Leader), Dr. Fidel Arévalo, Mary Cole, Anand Dhavle, Enid Kaabunga, David Lees, Mart Leesti, John Miner, Dr. Zakariaou Njournemi, Youssef Ouadi, Axel Rex, Waldo Rochow and Goberdhan Singh, as well as the translators - Marje Aksli, Helena Chou Kwan, Dorothy Ferdinand, Khawla Hasna and Ivonne Wong.

1557 Bella Vista Dr.  
Cumberland  
Ontario K4C 1A7

Tel: +1-613-833-2494 x105  
[www.capra.net](http://www.capra.net)

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## ACRONYMS

AIDS	Acquired Immuno Deficiency Syndrome
ANDI	African Network for Drug and Diagnostic Innovation
ASEAN	Association of South-East Asian Nations
CEWG	Consultative Expert Working Group on Research and Development: Financing and Coordination
CO	Country office
GSPOA	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
HIV	Human Immunodeficiency Virus
ICTSD	International Conference on Trade and Sustainable Development
IP	Intellectual property
NGO	Nongovernmental organization
NVivo	NVivo is a qualitative data analysis software
OIO	Other International Intergovernmental Organizations
ORS	Other Relevant Stakeholders
PDP	Product Development Partnerships
PPP	Public-Private Partnership
R&D	Research and Development
RO	Regional office
SSFFC	Substandard/spurious/falsely labelled/falsified/counterfeit medical products
TDR	UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases
TOR	Terms of Reference
TRIPS	Trade-related aspects of intellectual property rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEG	United Nations Evaluation Group
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
UNITAID	Established in 2006 by Brazil, Chile, France, Norway and the United Kingdom. UNITAID is hosted and administered by the WHO.
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



## EXECUTIVE SUMMARY

*In 2008, following a two-year negotiation process, the Sixty-first World Health Assembly debated the output of an inter-governmental working group and subsequently the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) was adopted in resolution WHA61.21.*

*The aim of the strategy is to promote new thinking on innovation and access to medicines and to secure an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases that disproportionately affect developing countries. The strategy comprises eight elements, 25 sub-elements and 108 specific actions.*

*In the following year (2009) resolution WHA62.16 finalized the list of stakeholder categories responsible for the implementation of each element and sub-element, established progress indicators for each element and proposed time frames in which the actions specified in the GSPOA should be accomplished<sup>1</sup>.*

At the sixty-eighth World Health Assembly, Member States decided to extend the time frames of the plan of action from 2015 until 2022 and to undertake a comprehensive evaluation of the implementation of GSPOA in 2015/2016. The design of the evaluation, as well as the data analysis benefitted from the valuable input of the members of the *ad hoc Evaluation Management Group*, composed of six independent external subject matter experts and two evaluation experts from the United Nations Evaluation Group (UNEG), and the WHO Evaluation Office.

The overall purpose of the comprehensive evaluation is to assess the status of implementation of the eight elements of the global strategy: (a) prioritizing research and development needs, (b) promoting research and development, (c) building and improving innovative capacity, (d) transfer of technology, (e) application and management of intellectual property to contribute to innovation and promote public health, (f) improving delivery and access, (g) promoting sustainable financing mechanisms, and (h) establishing monitoring and reporting systems.

The goals of this evaluation include: assessing the implementation of GSPOA; informing the overall programme review planned for 2017; identifying achievements, gaps and remaining challenges; and providing a forward-looking view of improvements and their implementation with an assessment of the possible and existing constraints involved.

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<sup>1</sup> Global strategy and plan of action on public health, innovation and intellectual property, pages 1 and 20-37, available at: [http://www.who.int/phi/publications/Global\\_Strategy\\_Plan\\_Action.pdf?ua=1](http://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf?ua=1)

The scope of the evaluation covers the eight elements, 25 sub-elements and the 108 specific actions defined in the action plan over the period of 2008-2015.

The evaluation methodology followed the UNEG norms and standards for evaluations and ethical guidelines. The approach to the evaluation employed mixed methods, using both secondary and primary quantitative and qualitative data. To facilitate data collection throughout the 194 WHO Member States, the WHO invited all Member States to nominate one Focal Point each to facilitate data collection on behalf of relevant governmental entities, or to coordinate data collection among these. 101 Member States (52%) responded by providing a Focal Point; of these 101 Member States, 68 contributed to this evaluation. Data were collected in the six United Nations official languages (Arabic, Chinese, English, French, Russian and Spanish). The evaluation addressed the criteria of relevance, effectiveness and sustainability, as well as, in a limited way, some indications of early impact. The data sources comprised documents, key informant interviews, focus groups, three (3) survey tools (comprehensive online invitational survey to Member States and key stakeholder groups in GSPOA; short invitational survey to solicit participation from those who had not replied to the long invitational survey; and a web-based public survey) and 15 country case studies. The country case studies were stratified by the six WHO regions and four World Bank country income groups (high, upper-middle, lower-middle and low) and selected by sampling from among those countries that had appointed Focal Points.

In aligning the terminology of GSPOA with the four income groups of the World Bank, whenever GSPOA refers to developing countries, these countries are referred to in this evaluation as lower-middle-income and low-income countries, especially when evaluation findings are being reported and recommendations made.

GSPOA identifies stakeholders in the following groups:

- Governments (Member States);
- WHO Secretariat;
- Other international intergovernmental organizations, both global and regional; and
- Other relevant stakeholders, including international and national research institutions; academia; national and regional regulatory agencies; relevant health-related industries, including both public and private; public-private partnerships; public-private and product development partnerships; nongovernmental organizations, concerned communities; development partners; charitable foundations; publishers; research and development groups; and regional bodies and organizations.

The opinions of all stakeholder groups were represented to varying degrees in the data collected and analysed.

In the course of data collection it became evident that many activities related to the eight elements were being undertaken without reference to GSPOA and had already started prior to 2008, which indicates that there was not necessarily a causal relationship in terms of attribution between many observed actions and GSPOA.



## Emergence of a theory of change

GSPOA, being a Member States-negotiated instrument, does not spell out a Theory of Change. Since no Theory of Change currently exists, the Evaluators developed one during the course of the evaluation based on the *Force Field Analysis* model. Change is not an event, but rather a process and there are many different factors (forces) for and against making any change. Force Field Analysis enhances awareness of these factors. If the factors **for** change outweigh the factors **against** change, the change to the desired state will be successful.

The **positive factors** for change include: stakeholders' awareness of and support for the programme; the priority given to the health sector; prioritization and promotion of R&D needs by stakeholders; strong willingness to build and improve innovative capacity; willingness to improve delivery and access; and support for Member States by WHO and its partners.

The **negative risk forces** impeding change include: weak awareness of GSPOA; weak building and improvement of innovative capacity, particularly in low-income countries; weak sustainable financing mechanisms; lack of coordination among partners; weak monitoring and reporting systems; and weak local ownership and leadership, particularly in low-income countries.

**The evaluation resulted in the following key overall findings:**

- **Awareness and engagement of stakeholders.** The evaluation sample is restricted to countries that at least named a Focal Point and responded. The observed findings may therefore be better than the reality, as a result of excluding countries that have not even named a Focal Point, and may not have made as much progress or are not aware of GSPOA. It was also noted that many local stakeholders in the countries visited were not aware of or engaged in the implementation of GSPOA.
- **Variance across income groups.** For several, if not all, elements the finding is quite similar: stakeholders may be aware of GSPOA, but progress in implementation varies and it seems to be smaller in lower-middle-income and low-income countries with less resources. The way in which each element was implemented therefore depended on the priorities and capacity of each country.
- **Attribution.** Findings show countries doing related activities, but not considered a result of GSPOA. This also has to be taken into account in the interpretation of this report. GSPOA does not occur in a vacuum and the challenge here is to see what effects can be attributed to GSPOA. It may not be possible to separate the effect as a result of GSPOA from the internal dynamics of the countries in some cases.

**Note:** This evaluation report presents a comprehensive list of recommendations which are aimed at addressing areas identified for future work. While it may not be possible for all recommendations to be taken further, the ultimate intention was to provide the forthcoming overall programme review with a comprehensive list of areas for future work and forward-looking recommendations for discussion and provision of guidance.

## Element 1: Prioritizing research and development needs

GSPOA suggests that health R&D policies of developed countries need to reflect adequately the health needs of developing countries. Mapping global R&D for identifying gaps in R&D is needed and R&D in traditional medicine needs to be encouraged.

**Key findings.** Mapping of health R&D for identifying gaps was conducted by stakeholders and gaps were identified. There is evidence that some countries prioritize R&D needs at national level; however the level of effort differs across and within different regions and income groups. There is some evidence of collaborative partnerships in R&D in traditional medicine between countries.

**Key observations from country case studies.** *High-income and upper-middle-income* countries prioritize R&D from both the national and global perspectives. They reviewed their health policies, including the research components, during the implementation of GSPOA, but not necessarily as a consequence of GSPOA. *Upper-middle-income* countries have relatively well defined national R&D policies and/or strategies. Most health R&D work is being done in the private sector. At the *lower-middle-income* level, national R&D policies exist in some countries; however, even in countries where they exist, the overall national coordination between different agencies is less than optimal. In *low-income* countries, national health policies exist; however, without precisely addressing health research needs. The main gap in the implementation is the low level of awareness of GSPOA in all country income groups.

**Key achievements.** The WHO engagement with Member States led to progress towards a global framework for R&D and to the coordination of R&D for diseases that disproportionately affect lower-middle-income and low-income countries.

**Key gaps and challenges identified.** Investments in health research, in particular in traditional medicine, are insufficient and not appropriately directed towards tackling priority health problems. Current market mechanisms and publicly-funded research result in far too little investment in R&D for diseases that mainly affect lower-middle-income and low-income countries. There are challenges of explicitly linking the R&D needs, gaps and activities to an

evidence-based and transparent R&D prioritization process and in orchestrating health R&D at the global level.

## Recommendations

### Recommendations for consideration by Member States

1. Member States to ensure that their health R&D at national and sub-national level is prioritized, including for traditional medicine, through multi-stakeholder consultation, using national focal points or units for effective inter-sectoral coordination.

### Recommendations for consideration by the WHO Secretariat

2. WHO Secretariat to support Member States to monitor progress in R&D prioritization;
3. WHO Secretariat, in collaboration with partners across all sectors, to promote coordination of health R&D at national, regional and global levels, with a view to closing critical gaps in research agendas in support of global health research priorities;
4. WHO Secretariat to promote publicly accessible repositories for health research in order to improve access to knowledge;
5. WHO Secretariat to further support Member States in carrying out national assessments and analyse and compare data gained at national and regional level and identify further steps for improved assessment;
6. WHO Secretariat and partners to conduct periodical re-evaluations of the coordination of health research.

## Element 2: Promoting research and development

GSPOA recognizes the need for political, economic and social institutions in each country to participate in the development of health research policy.

**Key findings.** GSPOA promoted health R&D, and improved access to knowledge and technology via databases and libraries, as well as by capacity building; however, the extent and the effectiveness vary among regions. Political and economic institutions participated in the development of health research policies; however, the involvement of social institutions was weak and varied across income groups.

**Key observations from country case studies.** *High-income* countries promote R&D in all three types of disease. These countries also promote health research in *lower-middle-income* and *low-income* countries with the involvement of governmental bodies from both sides and, in certain cases nongovernmental organizations. In *upper-middle-income* countries, several institutions are dedicated to R&D in health, including some that conduct research in traditional medicine. In *lower-middle-income* countries, national research or science and technology policies are in place; however, the national coordination between the different agencies is less than optimal. Innovation is primarily demonstrated by the private sector in market-driven

conditions and largely outside the scope of GSPOA. Health research capacity is very low in *low-income* countries. In terms of gaps, the overall national coordination between the different agencies is limited in *upper-middle-income*, *lower-middle-income* and *low-income* countries.

**Key achievements.** GSPOA has promoted health R&D in all income groups and improved access to knowledge and technology. Databases on clinical trials, patents, intellectual property (IP) and health knowledge were created or became available.

**Key gaps and challenges identified.** Lack of funding for health research impedes complying with many aspects of GSPOA in almost every region, predominantly in lower-middle-income and low-income countries. Funds are often provided for research activities which do not address the health needs of these countries. There is a clear need for a communications strategy to overcome the current lack of communication tools for increasing access to knowledge in many lower-middle-income and low-income countries. Measures to promote and coordinate research into all types of disease need to be substantially enhanced. Greater investment in Member States into development and implementation of national health research programmes and establishing strategic research networks is also needed.

## Recommendations

### Recommendations for consideration by Member States

1. Member States to promote upstream research in lower-middle-income and low-income countries with strengthened international cooperation and joint work between the public and private sector in areas that address their health needs, as well as at the international level and between high-income and lower-middle-income countries;
2. Member States to enhance national capacity for analysing and managing clinical trial data;
3. Member States to promote broader multi-sectoral participation in the development of health research policy.

### Recommendations for consideration by the WHO Secretariat

4. WHO Secretariat to strengthen its work with partners for creating and renewing strategic research networks to support governments to develop their national health programmes, including the necessary communication tools.

### Recommendations for consideration by all stakeholders

5. All stakeholders to improve access to scientific and technological knowledge, including wider availability of libraries and databases;
6. All stakeholders to strengthen the efforts towards improving cooperation, participation and coordination of health and biomedical R&D with and between lower-middle-income and low-income countries.

### Element 3: Building and improving innovative capacity

GSPOA acknowledges the need for framing, developing and supporting policies which promote health innovation capacity improvement in developing countries. The key areas for capacity development are science and technology, regulation, clinical trials, IP, production of pharmaceuticals and evidence-based traditional medicine.

**Key findings.** The investments made in building and improving health innovation capacity were disproportionally allocated and implemented across regions and country income groups.

**Key observations from country case studies.** Several *high-income* countries promote R&D capacity in *lower-middle-income* and *low-income* countries at national agencies, research institutes and universities. Public-private partnerships participate in applied research in collaboration with local partners of *lower-middle-income* and *low-income* countries. Public-private partnerships build and improve innovative capacity. Nongovernmental organizations support the development and use of traditional medicine. While much innovative capacity has been built or improved, this is not necessarily a consequence of GSPOA. In one *upper-middle-income* country it was noted that coordination of innovative capacity building throughout the different departments of the Ministry of Health was limited. In *lower-middle-income* countries, respondents indicated that policies to build and improve innovative capacity existed, but their implementation remained fragmented. Furthermore, investment in health R&D is not coordinated at an optimal level. In *low-income* countries there are limited research activities due to restricted access to research funding. In terms of gaps, the health innovation system is often rudimentary and fragmented in most *low-income*, *lower-middle-income* and some *upper-middle-income* countries.

**Key achievements.** Several networks and partnerships were built for promoting investments in R&D capacity in lower-middle-income and low-income countries, such as a regional platform on access and innovation for health technologies to look into research funding needs and gaps.

**Key gaps and challenges identified.** Policies to promote the development of health innovation capacity exist; however, their implementation remained fragmented in many countries. The public sector provides most funding and infrastructure for research. R&D is generally still not a major priority for lower-middle-income and low-income countries which face daunting issues stemming from a lack of skilled researchers and financial resources, together with competing, seemingly more urgent, priorities. Although research is conducted in academic institutions, owing to the lack of capacity to conduct translational research, and the limited local manufacturing capacity, it often has little applicability to local health problems. Despite the achievements noted in the implementation of this Element, the remaining challenges are considerable and multiple. They include the lack of baseline data and effective policies in several lower-middle-income and low-income countries, as well as the often limited capacity of regulatory agencies, research institutions and production facilities. Capacity improvement should be pursued in parallel in different fields, including policy development, education and training, research and regulatory institutions.

## Recommendations

### Recommendations for consideration by Member States

1. Member States, with the support of the WHO Secretariat and other international organizations, to strengthen their efforts for tapping the still largely unrealized potential contained in traditional medicinal knowledge, notably by boosting local R&D and manufacturing capacity, enhancing educational and training efforts to safeguard the locally available knowledge base on traditional herbal medicine and traditional medical treatment methods; and to negotiate partnerships with high-income and upper-middle-income countries for mutual advantage;
2. Member States to align their R&D objectives with the public health needs of their populations.

### Recommendations for consideration by the WHO Secretariat

3. WHO Secretariat to explore options to support the development of health products in accordance with the demonstrated R&D needs of lower-middle-income and low-income countries, focusing on Type II and Type III diseases and the specific needs of these countries in relation to Type I diseases;
4. WHO Secretariat and partners to increase their support to lower-middle-income and low-income countries in the area of better safeguarding and exploiting the existing traditional medicinal knowledge in terms of development of new products and treatments;
5. WHO Secretariat, in collaboration with Member States, to promote, organize and support more actions in teaching and training, including building R&D capacity, with a focus on Type II and Type III diseases and the specific needs of lower-middle-income and low-income countries in relation to Type I diseases.

### Recommendations for consideration by all stakeholders

6. All stakeholders to actively contribute to the development of possible new incentive schemes for health-related innovation, in line with the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination regarding sustainable funding and the coordination of health-related R&D;
7. All stakeholders to improve innovative capacity in lower-middle-income and low-income countries by providing more funding and infrastructure for research, including translational research.

## Element 4: Transfer of technology

GSPOA supports development cooperation, partnerships and networks for building and improving transfer of technology related to health innovation. The aim of Element 4 is the promotion of technological innovation and transfer of technology to the mutual advantage of producers and users of health technologies.

**Key findings.** Several national, regional and global coordination initiatives have been set up for increasing and facilitating transfer of health-related technologies. However, there are significant variations across regions and income groups. There is evidence of several North-South collaborations that involve international organizations, international nongovernmental organizations, philanthropic organizations, academia and the private sector. Furthermore, there is evidence of some South-South cooperation initiatives that mainly involve harmonization of strategies, regulations and commercially-based activities. The promotion of health technology transfer to enable production of health products is mainly taking place between countries that have an established production capacity. Low-income countries are still encumbered with weak regulatory and institutional frameworks that impede the absorption of technologies, although there is evidence that a number of these countries have developed strategies to overcome this obstacle. United Nations agencies, such as UNCTAD, WHO and WIPO, have played a pivotal role in promoting the transfer of health-related technologies between the owners of the technologies and lower-middle-income and low-income countries. The most frequent types of activity include technical assistance, facilitating dialogue, increasing availability of information, and more directly setting up concrete initiatives to support technology transfer.

**Key observations from country case studies.** In a *high-income* country a respondent pointed out that technology transfer is voluntary and that the private sector leads, and there is some skepticism regarding production in *lower-middle-income* and *low-income* countries. In particular, it was pointed out that sub-standard/spurious/falsely labelled/falsified/counterfeit (SSFFC) medical products pose significant risks to consumer health and safety. In other *high-income* countries there is evidence of the transfer of knowledge and technologies by the public and private sectors, as well as by nongovernmental organizations. While there is evidence of much activity, it is not necessarily a consequence of GSPOA. In *upper-middle-income* countries, transfer of technology is taking place; however, often without assessing its value to the local health systems. Most *lower-middle-income* and *low-income* countries lack health innovation structures that can receive and make good use of transferred technologies. In terms of gaps, despite the achievements in health-related technology transfer to lower-middle-income and low-income countries, at global level the number of collaboration initiatives seems to be limited. Most pharmaceutical manufacturers in low-income and lower-middle-income countries lack the capacity to use transferred technology effectively.

**Key achievements.** National initiatives in *high-income* countries include incentive programmes to encourage large, established private sector organizations to undertake technology transfer initiatives, as well as guidance on modalities of technology transfer to the *low-income* countries. Global initiatives are driven by international organizations, e.g. WHO, WTO, and development banks. These organizations facilitate collaboration by promoting technical

cooperation between large private sector organizations and the global initiatives; and by providing capacity development through direct technical assistance to countries.

**Key gaps and challenges identified.** The gaps identified in technology transfer in many cases are correlated with the income group into which a given country falls. Several low-income countries lack technology transfer strategies, initiatives for investments and capacity to become the users of new pharmaceutical and health technologies. These countries are encumbered with weak regulatory and institutional frameworks that impede the absorption of technologies. Speeding up capacity development in the regulatory sector is one of the challenges facing several lower-middle-income and low-income countries. On the other hand, there is evidence that a number of these countries have developed and implemented strategies to overcome those challenges with the help of North–South and South–South cooperation.

## Recommendations

### Recommendations for consideration by Member States

1. Member States to work with other stakeholders to improve the enabling environment for technology transfer for the production of health products.

### Recommendations for consideration by the WHO Secretariat

2. WHO Secretariat and other stakeholders to undertake or encourage further work in needs assessment of lower-middle-income and low-income countries with a view to continuing to provide support for technology transfer;
3. WHO Secretariat to encourage relevant studies and analyses to better understand local needs with a view to improving local capacity for providing essential medicines and health technologies for those in need and creating a business-friendly environment for these efforts.

### Recommendations for consideration by all stakeholders

4. All stakeholders to undertake or encourage further capacity building in lower-middle-income and low-income countries regarding technology transfer and related action plans.

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

GSPOA acknowledges the need for strengthening innovation capacity and the capacity to manage and apply IP in developing countries. This includes the use of flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to take measures to protect public health.

**Key findings.** Many GSPOA stakeholders are engaged in the implementation of this Element. International organizations with a mandate in this field provide support for the implementation



of the TRIPS Agreement in a way that facilitates access to affordable medicines.

**Key observations from country case studies.** Traditional IP models appear to support predominantly large companies, and it is difficult to promote alternative (non-commercial) IP models. Efforts are evident in some countries to balance IP rights and make research findings and new health products accessible to low-income countries. In one *upper-middle-income* country, there are efforts to develop an IP database. Many *lower-middle-income* countries are involved in clinical trial and ethical review processes. There is limited capacity in most *low-income* countries and *lower-middle-income* countries to address the issue of SSFFC medical products. There is limited capacity in some *low-income* countries to apply the TRIPS flexibilities effectively. In terms of gaps, IP barriers continue to be a challenge in most income groups, especially in lower-middle-income and low-income countries. They limit access to, and affordability of, medicines for poor people in most countries, including those countries that are excluded from licensing agreements sometimes available to poorer countries.

**Key achievements.** Countries are engaged in initiatives to strengthen capacity to manage and apply IP rights to contribute to innovation and promote public health. Upon request, WHO, WIPO, WTO, UNCTAD, UNDP and other international organizations provide support to those countries that intend to use the flexibilities provided in the TRIPS Agreement for the application and management of IP in a manner that promotes access to health products. This involves guidance on developing public health-sensitive patent legislation and incorporating TRIPS flexibilities within domestic legislation. Some pharmaceutical companies support the spirit of these flexibilities by not enforcing patents in lower-middle-income and low-income countries. Flexibilities for protection of public health in the TRIPS Agreement have been integrated into national legislation by some countries. There are Member States which implemented the WTO 30 August 2003 decision on the implementation of paragraph 6 of the Doha Declaration on compulsory licensing, primarily to export medicines.

**Key gaps and challenges identified.** It is still difficult to obtain clear and up-to-date information about the patent status of most health products and the available information is usually scattered in many places. Resources and know-how required for the implementation of TRIPS flexibilities are still scarce in most countries, coupled with reluctance to use these or other legitimate mechanisms to advance access to medicines. The lack of baseline data on the actual status of the implementation of IP rights conducted in lower-middle-income and low-income countries makes it difficult to judge the current situation. The resistance of some stakeholder groups with regard to the use of TRIPS flexibilities could complicate efforts to provide access to new medicines and health technologies for treating certain, mostly chronic, diseases and health conditions in lower-middle-income and low-income countries.

## Recommendations

### Recommendations for consideration by Member States, the WHO Secretariat, other international organizations and nongovernmental organizations

1. To strengthen awareness of the flexibilities provided in the TRIPS Agreement, IP rights and the need for equitable and affordable access to essential health products in lower-middle-income and low-income countries;
2. To strengthen capacity and create incentives related to IP management, taking into account the public health perspective in lower-middle-income and low-income countries;
3. To continue efforts to better integrate existing and new initiatives and schemes in this area in the implementation of GSPOA;
4. To focus more attention on creating the required baseline data, indicators and evidence base needed to properly evaluate the outcome of GSPOA initiatives under this element;
5. To support ongoing non-profit drug development models, by exploring and promoting possible incentive schemes to overcome IP barriers and promote public health.

## Element 6: Improving delivery and access

Access to medicines is directly related to income and, despite progress made during the last decade, this access is still a major problem for most lower-middle-income and low-income countries.

**Key findings.** GSPOA has addressed the availability of health products in lower-middle-income and low-income countries, and Member States have improved delivery and access. However, the extent of improvements varies highly and depends on the disease and the specific features of the health care system, in particular the available supply chains. Most low-income countries import essential, quality medicines and have little room to negotiate pricing. From the outset of the implementation of GSPOA, initiatives have emerged to increase access to essential medicines. Nevertheless, inexistent, or limited, coordination among stakeholders constitutes the main challenge for these initiatives. Member States and the WHO Secretariat are joining efforts to establish and strengthen mechanisms to improve the ethical review of health products and medical devices and ensure their quality, safety and efficacy.

**Key observations from country case studies.** One *high-income* country provided evidence of its support for *lower-middle-income* and *low-income* countries in prioritizing health care in national agendas. That country also contributed to the strengthening of national health systems in some *lower-middle-income* and *low-income* countries by advocating for improving access and by providing training. One *high-income* country is very active in improving access to affordable health products, but not as a consequence of GSPOA. In one *upper-middle-income* country, the Government aims to increase accessibility to essential medicines and treatment and has introduced a central procurement system. In most *lower-middle-income* and *low-income* countries there is a lack of effective communication between government officials and other

stakeholders regarding issues related to access and affordability. In terms of gaps, access to health products depends on the bargaining capacity of countries, which is weak in the case of most *low-income* and *lower-middle-income* countries. In *upper-middle-income* countries, there is a move away from traditional medicine due to the easier availability of modern medicine.

**Key achievements.** During the implementation of GSPOA, some initiatives have emerged to increase access to essential medicines. Examples include increasing access to HIV treatment over the past 15 years and, more recently, accelerating access to the treatment for Hepatitis C viral infections. Among other achievements, these initiatives have developed tools to help lower-middle-income and low-income countries to conduct self-assessment, develop strategies, build or improve capacity and engage in partnerships to improve access to essential medicines.

**Key gaps and challenges identified.** The availability and accessibility of health products is still limited in many lower-middle-income and low-income countries. This is usually the outcome of systemic failures within, and the lack of financing for, health systems in these countries which require a strongly-coordinated whole-of-government multi- and inter-sectoral response to address the underlying causes. In order to strengthen the health systems and improve delivery and access to health products, the lack of resources in lower-middle-income and low-income countries should be addressed. The weak infrastructure in lower-middle-income and low-income countries represents a barrier to the improvement of the delivery chain of health products as well as to the accessibility of health care services.

## Recommendations

### Recommendations for consideration by Member States

1. Member States, in collaboration with other stakeholders, to join efforts for increasing funding to improve delivery of, and access to, health products;
2. Member States to strengthen their national regulatory agencies to facilitate rapid access to health products for their citizens;
3. Member States, in collaboration with other stakeholders, to explore regional partnerships to share expertise between countries and strengthen policies and regulations for health products.

### Recommendations for consideration by the WHO Secretariat

4. WHO Secretariat to continue and strengthen its efforts under the Prequalification of Medicines Programme;
5. WHO Secretariat, in collaboration with its partners, to expand its efforts at conducting and coordinating joint reviews of clinical trials of medicines and vaccines;
6. WHO Secretariat, in collaboration with its partners and relevant stakeholders, to further strengthen national drug regulatory capacity, improve ethical review of clinical trials, and help to develop capacity to address barriers to access to affordable health products and medical devices.

## Element 7: Promoting sustainable financing mechanisms

GSPOA aims to make health products available in developing countries through new and innovative mechanisms.

**Key findings.** Financing mechanisms for R&D of neglected and tropical diseases as well as diseases affecting all income group countries, including emerging, highly infectious diseases, were addressed during the implementation of this Element. During the implementation of GSPOA, new financing innovations and initiatives have emerged, including those of public-private partnerships and product development partnerships, many of them addressing Type III diseases, in partnership with international nongovernmental organizations, high-income countries and pharmaceutical companies.

**Key observations from country case studies.** *High-income* countries supported *lower-middle-income* and *low-income* countries through public-private partnerships and product development partnerships. One such country reported that it was active in pursuing sustainable financing mechanisms, but not as a consequence of GSPOA. Respondents in an *upper-middle-income* country felt that financing should come from the private and public sectors and support the entire process from R&D to market launch. Public-private partnerships are seen as an important incentive to involve the private sector and develop a balance between competition and affordability. The financing of health-related infrastructure is a major challenge in most *low-income* and *lower-middle-income* countries. In terms of gaps, one *upper-middle-income* country stated that the funding in health services, health technology, health financing and health governance research is not adequate and needs to be increased. It is evident that *low-income* and *lower-middle-income* countries have very limited access to sustainable financing mechanisms.

**Key achievements.** There are promising grant schemes in lower-middle-income and low-income countries for stimulating innovation through broad participation of small and medium-sized enterprises in support of relevant R&D. These schemes contribute to the promotion of high-risk pre-proof-of-concept research and end-stage development by small and medium-sized enterprises. Available procurement funds under purchase or procurement agreements stimulate increased R&D and provide large-scale access to new products. Successful product development partnerships brought together the public, private and philanthropic sectors to fund and manage the discovery, development and delivery of new health products. A further achievement is the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination that have been endorsed by the World Health Assembly.

**Key gaps and challenges identified.** Most health sector financing in low-income countries has been aid-dependent, but major multilateral partners are now conditioning their support with a view to phased withdrawal. In order to reach long-term sustainability there is a need to pool resources to ensure that lower-middle-income and low-income countries are enabled to carry out the necessary research and regulatory work to secure their own requirements in terms of

health products. Such steps are still in the early stages in many of these countries, including domestic investment in research institutions, capacity development in regulatory systems, education and training. Facilitating the use of financing through public-private partnerships and product development partnerships may require stronger global or regional efforts in identifying possible partners, the countries where the business environment is favourable and where the capacity is available or where it can be developed within a relatively short period of time.

## Recommendations

### Recommendations for consideration by Member States

1. Member States, in the context of Sustainable Development Goal 3.8 on universal health coverage, to secure adequate funding and facilitate R&D efforts for development of health products and medical devices;
2. Member States to increase funding and encourage public-private partnerships and product development partnerships to ensure availability and affordability of health products and medical devices in lower-middle-income and low-income countries;
3. Member States and other stakeholders to lend their political support to new innovative schemes for identifying new sources of funding for health R&D and operationalize their use, such as those recommended by the Consultative Expert Working Group on Research and Development: Financing and Coordination.

### Recommendations for the Consideration by WHO Secretariat

4. WHO Secretariat to work with other stakeholders to implement the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination.

## Element 8: Establishing monitoring and reporting systems

GSPOA supports the establishment of systems to monitor performance and progress towards the objectives contained in the strategy and the plan of action.

**Key findings.** While several countries listed many health-related initiatives of relevance to their countries, which they monitor regularly and on which they report to their national governments, donors or WHO, these were not comprehensive national strategies set up specifically to implement GSPOA or WHO initiatives in this context. The majority of national stakeholders and survey respondents were not aware of whether their country monitored and reported on investments in health R&D.

**Key observations from country case studies.** Many stakeholders in all income groups stated that they were asked to report on their activities without knowing that this was a GSPOA requirement. Others cited a lack of incentives to use the WHO monitoring system. Weaknesses in Element 8 are also partly a reflection of the limited resource base in many countries. In terms

of gaps, in all income groups, WHO Member States experienced difficulty in complying with the strategy's provision to establish monitoring and reporting systems for gathering evidence about their implementation processes and results of GSPOA. There is a lack of regular reporting on progress towards implementation of GSPOA, in most cases in all income groups. There is some evidence among *low-income*, *upper-middle-income* and *high-income* countries that gaps and needs in health products have been monitored and assessed. However, there is little evidence that this monitoring was implemented due to GSPOA.

**Key achievements.** WHO submitted biennial progress reports on GSPOA implementation to the World Health Assembly in 2010, 2012 and 2014. Furthermore, several countries monitor and report on their health-related initiatives without necessarily referring to the goals of GSPOA.

**Key gaps and challenges identified.** While there were multiple examples of national strategies to tackle health issues in a given country, these were not comprehensive national strategies set up specifically to implement GSPOA. There was little awareness of GSPOA in a few countries as it was not well disseminated, promoted and financed. The limited resources, weak capacity and competence base of many countries in this area, together with insufficient WHO capacity for support and guidance, further contributed to the observed weaknesses in achieving the monitoring and reporting goals of GSPOA. Some countries undertake knowledge gap analyses created by advances in the development of health products and medical devices, but there is no evidence that these are directly related to GSPOA and are reported to WHO. While there appeared to have been various country-specific monitoring efforts, no specific evidence was provided regarding the monitoring by countries of the impact of IP rights on the development of, and access to, health products during GSPOA implementation. There is also little evidence of countries of any income level actively monitoring and reporting the impact of incentive mechanisms on the innovation of, and access to, health products and medical devices. The same is true regarding the impact of investment in R&D to address the health needs of lower-middle-income and low-income countries.

## Recommendations

### Recommendations for consideration by Member States

1. Member States and the WHO Secretariat to plan for a final evaluation of GSPOA implementation in 2023;
2. Member States to strengthen their monitoring and evaluation systems to monitor progress and evaluate the performance of the implementation of GSPOA in their countries.

Recommendations for consideration by the WHO Secretariat

3. WHO Secretariat to complete the development of a web-based platform for monitoring and information-sharing regarding Member States' progress and experience in implementing GSPOA;
4. WHO Secretariat to revise the National Assessment Tool appropriately so as to capture better the existing capacity of Member States to effectively discharge their obligations and responsibilities regarding GSPOA monitoring and reporting.

**Overall programme review 2017**

An overall programme review is envisaged to be initiated in 2017 and is to be informed by this evaluation.

Recommendations for the overall programme review

1. The overall programme review should address areas identified for future work in this report and consider and provide guidance on the recommendations;
2. Member States, through the overall programme review, to further review resources expended and financing available for the implementation of GSPOA in order to identify best practices and constraints.

# 1 INTRODUCTION

*In 2008, following a two-year negotiation process, the Sixty-first World Health Assembly debated the output of an inter-governmental working group and subsequently the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) was adopted in resolution WHA61.21.*

*The aim of the strategy is to promote new thinking on innovation and access to medicines and to secure an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases that disproportionately affect developing countries. The strategy comprises eight elements, 25 sub-elements and 108 specific actions.*

*In the following year (2009) resolution WHA62.16 finalized the list of stakeholder categories responsible for the implementation of each element and sub-element, established progress indicators for each element and proposed time frames in which the actions specified in the GSPOA should be accomplished.<sup>2</sup>*

At the sixty-eighth World Health Assembly, Member States decided to extend the time frames of the plan of action from 2015 until 2022 and to undertake a comprehensive evaluation of the implementation of GSPOA in 2015/2016. The design of the evaluation, as well as the data analysis benefitted from the valuable input of the members of the *ad hoc Evaluation Management Group*, composed of six independent external subject matter experts and two evaluation experts from the United Nations Evaluation Group (UNEG), and the WHO Evaluation Office.

The overall purpose of the comprehensive evaluation is to assess the status of implementation of the eight elements of the global strategy: (a) prioritizing research and development needs, (b) promoting research and development, (c) building and improving innovative capacity, (d) transfer of technology, (e) application and management of intellectual property to contribute to innovation and promote public health, (f) improving delivery and access, (g) promoting sustainable financing mechanisms, and (h) establishing monitoring and reporting systems.

The goals of this evaluation include: assessing the implementation of GSPOA; informing the overall programme review planned for 2017; identifying achievements, gaps and remaining challenges; and providing a forward-looking view of improvements and their implementation with an assessment of the possible and existing constraints involved.

The scope of the evaluation covers the eight elements, 25 sub-elements and the 108 specific actions defined in the action plan over the period of 2008-2015.

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<sup>2</sup> Global strategy and plan of action on public health, innovation and intellectual property, pages 1 and 20-37 available at [http://www.who.int/phi/publications/Global\\_Strategy\\_Plan\\_Action.pdf?ua=1](http://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf?ua=1)



The evaluation addressed the criteria of relevance, effectiveness and sustainability, as well as, in a limited way, some indications of early impact. The data sources comprised documents, key informant interviews, focus groups, three survey tools (comprehensive online invitational survey to Member States and key stakeholder groups in GSPOA; short invitational survey to solicit participation from those who had not replied to the long invitational survey; and a web-based public survey) and 15 country case studies. The country case studies were stratified by the six WHO regions and four World Bank country income groups (high, upper middle, lower middle and low) and selected by sampling from among those countries that had appointed Focal Points.

In the course of data collection it became evident that many activities related to the eight elements were being undertaken without reference to GSPOA and had already started prior to 2008, which indicates that there was not necessarily a clear causal relationship in terms of attribution between many observed actions and the implementation of GSPOA.

## Emergence of a Theory of Change

GSPOA, being a Member States-negotiated instrument, does not spell out a Theory of Change. Since no Theory of Change currently exists, the Evaluators developed one during the course of the evaluation, based on the *Force Field Analysis* model<sup>3</sup>. Change is not an event, but rather a process and there are many different factors (forces) for and against making any change. Force Field Analysis enhances awareness of these factors. If the factors **for** change outweigh the factors **against** change the change, to the desired state will be successful.

The **positive factors** for change include: stakeholders' awareness of and support for the program; the priority given to the health sector; prioritization and promotion of R&D needs by stakeholders; strong willingness to build and improve innovative capacity; willingness to improve delivery and access; and support for Member States by WHO and its partners.

The **negative risk forces** impeding change include: weak awareness of GSPOA; weak building and improvement of innovative capacity, particularly in low-income countries; weak sustainable financing mechanisms; lack of coordination among partners; weak monitoring and reporting systems; and weak local ownership and leadership, particularly in low-income countries.

## 2 METHODOLOGY

### Approach to the Evaluation

The evaluation methodology followed the UNEG norms and standards for evaluations and ethical guidelines and adhered to WHO cross-cutting strategies on gender, equity and human rights.

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<sup>3</sup> See Section 4 of this report.

The approach to the evaluation employed mixed methods, using both secondary and primary quantitative and qualitative data. Secondary data are such that already exist in documentary form, while primary data are developed specifically for this evaluation, using surveys, country case studies, key informant interviews and focus groups.

To facilitate data collection throughout the 194 WHO Member States, the WHO invited all Member States to nominate one Focal Point each to facilitate data collection on behalf of relevant governmental entities, or to coordinate data collection among these. 101 Member States (52%) responded by providing a Focal Point; of these 101 Member States, 68 contributed to this evaluation.

Data were collected in the six United Nations official languages (Arabic, Chinese, English, French, Russian and Spanish). A key aspect of data reporting was the decision not to report by Member States, but rather globally and/or by WHO Regions, where the regions were differentiated by the four World Bank country income groups.

**In aligning the terminology of GSPOA with the four income groups of the World Bank, whenever GSPOA refers to developing countries, these countries are referred to in this evaluation as lower-middle-income and low-income countries, especially when evaluation findings are being reported and recommendations made.**

In keeping with the UNEG ethical guidelines, the evaluators assured all respondents in primary data collection, whether by survey, country case studies, key informant interviews or focus groups, that their participation was voluntary and anonymous and that data gathered would not be attributed to individual countries or persons in the evaluation report.

## Evaluation Criteria and Questions

The evaluation addressed the criteria of relevance, effectiveness and sustainability, as well as, in a limited way, some indications of early impact. It must be noted that impact as an evaluation criterion is normally used in summative evaluations, and there, in its pure form, it requires an experimental or quasi-experimental design in order to make reliable judgments regarding attribution or contribution. This is a formative evaluation and, as such, impact was not assessed.

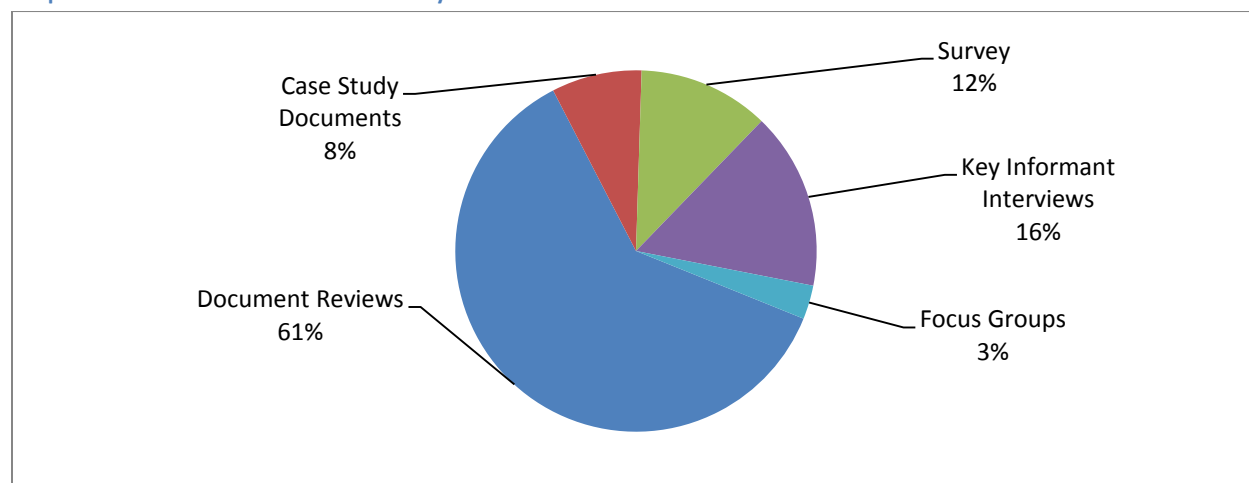
In this evaluation, therefore, a counterfactual approach was used as an alternative to an experimental or quasi-experimental design, which argues that certain results would not have been obtained if GSPOA had not been implemented. From that perspective, this formative evaluation will offer preliminary indications of “impact” where GSPOA has contributed to the achievement of effects and where a causal relationship can be demonstrated. Examples of counterfactual evidence will be presented in text boxes in the Conclusions section of each Element.

The evaluation questions were drawn from GSPOA.<sup>4</sup>

## Lines of Evidence

The evaluation drew on five lines of secondary and primary evidence, involving document reviews, three surveys, country case studies, key informant interviews and focus groups.

Graph 2.1 Distribution of sources of data by lines of evidence



The secondary evidence consisted of 287 documents and relevant websites.<sup>5</sup>

The main sources of primary data were three online surveys<sup>6</sup> (a comprehensive online invitational survey to Member States, WHO and other key stakeholder groups in GSPOA; a follow-up shorter invitational survey to solicit participation from those who had not replied to the longer survey after reminders; and a web-based public survey).

The online survey to Member States, WHO and other GSPOA stakeholder groups was launched on 18 May 2016 and was open for 15 weeks. 85 participants from the invited stakeholder groups responded to the longer survey. A further 4 responded to the shorter survey.

The web-based public survey was launched on 27 July 2016 and was open for 5 weeks, resulting in 62 contributions which were also considered during the data analysis.

Key informant interviews and focus groups at the global level were another important source. interviews were held with WHO, WIPO, WTO, UNCTAD and UNITAID. Further key informant interviews and focus groups were also conducted as part of the country case studies below.

<sup>4</sup> See list of evaluation criteria and questions in Annex 6.

<sup>5</sup> See list of documents and relevant websites in Annex 3.

<sup>6</sup> See detailed results from surveys in Annex 1.

## Country case studies

In view of the fact that surveys offer, by their nature, limited opportunities to explore certain aspects in depth, a limited country case study approach was considered to be appropriate. Only countries that had named a Focal Point were considered to be eligible for participation in country case studies, since the Focal Points were expected to play an active role in generating lists of contact persons who had good GSPOA knowledge and also providing logistics support to the Evaluators during the country visit.

While the ultimately chosen sampling approach was purposive, the countries were initially chosen by stratified random sample using a frame consisting of the six WHO Regions and the four World Bank country income groups (high, upper middle, lower middle and low). The resulting theoretical maximum of 24 countries was initially reduced to 20 because the candidate countries in the South-East Asia Region that had nominated Focal Points lacked both the country high-income and low-income categories, and those of both the European and Western Pacific Regions lacked Focal Points from low-income countries. Based on purposive considerations, the South-East Asia Region was awarded two countries in the lower-middle-income category. This resulted in a potential of 21 countries in which to conduct case studies. However, the ultimate number of country case studies was reduced to 15 since a further 6 Focal Points opted out of the case study at a later stage before the visits commenced. The case study data comprised available documents, survey data and key informant interviews, as well as focus groups.

**Table 2.1 Country Case Study Selection**

Regions	Income Groupings				T
	High	Upper Middle	Lower Middle	Low	
Africa		South Africa	Cameroon	Rwanda	3
Americas	USA	Brazil	Guatemala		3
South-East Asia		Thailand	Sri Lanka		3
			Bangladesh		
Europe	Switzerland				1
Eastern Mediterranean	Qatar	Jordan	Morocco	Afghanistan	4
Western Pacific			Philippines		1
<b>TOTAL</b>	3	4	6	2	15

The country case studies are a critical source of additional data. The case studies were done through country visits or, in three cases, remotely. For all country case studies, the Evaluators worked with the national Focal Point and with the support of the WHO country office, as necessary, to collect available documents, any survey data and organize key informant interviews as well as focus groups. The key informants and focus groups were identified representing the stakeholder groups in GSPOA. Questionnaires for the key informant interviews, were differentiated by stakeholder group and language. The selection of which questions would be asked of each stakeholder group was based on GSPOA.

During the interviews, the evaluators focused on the main areas of experience of respondents in respective stakeholder categories, prioritizing the questions that reflected those areas. Time permitting, other questions were also addressed. The same principle was used in facilitating focus group discussions that were considered as a data collection option during country case studies where logistically feasible. The 68 Member States who contributed to this evaluation through surveys and country case studies are presented in the table below:

**Table 2.2 Participation of WHO Member States<sup>7</sup>**

<b>High-income Group (23)</b>	<b>Upper-middle-income Group (12)</b>
Argentina Australia Bahamas Bahrain Brunei Darussalam Canada Chile Czech Republic Estonia Hungary Iceland Japan Netherlands Oman Poland Qatar Russian Federation Seychelles Spain Switzerland Trinidad and Tobago United States of America Venezuela (Bolivarian Republic of)	Belarus Bosnia and Herzegovina Brazil Costa Rica Fiji Jordan Lebanon Maldives Peru Serbia South Africa Thailand
<b>Lower-middle-income Group (17)</b>	<b>Low-income Group (16)</b>
Bangladesh Bhutan Cameroon Côte d'Ivoire Egypt Guatemala Kiribati Morocco Myanmar Nigeria Philippines Sao Tome and Principe Senegal Sri Lanka Tajikistan	Afghanistan Benin Burkina Faso Burundi Democratic Republic of the Congo Haiti Liberia Madagascar Malawi Niger Rwanda South Sudan Togo Uganda United Republic of Tanzania

<sup>7</sup> Based on World Bank Income Classification Fiscal Year 2016.

Timor-Leste Zambia	Zimbabwe
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The data for GSPOA were expected to be very complex, since they would involve several sources of mixed methods (both quantitative and qualitative) and in all six UN official languages and would need to be analyzed across region and income group. To address this complexity and to make the triangulation of the resulting data possible, the Evaluators chose to use NVivo<sup>8</sup>. This tool can be seen as an electronic “filing cabinet” to which each Evaluator contributes, in English, the data collected from all lines of evidence.

The data summaries were synthesized into a finding statement for each GSPOA Element. Diagrams explaining the node structure and the flow of analysis, as well as the analysis worksheet template itself, are included in Annex 4.

The Evaluators encountered a number of limitations and problems. While 194 Member States of the WHO adopted resolution WHA61.21 at the Sixty-first WHO World Health Assembly, only 101 (52%) Member States appointed Focal Points to support this evaluation. However, not all Focal Points responded, with the result that the evaluation sample is restricted to countries that at least named a Focal Point and responded. Therefore, the results presented in this report only reflect the situation of 68 countries that were responsive. The others, which were excluded because they had not named a Focal Point, may have made less progress in this strategy, and they are not reflected in the report.

However, despite this limitation of only 68 Member States providing inputs to the survey, that number is adequate to provide useful findings and to draw conclusions. Another limitation concerned the country case studies, where a larger number of case studies could have generated more data. The variability of experience within stakeholder categories imposed constraints on key informant interviews, in that invited informants focussed on priority areas that reflected their expertise. That fact may have constrained the number of potentially valuable responses.

## Stakeholder Profile

GSPOA identifies stakeholders in the following groups:

- Governments (Member States);
- WHO Secretariat;
- Other international intergovernmental organizations, both global and regional; and
- Other relevant stakeholders, including international and national research institutions; academia; national and regional regulatory agencies; relevant health-related industries, including both public and private; public-private partnerships; public-private and product development partnerships; nongovernmental organizations, concerned communities;

<sup>8</sup> <http://www.qsrinternational.com/>

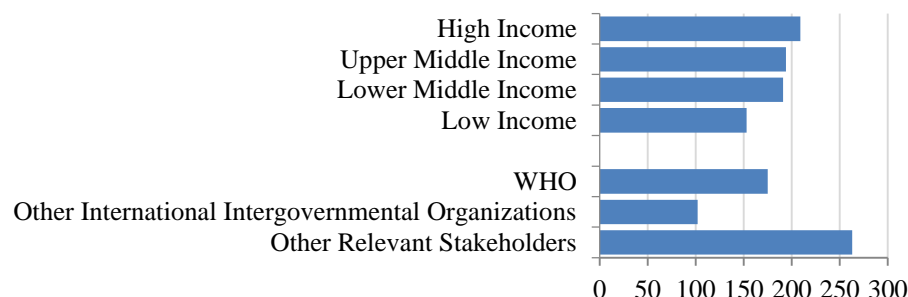
development partners; charitable foundations; publishers; research and development groups; and regional bodies and organizations.

The opinions of all stakeholder groups were represented to varying degrees in the data collected and analysed. A thorough stakeholder analysis is contained in Annex 5. In order to better present the data throughout this report, the stakeholder groups have been merged into the following four Macro-level Groups:

- Governments of Member States
- WHO Secretariat
- Other International Intergovernmental Organizations (OIIO)
- Other Relevant Stakeholders (ORS)

The data for Member States have been split according to the four World Bank income levels.

Graph 2.2 Distribution of sources of data by Stakeholder Group



### 3 KEY OVERALL FINDINGS

- **Awareness and engagement of stakeholders.** The evaluation sample is restricted to countries that at least named a Focal Point and responded. The observed findings may therefore be better than the reality, as a result of excluding countries that have not even named a Focal Point, and may not have made as much progress or are not aware of GSPOA. It was also noted that many local stakeholders in the countries visited were not aware of or engaged in the implementation of GSPOA.
- **Variance across income groups.** For several, if not all, elements the finding is quite similar: stakeholders may be aware of GSPOA, but progress in implementation varies and it seems to be smaller in lower-middle-income and low-income countries with less resources. The way in which each element was implemented therefore depended on the priorities and capacity of each country.

- **Attribution.** Findings show countries doing related activities, but not considered a result of GSPOA. This also has to be taken into account in the interpretation of this report. GSPOA does not occur in a vacuum and the challenge here is to see what effects can be attributed to GSPOA. It may not be possible to separate the effect as a result of GSPOA from the internal dynamics of the countries in some cases.

As one of the goals of the evaluation was to inform the overall programme review of GSPOA, planned for 2017, the evaluators have identified in this report areas for future work and proposed recommendations which the overall programme review may wish to consider. Through this overall programme review, Member States may also wish to further review resources expended and financing available for the implementation of GSPOA in order to identify best practices and constraints.



## Element 1: Prioritizing research and development needs

### Background

GSPOA suggests that health R&D policies of developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases need to be identified. A good understanding of the health needs of developing countries is essential to drive sustainable R&D on health products. Mapping global R&D for identifying gaps in R&D is needed and, based on the findings, strategies should be formulated at country, regional and interregional levels. GSPOA specifically acknowledges the need for encouraging R&D in traditional medicine.

#### GSPOA Element 1. Prioritizing research and development needs<sup>9</sup>

Health research and development policies of developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the specific research and development needs of developing countries in relation to Type I diseases need to be identified urgently. A better understanding of the developing countries' health needs and their determinants is essential to drive sustainable research and development on new and existing products. The actions to be taken to prioritize research and development needs are as follows:

- (1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries:
  - (a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases;*
  - (b) disseminate information on identified gaps, and evaluate their consequences on public health;*
  - (c) provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs.*
- (1.2) formulating explicit prioritized strategies for research and development at country and regional and interregional levels:
  - (a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments;*
  - (b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries;*
  - (c) include research and development needs on health systems in a prioritized strategy;*
  - (d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for research and development to address public health needs;*
  - (e) increase overall research and development efforts on diseases that disproportionately affect developing countries, leading to the development of quality products that address public health needs, and that are user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability).*

<sup>9</sup> GSPOA, available at: <http://www.who.int/phi/publications/gspa-phi/en/>

(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples:

*(a) set research priorities in traditional medicine;*

*(b) support developing countries to build their capacity in research and development in traditional medicine;*

*(c) promote international cooperation and the ethical conduct of research;*

*(d) support South–South cooperation in information exchange and research activities;*

*(e) support early-stage drug research and development in traditional medicine systems in developing countries.*

## Key findings

**Mapping global research and development:** There is evidence of mapping health research needs and efforts at global level. However, the methodologies and tools applied in those exercises differ substantially across and even within countries. Furthermore, qualitative data confirmed that there is no best practice in mapping health-related R&D needs, identifying gaps and setting health research priorities.

There are good examples of the provision of support from high-income countries to low-income and lower-middle-income countries in identifying gaps in health research and local needs. There is qualitative and quantitative evidence that WHO, Member States and national organizations produce, publish and disseminate reports on gaps in health-related research; however, the differences among regions and income groups are significant. Survey data show that the majority of countries that reported published reports fall into the high-income or the lower-middle-income groups.

Data also show that WHO assists Member States in developing their health-related R&D policies, in particular with regard to Type III diseases.

There is evidence that the normative work conducted by WHO in mapping and identifying R&D gaps is highly valued by national and international health policy experts, and is requested and well-received by the Member States.

**Formulating prioritised strategies for research and development:** There is sporadic evidence, based on document reviews, the invitational survey and interviews, that some countries prioritize R&D needs at national level; however, the level of effort differs across and within different regions and income groups. Data reveal that prioritizing health research is not in the focus at national level in many Member States, and national health R&D plans in some Member States lack chapters on health issues.

There are good examples which suggest that WHO

### WHO support to research prioritization

WHO played a key role in prioritizing research needs, including not only for emerging infectious diseases such as the Zika virus infection and Ebola, but also for palliative and emergency care, and certain groups of chronic disease, such as epilepsy.

supported lower-middle-income and low-income countries in prioritizing health research, in particular addressing emerging diseases such as Zika and Ebola; developing products for regional needs; and engaging countries in the creation of R&D frameworks for diseases that disproportionately affect people in lower-middle-income and low-income countries.

Country case studies revealed that universities and academic institutions develop their own strategies and reports on R&D gaps in health; however, the gaps identified by the different stakeholders in the same country are not always the same.

Countries which provided information on this issue reported the existence of prioritized strategies for R&D at country level. However, there is significant evidence that, in many countries, the R&D strategies lack a focus on health and have no chapters or paragraphs dealing with health-related research. Qualitative data show that in some countries strategies prioritized by different stakeholders and institutes, such as academia and universities, are not consolidated at national level. Progress in prioritizing R&D at national level in most countries is less than optimal.

On the other hand, there are countries with a strong focus on pharmaceutical and biotechnological research and strategies for those research areas but, in many of those cases, available information suggests that commercial interests are the main drivers for investing in health research.

Among the available best-practice examples, there are a few high-income countries with prioritized strategies or policies for addressing diseases affecting lower-middle-income and low-income countries. Data from all three lines of evidence show that, based on those strategies and policies, national regulatory agencies in lower-middle-income and low-income countries were strengthened, clinical research centres were established and phases of clinical drug trials of diseases with a high burden in lower-middle-income and low-income countries were conducted.

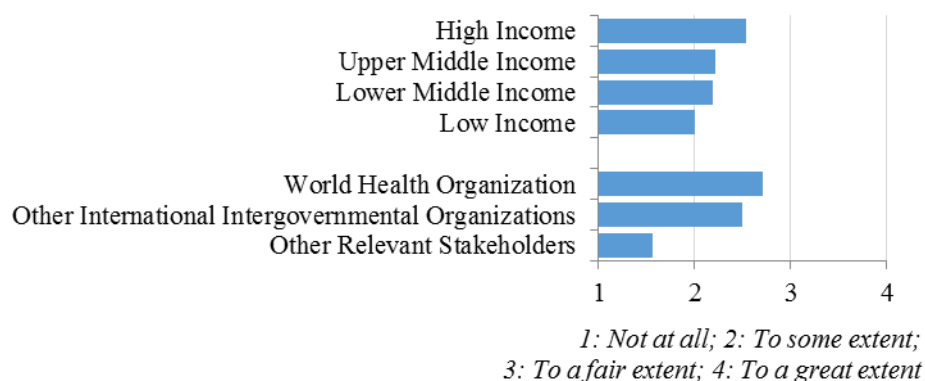
**Encouraging research and development in traditional medicine:** Research in traditional medicine involves identifying compounds, conducting clinical trials to prove the safety and efficacy of those compounds and developing new and modern technologies to produce traditional medicines. There is some evidence of collaborative partnerships between countries of different WHO regions and income groups in R&D in traditional medicine. Among other benefits, they address safety issues, including the production of traditional medicine following modern scientific methods. However, these efforts are far from being widespread. Both access to evidence-based information on traditional medicine and the involvement of the private sector in this field of R&D are limited.

Traditional medicine contributes to the health status of communities of lower-middle-income and low-income countries. An increased trade of health products appears to contribute to the use of traditional medicine in high-income and upper-middle-income countries. However, there is evidence that in most countries, traditional medicine is not an important element of national

health policies, nor is it integrated into the national health care system. The same apply to countries with appropriate recognition of traditional medicine.

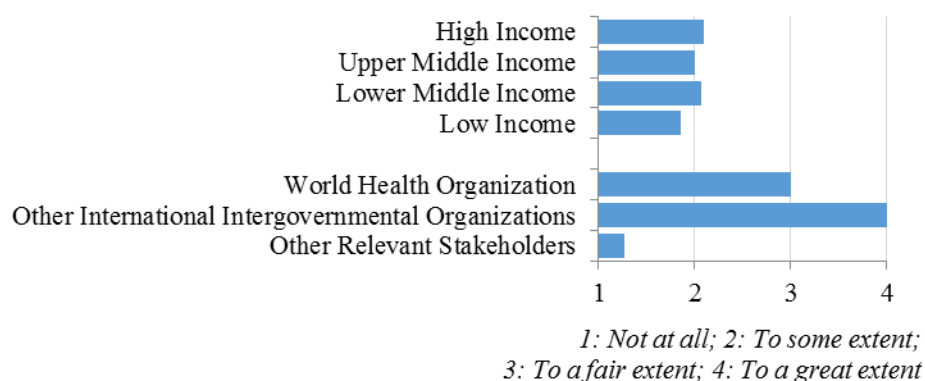
## Survey Results

Graph 3.1 To what extent did your country or organization implement Element 1?



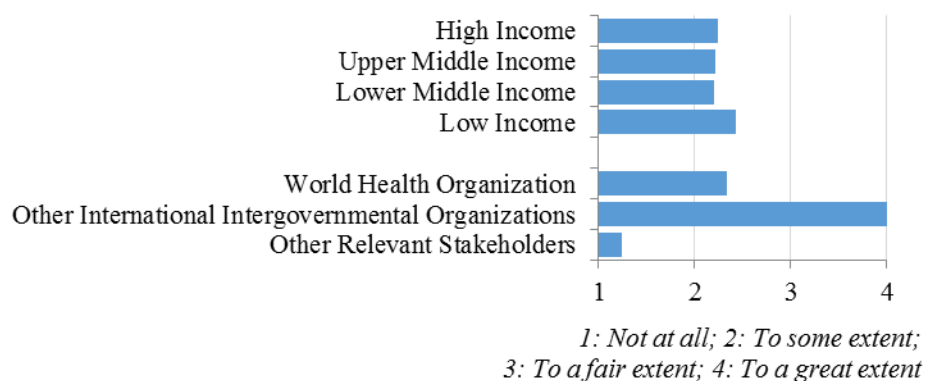
### 1.1 Mapping global research and development

Graph 3.2 Within Element 1, to what extent did your country or organization implement Sub-Element 1.1?



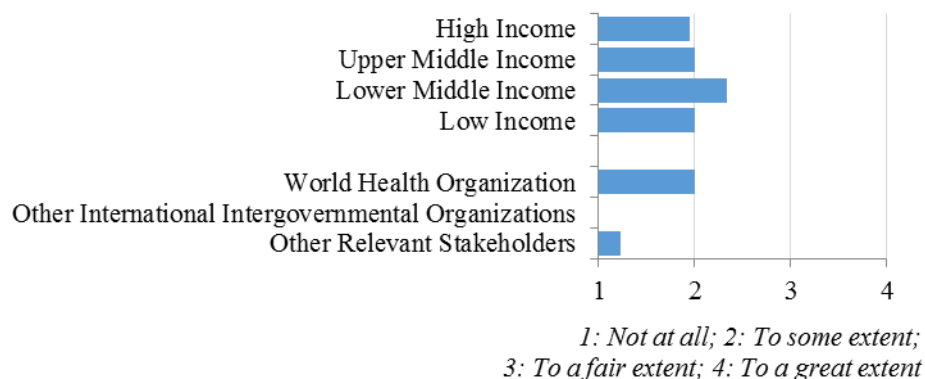
### 1.2 Formulating prioritized strategies for research and development

Graph 3.3 Within Element 1, to what extent did your country or organization implement Sub-Element 1.2?



### 1.3 Encourage research and development in traditional medicine

Graph 3.4 Within Element 1, to what extent did your country or organization implement Sub-Element 1.3?



#### Key observations from country case studies

High-income and upper-middle-income countries, especially in the Americas and in Europe, prioritize R&D from both the national and global perspectives. They reviewed their health policies, including the research components, during the implementation of GSPOA, but not necessarily as a consequence of GSPOA. There are newly published documents relating to health policy that address the health problems that disproportionately affect the lower-middle-income and low-income countries. There is also evidence that NGOs contributed to disseminating information on identified research gaps, and the consequences of gaps on public health.

Upper-middle-income countries have relatively well defined national R&D policies and/or strategies. However, an adequate implementation strategy may be lacking at the national level. Most health R&D work is being done in the private sector.

At the lower-middle-income level, national R&D policies exist in some countries; however, even in countries where they exist, the overall national coordination between different agencies is less than optimal.

In low-income countries, national health policies exist; however, without precisely addressing health research needs.

The main gap in the implementation is the low level of awareness of GSPOA in all country income groups. A system is lacking that can efficiently manage research priorities in most countries. Also lacking are platforms where stakeholders can engage, create affinities, establish common goals and work together. In upper-middle-income and lower-middle-income countries, national R&D policies/strategies have limited relevance to the focus areas of GSPOA. Prioritization of R&D needs in GSPOA focus areas is also lacking. The main challenge is the coordination throughout the different ministries at country level.

#### Key achievements

**Mapping global research and development:** There is evidence that Member States identified health needs and prioritized health research. The engagement of WHO with Member States led to progress towards a global framework for R&D and to the coordination of R&D for diseases that disproportionately affect lower-middle-income and low-income countries<sup>10</sup>. A WHO project on the establishment of the *Global Observatory on Health Research and Development* is under implementation. Its main objective is identifying gaps in R&D, specifically for diseases that disproportionately affect lower-middle-income and low-income countries. Once finalized, the *Observatory* will contribute to collecting information on research related to 37 diseases and health conditions, including tuberculosis, HIV/AIDS and malaria.

#### Good practices

The coordination and cooperation among different groups of national stakeholders of a high-income country has resulted in prioritized research needs for lower middle and low-income countries. Those priorities are taken into consideration when this high-income country sets up the annual priorities with its partners.

There are good examples of the provision of support from high-income countries to lower-middle-income and low-income countries in identifying gaps in health research and local needs; in publishing and disseminating reports on such gaps; and in engaging countries in the creation of R&D frameworks for diseases that disproportionately affect people in lower-middle-income and low-income countries. However, the differences among regions and income groups regarding these efforts are significant.

Data show that WHO supported lower-middle-income and low-income countries in those activities. There are a variety of research priority exercises undertaken by WHO predominantly involving infectious diseases, and, to a lesser extent, chronic diseases and conditions and emergencies. Data also show that WHO is active in assisting Member States in developing their health-related R&D policies, in particular with regard to Type III diseases.

The normative work of WHO in mapping and identifying R&D gaps informed policy development in several lower-middle-income and low-income countries and is highly valued by national and international health policy makers as well as in demand and well-received by Member States.

**Formulating prioritized strategies for research and development:** Data also show achievements at global level in identifying R&D needs related to emerging diseases and outbreaks and developing health products to prevent, diagnose and treat those diseases. WHO supported lower-middle-income and low-income countries in prioritizing health research, in particular addressing emerging diseases and developing products for national and regional needs.

<sup>10</sup> [http://apps.who.int/iris/bitstream/10665/150173/1/A66\\_R22-en.pdf?ua=1&ua=1](http://apps.who.int/iris/bitstream/10665/150173/1/A66_R22-en.pdf?ua=1&ua=1)

WHO led the development of tools and guidance for identifying gaps at national level which contributed to the amendment of national regulations. Country case studies revealed that universities and academic institutions develop their own strategies and reports on R&D gaps in health; however, the gaps identified and resulting R&D strategies developed by the different stakeholders in the same country are not always the same, are not consolidated at the national level, and progress in prioritizing R&D at national level in most countries is still insufficient.

Capacity in strategy and policy development and regulatory agencies were improved in several lower-middle-income and low-income countries.

Among the available best-practice examples, a few high-income and upper-middle-income countries have elaborated prioritized R&D strategies or policies for addressing diseases affecting lower-middle-income and low-income countries. Based on the latter, national regulatory agencies in lower-middle-income and low-income countries were established and phases of clinical drug trials for diseases with a high burden in those countries were conducted.

**Encouraging research and development in traditional medicine:** There is evidence that a few Member States made steps to establish national inventories of medicinal plants for the preservation and protection of traditional medical knowledge.

WHO developed basic training guidelines in various types of traditional medicine/complementary or alternative medicine, as well as training on regulation and qualification in this area. Training and technical guidance on clinical research in traditional medicine were developed and work was initiated on a WHO technical guide on this subject.

South-South cooperation has improved in traditional medicine through information exchange and research activities.

## Key gaps and challenges identified

**Mapping global research and development:** Investments in health research, in particular in traditional medicine, are insufficient and not appropriately directed towards tackling priority health problems. Current market mechanisms and publicly-funded research result in far too little investment in R&D for diseases that mainly affect lower-middle-income and low-income countries. Data from different lines of evidence show that, despite the efforts made by several Member States to map health-related research and identify gaps, there are countries that did not report any data in this field. Low-income countries in particular are faced with a diverse range of donor driven research agendas that often result in shifting national priorities.

Many countries are facing significant challenges in training and retaining researchers.

Qualitative data reveal the challenges of explicitly linking the R&D needs, gaps and activities to an evidence-based and transparent R&D prioritization process. Involving all relevant stakeholder groups for R&D in appropriate investments and coordination mechanisms presents another challenge.

Data gained, particularly from document reviews and interviews with national key informants, show that, despite the fact that national institutes, universities and academia are dedicated to promoting R&D in general, and health in particular, several Member States are still facing challenges in prioritizing R&D to support public health objectives and coordinate R&D effectively.

Qualitative data show the challenges in orchestrating health R&D at the global level.

**Formulating prioritized strategies for research and development:** In general, prioritizing health research is still not sufficiently in the focus at national level in many Member States and the existing national plans in some of them lack specific chapters on health issues.

Furthermore, the lack of or non-effective prioritization of research for health at national level leads to inordinately low research outputs on several diseases and health conditions that cause a major disease burden in lower-middle-income and low-income countries. This urges engagement in needs-driven R&D at national, regional and global level; innovation and decentralization of R&D capacity; establishment of new funding mechanisms and sources, in particular at global level; and prioritization of funds allocation.

Efforts in support of ethical review and public accountability of research also need to be intensified.

The opportunity of creating a shared framework for storing and sharing research data, tools and materials in different countries has not been seized with the same energy in the area of health as it has in other scientific fields. Moreover, the available evidence to inform policy-making is also limited.

While several countries have policies in place which are related to health research, these are often not translated into a separate specific national health research policy. Even in countries where national R&D policies are in place, investment in health R&D is uncoordinated and the overall coordination between the different agencies involved less than optimal.

A wide range of criteria must be taken into account for formulating prioritized strategies for R&D. The lack of baseline data and under-developed capacity in health R&D are often coupled with limited efforts of policy makers to develop health strategies.

Collaboration on R&D for health products and technologies should focus more on building local capacity relevant to local health needs, rather than on trade-related interests.

**Encouraging research and development in traditional medicine:** Coordination and collaboration of R&D in traditional medicine is weak and capacity in R&D in traditional medicine is still limited in many lower-middle-income and low-income countries. Despite the efforts of WHO, standard-setting to ensure quality, safety and efficacy in traditional medicine needs to be improved.



Involving the private sector more in this domain may lead to a significant increase in resources. Databases and libraries with evidence-based information on traditional medicine should also be further developed.

### Areas for Further Work Identified

The following areas have been identified where further work needs to be done in order to completely implement this element:

- a. To improve coordination of health R&D at national, regional and global levels;
- b. To strengthen collaboration among partners across all sectors that influence research for health;
- c. To develop publicly accessible repositories for health research in order to improve access to knowledge, including for traditional medicine;
- d. To advocate support for research areas, research groups and institutions that are working to close critical gaps in research agendas in support of global research priorities;
- e. To further assist Member States in carrying out national assessments and analyse and compare data gained at national and regional level and identify further steps for improved assessment;
- f. To conduct periodical re-evaluations of the coordination of health research;
- g. To support those Member States where research priority setting is fragmented, incomplete or still absent in their endeavours related to conducting this exercise;
- h. To support R&D and promote standard-setting for traditional medicine.

## Conclusions

Relevance	<ul style="list-style-type: none"> <li>The value of research is widely recognized.</li> </ul>
Effectiveness	<ul style="list-style-type: none"> <li>While Member States are prioritizing, to varying extents, health-related R&amp;D needs, high and upper-middle-income countries in the Americas and Europe seem to be the more effective in doing so.</li> <li>While Member States prioritize R&amp;D needs at the national level, the effectiveness of these actions differs across and within different regions and income groups, depending on political will, and human and financial capacity.</li> <li>WHO and high-income countries supported lower-middle-income and low-income countries effectively in prioritizing health research, in particular addressing emerging diseases and developing products for regional needs.</li> <li>Interest in traditional medicine has increased at global level, and there is some evidence of effective collaborative partnerships in traditional medicine between countries.</li> </ul>
Sustainability	<p>Sustainability is uncertain, since:</p> <ul style="list-style-type: none"> <li>Investments in health research are insufficient and not appropriately directed towards tackling priority health problems.</li> <li>Funding for research in traditional medicine and capacity to conduct that research is limited.</li> <li>Low-income countries are faced with a diverse range of donor-driven research agendas that often result in shifting national priorities.</li> </ul>
Early Impact	<ul style="list-style-type: none"> <li>The engagement of WHO with Member States led to substantial progress towards a global framework for R&amp;D and to the coordination of R&amp;D for diseases that disproportionately affect lower-middle-income and low-income countries.</li> <li>The <i>Global Observatory on Health Research and Development</i> which is under implementation is one of the collaborative activities that may boost the prioritization of R&amp;D of Member States.</li> <li>There are a few high-income and upper-middle-income countries with prioritized strategies or policies for addressing diseases affecting lower-middle-income and low-income countries.</li> <li>WHO played a key role in prioritizing research needs, including not only for emerging infectious diseases such as the Zika virus infection and Ebola but also for palliative and emergency care, and certain groups of chronic disease, such as epilepsy.</li> </ul>

## Recommendations

### Recommendations for consideration by Member States

1. Member States to ensure that their health R&D at national and sub-national level is prioritized, including for traditional medicine, through multi-stakeholder consultation, using national focal points or units for effective inter-sectoral coordination.

### Recommendations for consideration by the WHO Secretariat

2. WHO Secretariat to support Member States to monitor progress in R&D prioritization;
3. WHO Secretariat, in collaboration with partners across all sectors, to promote coordination of health R&D at national, regional and global levels, with a view to closing critical gaps in research agendas in support of global health research priorities;
4. WHO Secretariat to promote publicly accessible repositories for health research in order to improve access to knowledge;
5. WHO Secretariat to further support Member States in carrying out national assessments and analyse and compare data gained at national and regional level and identify further steps for improved assessment;
6. WHO Secretariat and partners to conduct periodical re-evaluations of the coordination of health research.

## Element 2: Promoting research and development

### Background

GSPOA recognizes the need that political, economic and social institutions in each country should participate in the development of health research policy. Measures to promote, coordinate and finance public and private research on Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases need to be substantially enhanced. Greater investment in all countries is essential in supporting governments to develop or improve national health research programmes and establishing strategic research networks. Further efforts are needed to promote upstream research and product development in developing countries; to provide access to knowledge and technology; and to improve cooperation and coordination of health and biomedical R&D. The global strategy supports the establishment and strengthening of national and regional coordinating bodies on R&D.

#### GSPOA Element 2. Promoting research and development<sup>11</sup>

There are many determinants of innovation capacity. Political, economic and social institutions in each country should participate in the development of health research policy, taking into consideration their own realities and needs. The range of measures to promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases needs to be substantially enhanced. Greater investment, in both developed and developing countries, is essential. The actions to be taken to promote research and development are as follows:

- (2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area:
  - (a) promote cooperation between private and public sectors on research and development;*
  - (b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding;*
  - (c) support governments in establishing health-related innovation in developing countries.*
- (2.2) promoting upstream research and product development in developing countries:
  - (a) support discovery science, including, where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products;*
  - (b) promote and improve access to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries;*
  - (c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international – that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools;*
  - (d) support basic and applied scientific research on Type II and Type III diseases and on the specific research and development needs of developing countries in relation to Type I diseases;*
  - (e) support early-stage drug research and development in developing countries;*
  - (f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries;*
  - (g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries.*

<sup>11</sup> GSPOA, available at: <http://www.who.int/phi/publications/gspa-phi/en/>

- (2.3) improving cooperation, participation and coordination of health and biomedical research and development:
- (a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources;*
  - (b) enhance existing forums and examine the need for new mechanisms in order to improve the coordination and sharing of information on research and development activities;*
  - (c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical research and development, including, inter alia, an essential health and biomedical research and development treaty;*
  - (d) support active participation of developing countries in building technological capacity;*
  - (e) promote the active participation of developing countries in the innovation process.*
- (2.4) promoting greater access to knowledge and technology relevant to meet public health needs of developing countries:
- (a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centres, especially in developing countries;*
  - (b) promote public access to the results of government-funded research by strongly encouraging all investigators funded by governments to submit to an open access database an electronic version of their final, peer-reviewed manuscripts;*
  - (c) support the creation of voluntary open databases and compound libraries, including voluntary provision of access to drug leads identified through the screening of such compound libraries;*
  - (d) encourage the further development and dissemination of publicly or donor funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms;*
  - (e) consider, where appropriate, use of a “research exception” to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights.*
- (2.5) establishing and strengthening national and regional coordinating bodies on research and development:
- (a) develop and coordinate a research and development agenda;*
  - (b) facilitate the dissemination and use of research and development outcomes.*

## Key findings

**Supporting governments to develop or improve national health research programmes and establish strategic research networks:** GSPOA has promoted health R&D in Member States and improved access to knowledge and technology. Databases on clinical trials, patents, IP and health knowledge were created or became available.

Qualitative and quantitative data show that many countries have created or strengthened national initiatives on health-related R&D. A significant number of those initiatives cover public and private entities as well as the extent of their collaboration in improving participation in, and coordination of, health and biomedical R&D.

There is evidence that most countries have created strategic plans for health, including an R&D component. Data show that political and economic institutions were participating in the development of health research policies; however, the involvement of social institutions was weak and varied across income groups.

While there is evidence of the extensive work conducted by WHO in creating platforms for assisting governments to develop their national health strategies, the direct link between the planning processes of the Member States and WHO work is not always obvious.

Some Member States have created strategic plans for their health workforce and related professionals including an R&D component.

There are varied results in establishing strategic research networks to facilitate better coordination of stakeholders in R&D. Low-income countries, with the exception of some countries in the African and Eastern Mediterranean regions, reported significantly less activities in this sub-element.

**Promoting upstream research and product development in developing countries:** Some high-income countries promoted upstream research in lower-middle-income and low-income countries; however, data on the results were not always available.

At global level, the range of measures to promote, coordinate and finance public and private research on Type II and Type III diseases seem to depend on the income level of countries. There is limited evidence of a commitment to or support for long-term funding for health research programmes in lower-middle-income and low-income countries.

The limited communication on GSPOA, as a whole, and on the availability and accessibility of knowledge and information related to it is also evident from the data.

Promoting product development in lower-middle-income and low-income countries is supported only by a limited number of countries and the distribution of both donor and recipient countries is uneven among the regions.

In the Americas and Europe, new or strengthened initiatives aimed at enhancing capacity to analyze and manage clinical trial data have been largely successful.

While there is a wide range of R&D activities that countries undertake to promote and share their research in other regions, it is hard to attribute this action to the GSPOA, and it is therefore not possible to estimate to what degree GSPOA has lived up to its aim to guide the thinking and to propel countries' actions in promoting R&D.

**Improving cooperation, participation and coordination of health and biomedical research and development:** Data from different lines of evidence, including desk review, interviews, and surveys, show that cooperation, participation and coordination of health and biomedical R&D with lower-middle-income and low-income countries was generally effective. The Americas seem to be most successful in this area.

The Special Programme for Research and Training in Tropical Diseases (TDR), hosted by WHO and sponsored by UNICEF, UNDP, the World Bank and WHO, helps facilitate, support and influence efforts to combat diseases of poverty. In 2012 TDR published a *Global Report for Research on Infectious Disease of Poverty*<sup>12</sup>. Initiatives such as the African Network for Drug and Diagnostics Innovation (ANDI) was incubated in TDR as a follow-up to GSPOA.

**Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries:** There is evidence that GSPOA promoted health R&D by improving access to knowledge and technology via databases and libraries, as well as by capacity building; however, the extent and the effectiveness of these efforts vary among regions.

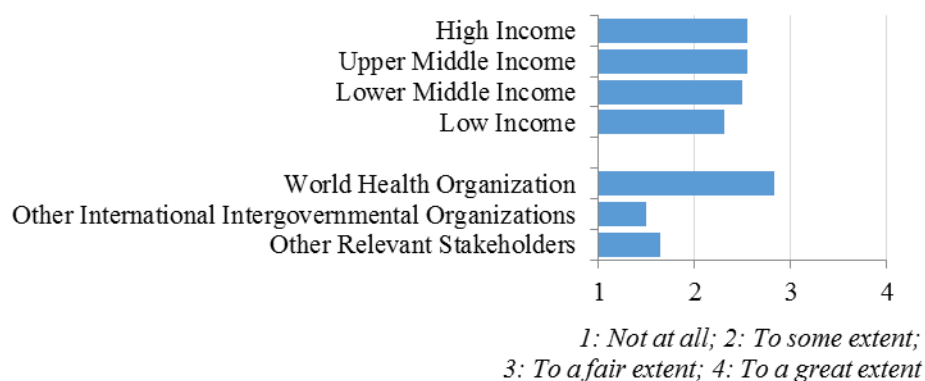
Data show that many Member States facilitated the dissemination and use of R&D outcomes.

Evidence from different types of source shows that high-income and upper-middle-income countries have created or strengthened initiatives aimed at providing access to publications and research knowledge.

**Establishing and strengthening national and regional coordinating bodies on research and development:** There is evidence that high-income and upper-middle-income countries in most regions strengthened their national and regional coordinating bodies on R&D.

## Survey Results

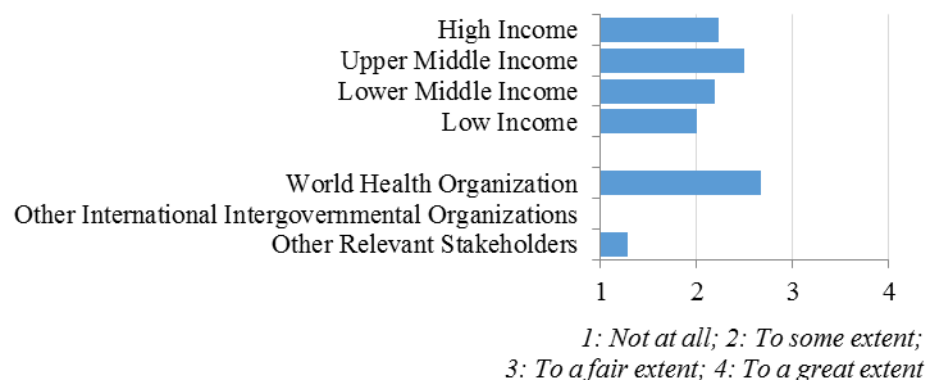
Graph 3.5 To what extent did your country or organization implement Element 2?



<sup>12</sup>Global Report for Research on Infectious Diseases of Poverty 2012, [http://apps.who.int/iris/bitstream/10665/44850/1/9789241564489\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44850/1/9789241564489_eng.pdf)

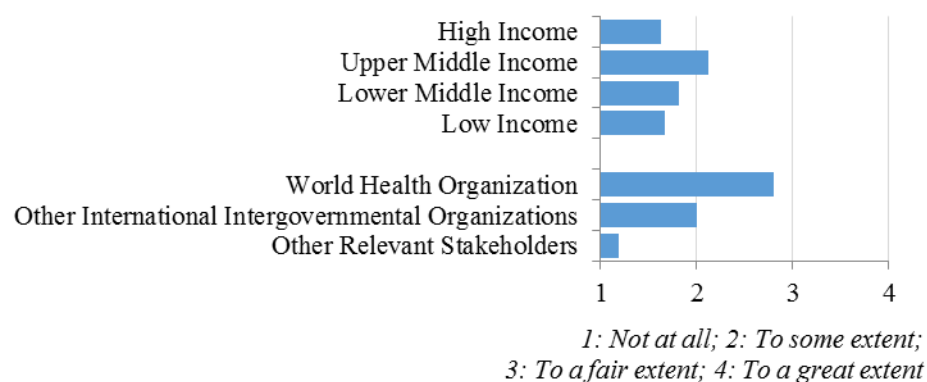
## 2.1 Supporting governments to develop or improve national health research programmes and establish strategic research networks

Graph 3.6 Within Element 2, to what extent did your country or organization implement Sub-Element 2.1?



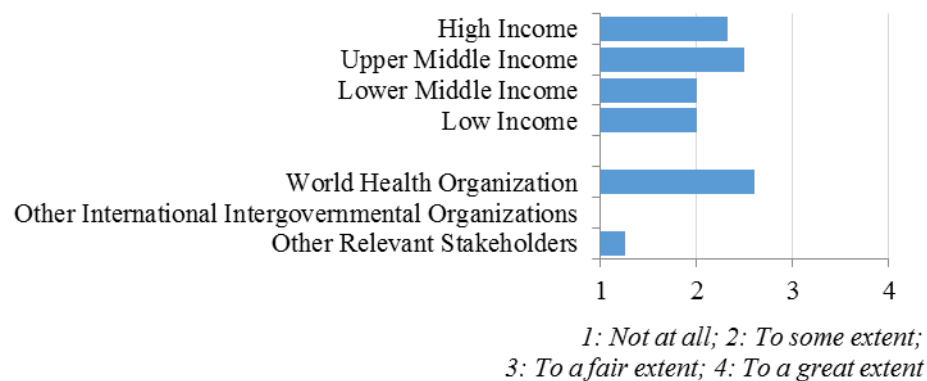
## 2.2 Promoting upstream research and product development in developing countries

Graph 3.7 Within Element 2, to what extent did your country or organization implement Sub-Element 2.2?



## 2.3 improving cooperation, participation and coordination of health and biomedical research and development

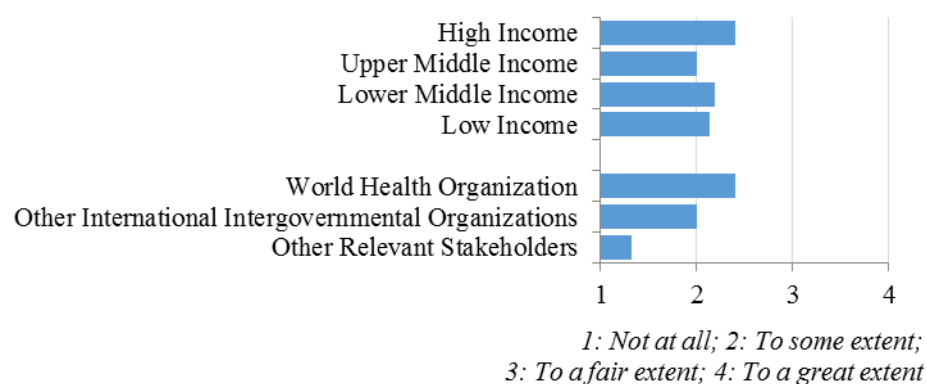
Graph 3.8 Within Element 2, to what extent did your country or organization implement Sub-Element 2.3?





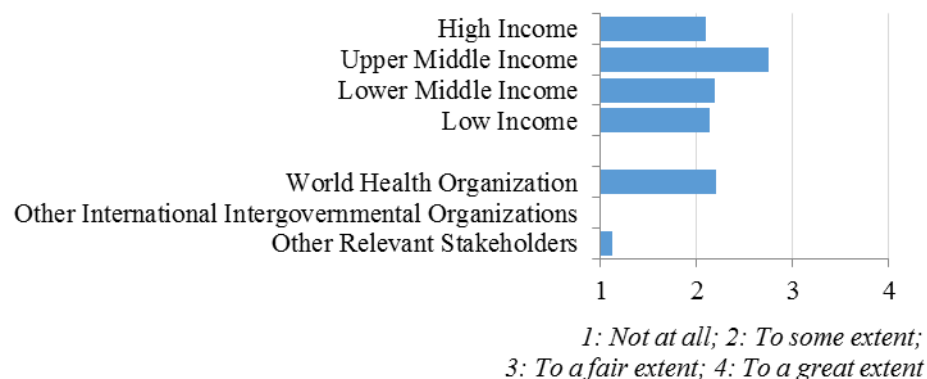
## 2.4 Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries

Graph 3.9 Within Element 2, to what extent did your country or organization implement Sub-Element 2.4?



## 2.5 Establishing and strengthening national and regional coordinating bodies on research and development

Graph 3.10 Within Element 2, to what extent did your country or organization implement Sub-Element 2.5?



## Key observations from country case studies

High-income countries promote R&D in all three types of disease. These countries also promote health research in lower-middle-income and low-income countries with the involvement of governmental bodies from both sides and, in certain cases NGOs. The NGOs also contributed to the priority-setting work. In upper-middle-income countries, several institutions are dedicated to R&D in health, including some that conduct research in traditional medicine. In lower-middle-income countries, national research or science and technology policies are in place; however, the national coordination between the different agencies is mostly less than optimal. Innovation is primarily demonstrated by the private sector under market-driven conditions and largely outside the scope of GSPOA. One country has established a database in traditional medicine. Health research capacity is generally very low in low-income countries.

In terms of gaps, the overall national coordination between the different agencies is limited in upper-middle-income, lower-middle-income and low-income countries. Greater investment is needed in most income group countries, particularly in lower-middle-income and low-income countries, to develop or improve national health research programmes and establish strategic research networks. In most lower-middle-income countries, the pharmaceutical sector is still small and would need major investments to support the existing public health objectives effectively; furthermore, relevant stakeholders are not aware of GSPOA.

## Key achievements

**Supporting governments to develop or improve national health research programmes and establish strategic research networks:** GSPOA has promoted health R&D in all income groups. Several examples show that there are Member States which have developed and implemented health R&D programmes that are based on their health strategy.

### Good Practices

Collaboration between UN agencies and international organizations has permitted the implementation of training workshops on health issues and the promotion of health R&D in some developing countries.

Data from different regions reveal the cooperation between the public and the private sector in improving cooperation, participation and coordination of health and biomedical R&D. Available data show that many countries have created or strengthened national initiatives on health-related R&D. A significant number of them cover public and private entities as

well as the extent of their collaboration in improving participation in, and coordination of, biomedical R&D.

**Promoting upstream research and product development in developing countries:** The range of measures to promote, coordinate and finance public and private research into Type II and Type III diseases seems to depend on the respective income levels. There are examples of all income group countries having established open-access databases of scientific information, publications and clinical trials.

### R&D Blueprint

In June 2015, in response to resolution EBSS3.R1 (2015) on Ebola, WHO developed a blueprint for R&D preparedness and response for potentially epidemic diseases. Its overall goal is to reduce delays between the identification of an outbreak and the deployment of effective medical interventions to save lives and minimize socioeconomic disruption.

The Blueprint focuses on identifying priority infectious disease threats as well as gaps and priorities in R&D; improving collaboration between stakeholders; and promoting an enabling environment for the conduct of R&D during outbreaks. In addition, it aims to complement the Secretariat's efforts to foster R&D related to Type II and Type III diseases, and the specific R&D needs of lower middle and low-income countries in relation to Type I diseases, in line with GSPOA and the recommendations of the CEWG.

**Improving cooperation, participation and coordination of health and biomedical research and development:** Cooperation, collaboration and coordination of health research include research activities at global level for the prevention and treatment of Zika and Ebola virus infections. WHO supported the generation of evidence needed to strengthen essential public health

guidance and actions to prevent and limit the impact of these viruses and their complications.

**Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries:** GSPOA has improved access to knowledge and technology. Member States and other stakeholders promoted greater access to knowledge by making scientific databases, publications, and tools available free of charge. Databases on clinical trials, patents, IP and health knowledge were created or became available.

#### Library

An upper-middle-income country has established and maintains a library that offers access to several scientific databases; databases of patents and tools for analysis of IP; international collection of chemical, biochemical and pharmaceutical information; and publications of indexed journals. The library also performs searches for papers in other national and international libraries.

**Establishing and strengthening national and regional coordinating bodies on research and development:** Member States from all region and income groups reported strengthening their national and regional coordinating bodies on health R&D. Overall, the progress reported from African and European countries was the highest.

### Key gaps and challenges identified

**Supporting governments to develop or improve national health research programmes and establish strategic research networks:** Very few countries or institutions supported national health research programmes in lower-middle-income and low-income countries through long-term funding.

There is evidence that lack of funding for health research impedes complying with many aspects of GSPOA in almost every region, predominantly in lower-middle-income and low-income countries. Funds are often provided for research activities which do not address the health needs of these countries.

Data from different sources show that measures to promote and coordinate research into all types of disease need to be substantially enhanced. Greater investment in Member States is needed for the development and implementation of national health research programmes and the establishment of strategic research networks.

There is limited capacity in several lower-middle-income and low-income countries at governmental level for planning health research programmes, and health research is furthermore not the priority of all Member States.

**Promoting upstream research and product development in developing countries:** Many sources of this evaluation identified the lack of host-country capacity as a major barrier in global health R&D. Furthermore, once a product is developed, there is often lack of infrastructure in other countries to absorb new products.

**Improving cooperation, participation and coordination of health and biomedical research and development:** Some Member States have no health research policy and others do not have a strong research policy. Furthermore, certain national action plans lack any linkage between the national plan and the plans of the various research organizations. In particular, lower-middle-income countries in several regions appeared not to have made progress on this count.

The limited funding available for health and medical research at global, regional and national level, coupled with emerging diseases and outbreaks presenting global threats, necessitate improved cooperation and coordination in health research. In this context, long-term funding sources need to be developed with particular urgency.

**Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries:** While open-access to health and medical knowledge and technology improved significantly during the implementation of GSPOA, it is still an issue in lower-middle-income and low-income countries. Difficulties experienced by these countries in accessing health and medical knowledge and technology are illustrated by the document review and key informant interviews. Some lower-middle-income and low-income countries have limited access to the most basic communication tools (websites, internet, physical libraries).

Despite all efforts, many lower-middle-income and low-income countries still have limited access to medical and health literature. There are barriers to accessing and sharing knowledge.

Data show that the number of scientific publications published in peer-reviewed journals by researchers from lower-middle-income and low-income countries as the first author or a co-author varied highly among regions. Data indicate that in countries where the language of instruction is not English, or another widely-spoken language such as other UN official languages, the ability to publish internationally is hampered.

There is thus a clear need for a communications strategy to overcome the current lack of communication tools and thus ensure better access to knowledge in these countries. In this regard, vastly enhancing the affordable access to publications appears to be particularly important.

A large number of lower-middle-income and low-income countries in several regions self-reported having made no progress on this count.

**Establishing and strengthening national and regional coordinating bodies on research and development:** While many countries reported progress in establishing or strengthening coordinating bodies on health R&D, qualitative data revealed little information about this issue.

Even where such coordinating bodies were established, these efforts may not be effective due to the lack of health R&D strategies in many lower-middle-income and low-income countries.

## Areas for Further Work Identified

The following areas have been identified where further work needs to be done in order to implement this element completely:

- a. To promote upstream research in lower-middle-income and low-income countries;
- b. To develop strategic plans for the health workforce and related professionals including an R&D component;
- c. To strengthen the work in creating and renewing platforms for assisting governments to develop their national health programmes;
- d. To strengthen initiatives aimed at providing access to publications and research knowledge;
- e. To promote broader multi-sectoral participation in the development of health research policy;
- f. To enhance national capacity for analyzing and managing clinical trial data;
- g. To create better and more targeted communication strategies to remedy the current lack of communication tools for increasing affordable access to knowledge in many lower-middle-income and low-income countries;
- h. To strengthen efforts towards improving cooperation, participation and coordination of health and biomedical R&D with lower-middle-income and low-income countries.

## Conclusions

<b>Relevance</b>	<ul style="list-style-type: none"> <li>The promotion of R&amp;D is relevant to the interests of most political and economic institutions of Member States.</li> </ul>
<b>Effectiveness</b>	<ul style="list-style-type: none"> <li>Cooperation, participation and coordination of health and biomedical R&amp;D with lower-middle-income and low-income countries was effective.</li> <li>GSPOA promoted health R&amp;D, including greater access to knowledge and technology.</li> <li>The level of promotion of health-related R&amp;D differs among the regions and countries and cannot be explained solely by the income level of countries.</li> <li>Countries in all income groups created or strengthened initiatives aimed at providing access to publications and information, such as research knowledge, results and technology; however, lower-middle-income and low-income countries experience difficulties in accessing those databases.</li> </ul>
<b>Sustainability</b>	<p>Sustainability is not assured, because:</p> <ul style="list-style-type: none"> <li>The lack of funding for health research impedes complying with many aspects of GSPOA in almost every region, most dominantly in lower-middle-income and low-income countries.</li> <li>Funds for health research are often provided for research activities which do not address the national health needs.</li> <li>Very few countries or institutions supported national health research programmes in lower-middle-income and low-income countries through long-term funding.</li> </ul>
<b>Early Impact</b>	<ul style="list-style-type: none"> <li>Some initiatives promoted access to scientific databases, libraries and other sources of scientific information.</li> </ul>

## Recommendations

### Recommendations for consideration by Member States

1. Member States to promote upstream research in lower-middle-income and low-income countries with strengthened international cooperation and joint work between the public and private sector in areas that address their health needs, as well as at the international level and between high-income and lower-middle-income countries;
2. Member States to enhance national capacity for analysing and managing clinical trial data;
3. Member States to promote broader multi-sectoral participation in the development of health research policy.

### Recommendations for consideration by the WHO Secretariat

4. WHO Secretariat to strengthen its work with partners for creating and renewing strategic research networks to support governments to develop their national health programmes, including the necessary communication tools.

### Recommendations for consideration by all stakeholders

5. All stakeholders to improve access to scientific and technological knowledge, including wider availability of libraries and databases;
6. All stakeholders to strengthen the efforts towards improving cooperation, participation and coordination of health and biomedical R&D with and between lower-middle-income and low-income countries.

## Element 3: Building and improving innovative capacity

### Background

GSPOA acknowledges the need for framing, developing and supporting policies which promote health innovation capacity improvement in developing countries. The key areas for capacity development are science and technology, regulation, clinical trials, IP, production of pharmaceuticals and evidence-based traditional medicine. The global strategy supports the investment of developing countries in R&D groups and institutions, and the strengthening of surveillance and information systems. GSPOA recognized the importance of policies which promote innovation in the field of traditional medicine and also develop and implement, where appropriate, possible incentive schemes for health related innovation.

#### GSPOA Element 3. Building and improving innovative capacity<sup>13</sup>

There is a need to frame, develop and support effective policies that promote the development of capacities in developing countries related to health innovation. Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property and traditional medicine. The actions to be taken to build and improve innovative capacity are as follows:

- (3.1) building capacity of developing countries to meet research and development needs for health products:
  - (a) support investment by developing countries in human resources and knowledge bases, especially in education and training, including in public health;*
  - (b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries;*
  - (c) strengthen health surveillance and information systems.*
- (3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation
  - (a) establish and strengthen regulatory capacity in developing countries;*
  - (b) strengthen human resources in research and development in developing countries through long-term national capacity-building plans;*
  - (c) encourage international cooperation to develop effective policies for retention of health professionals, including researchers, in developing countries;*
  - (d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations.*
- (3.3) providing support for improving innovative capacity in accordance with the needs of developing countries:
  - (a) develop successful health innovation models in developing innovative capacity;*
  - (b) intensify North–South and South–South partnerships and networks to support capacity building;*
  - (c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries.*

<sup>13</sup> GSPOA, available at: <http://www.who.int/phi/publications/gspa-phi/en/>

- (3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities, taking into account the relevant provisions of relevant international instruments:
- (a) establish and strengthen national and regional policies to develop, support and promote traditional medicine;*
  - (b) encourage and promote policies on innovation in the field of traditional medicine;*
  - (c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards;*
  - (d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine;*
  - (e) promote South–South collaboration in traditional medicine;*
  - (f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation.*
- (3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation:
- (a) encourage the establishment of award schemes for health-related innovation;*
  - (b) encourage recognition of innovation for purposes of career advancement for health researchers.*

## Key findings

There is evidence that this element is relevant for all stakeholders across regions and income groups and it thus constitutes a catalyst for the effective implementation of several other elements of GSPOA. However, the lack of baseline data severely limited the analysis of the level of implementation and performance achieved in regard to all sub-elements and specific actions under Element 3. The same lack of baseline data also severely limited the comparison of relative achievements between countries or regions, since their existing status in terms of R&D, available innovative capacity and baseline indicators at the beginning of GSPOA were not documented.

**Building capacity of developing countries to meet research and development needs for health products:** Data indicate that health innovation capacity was promoted and developed in many lower-middle-income and low-income countries with the support of several organizations and high-income countries.

Evidence demonstrates investments made in building and improving health innovation capacity, but this was disproportionally allocated and implemented across regions and country income groups. Based on the interviews and surveys, it is evident that high-income countries invested most in health innovation capacity in lower-middle-income and low-income countries, in particular in Africa.

**Framing, developing and supporting effective policies that promote the development of capacities for health innovation:** There is evidence that framing, developing and supporting effective policies has in fact promoted the building and improvement of health-related innovative capacity in some lower-middle-income and low-income countries.

Based on WHO guidelines, tools and ethical standards were developed and promoted for quality regulation of health products in many lower-middle-income and low-income countries.



From the outset of the implementation of GSPOA, national health regulatory authorities have been supported, evaluated and accredited, often as regional regulatory reference authorities.

**Support for improving innovative capacity in accordance with the needs of developing countries:** There is evidence that health-related research centres were established or strengthened in all regions, but they were more prevalent in high and upper-middle-income countries in the Americas and Europe.

Data reveal that the funding provided for research centres by the governments of lower-middle-income and low-income countries was limited and in most cases the governments only supported staff emoluments. As a result, many research activities are donor funded and do not necessarily address regional health priorities.

Networks and partnerships, including with pharmaceutical companies, were built for promoting investments in science and technology in lower-middle-income and low-income countries.

Investments were also made to strengthen regulatory capacity in lower-middle-income and low-income countries, clinical research centres were established, and industry-sponsored clinical trials of diseases with high burden in lower-middle-income and low-income countries were conducted.

**Supporting policies that promote innovation based on traditional medicine:** The evidence gained from different sources is somewhat contradictory. On the one hand, survey data indicate that in most countries traditional medicine is not an important element of national health policies and it is not integrated into the national health care system. The same applies to countries that have appropriate recognition of traditional medicine. On the other hand, qualitative data indicate that there is considerable interest in traditional medicine as a potential source for new medicines, and research institutions explore compounds of medicinal herbs to generate new and novel raw materials for the treatment of diseases.

A few countries have meanwhile elaborated effective national traditional medicine policies with an R&D component, but the vast majority still seems to neglect this area.

Data from different sources show that WHO contributed to technical guideline development, capacity building and the coordination of activities in the field of traditional medicine.

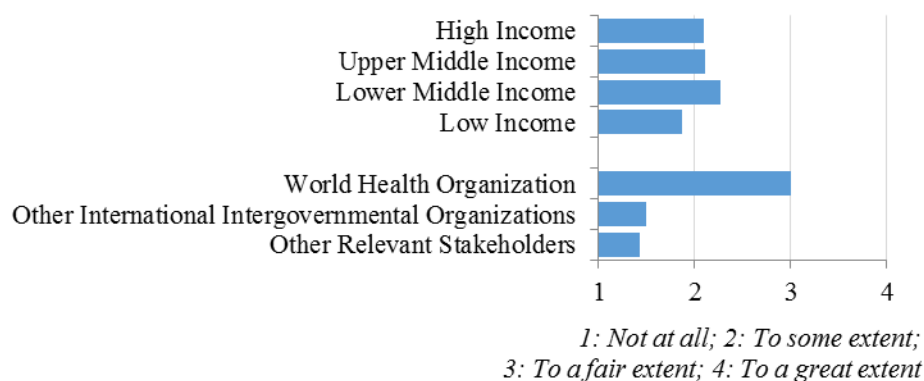
**Developing and implementing possible incentive schemes for health-related innovation:** The available data suggest that, unlike high-income and upper-middle-income countries, the health innovation system in many lower-middle-income and low-income countries is often rudimentary and fragmented. The public sector still provides most of the funding and infrastructure for research. Although research is conducted in academic institutions, it often has little applicability to local health problems, due to the lack of capacity to conduct translational research and limited manufacturing capacity.

Lower-middle-income countries with some industry and manufacturing experience are usually limited to manufacturing low-technology products or higher-technology products only under technology transfer agreements, rather than producing “home-grown” innovation for local health needs. The lack of national IP capacity and the absence of a viable technology transfer policy with a clear incentive scheme appear to be the major bottlenecks hampering progress. There is a clear need to develop better incentive and reward systems.

In lower-middle-income and low-income countries innovation is mostly driven by the private sector, and the incentives existing in the public sector are usually limited to salary contributions and academic promotion. Rather, innovation and new products are brought in - and quite often imposed - almost exclusively by the multinational manufacturers.

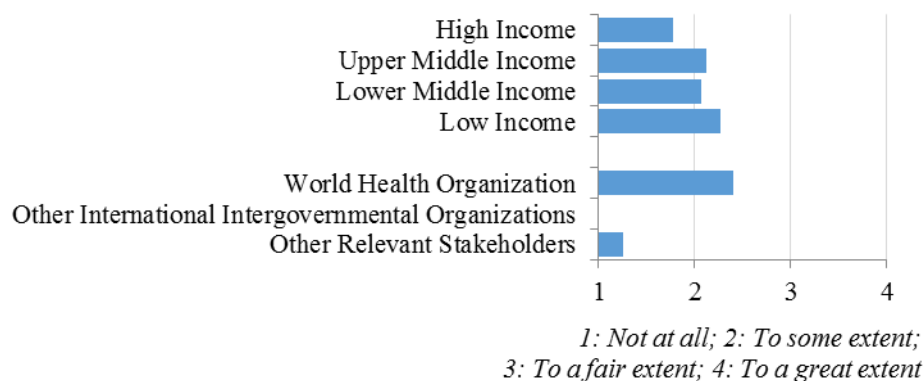
## Survey Results

Graph 3.11 To what extent did your country or organization implement Element 3?



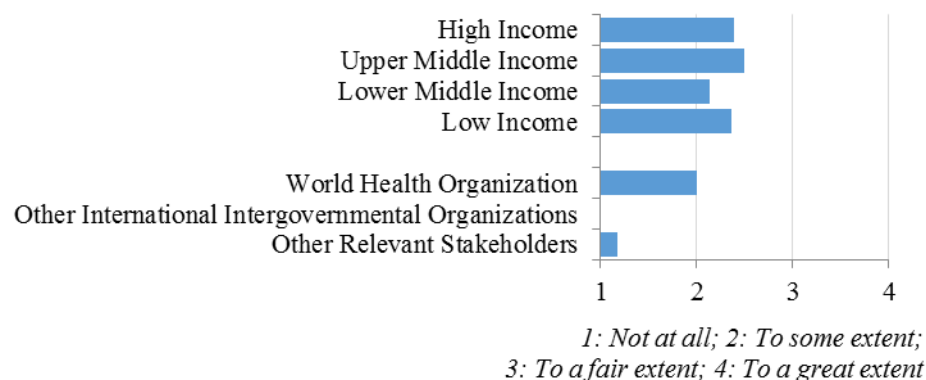
### 3.1 Building capacity of lower-middle-income and low-income countries to meet R&D needs for health products

Graph 3.12 Within Element 3, to what extent did your country or organization implement Sub-Element 3.1?



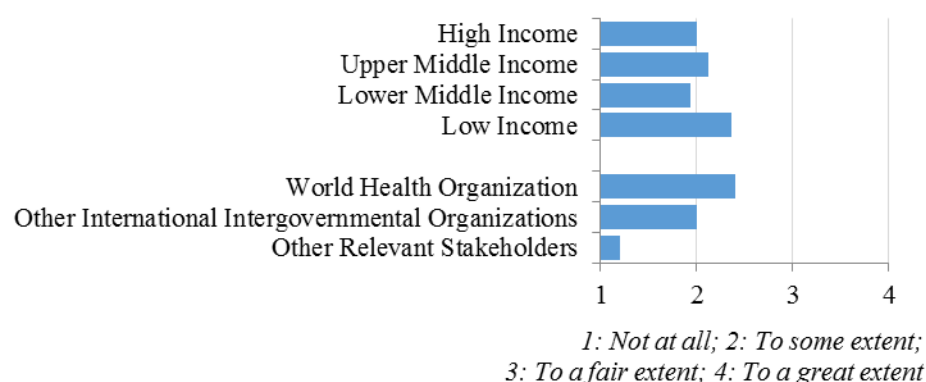
### 3.2 Framing, developing and supporting effective policies that promote the development of capacities for health innovation

Graph 3.13 Within Element 3, to what extent did your country or organization implement Sub-Element 3.2?



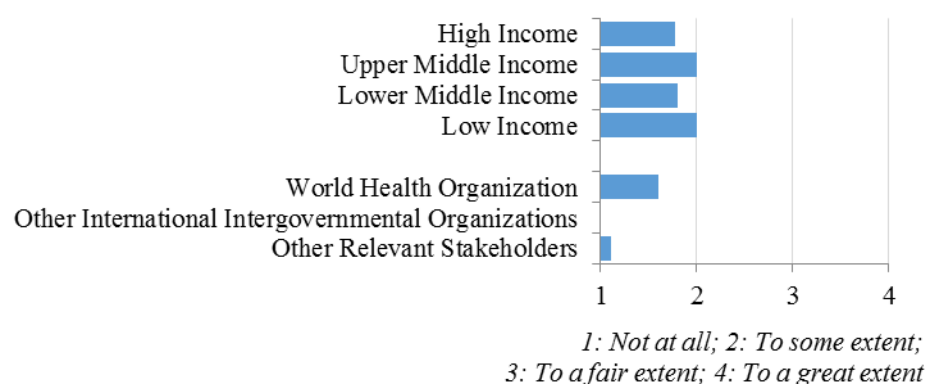
### 3.3 Support for improving innovative capacity in accordance with the needs of developing countries

Graph 3.14 Within Element 3, to what extent did your country or organization implement Sub-Element 3.3?



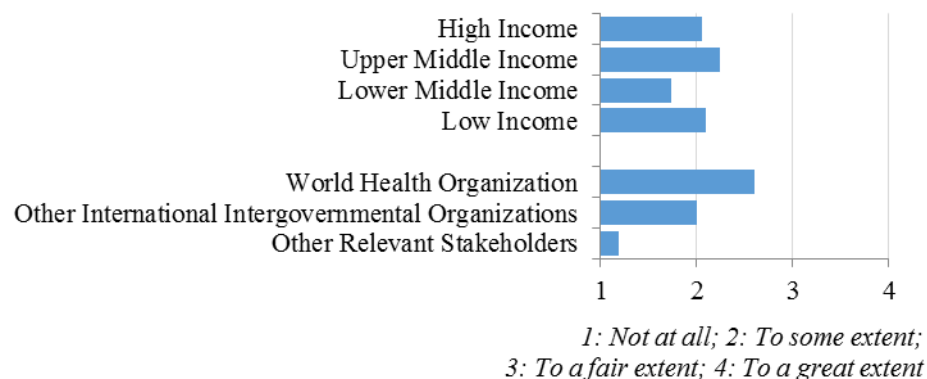
### 3.4 Supporting policies that promote innovation based on traditional medicine

Graph 3.15 Within Element 3, to what extent did your country or organization implement Sub-Element 3.4?



### 3.5 Developing and implementing possible incentive schemes for health-related innovation

Graph 3.16 Within Element 3, to what extent did your country or organization implement Sub-Element 3.5?



#### Key observations from country case studies

Several high-income countries promote R&D capacity in lower-middle-income and low-income countries at national agencies, research institutes and universities. Public-Private Partnerships (PPPs) participate in applied research in collaboration with local partners of lower-middle-income and low-income countries. PPPs build and improve innovative capacity. NGOs also support the development and use of traditional medicine.

While much innovative capacity has been built or improved, this is not necessarily a consequence of GSPOA. In one upper-middle-income country it was noted that coordination of innovative capacity building throughout the different departments of the Ministry of Health was limited. In lower-middle-income countries, respondents indicated that policies to build and improve innovative capacity existed, but their implementation remained fragmented. Furthermore, investment in health R&D is not coordinated at an optimal level. In low-income countries there are only limited research activities due to restricted access to research funding.

In terms of gaps, the health innovation system is often rudimentary and fragmented in most low-income, lower-middle-income and some upper-middle-income countries. In one high-income country, respondents indicated that PPPs and the private sector were not active in traditional medicine and that the academic sector had only a limited involvement in traditional medicine research in lower-middle-income and low-income developing countries. Low-income and lower-middle-income countries still lag behind the other income group countries in terms of investments made for building and improving health innovation capacity.

While health-related research centres have been established to varying degrees in all income group countries, low-income and lower-middle-income countries still struggle to ensure sustainable financing for these centres. In low-income countries, there is no, or only limited, coordination throughout the public and private sectors. While innovation occurs, it does not necessarily occur in areas identified by public health needs. At least in one country, there are no national incentive schemes. In the same country there is an innovation fund in the health

sector; however, it is not utilized. In several countries innovation is not driven by the national or regional agencies or public organizations but by the pharmaceutical companies. In some low-income countries, language barriers further limit their ability to access publicly available research documents.

## Key achievements

**Building capacity of developing countries to meet research and development needs for health products:** Many lower-middle-income and low-income countries had policies in place that promote the development of capacity for health innovation. The promoted national policies placed particular emphasis on boosting investment in R&D covering all aspects of health innovation, including patenting, regulating, manufacturing, taxing and pricing.

There are regions where national institutions focused their health R&D efforts on local health priorities.

The data suggest that health surveillance information was strengthened in many lower-middle-income and low-income countries.

**Framing, developing and supporting effective policies that promote the development of capacities for health innovation:** Some lower-middle-income and low-income countries established national mechanisms to mitigate the adverse impact of the loss of health personnel and researchers.

### An enterprise

The document review showed that in a lower-middle-income country an enterprise group was created during the implementation of GSPOA. This enterprise group oversees the implementation of the health R&D policy of that country and aims to integrate the biotechnology and pharmaceutical sectors. It comprised biotechnology research institutions, manufacturers and service providers and produces health products, including essential medicines.

WHO has developed training materials with professional organizations to assist national regulatory agencies to recruit qualified biomedical engineers, technicians and regulatory professionals to perform evaluation, registration pre-market approval and post-market surveillance activities for medical devices.

Other development partners also strengthened human resources in R&D in lower-middle-income and low-income countries through long-term national capacity-building plans. However, the related training and continuing education do not correspond to a national plan, but depend on the availability of resources among development partners, which is not always coordinated.

**Support for improving innovative capacity in accordance with the needs of developing countries:** The evidence suggests that many countries or organizations promoted the development of capacity for health innovation by creating an enabling environment for

government departments, establishing industry and venture capital; and interacting with academia, researchers and private sector entrepreneurs to create value.

Mechanisms have been established by countries in all income groups to build and improve innovative capacity for health-related R&D in lower-middle-income and low-income countries. These mechanisms focus on developing policies and strategies with subsequent plans of action; setting up facilities to increase research capacity; and strengthening the pharmaceutical manufacturing sector.

Several networks and partnerships were built for promoting investments in R&D capacity in lower-middle-income and low-income countries: for example, the African Network for Drug and Diagnostics Innovation (ANDI) was established by a series of partners, notably the African Development Bank, the European Union, WHO and several national African institutions; a business plan has been developed and broader interest has been expressed by several stakeholder groups in Asia; and some preliminary mapping of innovation centres is already under way in China, India and several ASEAN countries.

#### Good Practices

A regional network has been established with the goal to promote product R&D innovation through the discovery, production and delivery of affordable new tools, including those based on traditional medicine, with the aim to provide support to infrastructure and capacity development in that region.

#### Networks and partnerships

For the past five years, an Alliance composed of eleven leading international public health research organizations, has been coordinating a consortium of research projects on hypertension prevention in fifteen low-income and middle income countries involving a “pairing” and partnership of investigators in high-income and in the target countries.

The evidence also showed that the implementation of focused strategies of international organizations for the management of IP, both in the context of training and of specific projects, increased R&D collaboration among institutions and countries.

UNCTAD assessed the ways in which lower-middle-income and low-income countries can

develop their domestic productive capability to supply essential medicines in cooperation with pharmaceutical companies.

WHO has established a clinical trials registry platform that makes clinical trial data publicly available, in the interest of both public health and science.

WIPO Re:Search<sup>14</sup> was established in 2011, in collaboration with BIO Ventures for Global Health and with the active participation of leading pharmaceutical companies and other private and public sector research organizations, with the aim of supporting least developed countries in the development of local capacity, including in the area of reverse engineering, and promoting technology transfer. It catalyzes the development of medical products for neglected tropical

<sup>14</sup> See: <http://www.wipo.int/research/en/>

diseases, malaria, and tuberculosis through innovative research partnerships and knowledge sharing.

At the regional level, PAHO has established a regional platform on access and innovation for health technologies (PRAIS), a series of virtual tools designed to support and promote technological innovation, access, rational use, regulation and governance of health technologies from a public health perspective, to look into research funding needs and gaps.

Furthermore, there is evidence that countries invested in local production of health products, in particular pharmaceuticals.

There is evidence that TDR has organized training to improve innovation capacity in accordance with the needs of lower-middle-income and low-income countries. For example, many of the advances made in disease management and control can be traced to the support TDR has offered developing country scientists and research institutions to come up with new and realistic innovations, which has shaped health policies over the years.

**Supporting policies that promote innovation based on traditional medicine:** The evidence shows that the effectiveness of traditional medicine has been progressively recognized over the last few years, and that there are countries which invested in research related to health innovation based on traditional medicinal knowledge. Furthermore, data reveal that the establishment and strengthening of the regulatory framework in traditional medicine was promoted in a few lower-middle-income and low-income countries.

#### WHO strengthens cooperation in traditional medicine

The resolution on traditional medicine adopted at the Sixty-second World Health Assembly in 2010 requests WHO Secretariat to strengthen cooperation with collaborating centres, research institutions and non-governmental organizations in order to share evidence based information and to support training programmes for national capacity building in traditional medicine. It also requested WHO to continue providing technical guidance to support countries in ensuring the safety, efficacy and quality of traditional medicine; and provide policy guidance on how to integrate traditional medicine into health systems.

More than one third of African countries by now have established traditional medicine research centers and a few of them dedicate national budget funds to exploring and promoting indigenous knowledge.

**Developing and implementing possible incentive schemes for health-related innovation:** Data from all sources suggest that Member States, international organizations and NGOs intensified North–South and South–South partnerships during the implementation of GSPOA in order to support capacity building and address the needs of lower-middle-income and low-income countries.

## Key gaps and challenges identified

**Building capacity of developing countries to meet research and development needs for health products:** There is evidence that, unlike high-income and upper-middle-income countries, the

health innovation system in many lower-middle-income and low-income countries is still rudimentary and fragmented and the public sector provides most funding and infrastructure for research.

Both qualitative and quantitative data show that policies to promote the development of health innovation capacity exist; however, their implementation remained fragmented in many countries.

Challenges include the lack of baseline data and effective policies in several lower-middle-income and low-income countries, as well as the often limited capacity of regulatory agencies, research institutions and production facilities.

**Framing, developing and supporting effective policies that promote the development of capacities for health innovation:** The development of and support for effective policies for promoting health innovation capacity need to be based on local needs, while addressing and taking into consideration the local research, regulatory and production capacity and constraints.

Capacity improvement is still not being pursued sufficiently in parallel in different fields, including policy development, education and training, research and regulatory institutions, so as to enable Member States to attain their objectives more efficiently and effectively.

R&D is generally still not a major priority for lower-middle-income and low-income countries that face daunting issues stemming from a lack of skilled researchers and financial resources, together with competing, seemingly more urgent, priorities. Despite the investment in human resources in these countries, there is a lack of skilled personnel in the pharmaceutical sector, primarily pharmacists, chemists, microbiologists and technicians, who are adequately trained in production, quality control, quality assurance, equipment maintenance and management.

In addition, despite the available training materials, which have been developed by Member States, WHO, other international organizations and NGOs, skilled staff, for example qualified biomedical engineers and regulatory professionals to perform evaluation, registration, pre-market approval and post-market surveillance activities for health products, remain in short supply. This is a key unresolved issue in several lower-middle-income and low-income countries.

**Support for improving innovative capacity in accordance with the needs of developing countries:** Training and continuous education delivered by donors do not always respond to the national plans of the lower-middle-income and low-income countries. Rather, they depend on the availability of resources among development partners.

Although research is conducted in academic institutions, owing to the lack of capacity to conduct translational research, and the limited local manufacturing capacity, it often has little applicability to local health problems.



Data show that innovation in several lower-middle-income and low-income countries was driven mainly by pharmaceutical companies for commercial reasons and only to a lesser extent by the national, regional or public organizations.

Despite the achievements at global, regional and national level in strengthening capacity for surveillance, regulatory and ethical reviews, dealing with emergency situations still presents a challenge, in particular, in cases of outbreaks of highly infectious diseases.

**Supporting policies that promote innovation based on traditional medicine:** Despite the innovative approaches in the field of traditional medicine, the data collected in this evaluation show that the potential of traditional medicine has not yet properly been exploited to tackle health challenges in Member States

While there is much interest in traditional medicine as a potential source of compounds for the treatment of diseases, there is evidence of a lack of capacity in this respect. Although many R&D institutions in lower-middle-income and low-income countries are able to screen plant extracts for active compounds, these institutions are unable to move beyond screening and structure elucidation of natural products due to the lack of equipment and expertise in drug discovery. There is thus a clear need to build drug discovery platforms in the regions.

While global trade data prove the increase in traditional medicine trade and the growing interest in those products in high-income and upper-middle-income countries, the development of new products based on traditional medicine knowledge with new technologies still lacks the necessary level of investment. The strong interest in traditional medicine as a potential source of lead molecules for new treatment avenues for diseases is thus still severely hampered by a lack of capacity in this regard.

**Developing and implementing possible incentive schemes for health-related innovation:** The lack of national innovative capacity and the absence of a viable technology transfer policy with a clear incentive scheme are the major issues of relevance for this sub-element.

There is evidence that research conducted in lower-middle-income and low-income countries does not always address the local needs.

Document reviews, key informant interviews and survey data suggest that several Member States developed possible incentive schemes for health-related innovation. However, the effectiveness of these schemes often appears to be limited and they are also mostly not complemented by appropriate related accompanying measures. Incentive schemes alone are not sufficient for securing achievements in health-related innovation.

## Areas for Further Work Identified

- a. To support the strengthening of R&D innovation capacity, in accordance with the needs of lower-middle-income and low-income countries, focusing on Type II and Type III diseases and the specific needs of these countries in relation to Type I diseases;
- b. To boost investment levels in local capacity for the development of products based on traditional medicinal knowledge, as well as to build regional drug discovery platforms;
- c. To continue to explore new possible incentive schemes for health-related innovation;
- d. To increase funding and improve infrastructure for research, including translational research.

## Conclusions

Relevance	<ul style="list-style-type: none"> <li>Element 3 is relevant for all stakeholders across regions and income groups.</li> </ul>
Effectiveness	<ul style="list-style-type: none"> <li>The level of implementation varies greatly in Member States because the sub-elements are differently prioritized in different regions and countries; available capacity and funding are insufficient; and the health innovation system is often still rudimentary and fragmented, so that innovation is mostly driven by the private sector</li> <li>Policies for framing and supporting innovations were developed and implemented with the support of WHO, other international organizations and NGOs.</li> <li>Different stakeholder groups developed new incentive schemes for building and improving innovative capacity. However, these incentive schemes are often still too rudimentary and isolated to have much effect.</li> </ul>
Sustainability	<p>Sustainability varies among income groups and regions:</p> <ul style="list-style-type: none"> <li>Since funding for research centres by the governments of some lower-middle-income and low-income countries was limited and depended on donors, sustainability of building and improving innovative capacity in those countries is in question.</li> <li>Many countries, especially low-income countries, lack the enabling environment (for example, skilled specialised staff; research and testing expertise, equipment and capacity; appropriate regulatory and technology transfer support) that would promote the building and improvement of innovative capacity in a sustainable way.</li> <li>More than one third of African countries have traditional medicine research centers, and a few of them are dedicating national budget funds to indigenous knowledge, which positively affects sustainability in those countries.</li> </ul>
Early Impact	<ul style="list-style-type: none"> <li>Health innovation capacity was improved to some extent in many lower-middle-income and low-income countries with the support of several organizations, high-income and upper-middle-income countries.</li> <li>Focused strategies of international organizations for the management of IP, both in the context of training and specific projects, have increased R&amp;D collaboration among institutions and countries.</li> <li>WHO leadership contributed to the development and application of improved guidelines, tools and ethical standards to varying extents in several lower-middle-income and low-income countries.</li> <li>Existing health research innovative capacity and local production of health products, were strengthened to varying extents in several lower-middle-income and low-income countries.</li> </ul>

## Recommendations

### Recommendations for consideration by Member States

1. Member States, with the support of the WHO Secretariat and other international organizations, to strengthen their efforts for tapping the still largely unrealized potential contained in traditional medicinal knowledge, notably by boosting local R&D and manufacturing capacity, enhancing educational and training efforts to safeguard the locally available knowledge base on traditional herbal medicine and traditional medical treatment methods; and to negotiate partnerships with high-income and upper-middle-income countries for mutual advantage;
2. Member States to align their R&D objectives with the public health needs of their populations.

### Recommendations for consideration by the WHO Secretariat

3. WHO Secretariat to explore options to support the development of health products in accordance with the demonstrated R&D needs of lower-middle-income and low-income countries, focusing on Type II and Type III diseases and the specific needs of these countries in relation to Type I diseases;
4. WHO Secretariat and partners to increase their support to lower-middle-income and low-income countries in the area of better safeguarding and exploiting the existing traditional medicinal knowledge in terms of development of new products and treatments;
5. WHO Secretariat, in collaboration with Member States, to promote, organize and support more actions in teaching and training, including building R&D capacity, with a focus on Type II and Type III diseases and the specific needs of lower-middle-income and low-income countries in relation to Type I diseases.

### Recommendations for consideration by all stakeholders

6. All stakeholders to actively contribute to the development of possible new incentive schemes for health-related innovation, in line with the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination regarding sustainable funding and the coordination of health-related R&D;
7. All stakeholders to improve innovative capacity in lower-middle-income and low-income countries by providing more funding and infrastructure for research, including translational research.

## Element 4: Transfer of technology

### Background

GSPOA supports development cooperation, partnerships and networks for building and improving transfer of technology related to health innovation. The aim of Element 4 is the promotion of technological innovation and transfer of technology to the mutual advantage of producers and users of health technologies. North-South and South-South development cooperation is supported by GSPOA with the aim of improving social and economic welfare, while balancing rights and obligations to increase the availability of health technologies and products in developing countries.

#### GSPOA Element 4. Transfer of Technology<sup>15</sup>

North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights states that the protection and the enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations. The actions to be taken in relation to this element are as follows:

- (4.1) promoting transfer of technology and the production of health products in developing countries:
  - (a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries;*
  - (b) promote transfer of technology and production of health products in developing countries through investment and capacity building;*
  - (c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate.*
- (4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development:
  - (a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry;*
  - (b) facilitate local and regional networks for collaboration on research and development and transfer of technology;*
  - (c) continue to promote and encourage technology transfer to least developed country members of WTO consistent with Article 66.2 of the Agreement on Trade -Related Aspects of Intellectual Property Rights;*
  - (d) promote the necessary training to increase absorptive capacity for technology transfer;*
- (4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies:
  - (a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices;*
  - (b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries, especially on Type II and III diseases and the specific research and development needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement, which provide flexibilities to take measures to protect public health.*

<sup>15</sup> GSPOA, available at: <http://www.who.int/phi/publications/gspa-phi/en/>

## Key findings

**Promoting transfer of technology and the production of health products in developing countries:** All sources of data provide evidence that the mechanisms implemented under GSPOA contributed to technology transfer and the production of locally needed health products in the lower-middle-income and low-income countries.

UN agencies, in particular UNCTAD, WHO and WIPO, played a pivotal role in promoting the transfer of health-related technologies between the owners of the technologies and lower-middle-income and low-income countries. The most frequent types of activity include technical assistance, capacity building, facilitating dialogue, increasing availability of information, and more directly setting up concrete initiatives to support technology transfer.

Academic institutions also have technology transfer strategies to increase collaboration between researchers and the private sector, as well as to increase capacity development, especially of low-income countries.

Quantitative and qualitative data show that several national, regional and global coordination initiatives have been set up for increasing and facilitating transfer of health-related technologies. However, there are significant variations across regions and income groups. The main barriers and obstacles identified include a lack of enabling legal and business environment, as well as limited capacity in lower-middle-income and low-income countries.

Low-income country strategies aim at increasing local capacity, e.g. in attaining WHO pre-qualified product status.

Qualitative and quantitative data indicate that the implementation of GSPOA includes support for local production in lower-middle-income and low-income countries through technology transfer, training, policy advice, capacity building, institutional strengthening and analysis. Organizations that provide support include the African Union, the International Finance Corporation, UNCTAD, UNDP, UNICEF, UNIDO, WHO and the World Bank.

**Supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development:** The nature of collaboration of technology transfer has changed since 2008 and high-income and upper-middle-income countries are increasing their engagement with the lower-middle-income and low-income countries. Typical examples of such collaboration are the establishment or improvement of research facilities in lower-middle-income and low-income countries and the conduct of joint research activities in diseases that disproportionately affect lower-middle-income and low-income countries.

North-South cooperation initiatives take the form of collaboration through not-for-profit arrangements; setting up research institutes to develop products for diseases that disproportionately affect lower-middle-income and low-income countries; commercial arrangements; and investment by large manufacturers.

### South-South collaboration in health technology assessment

An example of the South-South collaboration is the recently created Health Technology Assessment Network of the Americas. The Network is headed by the national health authorities, consists of experts from the collaborating centres of the region and aims to improve the ability of the partners to justify decisions on innovation and use of health technologies.

There is evidence of several North-South projects that involve international organizations, international NGOs, philanthropic organizations, academia and the private sector. Typical examples of South-South cooperation initiatives include investments by established manufacturers in lower-middle-income countries, and collaboration among countries to harmonize their strategies, regulations and commercially-based activities.

The promotion of health technology transfer to enable production of health products is mainly taking place between countries that have an established production capacity. Low-income countries are still encumbered with weak regulatory and institutional frameworks that impede the absorption of technologies, although there is evidence that a number of these countries have developed strategies to overcome this obstacle.

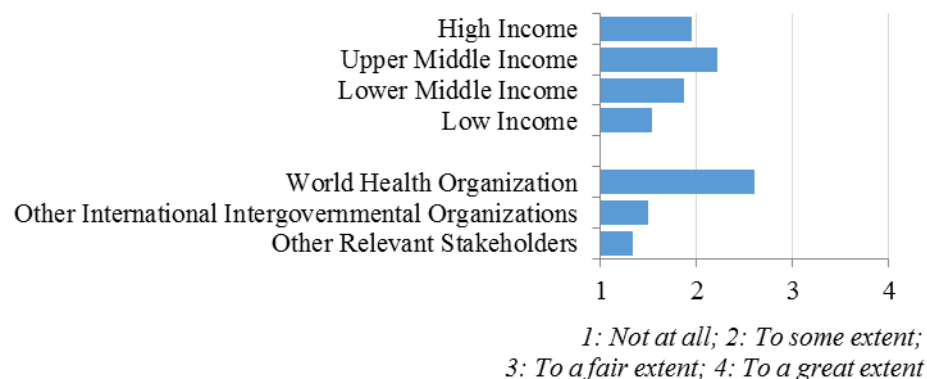
**Developing possible new mechanisms to promote transfer of and access to key health-related technologies:** There is evidence that several countries in all income groups have developed new mechanisms to promote access to key health-related technologies. In many high-income and upper-middle-income countries, public institutions have strategies to support their research interests.

Concentrated vaccine manufacturing capacity exists in a number of countries which, combined with political commitment in the other countries of those regions, can provide the necessary platform for continued development of capacity building for vaccine production.

A few best-practice examples in this area exist: for example, UNIDO has embarked on a promising global project to strengthen the local production of essential generic medicines in lower-middle-income and low-income countries through Small and Medium Enterprises, business partnerships, investment promotion and South-South cooperation. International organizations facilitate collaboration by promoting technical cooperation between large private sector organizations and global initiatives, e.g. the WIPO Re:Search consortium; and provide capacity development through publications and technical assistance to countries.

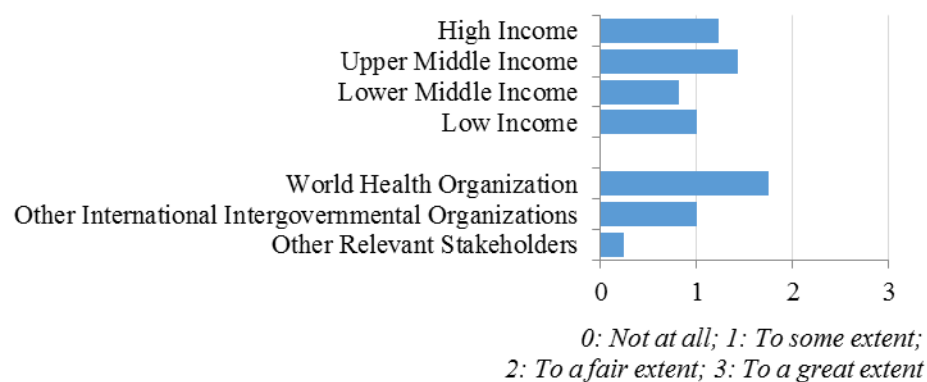
## Survey Results

Graph 3.17 To what extent did your country or organization implement Element 4?



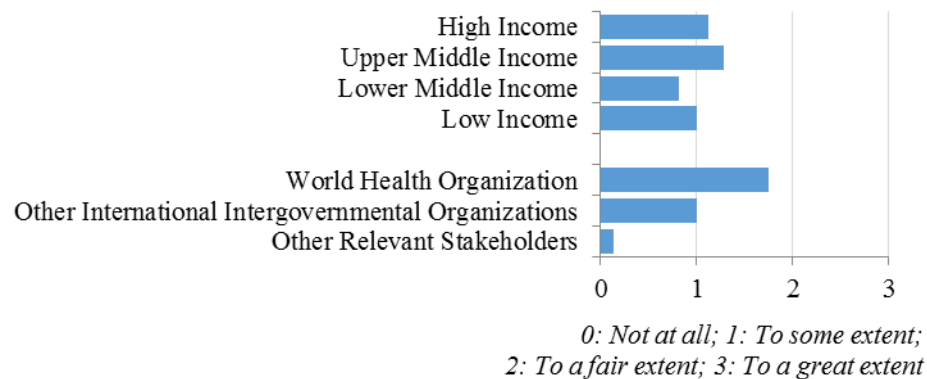
### 4.1 Promoting transfer of technology and the production of health products in lower-middle-income and low-income countries

Graph 3.18 Within Element 4, to what extent did your country or organization implement Sub-Element 4.1?



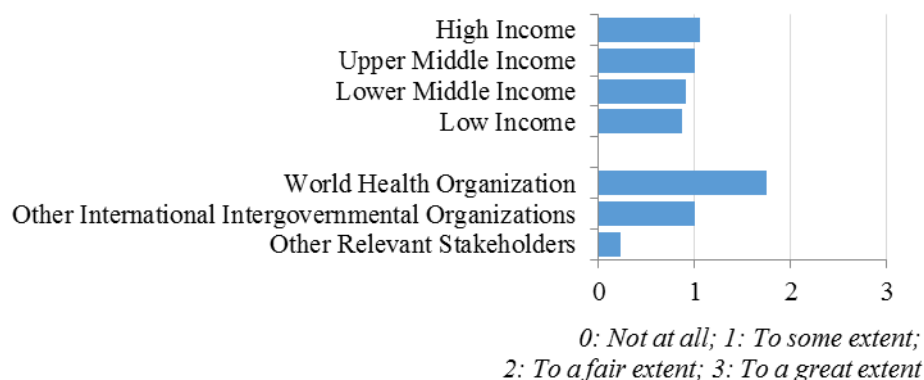
### 4.2 Supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development

Graph 3.19 Within Element 4, to what extent did your country or organization implement Sub-Element 4.2?



### 4.3 Developing possible new mechanisms to promote transfer of and access to key health-related technologies

Graph 3.20 Within Element 4, to what extent did your country or organization implement Sub-Element 4.3?



#### Key observations from country case studies

A respondent in one high-income country pointed out that technology transfer is voluntary and that the private sector leads, and there is some skepticism regarding production in lower-middle-income and low-income countries. In particular, it was pointed out that SSFFC medical products pose significant risks to consumer health and safety. In other high-income countries there is also evidence of transfer of knowledge and technologies by the public and private sectors, as well as by NGOs. Some technology transfer was conducted by non-profit institutes of a private company. In some cases the technology transfer was accompanied by technical assistance. While there is evidence of much activity, it is not necessarily a consequence of GSPOA.

In upper-middle-income countries, transfer of technology is taking place; however, often without assessing its value to the local health systems. Most lower-middle-income and low-income countries lack health innovation structures that can receive and make good use of transferred technologies.

Despite the achievements in health-related technology transfer to lower-middle-income and low-income countries, at global level the number of collaboration initiatives seems to be limited. A respondent in an upper-middle-income country indicated that the cost of producing products through transfer of technology is often not competitive as newer products are introduced at much cheaper prices. Many pharmaceutical manufacturers in low-income and lower-middle-income countries lack the capacity to use transferred technology effectively.

#### Key achievements

**Promoting transfer of technology and the production of health products in developing countries:** There is evidence that until 2010 thirty technology transfer initiatives<sup>16</sup> for

<sup>16</sup> WHO Pharmaceutical Production and Related Technology Transfer, [http://apps.who.int/iris/bitstream/10665/44713/1/9789241502351\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44713/1/9789241502351_eng.pdf)



pharmaceutical production for medicines were implemented. Twenty of those initiatives supported formulation; nine transferred technology; and one provided support for packaging. Two thirds of these initiatives involved North-South collaborations and one third South-South collaborations.

Country level and regional technology transfer initiatives recorded in documents, or reported by key informants or survey respondents, include: integrating supply systems; rational use of medicines and public medicine financing programmes; and use of price banks to support public procurement of medicines.

National initiatives in high-income countries include incentive programmes to encourage large, established private sector organizations to undertake technology transfer initiatives, as well as guidance on modalities of technology transfer to the low-income countries.

**Supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development:** Global initiatives are driven by international organizations, e.g. WHO, WTO, and development banks. These organizations facilitate collaboration by promoting technical cooperation between large private sector organizations and the global initiatives; and by providing capacity development through direct technical assistance to countries.

For example, a collaborative effort of WHO, UNCTAD and the International Centre for Trade and Sustainable Development (ICTSD) initiated a European Commission-supported project to examine the main obstacles to the transfer of pharmaceutical-related technology and local production in lower-middle-income and low-income countries for health products. Collaborative initiatives in these countries include national strategies for creating a supportive environment for improvements in local production of health products.

Evidence from different sources show that several North-South collaborations involve international organisations or large established institutions in the North as providers of technologies to the lower-middle-income and low-income countries.

#### Good practices

Collaboration and support from the BRICS countries (Brazil, the Russian Federation, India, China, South Africa), which are home to many pharmaceutical companies, can help address health inequities through supply shortages and be instrumental for building capacity for quality local manufacturing, especially in Africa, as was highlighted by WHO in its 2014 Bulletin on BRICS<sup>17</sup> and during the Abuja Summit of African leaders for strengthening South-South cooperation.

**Developing possible new mechanisms to promote transfer of and access to key health-related technologies:** Available evidence suggests that the nature of collaboration in technology transfer has changed since 2008. High-income countries are increasing their engagement with lower-middle-income and low-income countries by contributing to the establishment or improvement of research capacity in these

<sup>17</sup> Commodities for better health in Africa – time to invest locally, available at <http://apps.who.int/bulletin/volumes/92/6/en/>

countries. However, the promotion of technology transfer to enable production of health products is still too centred on projects between high-income countries and middle income countries that have established manufacturing sectors.

WHO is playing a pivotal role in the promotion of key health-related technologies by: highlighting emerging opportunities, availability of and challenges related to health technologies; facilitating dialogue between relevant stakeholders; demonstrating effectiveness of innovations; and directly through its Technology Transfer Initiative, which helps identify where transfer of health-related technologies to lower-middle-income and low-income countries will improve access to these products and lead to improved health.

In this context, WHO has set up a technology transfer hub allowing for more efficient multilateral technology transfer than the usual, slower country-to-country arrangements: In 2010, it set up the Vaccine Formulation Laboratory<sup>18</sup> to provide know-how and training on adjuvant technology.

UNITAID established the Medicines Patent Pool<sup>19</sup>, in 2010, with the aim of increasing access to HIV, viral hepatitis C and tuberculosis treatments in low-and middle-income countries. It partners with governments, industry, civil society, international organizations, patient groups and other stakeholders to forecast, prioritise and license needed medicines. The organization encourages generic manufacture and the development of new formulations through patent pooling.

#### Technology transfer in vaccination

WHO has set up a technology transfer hub, which allows for more efficient multilateral technology transfer than the usual country-to-country arrangements. This hub has transferred adjuvants to vaccine manufacturers in lower-middle-income and low-income countries to help stretch supplies of pandemic influenza vaccines.

The technology transfer hub currently runs a new programme on adjuvants for inactivated polio vaccines, to make these vaccines more affordable for lower-middle-income and low-income countries.

There has also been an observed increase in the number of patent applications from companies based in high-income countries that are now co-owned by companies of lower-middle-income and low-income countries.

Lower-middle-income and low-income countries are engaged in transformation processes which include setting up regulatory and institutional frameworks that guide their engagement in technology transfer initiatives. These changes led to promoting the use of locally produced products.

## Key gaps and challenges identified

**Promoting transfer of technology and the production of health products in developing countries:** There is insufficient data related to the obstacles to the transfer of technology and to local production of health products in the lower-middle-income and low-income countries.

<sup>18</sup> at the University of Lausanne, Switzerland.

<sup>19</sup> See: <http://www.medicinespatentpool.org>

Certain sources of information highlighted that products resulting from technology transfer tend to be more expensive than importing the same products from lower-middle-income and low-income countries. Furthermore, they are not always aligned with the relevant national health system priorities.

The gaps identified in technology transfer in many cases are correlated with the income group into which a given country falls. Several low-income countries lack technology transfer strategies, initiatives for investments and capacity to become effective users of new pharmaceutical and health technologies.

A WHO report on technology transfer in 2011<sup>20</sup> acknowledged the shortage of skilled personnel in lower-middle-income and low-income countries as a major hindrance to the production of health products in these countries.

**Supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development:** Several low-income countries are still encumbered with weak regulatory and institutional frameworks that impede the absorption of technologies coupled with low purchasing power of the populations concerned. Speeding up capacity development in the regulatory sector is one of the challenges facing several lower-middle-income and low-income countries. On the other hand, there is evidence that a number of these countries have developed and implemented strategies to overcome those challenges with the help of North–South and South–South cooperation.

Country-to-country arrangements for technology transfer are often time-consuming and their benefits are limited to the population of one country.

Private sector-led voluntary transfer initiatives or programmes of public institutions face challenges in lower-middle-income and low-income countries, due to a lack of developed incentives schemes and insufficient research and manufacturing capacity in these countries.

Several low-income countries still lack strategies to increase local capacity in procurement to attain acceptable standards of quality and safety and WHO prequalified product status.

**Developing possible new mechanisms to promote transfer of and access to key health-related technologies:** While achievements have been made in technology transfer in WHO Member States from the outset of GSPOA, creating a supportive business environment for promoting investment in health technology remains absent in several countries.

Very few countries and institutions have examined the feasibility of voluntary patent pools, or if they have done so, this was not publicised. The only example at global level is UNITAID's Medicines Patent Pool.

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<sup>20</sup> WHO Pharmaceutical Production and Related Technology Transfer, <http://apps.who.int/medicinedocs/documents/s19064en/s19064en.pdf>

There was an observed notable absence of initiatives for local pharmaceutical production and related technology transfer targeting specific products, e.g. biotechnology medicines (excluding vaccines), traditional medicine, (excluding artemisinin derivatives) and medicines for Type I diseases such as diabetes or mental illnesses.

### Areas for Further Work Identified

- a. While countries in all income groups promote technology transfer to varying degrees, continued broad consultation of relevant stakeholders is needed, including the screening of existing initiatives and support schemes and the identification of specific needs and best practices.
- b. Further work is needed to: support lower-middle-income and low-income countries in their efforts to develop technology transfer strategies and related action plans; better understand local needs with the view to improving local capacity for producing health products for those in need; and creating a business friendly environment.
- c. Continued financial and technical support to lower-middle-income and low-income countries is needed, as is the provision of further incentives to established companies and academic institutions for building capacity in lower-middle-income and low-income countries.
- d. Enhanced additional capacity building activities related to technology transfer, such as publications, workshops and seminars, are needed to increase understanding of the available technologies and their effectiveness.
- e. Greater support to Member States is needed to identify specific needs, challenges, obstacles and best practices. Support is also needed to facilitate the work of regional and global networks and to contribute to awareness-raising and communication activities.
- e. South-South collaboration in transfer of technology should be promoted as it can help address health inequities and meet supply shortages for health technologies by scaling up investment into the pharmaceutical manufacturing capacity of lower-middle-income and low-income countries especially for generic essential medicines.

## Conclusions

Relevance	<ul style="list-style-type: none"> <li>Transfer of technology is an important dimension of GSPOA, especially for lower-middle-income and low-income countries.</li> </ul>
Effectiveness	<ul style="list-style-type: none"> <li>The effectiveness of transferring technology varies considerably across regions and income groups.</li> <li>UN agencies, as well as North-South and South-South initiatives, have improved the effectiveness of transferring technology through actions such as technical assistance and workshops that aim to increase the understanding of technologies available worldwide.</li> <li>Several countries in all income groups have developed new mechanisms to promote access to key health-related technologies.</li> <li>Factors hampering effectiveness are a shortage of skilled staff in some countries; a still insufficient focus on diseases mainly affecting lower-middle-income and low-income countries; and insufficient or inadequate technology transfer strategies and initiatives for related investments.</li> </ul>
Sustainability	<p>Some factors have promoted sustainability, including the fact that:</p> <ul style="list-style-type: none"> <li>High-income and upper-middle-income countries are increasing their engagement with the lower-middle-income and low-income countries.</li> </ul> <p>Factors discouraging sustainability are:</p> <ul style="list-style-type: none"> <li>Very low production capacity in some lower-middle-income and low-income countries;</li> <li>The pharmaceutical manufacturing industries of some lower-middle-income and low-income countries are encumbered with weak regulatory and institutional environments;</li> <li>Products resulting from technology transfer tend to be more expensive than importing the same products from a lower-middle-income or low-income country; and are not necessarily relevant to the national health priorities.</li> </ul>
Early Impact	<ul style="list-style-type: none"> <li>Technology transfer does occur, but it is not applied in an equitable manner.</li> <li>Local generic manufacturers in some lower-middle-income and low-income countries produced new health products as a result of transfer of technology.</li> </ul>

## Recommendations

### Recommendations for consideration by Member States

1. Member States to work with other stakeholders to improve the enabling environment for technology transfer for the production of health products.

### Recommendations for consideration by the WHO Secretariat

2. WHO Secretariat and other stakeholders to undertake or encourage further work in needs assessment of lower-middle-income and low-income countries with a view to continuing to provide support for technology transfer;
3. WHO Secretariat to encourage relevant studies and analyses to better understand local needs with a view to improving local capacity for providing essential medicines and health technologies for those in need and creating a business-friendly environment for these efforts.

### Recommendations for consideration by all stakeholders

4. All stakeholders to undertake or encourage further capacity building in lower-middle-income and low-income countries regarding technology transfer and related action plans.

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

### Background

GSPOA acknowledges the need for strengthening innovation capacity and the capacity to manage and apply IP in developing countries. This includes the use of the flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health, to take measures to protect public health. While the international regimes on IP provide incentives for the development of new health products, there is still a need to further explore those incentives and support those developing countries which are entitled to implement incentives schemes. Specific R&D needs of the developing countries in respect of Type I diseases are also part of the international regimes. GSPOA supports information sharing and capacity building in the application and management of IP of health-related innovation in developing countries. Upon request, and in collaboration with other competent international organizations, WHO provides technical support to developing countries that intend to make use of the flexibilities provided by the TRIPS Agreement in order to promote access to pharmaceutical products.

### **GSPOA Element 5. Application and management of intellectual property to contribute to innovation and promote public health<sup>21</sup>**

The international regimes on intellectual property aim, inter alia, to provide incentives for the development of new health products. However, incentive schemes for research and development, especially on Type II and Type III diseases and the specific research and development needs of developing countries in respect of Type I diseases, need to be explored and implemented, where appropriate. There is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement, which provide flexibilities to take measures to protect public health. The actions to be taken in relation to this element are as follows:

(5.1) supporting information sharing and capacity building in the application and management of intellectual property with respect to health-related innovation and the promotion of public health in developing countries:

*(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and other WTO instruments related to that agreement and meets the specific research and development needs of developing countries;*

*(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries;*

*(c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases that contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents;*

<sup>21</sup> GSPOA, available at: <http://www.who.int/phi/publications/gspa-phi/en/>

- (d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs;*
- (e) strengthen education and training in the application and management of intellectual property from a public health perspective, taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights;*
- (f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including, where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries;*
- (g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs;*
- (h) strengthen efforts to coordinate effectively work relating to intellectual property and public health among the secretariats and governing bodies of relevant regional and international organizations in order to facilitate dialogue and dissemination of information to countries.*
- (5.2) providing as appropriate, upon request, in collaboration with other competent international organizations, technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights, in order to promote access to pharmaceutical products;
- (a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003;*
- (b) take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States;*
- (c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003;*
- (d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to facilitate, through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003;*
- (e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider, where appropriate, legislative and other measures to help to prevent misappropriation of such traditional knowledge.*
- (5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases:
- (a) explore and, where appropriate, promote a range of incentive schemes for research and development, including addressing, where appropriate, the delinking of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases that disproportionately affect developing countries.*



## Key findings

Available data indicate that many GSPOA stakeholders are engaged in the implementation of this Element.

**Supporting information sharing and capacity building in the application and management of intellectual property with respect to health-related innovation and the promotion of public health in developing countries:** There is evidence that activities supporting the application of IP, facilitating access and strengthening training of health-related IP management in lower-middle-income and low-income countries is being undertaken. However, this is not done consistently across or within regions nor across income groups.

### Information-sharing on IP

Some countries share information on the application and management of IP with respect to health-related innovation. One good example in this regard is the two day meeting in April 2014 with participants from the Pan American Health Organization/WHO Regional Office for the Americas (PAHO), a WHO Member State and a civil society organization to review options to facilitate access to high cost medicines, in particular for the new hepatitis C treatments.

In particular, there is significant documentation to show that international stakeholders, such as WHO, WIPO, and WTO, are building capacity, providing training and technical assistance to build health-related IP management in lower-middle-income and low-income countries.

There is evidence that collaboration between institutions at different levels and governments to promote information-sharing relevant to public health needs has been stimulated. Data also indicate that the global availability of education and training in the management of IP from a public health perspective has been further strengthened during the implementation of GSPOA. However, qualitative data indicated that the technical and legal knowledge related to IP protection is still uneven among the officials involved in such activities.

There is some facilitation of access to the administrative status of health-related patents across regions and income groups. What is lacking is consistent evidence that the education and training options have been seized. While access to traditional medicinal knowledge for use as prior art in the examination of patents is encouraged, this is still not universally accepted in the consideration of prior art during the patent process.

Available data, in particular survey data, show that active and effective participation of health representatives in IP related negotiations was not always as effective as would have been required from the public health perspective.

**Providing, upon request, technical support to countries that intend to make use of the provisions of the TRIPS Agreement and the flexibilities recognized by the Doha Declaration and other WTO instruments to promote access to pharmaceutical products:** The degree to which technical support was provided to countries that intend to make use of the provisions contained in the TRIPS Agreement varies widely, partly due to the lack of requests from

countries for technical support. International organizations with a mandate in this field, such as WHO, WIPO, WTO and UNCTAD and UNDP, provide support for the implementation of the TRIPS Agreement in a way that facilitates access to affordable medicines.

Most survey respondents stated that the impact on public health was taken into account when adopting or implementing more extensive IP protection. Data are published in the WHO, WIPO, WTO trilateral study<sup>22</sup> on the extent of bilateral trade agreements that go beyond the requirements of the TRIPS Agreement and acknowledge the existing additional flexibilities under the Agreement. All respondents to the survey that chose to answer this question indicated that their country had taken TRIPS flexibilities into account in their IP trade agreements to a varying extent and with mixed effectiveness.

The degree of legislative measures that have been considered to help to prevent misappropriation of health-related traditional knowledge varies. The data suggest that the high-income and upper-middle-income countries are more likely to feel that traditional knowledge issues have been addressed than the lower-middle-income and low-income countries. Furthermore, there is very little indication of the efficacy of such legislation as exists.

The lack of national IP legislation among least developing countries is likely due to the fact that key provisions of the TRIPS Agreement do not apply to pharmaceutical products in these countries and they can choose whether or not to protect pharmaceutical patents and clinical trial data before 2033.

**Developing new mechanisms to promote transfer of and access to key health-related technologies, exploring promoting possible incentive schemes for research and development:**

There are both secondary and primary data available to indicate that countries with excess manufacturing capacity have taken steps to enhance access to pharmaceutical products to countries with limited manufacturing capacity through export.

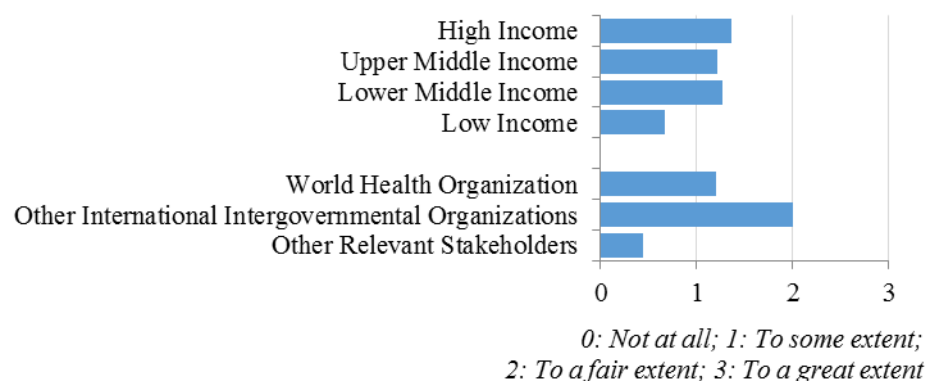
There is evidence of the promotion of incentive schemes for R&D; however, to what extent these incentives were targeting diseases affecting the developing world is uncertain. An exception to this would be Product Development Partnerships (PDPs), which show promise to delink the cost of R&D from the price of the developed products.

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<sup>22</sup> Promoting Access to Medical Technologies and Innovation, [https://www.wto.org/english/res\\_e/publications\\_e/who-wipo-wto\\_2013\\_e.htm](https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm)

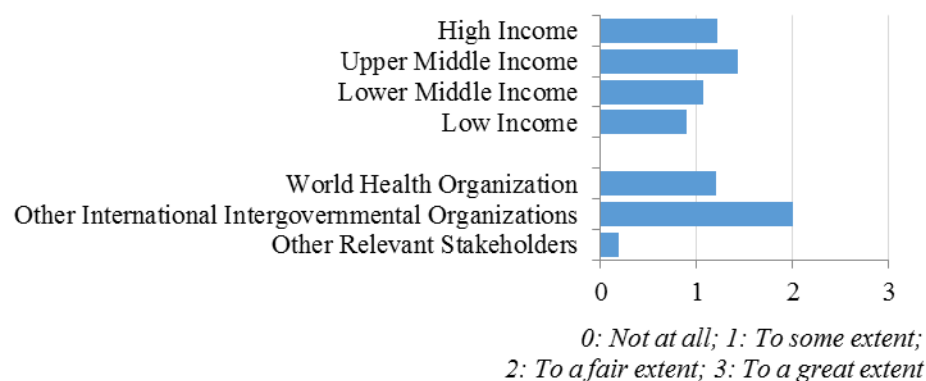
## Survey Results

Graph 3.21 - To what extent did your country or organization implement Element 5?



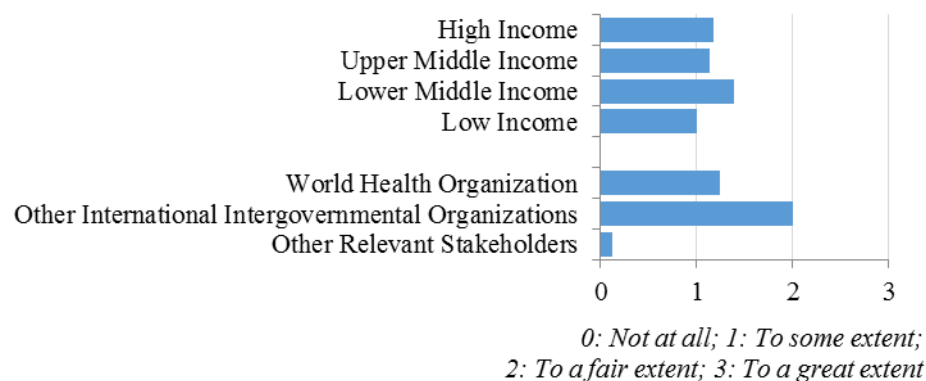
### 5.1 Supporting information sharing and capacity building in the application and management of intellectual property with respect to health-related innovation and the promotion of public health in lower-middle-income and low-income countries

Graph 3.22 - Within Element 5, to what extent did your country or organization implement Sub-Element 5.1?



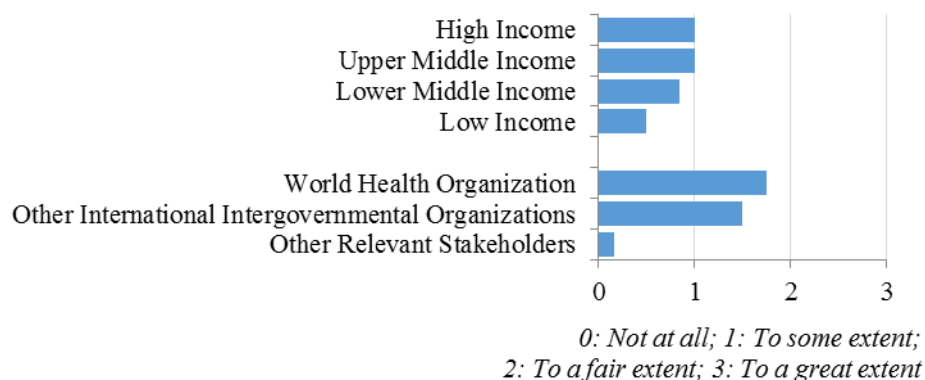
### 5.2 Providing, upon request, technical support to countries that intend to make use of the provisions of the TRIPS and the flexibilities recognized by the Doha Declaration and other WTO instruments to promote access to pharmaceutical products

Graph 3.23 - Within Element 5, to what extent did your country or organization implement Sub-Element 5.2?



### 5.3 Developing new mechanisms to promote transfer of and access to key health-related technologies, exploring promoting possible incentive schemes for research and development

Graph 3.24 - Within Element 5, to what extent did your country or organization implement Sub-Element 5.3?



#### Key Observations and Gaps from Country Case Studies

Traditional IP models appear to support predominantly large companies, and it is difficult to promote alternative (non-commercial) IP models. The TRIPS Agreement is widely seen as being favourable to the pharmaceutical industry. Efforts are evident in some countries to balance IP rights and make research findings and new health products accessible to low-income countries.

However, opinions on this issue are divided, so much so that one respondent stated that “patents are not the problem”. Some pointed out that university research rarely seeks patents in lower-middle-income and low-income countries. Others openly collaborate with vaccine producers in the manufacturing process.

In one upper-middle-income country, there are efforts to develop an IP database. However, there are issues with human resources and the financial support, and due to those issues the database is not user-friendly, nor is it updated regularly. Furthermore, there is no bibliography available as part of the database.

Many lower-middle-income countries are involved in clinical trial and ethical review processes. There is limited capacity in most low-income countries and lower-middle-income countries to address the issue of SSFFC medical products. There is limited capacity in some low-income countries to apply the TRIPS flexibilities effectively. On the other hand, one low-income country has developed an Intellectual Property Policy with six policy objectives and an Implementation Plan.

In terms of gaps, IP barriers continue to be a challenge in most income groups, especially in lower-middle-income and low-income countries. They tend to limit access to, and affordability of, medicines for poor people in most countries, including those countries that are excluded from licensing agreements sometimes available to poorer countries. While there are some efforts (negotiations between governments and pharmaceutical companies) to address these barriers in lower-middle-income and low-income countries, most other stakeholders, such as civil society and academia, were not involved in the process.

There is also not enough sharing of technology with those local manufacturers who would be able to innovate and build capacity.

However, in most low-income and lower-middle-income countries, there are capacity constraints among local manufacturers to produce local high quality and cost-effective medicines for the people who need them. Low-income countries furthermore appear to have limited capacity to negotiate and obtain good deals with the pharmaceutical industry, in part because of the smaller size of their markets.

## Key achievements

**Supporting information sharing and capacity building in the application and management of intellectual property with respect to health-related innovation and the promotion of public health in developing countries:** Collaboration between national, regional, and global institutions, and government departments to promote information sharing relevant to public health needs was stimulated.

Data show that the flexibilities for the protection of public health in the TRIPS Agreement were integrated into national legislation by some countries. There are Member States which implemented the WTO 30 August 2003 decision on the implementation of paragraph 6 of the Doha Declaration on compulsory licensing, primarily to export medicines.

WHO, WIPO and WTO, had a key role in information sharing and capacity building of health-related IP management in lower-middle-income and low-income countries. Through an exchange of letters between the Executive Heads of these three organizations, a trilateral cooperation on fostering mutual understanding between public health policy and IP considerations was agreed. This collaboration includes regular meetings between the three Secretariats to coordinate their activities and discuss possible areas of joint cooperation, such as promoting public health policy in IP and trade policy negotiations, issuing joint publications, or jointly organizing training courses and meetings. A good example is their joint report, *Promoting Access to Medical Technologies and Innovation*<sup>23</sup>.

Data indicate that countries are engaged in initiatives to strengthen capacity to manage and apply IP rights to contribute to innovation and promote public health. Upon request, WHO, WIPO, WTO, UNCTAD, UNDP and other international organizations provide support to those countries that intend to use the flexibilities provided in the TRIPS Agreement for the application and management of IP in a manner that promotes access to health products. This involves guidance on developing public health-sensitive patent legislation and incorporating TRIPS flexibilities within domestic legislation.

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<sup>23</sup> Promoting Access to Medical Technologies and Innovation,  
[https://www.wto.org/english/res\\_e/publications\\_e/who-wipo-wto\\_2013\\_e.htm](https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm)

A High-Level Panel on Access to Medicines was established in November 2015 to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules, and public health in the context of health technologies. UNDP, in collaboration with UNAIDS, served as the Secretariat for the High-Level Panel.<sup>24</sup>

UNDP furthermore facilitates pharmaceutical patent searches on essential medicines for a broad array of stakeholders in lower-middle-income and low-income countries, including health authorities and procurement agencies.

WIPO has conducted a systematic mapping of IP with the focus on Type II and Type III diseases.

**Providing, upon request, technical support to countries that intend to make use of the provisions of the TRIPS Agreement and the flexibilities recognized by the Doha Declaration and other WTO instruments to promote access to pharmaceutical products:**

Technical and legal knowledge of civil servants of lower middle and low-income countries on IP rights has increased as a result of training, workshops and other technical support provided by WHO and other UN agencies as well as international civil society organizations. This has helped several lower-middle-income and low-income countries to apply the provisions of the TRIPS Agreement providing flexibilities as reemphasized by the Doha Declaration.

**Good practices**

The IP authority of a lower-middle-income country granted a compulsory, public non-commercial licence to a pharmaceutical distributor with operations in that country. The compulsory licence covered a patent relating to an active ingredient which is used for the treatment of HIV/AIDS. The licence covered all the patent rights and was limited to use in that country. The licence was valid until the date on which the patent expired, and the licensee was required to pay the patent owner the adequate remuneration calculated according to the Tiered Royalty Method.

Data also indicate that some pharmaceutical companies support the spirit of these flexibilities by not enforcing patents in lower-middle-income and low-income countries.

WIPO has established a database on Flexibilities in the Intellectual Property System<sup>25</sup>.

UNDP joined efforts with WHO and other international organizations to try to make IP work for global health. The TRIPS-plus impact assessment tool, commissioned by the UNDP in partnership with other agencies, including the ICTSD, WHO and the World Bank, is used by many countries to measure the potential impact of various Free Trade Agreement provisions on medicine prices.

<sup>24</sup> Since the evaluation covers the period 2008-2015, the announcement by the United Nations Secretary-General, Ban Ki-moon, creating the High-Level Panel on Access to Medicines in November 2015, places that initiative largely out of the scope of this evaluation. The panel's report is available at: <http://www.unsgaccessmeds.org/final-report>

<sup>25</sup> <http://www.wipo.int/ip-development/en/agenda/flexibilities/search.jsp>

Together with UNDP and UNAIDS, WHO had published a policy brief on the flexibilities in the TRIPS Agreement to provide access to medicines used in the treatment of HIV/AIDS.<sup>26</sup>

**Developing new mechanisms to promote transfer of and access to key health-related technologies, exploring promoting possible incentive schemes for research and development:** Product Development Partnerships (PDPs) are good examples of promoting transfer of and access to key health-related technologies. UNIDO's South-South Industrial Cooperation Centres are among the more promising avenues for promoting such collaboration. A similar role is being played by various regional initiatives, such as the Organization for Coordination and Cooperation in the Fight Against Endemic Diseases in Central Africa.

UNITAID's Medicines Patent Pool, founded in 2010, brings together the varied stakeholders who work on medicines for its target diseases, including governments, pharmaceutical companies and the civil society. By inducing patent holders to contribute their IP into a pool accessible to lower-middle-income and low-income countries, it provides lower-income countries with cheaper access to licences for producing medicines.

## Key gaps and challenges identified

**Supporting information sharing and capacity building in the application and management of intellectual property with respect to health-related innovation and the promotion of public health in developing countries:** This evaluation found gaps in information-sharing to build health-related IP management at country level in lower-middle-income and low-income countries.

There is clear evidence that the global availability of education and training in the management of IP from a public health perspective has been strengthened during the timeframe in question. What is lacking, however, is consistent evidence that these education and training options have in fact been seized. Technical and legal knowledge related to IP and patent protection is thus still modest in some lower-middle-income and low-income countries even among officials involved in such activities.

Generally, it is still difficult to obtain clear and up-to-date information about the patent status of most health products and the available information is usually scattered in many places, e.g. the Medicines Patent Pool data base; WHO and UNITAID patent reports; Lawyers Collective Patent Data Base; I-MAK patent reports, and many others.

The lack of baseline data on the actual status of the implementation of IP rights conducted in lower-middle-income and low-income countries makes it difficult to judge the current situation. For example, no data sources have been found to quantify the actual scale of application and management of IP to contribute to innovation and promote public health. The resistance of

<sup>26</sup> Using TRIPS flexibilities to improve access to HIV treatment. Policy brief, [http://www.unaids.org/sites/default/files/media\\_asset/JC2049\\_PolicyBrief\\_TRIPS\\_en\\_1.pdf](http://www.unaids.org/sites/default/files/media_asset/JC2049_PolicyBrief_TRIPS_en_1.pdf)

some stakeholder groups with regard to the use of TRIPS flexibilities could complicate efforts to provide access to new medicines and health technologies for treating certain, mostly chronic, diseases and health conditions in lower-middle-income and low-income countries.

Limited capacity of those international organizations and national and international NGOs that provide information sharing and capacity building for IP management limits the speed and extent of activities related to IP.

**Providing, upon request, technical support to countries that intend to make use of the provisions of the TRIPS Agreement and the flexibilities recognized by the Doha Declaration and other WTO instruments to promote access to pharmaceutical products:** Flexibilities of the TRIPS Agreement were integrated into the national legislation of certain Member States, but not to the full extent and not by all Member States who could benefit from them. It should be noted, however, that least developed countries are currently not obliged, with respect to pharmaceutical products, to fully implement the TRIPS Agreement. The 30 August 2003 decision was implemented with the primary aim of developing capacity for producing medicines for export and to a lesser extent for domestic use.

Resources and know-how required for the implementation of TRIPS flexibilities are still scarce in most countries, coupled with reluctance to use these or other legitimate mechanisms to advance access to medicines.

**Developing new mechanisms to promote transfer of and access to key health-related technologies, exploring promoting possible incentive schemes for research and development:** Document review and key informant interviews revealed that exploring and promoting possible incentive schemes for R&D should result in new incentives that better address the needs of the lower-middle-income and low-income countries.

There is, however, a distinct contrast among those who feel that international incentives lead to the development of new products and those who feel they do not. Even within the camp of those who feel they are effective, the extent and efficacy of implementation are for the most part low. Furthermore, the innovations produced do not necessarily translate into product development due to lack of return on investment.

WIPO's Re:Search, launched in 2011, is currently the only international mechanism operating under the aegis of a UN specialized agency with policies that successfully address IP issues and facilitate private sector activities to accelerate early-stage research by public and private institutions for disease control in lower-middle-income and low-income countries.

Exploring and, at a later stage, promoting incentive schemes requires extended cooperation of all stakeholder groups. Furthermore, delinking of the costs of R&D from the price of medicines requires not only political will but also financial resources.



## Areas for Further Work Identified

- a. Technical support continues to be needed for those Member States that request assistance in availing themselves of the flexibilities of the TRIPS Agreement.
- b. Maintaining and improving technical and legal knowledge on IP at country level in lower-middle-income and low-income countries is a key issue for the proper application of IP, and the knowledge and competence of public servants and officials of the regulatory agency concerned is critical in this respect. Capacity building activities, such as workshops and seminars, are needed to increase the understanding of IP rights and flexibilities.
- c. Exploring possible incentive schemes for R&D and tailoring the existing schemes to the changing needs of lower-middle-income and low-income countries is a key issue in the implementation of GSPOA.

## Conclusions

Relevance	<ul style="list-style-type: none"> <li>Element 5 is relevant for most beneficiaries.</li> </ul>
Effectiveness	<ul style="list-style-type: none"> <li>The application and management of IP varies widely across income groups and regions. Therefore, Element 5 may be considered as having been only partially effective in contributing to innovation and promoting public health.</li> <li>While information sharing and capacity building of health-related IP management in lower-middle-income and low-income countries is taking place, it is not taking place consistently across or within regions and/or income groups.</li> <li>While technical support has been provided to countries intending to make use of the flexibilities of the TRIPS Agreement, the degree of that support varies widely.</li> <li>There is little indication of the efficacy of the existing legislation to prevent misappropriation of health-related traditional knowledge.</li> </ul>
Sustainability	<p>Sustainability of the efforts made under Element 5 is uncertain, since:</p> <ul style="list-style-type: none"> <li>There is significant disagreement among stakeholders regarding the scale of the efforts still required to remove IP barriers from lower-middle-income and low-income countries.</li> <li>The utilization of flexibilities available under the TRIPS Agreement has been hampered by resistance from interests opposed to this, which in turn has impeded creative new arrangements regarding strategies for the production and dissemination of health technologies.</li> </ul>
Early Impact	<ul style="list-style-type: none"> <li>While there are some benefits from the application and management of IP, especially in the case of vaccines and medicines for infectious diseases, there is still strong resistance from some stakeholders regarding the use of the TRIPS flexibilities. It is also still too early to judge the ultimate success for recent patent pooling efforts in favour of lower-middle-income and low-income countries. Therefore Element 5 may only be considered as partially implemented.</li> </ul>

## Recommendations

Recommendations for consideration by Member States, the WHO Secretariat, other international organizations and nongovernmental organizations

1. To strengthen awareness of the flexibilities provided in the TRIPS Agreement, IP rights and the need for equitable and affordable access to essential health products in lower-middle-income and low-income countries;
2. To strengthen capacity and create incentives related to IP management, taking into account the public health perspective in lower-middle-income and low-income countries;
3. To continue efforts to better integrate existing and new initiatives and schemes in this area in the implementation of GSPOA;
4. To focus more attention on creating the required baseline data, indicators and evidence base needed to properly evaluate the outcome of GSPOA initiatives under this element;
5. To support ongoing non-profit drug development models, by exploring and promoting possible incentive schemes to overcome IP barriers and promote public health.

## Element 6: Improving delivery and access

### Background

Access to medicines is directly related to income and, despite progress made during the last decade, this is still a major problem for most developing countries. The WHO World Medicines Situation Report (2004)<sup>27</sup> estimated that in low-income countries, almost 40 percent of the population had no access to essential medicines, versus 24 percent and 0.6 percent in middle and high-income countries respectively. High-income countries also increasingly dominate the world pharmaceutical production. Their share of production (by value) increased from 89.1 to 92.9 percent between 1985 and 1999, while the combined share of middle and low-income countries decreased from 10.9 to 7.1 percent over the same period. An update of the Report in 2013 found that public sector availability of generic medicines is still less than 60 percent in three WHO regions and at least one third of the world's population has no regular access to medicines.

GSPOA supports strengthening health systems through stimulation of competition and the adoption of appropriate pricing and taxation policies for health products. Mechanisms to regulate the safety, quality and efficacy of health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a health system. International agreements with impact on access to health products in developing countries need to be regularly monitored. There are a number of flexibilities contained in the WTO TRIPS Agreement that permit improved access to health products for developing countries. GSPOA furthermore supports investment in the health delivery infrastructure as well as for financing health products, improved ethical review and better regulation of the quality, safety and efficacy of health products and medical devices. GSPOA also acknowledges the need for promoting competition to improve availability and affordability of health products consistent with public health needs.

#### **GSPOA Element 6. Improving delivery and access<sup>28</sup>**

Support for and strengthening of health systems is vital for the success of the strategy as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products. Mechanisms to regulate the safety, quality and efficacy of medicines and other health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a well-functioning health system.

International agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements, including those contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Doha Declaration on the TRIPS Agreement and Public Health, that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries. The impact of such actions on innovation needs to be monitored. The actions to be taken to improve delivery and access are as follows:

<sup>27</sup> The World Medicines Situation Report, <http://apps.who.int/medicinedocs/en/d/Js6160e/>

<sup>28</sup> GSPOA <http://apps.who.int/medicinedocs/en/d/Js6160e/9.html>, available at: <http://www.who.int/phi/publications/gspa-phi/en/>

- (6.1) encouraging increased investment in the health delivery infrastructure and financing of health products in order to strengthen the health system:
- (a) invest in developing health delivery infrastructure and encourage financing of health products;*
  - (b) develop effective and sustainable mechanisms in least developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016;*
  - (c) prioritize health care in national agendas;*
  - (d) encourage health authorities to improve domestic management capacities in order to improve delivery of and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines;*
  - (e) increase investment in human resource development in the health sector;*
  - (f) develop effective country poverty reduction strategies that contain clear health objectives;*
  - (g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate.*
- (6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices:
- (a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards;*
  - (b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in settings with a high disease burden;*
  - (c) comply with good manufacturing practices for safety standards, efficacy and quality of health products;*
  - (d) strengthen the WHO prequalification programme;*
  - (e) where appropriate, initiate programmed actions on regional and subregional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals;*
  - (f) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines;*
  - (g) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for evaluation and approval of medicines.*
- (6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs:
- (a) support the production and introduction of generic versions, in particular of essential medicines, in developing countries through the development of national legislation and/or policies that encourage generic production and entry, including a “regulatory exception” or “Bolar”-type provision, and that are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement;*
  - (b) frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements;*
  - (c) consider, where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access;*
  - (d) encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law;*
  - (e) consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products, and further support WHO’s ongoing work on pharmaceutical pricing;*
  - (f) consider, where necessary, and provided that they are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products;*
  - (g) increase information among policy-makers, users, doctors and pharmacists regarding generic products.*

## Key findings

**Encouraging increased investment in the health delivery infrastructure and financing of health products:** Evidence shows that, while high-income and upper-middle-income countries have increased investment in the health delivery infrastructure and financing of health products, most lower-middle-income and low-income countries allocate a lesser percentage of their annual resources to health than high-income and upper-middle-income countries. Nevertheless, the majority of low-income countries have country poverty reduction strategies that contain clear health objectives.

There is evidence that GSPOA has addressed the availability of essential medicines and diagnostics in lower-middle-income and low-income countries, and Member States have improved delivery and access. However, the extent of improvements varies highly and depends on the disease and the specific features of the health care system, in particular the available supply chains. Data also show that access to medicines is directly related to income. Most low-income countries import essential, quality medicines and have little room to negotiate pricing.

There is evidence from both qualitative and quantitative data that, from the outset of the implementation of GSPOA, initiatives have emerged to increase access to essential medicines. Nevertheless, the inexistent, or limited, coordination among stakeholders constitutes the main challenge for these initiatives.

**Mechanisms for improving ethical review and regulation of health products and medical devices:** Document review shows that Member States and the WHO Secretariat are joining efforts to establish and strengthen mechanisms to improve the ethical review of health products and medical devices and ensure their quality, safety and efficacy. Technical assistance is provided by WHO and other international organizations in this regard through awareness-raising, training and legislative assistance.

Data show that, to different degrees, most countries have put in place policies and actions to improve access to, and the quality and use of, essential medical products and technologies, while also strengthening the regulation of health products and medical devices; however, lower-middle-income and low-income countries still face serious challenges in this regard.

Both qualitative and quantitative data show the need to further improve capacity of agencies in lower-middle-income and low-income countries to ensure safe, affordable, effective, high-quality medicines. Inspection capacity, quality control and laboratory work are particularly weak in several lower-middle-income and low-income countries.

There is also evidence that the cost-effectiveness of health products is assessed for informing health policy.

**Promoting competition to improve availability and affordability of health products:** There is evidence that, to a varying extent, countries are engaged in a number of initiatives to improve the availability and affordability of needed health products; however, there is also evidence that these initiatives may not be directly related to GSPOA.

#### The impact of biosimilar competition on price

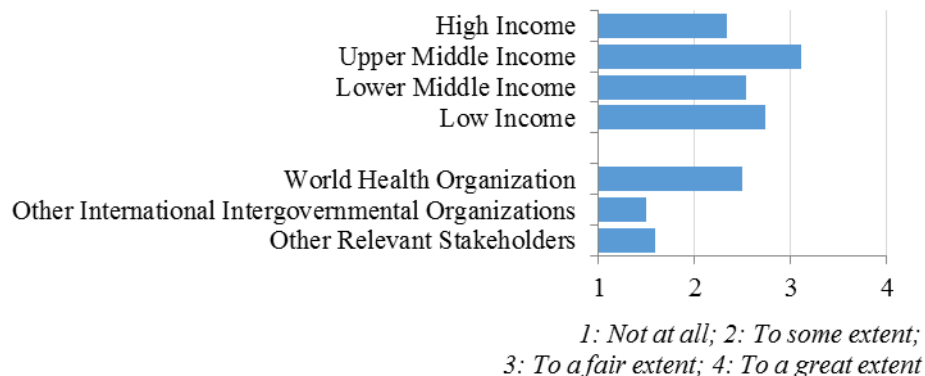
A similar biological or 'biosimilar' medicine is a biological medicine that is similar to another biological medicine that has already been authorized for use. Biological medicines are medicines that are made by or derived from a biological source, such as a bacterium or yeast.

Increased biosimilar competition affects not just the price for the directly comparable products but has an effect on the price of the whole product class and has thus increased access to biological medicines in many countries.

While projects and technical assistance have generally enhanced the capacity of national institutions, there are still lower-middle-income and low-income countries which lack the capacity and/or resources to significantly improve the access of their population to health products.

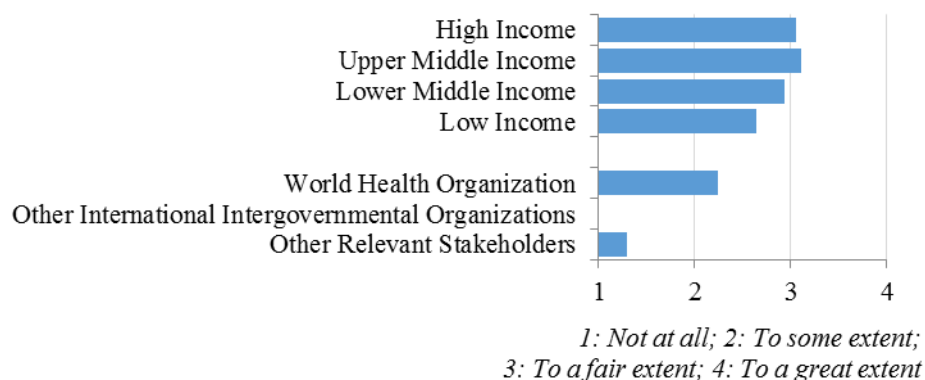
## Survey Results

Graph 3.25 To what extent did your country or organization implement Element 6?



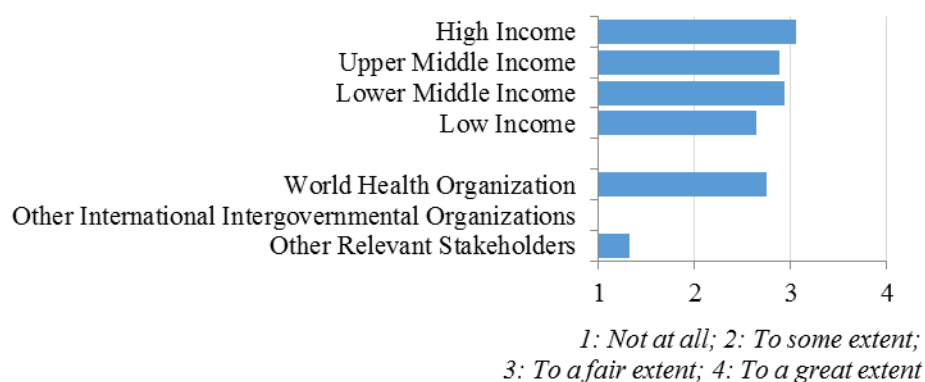
### 6.1 Encouraging increased investment in the health delivery infrastructure and financing of health products

Graph 3.26 Within Element 6, to what extent did your country or organization implement Sub-Element 6.1?



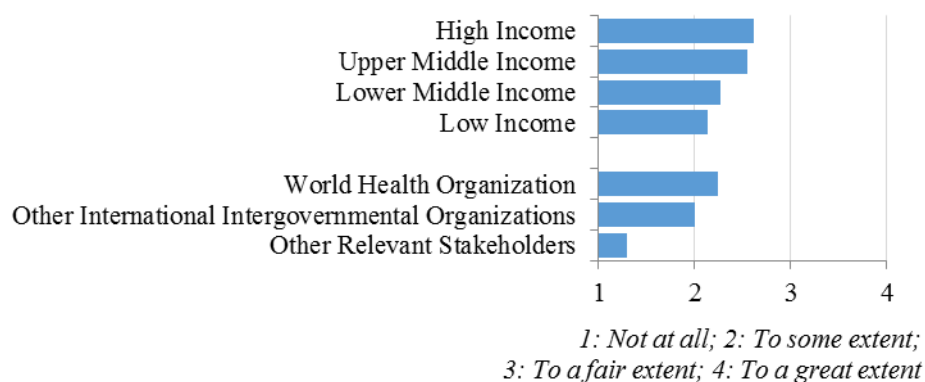
### 6.2 Mechanisms for improving ethical review and regulation of health products and medical devices

Graph 3.27 Within Element 6, to what extent did your country or organization implement Sub-Element 6.2?



### 6.3 Promoting competition to improve availability and affordability of health products

Graph 3.28 Within Element 6, to what extent did your country or organization implement Sub-Element 6.3?



### Key observations from country case studies

One high-income country provided evidence of its support for lower-middle-income and low-income countries in prioritizing health care in national agendas. That country also contributed to the strengthening of national health systems in some lower-middle-income and low-income countries through its advocacy efforts for improving access and by providing training. In a high-income country, the mandate and narrow focus of the UN High-Level Panel on Access to Medicines<sup>29</sup> was highlighted. Still in that same high-income country, others pointed out that they are very active in improving and delivering access, but not as a consequence of GSPOA.

In one upper-middle-income country, the Government aims to increase accessibility to essential medicines and treatment and has introduced a central procurement system. Furthermore, efforts have been made to upgrade the facilities at all levels of care with a particular focus on rural areas. In one upper-middle-income country, the government encourages hospitals to use traditional medicine through increased prescriptions.

In most lower-middle-income and low-income countries, there is a lack of effective communication between government officials and other stakeholders regarding issues related to access and affordability. On the other hand, there is evidence that at least one of the case study countries in the low-income group is committed to improving communication between the Government and other stakeholders. There is also evidence that some of the case study countries are committed to achieving or providing access to affordable health products. In one lower-middle-income country, all equipment and health products destined for the public health system are tax free. For private hospitals, some types of equipment and consumables are likewise tax free. In another lower-middle-income country, the key informant said that theirs is a free market and they do not regulate prices. However, there are efforts at present to control prices due to changes in the national law.

In one of the low-income countries, the Ministry of Public Health has a health financing and revenue generation policy to increase the efficiency and equity of public spending, improve financial risk protection, and reduce dependence on international aid.

In terms of gaps, access to medicines depends largely on the bargaining capacity of countries, which is weak in the case of most of the low-income and lower-middle-income countries. In upper-middle-income countries, there is a move away from traditional medicine due to the easier availability of modern medicine.

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<sup>29</sup> Since this evaluation covers the period 2008-2015, the announcement by the United Nations Secretary-General, Ban Ki-moon, creating the High-Level Panel on Access to Medicines, in November 2015, places that initiative largely out of the scope of this evaluation. The Panel's Report is available at: <http://www.unsgaccessmeds.org/final-report>



While there is evidence that most lower-middle-income countries have, to varying degrees, improved delivery and access, some low-income countries and lower-middle-income countries experience difficulties due to insufficient capacity building. To achieve universal access to health products there is a need to review and strengthen health financing in the country.

The fragmentation of the health financing system is an obstacle to its effectiveness. The share of expenditures of health coming from donors remains low. While PPPs are seen as key to finance access to health, low-income countries still experience difficulties in building sustainable PPPs. For example, in the case of vaccines, the price is mostly imposed by pharmaceutical companies that have the monopoly on the market.

## Key achievements

**Encouraging increased investment in the health delivery infrastructure and financing of health products:** Data show that health is an important part of national budgets in many Member States, in particular high-income and upper-middle-income countries. There are lower-middle-income and low-income countries where investment in health delivery and infrastructure was increased. Several of these countries have also developed country poverty reduction strategies that contain a clear health objective.

Nevertheless, there is also evidence of the low priority still accorded to the health sector in low-income country budgets in general: governments tend to allocate a lesser percentage of their annual domestically generated budget resources to health than they should and could afford. For example, the average health budget as a percentage of total government budget is just 8.7 percent in WHO's African region, as compared to 14.8 percent for Europe and 16.8 percent for the Americas.<sup>30</sup>

During the implementation of GSPOA, some initiatives have emerged to increase access to essential medicines. Examples include increasing access to HIV treatment over the past 15 years and, more recently, accelerating access to the treatment of Hepatitis C viral infections. Among other achievements, these initiatives have developed tools to help lower-middle-income and low-income countries to conduct self-assessment, develop strategies, build or improve capacity and engage in partnerships to improve access to essential medicines.

### Good Practices

The initiative "Strengthening Pharmaceutical Innovation Africa" was endorsed in March 2010 by the African Ministerial Conference on Science and Technology to implement GSPOA as well as the Pharmaceutical Manufacturing Plan for Africa. This initiative has developed a tool - the Pharmaceutical Innovation Framework and Grid - that helps African countries conduct self-assessments, develop strategies, and build capacity and partnerships to engage in innovation and improve access to essential medicines.

<sup>30</sup> Obligations of low-income countries in ensuring equity in global health financing, Barugahare and Lie BMC Medical Ethics (2015) 16:59. Available at: <http://bmcomedethics.biomedcentral.com/articles/10.1186/s12910-015-0055-3>

**Mechanisms for improving ethical review and regulation of health products and medical devices:** WHO and other stakeholders have co-sponsored programmes for assisting Member States to evaluate the use of existing health products in real-life situations as a basis for supporting regulatory and policy decisions. This occurred for medicines, vaccines and diagnostics and is primarily directed at the use of products against high-burden diseases in resource-poor settings.

WHO supports a strategic initiative for developing capacity for ethical reviews of health products. This network-based initiative is built upon regional and national fora and discussions and grounded in national and regional ownership. It has already been successful in South-East Asia and the Western Pacific in supporting the establishment and development of ethical review committees in collaboration with national authorities.

WHO also promotes regulatory exchanges and harmonization through confidentiality agreements and regulatory exchange programmes. It is furthermore strengthening pharmacovigilance by building country capacity in this area, as well as by providing training on how to conduct investigations of adverse events.

The Prequalification of Medicines Programme of WHO, which started in 2001, helps ensure that medicines supplied by procurement agencies meet acceptable standards of quality, safety and efficacy, as well as price reductions. At the end of 2012, the WHO List of Prequalified Medicinal Products contained 316 medicines for priority diseases, mainly HIV/AIDS, tuberculosis and malaria. WHO's list of prequalified medicinal products is used by international procurement agencies and increasingly also by countries to guide bulk their purchasing of medicines.

#### Coordination of clinical trial inspections

Joint reviews of clinical trials of meningitis and malaria vaccines have been conducted and coordinated by WHO. Good Clinical Practice inspections of a clinical trial for meningitis A vaccine have been conducted in Africa and all sites have been inspected.

UNITAID is one of the main donors to the WHO prequalification programme, which is complemented by the Expert Panel run by the Global Fund. Together, these mechanisms have been, and still are, instrumental in ensuring the quality as well as lower prices for the health products under their purview, and thus contributing to improved access.

**Promoting competition to improve availability and affordability of health products:** As part of its efforts to establish national policies on medicines and to promote the use of generics as the best strategy to ensure affordability and accessibility of medicines in lower-middle-income and low-income countries, WHO has demonstrated an ongoing commitment to support capacity building at country level.

## Key gaps and challenges identified

**Encouraging increased investment in the health delivery infrastructure and financing of health products:** There is a need for creating better coordination mechanisms in lower-middle-income and low-income countries of the same regions to ensure improved synergy among stakeholders in financing and improving access to health products.

SSFFC medical products present an increasing threat to all countries, even for those with a strong legal framework for the licensing, manufacturing and distribution of medicines. Data show that, despite the efforts in this field, illegitimate sale, in particular via the Internet, is increasing. There is thus a clear need for stricter and better enforced regulations on SSFFC medical products.

While health forms part of the public budgets in Member States, evidence from the literature shows that the availability and accessibility of essential medicines is still limited in many lower-middle-income and low-income countries. Essential medicines are often relatively high-priced and thus beyond the reach of many patients.

Poor availability and affordability of health products are usually outcomes of systemic failures within and the lack of financing for health systems in lower-middle-income and low-income countries. Both require a strong and coordinated whole-of-government multi- and inter-sectoral response to address the underlying causes, while it is precisely the lack of or limited coordination among stakeholders in many Member States that seems to be a serious and persisting challenge in this respect.

The weak infrastructure in lower-middle-income and low-income countries represents a further barrier to the improvement of the delivery chain of health products as well as to the accessibility of health care services.

Access to medicines is directly related to income. Despite progress made in the last decade, this access is still a major problem for most lower-middle-income and low-income countries.

**Mechanisms for improving ethical review and regulation of health products and medical devices:** Data from different lines of evidence show that regulatory capacity and experience in the area of diagnostics is particularly limited in several lower-middle-income and low-income countries. WHO prequalification is today still not widely used for medical devices. Most respondents stated that they are not aware of priority diagnostic tools that have been assessed and prequalified in their country for procurement.

Despite the improvements in regulatory capacity in lower-middle-income and low-income countries, human resources are still limited, in particular trained pharmacists, biomedical engineers and officials to conduct regulatory work. Qualitative data revealed that in several lower-middle-income and low-income countries, the number of trained staff is sufficient for conducting regulatory work; however, they have only limited practical experience.

While most countries surveyed have put in place policies and actions to strengthen the regulation of health products and medical devices, lower-middle-income and low-income countries still lag behind high-income and upper-middle-income countries and face serious challenges, e.g. in clinical trial practices, where the process of ethical approval is not yet standardized and faces many barriers which can take a long time to overcome.

**Promoting competition to improve availability and affordability of health products:** Data, in particular from qualitative sources, revealed that the main weaknesses and limitations to

developing local pharmaceutical production capacity in lower-middle-income and low-income countries include large variations in quality standards, weak regulatory capacity and limited manufacturing of active pharmaceutical ingredients.

Furthermore, promoting competition does not always improve availability and affordability of health products, especially in low-income countries, since it is increasingly acknowledged that local production may not always lead to price reductions of medicines. The small size and low technical capacity of local companies in lower-middle-income and low-income countries, as well as the substantial investment required to raise quality standards, may in fact lead to even higher prices.

An increasing number of national, regional and international policies are addressing the issue of availability and affordability of health products, including taxation and pricing. However, the cross-linkages and effective interplay between different areas are very intricate.

### Areas for Further Work Identified

The following areas have been identified where further work needs to be done in order to implement this element completely:

- a. To implement governmental and intersectoral actions for better investment in the health delivery infrastructure;
- b. To increase the financing of health systems of lower-middle-income and low-income countries to better ensure the availability and affordability of essential medicines and health products these countries;
- c. To create coordination mechanisms to ensure better synergy among key national and international stakeholders to improve access;
- d. To increase the capacity of national regulatory agencies, especially for inspection, quality control and laboratory work to ensure safe, high quality products;
- e. To further strengthen normative functions which support prequalification and provide more funding for the work of WHO in this area.

## Conclusions

<b>Relevance</b>	<ul style="list-style-type: none"> <li>• Element 6 is relevant to the needs of all Member States.</li> </ul>
<b>Effectiveness</b>	<ul style="list-style-type: none"> <li>• While Member States have generally improved delivery and access, some lower-middle-income and low-income countries still experience difficulties regarding the availability and accessibility of affordable health products and medical devices.</li> <li>• Systems are in place in the majority of Member States for conducting essential regulatory functions related to the authorization of health products.</li> <li>• While health is an important part of national budgets in high-income and upper-middle-income countries, limited health budgets are still a major barrier to accessibility to affordable health products and medical devices in lower-middle-income and low-income countries</li> <li>• WHO has undertaken efforts to put in place a framework and support structures for a network of countries which have introduced prequalified vaccines and to study the safety of these vaccines as they are introduced into national immunization programmes.</li> </ul>
<b>Sustainability</b>	<p>Sustainability is in question, since:</p> <ul style="list-style-type: none"> <li>• Further resources are needed for the coordination of improved availability and accessibility to health products;</li> <li>• Better global coordination is needed to promote regulatory capacity in lower-middle-income and low-income countries;</li> <li>• More resources are needed for assisting lower-middle-income and low-income countries to scale up their efforts in health product regulation;</li> <li>• Promoting competition in health product manufacturing does not always improve availability and affordability of these health products, especially in low-income countries;</li> <li>• Access to medicines is directly related to income and, despite progress made in the last decade, this access is still a major problem for most lower-middle-income and low-income countries.</li> </ul>
<b>Early Impact</b>	<ul style="list-style-type: none"> <li>• The majority of low-income countries have developed country poverty reduction strategies that contain clear health objectives.</li> <li>• While delivery and access improved, this did not happen in an equitable manner in all Member States.</li> <li>• WHO's Prequalification of Medicines Programme has, since 2001, aimed at helping procurement agencies to attain acceptable standards of quality, safety and efficacy and its List of Prequalified Medicinal Products already comprises well over 300 medicines for priority diseases today.</li> <li>• Increased biosimilar competition affects not only the price for the directly comparable products but has an effect on the price of the whole product class and has thus increased access to biological medicines in many countries.</li> </ul>

## Recommendations

### Recommendations for consideration by Member States

1. Member States, in collaboration with other stakeholders, to join efforts for increasing funding to improve delivery of, and access to, health products;
2. Member States to strengthen their national regulatory agencies to facilitate rapid access to health products for their citizens;
3. Member States, in collaboration with other stakeholders, to explore regional partnerships to share expertise between countries and strengthen policies and regulations for health products.

### Recommendations for consideration by the WHO Secretariat

4. WHO Secretariat to continue and strengthen its efforts under the Prequalification of Medicines Programme;
5. WHO Secretariat, in collaboration with its partners, to expand its efforts at conducting and coordinating joint reviews of clinical trials of medicines and vaccines;
6. WHO Secretariat, in collaboration with its partners and relevant stakeholders, to further strengthen national drug regulatory capacity, improve ethical review of clinical trials, and help to develop capacity to address barriers to access to affordable health products and medical devices.

## Element 7: Promoting sustainable financing mechanisms

### Background

GSPOA aims to make health products available in developing countries through new and innovative mechanisms. In recent years, donors have provided substantial financial resources for improving the availability and accessibility of health products and the control of diseases in developing countries. While financing was secured for R&D activities for the prevention, screening and treatment of the diseases covered by the global strategy, further funding is needed to support longer-term R&D activities for products to meet the local health needs of developing countries.

The objectives of this Element of GSPOA include identifying and analysing the gaps in the financing for health products and related R&D and thus securing a flow of fresh resources into innovation while maximizing the use of complementary current initiatives.

While Member States had identified the need for sustained efforts to ensure the replenishing of new product pipelines to deliver the breakthrough products that are needed, the issue of funding these efforts remained unresolved at the end of the negotiation of GSPOA.

In response to a specific action of this Element, the *Consultative Expert Working Group on Research and Development: Financing and Coordination* (CEWG) was established by the World Health Assembly in 2010 to address the issue of securing adequate and sustainable financing for R&D and improving the coordination of its use. The report of the CEWG which was submitted to the WHA through the WHO Secretariat in May 2015, recommended several approaches for financing R&D, including precompetitive R&D platforms, open source and open access schemes, prizes, equitable licensing and patent pools. It also proposed the creation of a Global Health R&D Observatory and relevant advisory mechanisms under the auspices of WHO in order to improve coordination within the existing structures and framework.

### GSPOA Element 7. Promoting sustainable financing mechanisms<sup>31</sup>

In recent years, donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional financing has also been secured for research and development activities relevant for the control and treatment of the diseases covered by this strategy. Nonetheless, further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries. The most serious gaps in financing for health products and research and development covered by this strategy need to be identified and analysed.

It is important to make maximum use of, and complement as appropriate, feasible current initiatives, thereby contributing to a flow of resources into innovation and implementation. The actions to be taken to promote sustainable financing mechanisms are as follows:

<sup>31</sup> GSPOA, available at: <http://www.who.int/phi/publications/gspa-phi/en/>

- (7.1) endeavouring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries:
- (a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases;*
  - (b) consider channelling additional funds to health-oriented research organizations, as appropriate, in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness, as recommended by resolution WHA58.34;*
  - (c) create a database of possible sources of financing for research and development.*
- (7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public–private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices:
- (a) document and disseminate best practices in public–private and product development partnerships;*
  - (b) develop tools for periodic assessment of performance of public–private and product development partnerships;*
  - (c) support public–private and product development partnerships and other appropriate research and development initiatives in developing countries.*

## Key findings

**Endeavouring to secure adequate and sustainable financing for research and development:** Financing mechanisms for R&D of neglected and tropical diseases as well as diseases affecting all income group countries, including emerging, highly infectious diseases, were addressed during the implementation of this Element.

In 2012, the CEWG recommended the creation of a new pooled financing mechanism to be used to fund all phases of R&D in the public and private sector as well as in public–private partnerships addressing the identified health needs of lower-middle-income and low-income countries. The CEWG also proposed open knowledge innovation, which is research and innovation that generate knowledge which is free to use without legal or contractual restrictions. One such example is milestone prizes

### **Facilitating the use of financing through public-private and product development partnerships:**

Data indicate that during the implementation of GSPOA, new financing innovations and initiatives have emerged, including those of Public-Private Partnerships (PPPs) and Product Development Partnerships (PDPs), many of them

#### **Milestone prizes**

Milestone prizes are cash prizes given for reaching interim steps along the development pathway. For example, one online marketplace offers the opportunity for public, private and philanthropic organizations to post challenges. The award is paid for those who best meet the solution requirements, and a commercial agreement may be negotiated between the “seeker” and the “solver”. This online market place seem to be cost effective with an average of 300 problems posted per year and around 130 solved for an annual cost of US\$ 6–9 million. Furthermore, one third of “solvers” were located in lower-middle-income and low-income countries. This also implies capacity building in lower-middle-income and low-income countries.



addressing Type III diseases, in partnership with international NGOs, high-income and upper-middle-income countries and pharmaceutical companies.

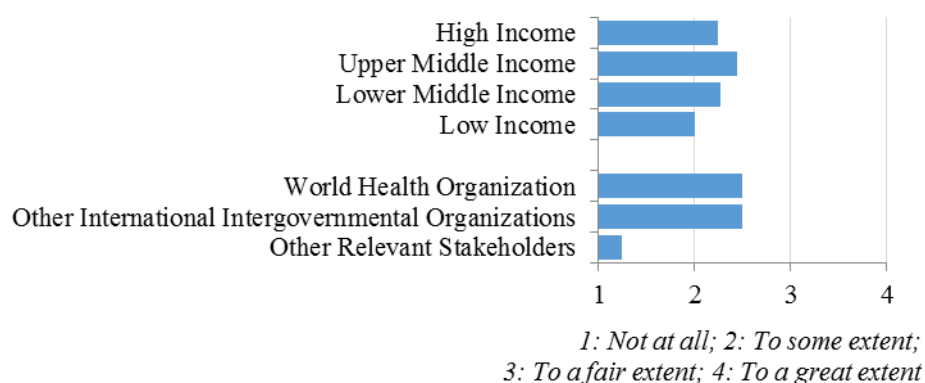
Until recently, PPPs in the biomedical sector were mostly based on bilateral agreements, typically between a pharmaceutical company and an academic institution. Recent years have seen the emergence of considerably enhanced support from existing funding institutions, including the World Bank, regional development banks, UNITAID, the Global Fund for AIDS, Tuberculosis and Malaria, the Global Alliance for Vaccines and Immunization, the Medicines for Malaria Venture and the programmes of the European Commission. Despite all of these endeavours, there remain a number of clearly identified gaps in both PPPs and PDPs, e.g. in areas such as traditional medicine.

There is evidence that countries or organizations facilitate the maximum use of existing financing in order to develop and deliver safe, effective and affordable health products and medical devices.

A growing body of experience illustrates the effectiveness of established public–private and product development partnerships, such as the Drugs for Neglected Diseases initiative, Medicines for Malaria Venture and the International AIDS Vaccine Initiative. This was also evidenced by the key role which WHO and others played in addressing emergency situations such as Ebola and Zika virus outbreaks.

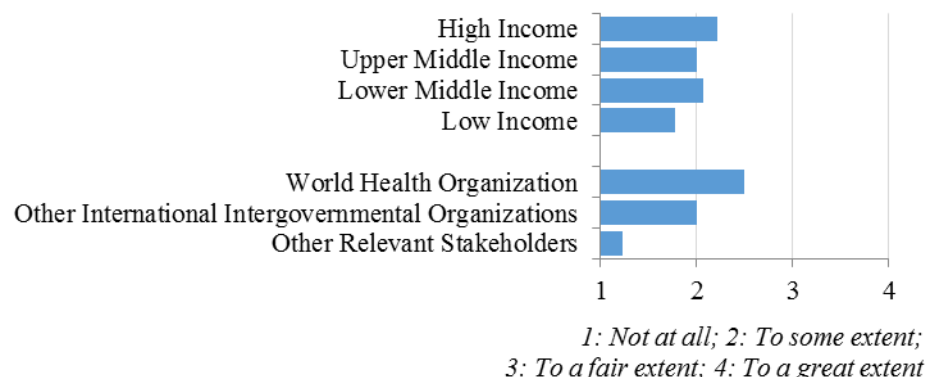
## Survey Results

Graph 3.29 To what extent did your country or organization implement Element 7?



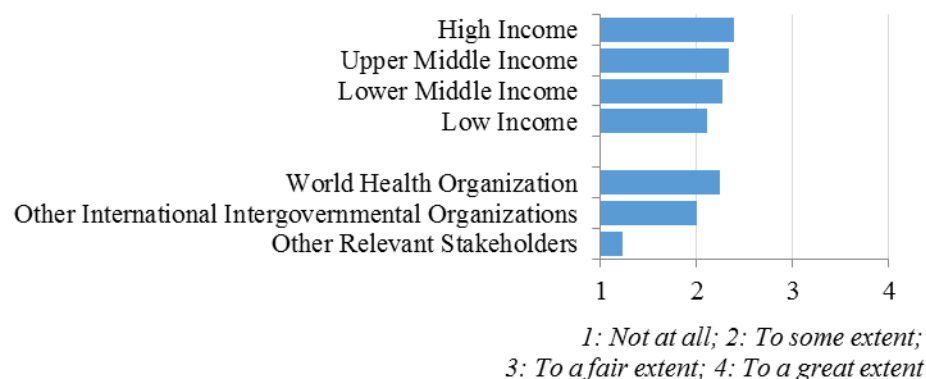
## 7.1 Endeavouring to secure adequate and sustainable financing for research and development

Graph 3.30 Within Element 7, to what extent did your country or organization implement Sub-Element 7.1?



## 7.2 Facilitating the use of financing through public–private and product development partnerships

Graph 3.31 Within Element 7, to what extent did your country or organization implement Sub-Element 7.2?



### Key observations from country case studies

High-income countries provided evidence of supporting lower-middle-income and low-income countries through PPPs and PDPs. One such country reported that it was active in pursuing sustainable financing mechanisms, but not as a consequence of GSPOA.

Respondents in an upper-middle-income country felt that financing should come from the private and public sectors and support the entire process from R&D to market launch. PPPs are seen as an important incentive to involve the private sector and develop a balance between competition and affordability. The financing of health-related infrastructure is a major challenge in most of the low-income and lower-middle-income countries. One low-income country aims to reduce dependence on international aid.

In terms of gaps, one upper-middle-income country stated that the funding for health services, health technology, health financing and health governance research is not adequate and needs to be increased. It is evident that low-income and lower-middle-income countries have very limited access to sustainable financing mechanisms. In one lower-middle-income country, considerable funding was available but underutilized.

## Key achievements

### Endeavouring to secure adequate and sustainable financing for research and development:

Data show that a wide range of options for securing financing was considered by the stakeholders of GSPOA, for example consumer-based indirect taxation, which involves a small tax imposed on specified products or transactions, such as UNITAID's airline tax; voluntary business and consumer contributions; and donor funds for health R&D.

#### UNITAID airline tax

UNITAID's airline tax has raised around US\$ 1 billion since it was launched in September 2006. Thirteen countries have passed the necessary legislation and several are in the process of doing so. UNITAID's successful initiative attests to the fact that an international solidarity micro-levy is well accepted by the public and causes no economic distortion.

The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) was set up to find ways to fund research on diseases afflicting poor populations which have little market incentive for the private sector and it provided recommendations to the WHA. The WHA adopted resolutions WHA65.22 and WHA66.22 on the follow up of the report of the CEWG and, in May 2016, the Director-General of WHO convened an open-ended meeting of Member States to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health R&D. TDR is actively engaged in the follow-up to the CEWG.

Based on resolution WHA66.22, health R&D demonstration projects were identified and are being funded. WHO is in the process of finalizing the terms of reference and a costed workplan of the Global Observatory on Health Research and Development; and a proposal for a voluntary pooled fund to support R&D for Type II and Type III diseases and specific R&D needs of developing countries in relation to Type I diseases; to be presented to its governing bodies.

There are promising grant schemes in lower-middle-income and low-income countries for stimulating innovation through broad participation of small and medium-sized enterprises in

#### Good Practices

Private companies are increasingly seeking to design new medical devices and health care delivery models that are adapted to the needs of, and affordable by, lower-middle-income and low-income countries. These actions reflect the commitment of several companies towards evaluating local and regional barriers and to design and manufacture products and services tailored to meet the needs of lower-middle-income and low-income countries.

support of relevant R&D. These schemes contribute to the promotion of high-risk pre-proof-of-concept research and end-stage development by small and medium-sized enterprises.

Purchase or procurement agreements are contracts between a purchaser and a product developer which set the price at which a product will be purchased and/or the volume of product that will be supplied. Available procurement funds under such agreements stimulate increased R&D and provide

large-scale access to new products.

**Facilitating the use of financing through public-private and product development partnerships:** Mechanisms have been established by countries in all income groups to build and improve innovative capacity for health-related R&D in lower-middle-income and low-income countries. These mechanisms focus on developing policies and strategies with subsequent plans of action, setting up facilities to increase research capacity, and strengthening the pharmaceutical manufacturing sector.

Available qualitative and quantitative data prove the beneficial impact of PDPs due to their focus on developing suitable and affordable products for the populations of lower-middle-income and low-income countries. A typical PDP works with researchers and developers of a lower-middle-income or low-income country and in that way also contributes to capacity-building. Some PDPs focus on regional needs in research and contribute to policy and advocacy programmes in lower-middle-income and low-income countries; others act at the global level.

Donors therefore increasingly favour PDPs as their vehicle of choice to disburse neglected disease funding, while smaller donors may even disburse virtually all their funding in this manner. Successful PDPs brought together the public, private and philanthropic sectors to fund and manage the discovery, development and delivery of new health products.

UNITAID has been supporting promising PDP activities that explore and promote possible incentive schemes to overcome IP barriers and promote public health, such as the Drugs for Neglected Diseases Initiative non-profit drug development model, the TB Alliance, and the Medicines for Malaria Venture.

## Key gaps and challenges identified

**Endeavouring to secure adequate and sustainable financing for research and development:** In order to reach long-term sustainability there is a need to go upstream of particular health products by pooling resources to ensure that lower-middle-income and low-income countries are enabled to carry out the research and regulatory work required to secure their own requirements in terms of health products. Such steps are still in the early stages in many of these countries, including domestic investment in research institutions, capacity development in regulatory systems, education and training.

There is evidence that countries and organizations identified and analysed gaps in financing R&D related to diseases affecting mostly lower-middle-income and low-income countries and that health products were developed and manufactured for those countries.

Most health sector financing in low-income countries has been aid-dependent, but major multi-lateral partners are now conditioning their support with a view to phased withdrawal.

Furthermore, working towards identifying and promoting new approaches to secure adequate financing for health R&D may require strengthening of the global efforts in this respect.

**Facilitating the use of financing through public-private and product development partnerships:** From quantitative data, it appears that most regions and countries, with a few

exceptions, rely more on global initiatives to come up with new and innovative means to finance health R&D in other countries.

Available data show the benefits of public-private and PDPs for the various groups of stakeholders and the countries involved. However, facilitating the use of financing through these partnerships may require stronger global or regional efforts in identifying possible partners, the countries where the business environment is favourable, and where the capacity is available or where it can be developed within a relatively short period of time.

### Areas for Further Work Identified

- a. Member States and WHO Secretariat to continue to explore and evaluate existing mechanisms with a view to establishing a pooled fund for voluntary contributions towards R&D for Type II and III diseases as well as the specific R&D needs of lower-middle-income and low-income countries in relation to Type I diseases, as recommended by the CEWG.
- b. Indirect tax approaches could potentially raise very significant amounts. Further work in this field may be particularly rewarding because this kind of tax can yield a remarkable amount of money.
- c. Donors are increasingly favouring PDPs as their vehicle of choice for disbursing funding. The activities undertaken within the framework of GSPOA should thus further intensify these efforts.
- d. Member States have suggested new incentive mechanisms for innovation, which separate rewards for innovation from the price of health products. This is an area which may bring together knowledge, tangible assets and skills for new treatments.

## Conclusions

Relevance	<ul style="list-style-type: none"> <li>Element 7 is highly relevant to all lower-middle-income and low-income countries.</li> </ul>
Effectiveness	<ul style="list-style-type: none"> <li>Incentives are critical for further improving the national health innovation systems and making health products available as needed in lower-middle-income and low-income countries. They contribute to the creation of local public-private R&amp;D partnerships, and to upgrading of the facilities of local manufacturers in order to conform to international guidelines and to obtain WHO prequalification.</li> <li>A number of large PPPs have been developed to support drug discovery and development for neglected diseases in lower-middle-income and low-income countries.</li> </ul>
Sustainability	<ul style="list-style-type: none"> <li>Under the leadership of WHO's Consultative Expert Working Group (CEWG), a new WHO pooled financing mechanism is under consideration.</li> </ul> <p>Sustainability is in question, however, because:</p> <ul style="list-style-type: none"> <li>Larger consortia are needed to tackle the major challenges facing the health care systems.</li> </ul>
Early Impact	<ul style="list-style-type: none"> <li>Providing more domestic investment in research institutions and enhancing capacity development in regulatory systems, education and training are in early stages of development.</li> <li>Milestone prizes given for reaching interim steps along the development pathway imply capacity building, and show promise, with one third of "solvers" being located in lower-middle-income and low-income countries.</li> <li>UNITAID's airline tax has already raised around US\$ 1 billion since it was launched in 2006.</li> </ul>

## Recommendations

### Recommendations for consideration by Member States

1. Member States, in the context of Sustainable Development Goal 3.8 on universal health coverage, to secure adequate funding and facilitate R&D efforts for development of health products and medical devices;
2. Member States to increase funding and encourage public-private partnerships and product development partnerships to ensure availability and affordability of health products and medical devices in lower-middle-income and low-income countries;
3. Member States and other stakeholders to lend their political support to new innovative schemes for identifying new sources of funding for health R&D and operationalize their use, such as those recommended by the Consultative Expert Working Group on Research and Development: Financing and Coordination.

### Recommendations for consideration by the WHO Secretariat

4. WHO Secretariat to work with other stakeholders to implement the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination.

## Element 8: Establishing monitoring and reporting systems

### Background

GSPOA supports the establishment of systems to monitor performance and progress towards objectives contained in this strategy and the plan of action.

#### GSPOA Element 8. Establishing monitoring and reporting systems<sup>32</sup>

##### **GSPOA Element 8. Establishing monitoring and reporting systems**

Systems should be established to monitor performance and progress of this 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. Steps to be taken will include:

- (8.1) measuring performance and progress towards objectives contained in the strategy and plan of action:
- (a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action;*
  - (b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries;*
  - (c) continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly;*
  - (d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices;*
  - (e) monitor and report on investment in research and development to address the health needs of developing countries.*

The evaluation team ascertained the degree of progress made on this element by focusing its data collection efforts around answers to the following key questions related to actions taken by Member States and organizations during the 2009-2015 period:

- Did they report regularly on progress towards the implementation of the strategy?
- Did they create new or strengthened existing initiatives at the national, regional and global levels to promote the implementation of the strategy?
- Did they submit reports on the compliance with Element 8?
- Have they been subjected to evaluation of the strategy?
- Did they measure performance and progress of their initiatives towards GSPOA objectives?
- Did they establish systems to monitor performance and progress on each of GSPOA elements?
- Did they monitor and report on the impact of IP rights on the development of, and access to, health care products to the WHA?

<sup>32</sup> GSPOA, available at: <http://www.who.int/phi/publications/gspa-phi/en/>



- Did they monitor and report on the impact of incentive mechanisms on innovation of, and access to, health products and medical devices?
- Did they monitor and report on investment in R&D to address the health needs of the country?

## Key findings

**Measuring performance and progress towards objectives of GSPOA:** Member States experienced considerable difficulties in complying with the provision of GSPOA for establishing monitoring and reporting systems to gather evidence about implementation processes and results of GSPOA.

While several countries listed many health-related initiatives of relevance to their countries which they monitor regularly and on which they report to their national governments, donors or WHO, these were not comprehensive national strategies set up specifically to implement GSPOA or WHO initiatives in this context.

Furthermore, there is evidence that the majority of national stakeholders and survey respondents were not aware of whether or not their country monitored and reported on investments in health R&D.

The evaluation team considers the following as the main possible reasons for this:

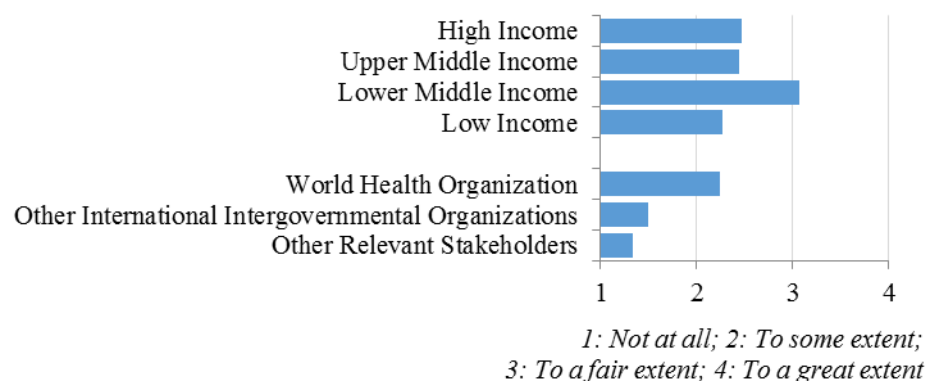
- a limited monitoring and evaluation resource base, coupled with weak capacity and competence in many Member States, which suggests the need for more guidance and support in this area;
- WHO's own capacity limitations in providing such guidance and support, either alone or in collaboration with other partners.

There is evidence that WHO is developing a monitoring system and a mechanism to understand the progress made by the stakeholders in the implementation of the specific actions of GSPOA.

Evidence from self-reporting pointed to evaluations of the implementation of GSPOA having taken place mostly in low-income and lower-middle-income countries in some regions. However, no clear examples of related reports were listed, except for one lower-middle-income country in the South-East Asia region that reported having been officially evaluated with regard to its progress made and the difficulties it encountered with the implementation of GSPOA.

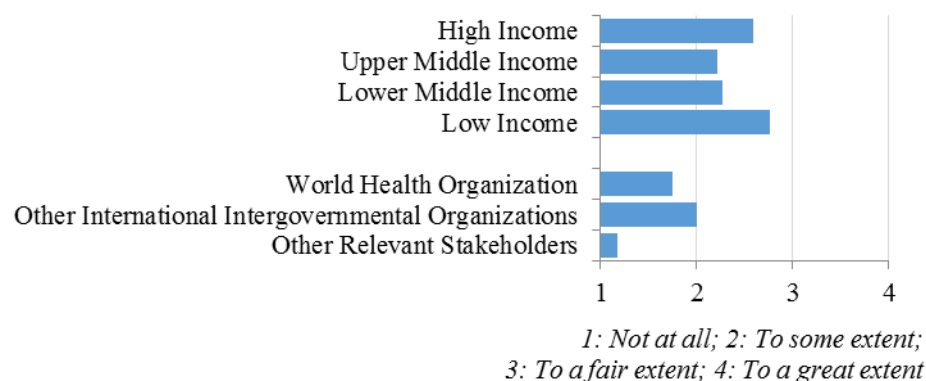
## Survey Results

Graph 3.32 To what extent did your country or organization implement Element 8?



### 8.1 Measuring performance and progress towards objectives of GSPOA

Graph 3.33 Within Element 8, to what extent did your country or organization implement Sub-Element 8.1?



### Key observations from country case studies

Many stakeholders in all income groups stated that they were asked to report on their activities without knowing that this was a GSPOA requirement. Others cited a lack of incentives to use the WHO monitoring system. Weaknesses in Element 8 are also partly a reflection of the limited resource base in many Member States. In one lower-middle-income country, an electronic data reporting system is under development to replace the paper-based one.

In terms of *gaps*, in all income groups, Member States experienced difficulties in complying with the strategy's provision to establish monitoring and reporting systems for gathering evidence about their implementation processes and results of GSPOA. There is a lack of regular reporting on progress towards implementation of GSPOA, in most cases in all income groups.

There is some evidence among low-income, upper-middle-income and high-income countries that gaps and needs in health products have been monitored and assessed. However, there is little evidence that this monitoring was implemented due to GSPOA. No relevant evidence was provided to show that Member States shared their experience of the implementation of GSPOA. Survey results suggested that Member States tended to support the implementation of

the strategy more through their national initiatives rather than through regional or global initiatives. In most low-income countries and lower-middle-income countries, there is sporadic evidence of outcome measurement for assessing health systems in general, but not necessarily regarding the specificities of GSPOA. High and upper-middle-income countries have reported having systems in place for monitoring health outcomes.

## Key achievements

**Measuring performance and progress towards objectives of GSPOA:** Several countries monitor and report on their health-related initiatives, without referring to the goals of GSPOA. Progress reports on GSPOA implementation were submitted to the World Health Assembly in 2010, 2012<sup>33</sup> and 2014<sup>34</sup> and these reports are publicly available on the WHO website.

## Key gaps and challenges identified

**Measuring performance and progress towards objectives of GSPOA:** While the survey revealed that there were multiple examples of national strategies to tackle health issues in a given country these were not comprehensive national strategies set up specifically to implement GSPOA. The feedback from survey respondents suggests that there was little awareness of GSPOA in a few countries as it was not well disseminated, promoted and financed.

Documentation revealed that WHO finalized its National Assessment Tool to facilitate a systematic assessment of the conducive environment to innovation for medical technologies, helping Member States to analyse their situation in terms of policies, regulations, legislations, infrastructure and funding. However, WHO's assistance to Member States in creating and setting up the necessary systems has been only partially effective. The WHO National Assessment Tool in its current form does not permit an adequate stock-taking of existing monitoring and evaluation capacity. The limited resources, weak capacity and competence base of many Member States in this area, together with insufficient WHO capacity for support and guidance, further contributed to the observed weaknesses in achieving the monitoring and reporting goals of GSPOA.

The development by WHO of the web-based platform for monitoring and information sharing regarding Member States' progress and experience in implementing GSPOA faced unexpected delays and it is not yet completed. Financial constraints and key personnel rotation were cited by WHO as obstacles to its completion, as well as the completion of other mechanisms to understand the progress in the implementation of the specific actions of GSPOA.

The examples that countries provided were often unrelated to the goal of GSPOA to promote new thinking on innovation and access to medicines and to secure an enhanced and sustainable basis for needs-driven essential health R&D relevant to diseases that disproportionately affect developing countries. Some countries do undertake knowledge gap analyses created by

<sup>33</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/WHA65/A65\\_26-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_26-en.pdf) page 9

<sup>34</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/WHA67/A67\\_40-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_40-en.pdf) page 17

advances in the development of health products and medical devices, but there is no evidence that these are directly related to GSPOA and are reported to WHO.

While there appeared to have been various country-specific monitoring efforts, no specific evidence was provided regarding the monitoring by countries of the impact of IP rights on the development of, and access to, health care products during GSPOA implementation.

There is also little evidence from the survey of examples of countries of any income level actively monitoring and reporting the impact of incentive mechanisms on the innovation of, and access to, health products and medical devices. The same is true regarding the impact of investment in R&D to address the health needs of lower-middle-income and low-income countries.

### Areas for Further Work Identified

The following areas where further work needs to be done in order to completely implement this element were identified:

- a. To strengthen efforts aimed at sharing Member States' experience of progress made in the implementation of GSPOA, for example through appropriate exchange platforms; strengthened support and guidance by international development agencies; and North-South and South-South cooperation;
- b. Wherever this has not yet been achieved, to devise comprehensive national strategies for implementing GSPOA, including a robust monitoring and evaluation component, and to monitor and report on each of its elements to the relevant stakeholders, including WHO;
- c. WHO Secretariat to complete its web-based platform for monitoring and information sharing regarding Member States' progress and experience in implementing GSPOA where Member States will be able input information related to their "innovation system";
- d. To further build the capacity of WHO and other international organizations to provide effective guidance and support to Member States for monitoring and reporting on progress in implementing GSPOA;
- e. WHO Secretariat to collect financial information regarding the efficiency of actions and activities related to the implementation of this element of GSPOA.

## Conclusions

Relevance	<p>There appears to be marginal or no relevance of efforts undertaken so far, because:</p> <ul style="list-style-type: none"> <li>• Several countries monitor and report on their health-related initiatives without referring to the goals of GSPOA.</li> <li>• There were multiple examples of national strategies to tackle health issues in a given country, but these were not comprehensive national strategies set up specifically to implement GSPOA.</li> </ul>
Effectiveness	<p>GSPOA monitoring and reporting system is not yet effective, because:</p> <ul style="list-style-type: none"> <li>• Although WHO finalized its National Assessment Tool, its assistance to Member States in creating and setting up the necessary systems has been only partially effective.</li> <li>• Very few countries/institutions reported on their activities to strengthen existing initiatives at the national, regional or global level to promote the implementation of GSPOA.</li> </ul>
Sustainability	<ul style="list-style-type: none"> <li>• Sustainability is in question, since financial constraints and key personnel rotation were cited as obstacles to completing the WHO web-based monitoring platform and mechanisms to assess progress made in the implementation of the specific actions of GSPOA.</li> </ul>
Early Impact	<ul style="list-style-type: none"> <li>• There is no evidence yet of early impact.</li> </ul>

## Recommendations

### Recommendations for consideration by Member States

1. Member States and the WHO Secretariat to plan for a final evaluation of GSPOA implementation in 2023;
2. Member States to strengthen their monitoring and evaluation systems to monitor progress and evaluate the performance of the implementation of GSPOA in their countries.

### Recommendations for the WHO Secretariat

3. WHO Secretariat to complete the development of a web-based platform for monitoring and information-sharing regarding Member States' progress and experience in implementing GSPOA;
4. WHO Secretariat to revise the National Assessment Tool appropriately so as to capture better the existing capacity of Member States to effectively discharge their obligations and responsibilities regarding GSPOA monitoring and reporting.

### **Overall programme review 2017**

An overall programme review is envisaged to be initiated in 2017 and is to be informed by this evaluation.

#### Recommendations for the overall programme review

3. The overall programme review should address areas identified for future work in this report and consider and provide guidance on the recommendations;
4. Member States, through the overall programme review, to further review resources expended and financing available for the implementation of GSPOA in order to identify best practices and constraints.

## 4 EMERGENCE OF A THEORY OF CHANGE

Since no Theory of Change currently exists, the Evaluators have developed one based on the *Force Field Analysis* model, as described in the diagram below.

Change is not an event, but rather a process and there are many different factors (forces) for and against making any change. Force Field Analysis helps us be aware of these factors. If the factors **for** change outweigh the factors **against** change the change to the desired state will be successful.

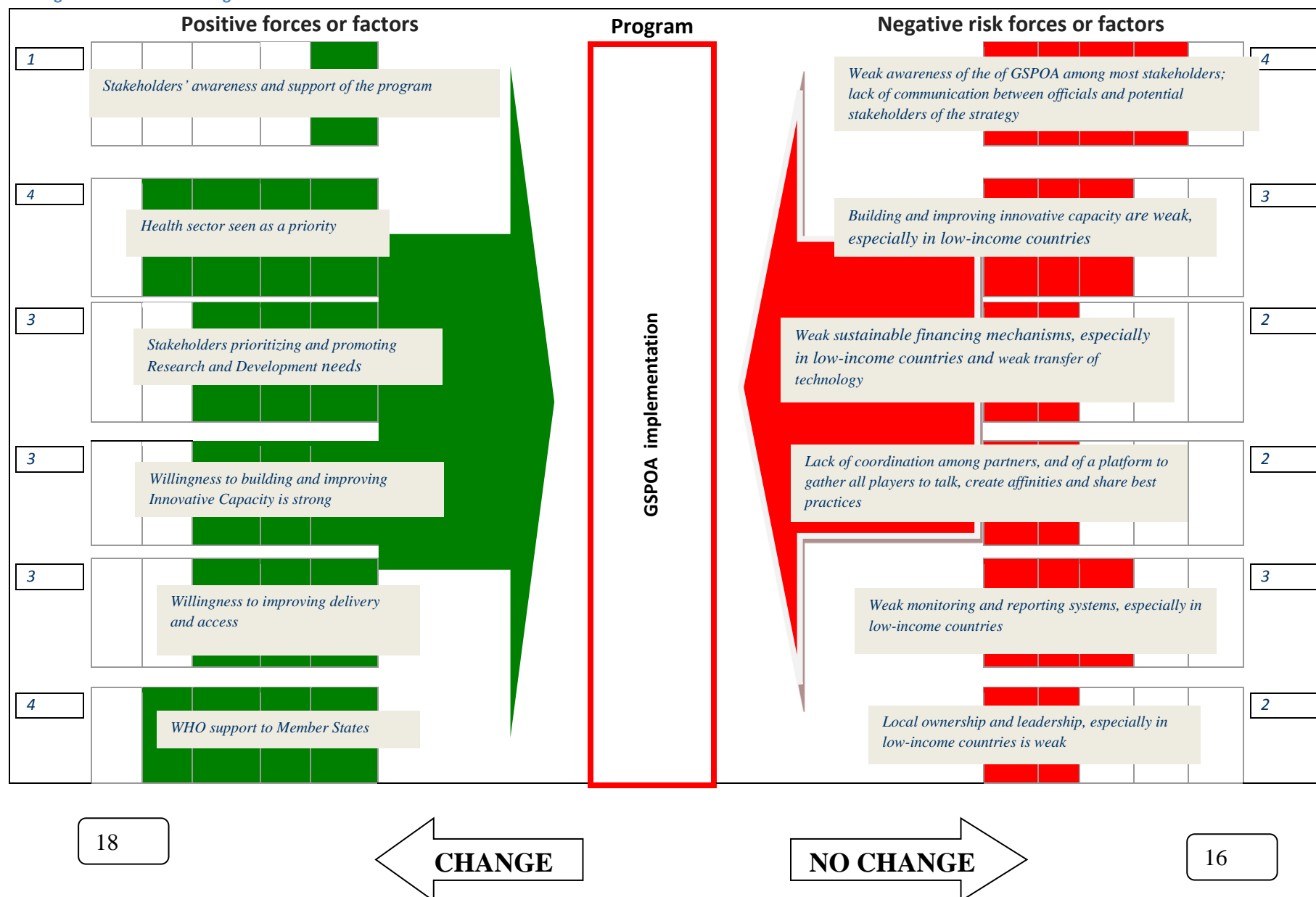
In our case, Force Field Analysis helped the evaluation team understand the driving and hindering forces impacting the successful implementation of GSPOA.

The steps outlined below helped the evaluation team capture these forces. They represent the process that was used for the implementation of Force Field Analysis.

1. Identify and understand the current state of the implementation of GSPOA.
2. Identify and understand the desired goal state relative to the implementation of GSPOA.
3. Identify and list driving (**Positive**) forces acting to support the full implementation of GSPOA.
4. Identify and list restraining (**Negative risk**) forces acting to hinder the full implementation of GSPOA.
5. For each force, designate the level of influence using a numerical scale (e.g. 1=extremely weak and 5=extremely strong).
6. Chart the forces by listing the driving forces on the left and restraining forces on the right. Also represent in the chart the numbers allocated in Step 5 for each force.
7. Evaluate the chart and determine whether change is viable.
8. Discuss how the change can be affected by decreasing the strength of the restraining forces or by increasing the strength of driving forces.
9. Discuss action strategies to eliminate the restraining forces and to capitalize on the driving forces.

The opposing green and red arrows define the centre column that represents the true change that will likely be achieved when the positive and negative forces have been taken into account and managed as opportunities and risks.

Figure 4.1 Force Field Diagram





The consolidation of data collected from the document reviews, survey and country case studies helped the evaluation team to list the most important positive and negative factors and rate their influence in coherence with stakeholders' views and survey finding. For example, more than 85% of stakeholders met during the country case study field visits stated that they were not aware of GSPOA, that they were not informed about it, and that this fact jeopardizes the successful implementation of the strategy. So, the *“weak awareness of GSPOA among most stakeholders, the lack of communication between officials and potential stakeholders of the strategy”* was listed as a negative force and rated 4 on a 5-point scale of influence. On the other hand, data from the survey (see charts above) show that the majority of participants state that their countries or organizations are *“prioritizing and promoting Research and Development needs”* to some extent. This factor was, then, rated as positive with 3 points on a 5-point scale of influence.

As shown in the above force field diagram, the total point value for Positive forces slightly exceeds the total value of the Negative risk forces or factors. This means that there is still a risk that the successful implementation of GSPOA might fail if nothing is done to reduce restraining forces, increase driving forces, or some combination of the two.

This evaluation report provides a clear idea on the importance and relationships among the many forces that impact change and suggests some recommendations to help GSPOA management elaborate some strategies to reduce or eliminate the restraining forces and to capitalize on the driving forces, if a decision is made to extend GSPOA.