EXECUTIVE BOARD
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Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property

Report by the Secretariat

1. In 2008, in resolution WHA61.21, the Sixty-first World Health Assembly adopted the global strategy on public health, innovation and intellectual property and the agreed parts of the related plan of action.[1] The following year, the Sixty-second World Health Assembly adopted the final plan of action in resolution WHA62.16.

2. In resolution WHA61.21, the Health Assembly requested the Director-General, inter alia, to provide biennial implementation reports, in addition to a comprehensive evaluation of the strategy after four years. In resolution WHA62.16, the Director-General was requested, among other things, "to conduct an overall programme review of the global strategy and plan of action in 2014 on its achievements, remaining challenges and recommendations on the way forward to the Health Assembly in 2015 through the Executive Board".

3. The Executive Board at its 133rd and 136th sessions considered reports on the question of evaluation of the global strategy and plan of action,[2] and adopted decision EB136(17) (2015), in which it decided, inter alia, to recommend to the Sixty-eighth World Health Assembly to extend the deadline of the overall programme review to 2018.

4. The Sixty-eighth World Health Assembly considered the Secretariat report on the matter[3] and adopted resolution WHA68.18 (2015), in which it decided to extend the time frame of the plan of action on public health, innovation and intellectual property from 2015 to 2022. It further decided to extend the deadline for the overall programme review to 2018 and to undertake the comprehensive evaluation and overall programme review in a staggered manner as set out in the report and its Annex.

5. In resolution WHA68.18, the Sixty-eighth World Health Assembly also requested the Director-General to initiate the comprehensive evaluation of the implementation of the global strategy and plan of action on public health, innovation and intellectual property, to establish a panel of 18 experts to

[1] On the specific actions and stakeholder components.

[2] Documents EB133/7 and EB136/31.

[3] Document A68/35.

conduct the overall programme review and to present the terms of reference of the overall programme review for approval by the Executive Board at its 140th session in January 2017.

COMPREHENSIVE EVALUATION

6. 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. Covering the period 2008−2015, the aim of the evaluation was to document achievements, gaps and remaining challenges and generate recommendations on the way forward.

7. The Evaluation Office provided an update on the progress of the evaluation to the Executive Board at its 138th session,[1] providing information on the establishment of an ad hoc evaluation management group, as requested in resolution WHA68.18, and on the selection of the external independent evaluation team to undertake this evaluation. Furthermore, key points from the evaluation team's draft inception report and initial comments by the ad hoc evaluation management group were also presented to the Executive Board.[2]

8. The comprehensive evaluation was conducted between January and November 2016 and the final report was presented by the external evaluation team to the WHO Evaluation Office in early December 2016. The ad hoc evaluation management group was engaged throughout the process and, in particular, reviewed and commented on the inception report in January 2016 and the draft evaluation report delivered by the evaluation team in late October 2016.

9. The evaluation methodology followed the United Nations Evaluation Group norms and standards for evaluations and ethical guidelines. The approach to the evaluation employed both secondary and primary quantitative and qualitative data. 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, online surveys for Member States, the Secretariat and other relevant stakeholders, together with a web-based public survey and 15 country case studies.

10. The evaluation report presents the methodological approach, key findings and key observations from country case studies; it highlights key achievements, documents key gaps and challenges and identifies areas for further work. For each of the eight elements of the global strategy, a number of recommendations are proposed for consideration by Member States, the Secretariat and other stakeholders.

11. The comprehensive list of recommendations and the areas identified for further work are intended to guide the forthcoming overall programme review.

[1] Document EB138/38.

[2] Document EB138/38 Add.1.

12. The executive summary of the evaluation is presented in Annex 1 to this report and the full report of this comprehensive evaluation will be available in English, French and Spanish on the website of the WHO Evaluation Office.[1] The terms of reference of the overall programme review are set out in Annex 2.

EXPERT PANEL FOR THE OVERALL PROGRAMME REVIEW

13. As requested in operative paragraph 2(4) of resolution WHA68.18, the Director-General invited Member States,[2] to nominate experts for the roster from which the panel of 18 members will be selected in order to conduct the overall programme review.

14. Furthermore, in line with resolution WHA68.18, Regional Directors were invited to propose six experts for each region to be included in the same roster. The deadline for submission of proposals was 21 October 2016.

15. The proposed experts were asked to disclose their potential interests, further to the WHO Guidelines for Declaration of Interests (WHO Experts) and section 4.6 of the WHO Regulations for Expert Advisory Panels and Committees.[3] Keeping in line with the WHO Guidelines for Declaration of Interests (WHO Experts), each disclosure was closely examined for conflicts of interest prior to the experts being placed on the roster.

16. The Director-General will select the 18 members of the overall programme review panel from the roster and present their names for consideration by the officers of the Executive Board in February 2017.

17. The composition of the review panel will respect gender balance and equal regional representation. It will also ensure a broad and balanced diversity of technical competence, practical experience and background, covering the eight elements of the global strategy and plan of action on public health, innovation and intellectual property, and including experts from developed and developing countries.

METHOD OF WORK OF THE PROGRAMME REVIEW PANEL

18. At its first meeting, the review panel will elect a chair and elaborate its method of work. It will be supported by a small secretariat.

19. The major portion of the panel's work will be conducted through plenary meetings at WHO headquarters. It is proposed that the panel meets three times at WHO headquarters, in February, June and September 2017 before submitting its final report.

20. The panel may decide to consult relevant stakeholders during the process; it may also seek broader inputs to the process through a public hearing or web-based consultation.

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[1] See http://www.who.int/about/finances-accountability/evaluation/en/, accessed 12 December 2016.

[2] See Circular Letter C.L.35.2016.

[3] See Basic documents, 48th ed. Geneva: World Health Organization; 2014: pp.121–130.

TIMELINE

21. As specified in resolution WHA68.18, the composition of the review panel will be presented for consideration to the officers of the Executive Board in February 2017. The review panel will meet for the first time in the first quarter of 2017.

22. A progress report will be presented to the Seventieth World Health Assembly in May 2017. The review panel will meet again in June 2017 and for a final discussion in September 2017.

23. The final report of the overall review will be presented to the Seventy-first World Health Assembly in May 2018 through the Executive Board at its 142nd session. The report will make specific recommendations on the way forward for the implementation of the global strategy and plan of action until 2022.

ACTION BY THE EXECUTIVE BOARD

24. The Executive Board is invited to note the Secretariat's report, to consider the report of the comprehensive evaluation of the global strategy and plan of action on public health innovation and intellectual property and to consider the following draft resolution:

> The Executive Board,
>
> Having considered the proposed terms of reference of the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property set out in the Secretariat's report,[1]
>
> APPROVES the terms of reference (as set out in Annex 2).

[1] See document EB140/20, Annex 2.

ANNEX 1

Comprehensive Evaluation of the Implementation of the Global Strategy and plan of action on Public Health, Innovation and Intellectual Property

EXECUTIVE SUMMARY

delivered to the

World Health Organization

by

Capra International Inc.

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[1].

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.

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

[1] 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

(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 multistakeholder consultation, using national focal points or units for effective intersectoral coordination.

Recommendations for consideration by the WHO Secretariat

2. The Secretariat to support Member States to monitor progress in R&D prioritization;

3. The 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. The Secretariat to promote publicly accessible repositories for health research in order to improve access to knowledge

5. The 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. The Secretariat and WHO 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 multisectoral participation in the development of health research policy.

Recommendations for consideration by the WHO Secretariat

4. The 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 WHO 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. The 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. The Secretariat and WHO 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. The 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 scepticism regarding production in *lower-middle-income* and *low-income* countries. In particular, it was pointed out that substandard/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. The 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. The 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 counties.

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. The Secretariat to continue and strengthen its efforts under the Prequalification of Medicines Programme;

5. The Secretariat, in collaboration with WHO partners, to expand its efforts at conducting and coordinating joint reviews of clinical trials of medicines and vaccines;

6. The Secretariat, in collaboration with WHO 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. The 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 Health Assembly in 2010, 2012 and 2014.[1] 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 WHO 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. The 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. The 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.

[1] Documents A63/6, A65/26 and A67/40.

Overall programme review in 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.

ANNEX 2

TERMS OF REFERENCE OF THE OVERALL PROGRAMME REVIEW

1. As proposed in document A68/35, the overall programme review, as distinct from the evaluation, will be a more policy-oriented, forward-looking exercise. Guided by the report of the comprehensive evaluation and, where appropriate, taking into account other evidence and involving relevant stakeholders, the programme review will:

(a) assess the continued relevance of the aim and objectives of the global strategy and plan of action;

(b) assess the implementation of the global strategy and plan of action so far;

(c) review achievements and success factors as well as gaps, weaknesses and remaining challenges;

(d) recommend a way forward, including details of what may need to be improved and modified in the next stage of implementation of the global strategy and plan of action until 2022;

(e) submit a final report to the Health Assembly, including the assessment of the global strategy and plan of action and recommendations on the way forward.

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