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In Focus

Expert commentary & opinion

Implementing the WHO Global Strategy on Public Health, Innovation & IP: An Opportunity that should not be Squandered by Poor Implementation

By Nicoletta Dentico, Health Policy Advisor, IQsensato

Abstract

On the basis of a review of the history and challenges faced by the World Health Organization's (WHO) essential medicines concept, this In Focus piece recommends that the implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (hereinafter "the Global Strategy") needs to be seen as an incremental endeavour. In fact, the WHO mid-term Global Strategy should provide the operational basis for a much longer-term vision and systematic global approach to socially relevant health research and development (R&D). This incremental approach entails significant advantages. It can subtly shift the public/private balance by replacing poor policies with new devices aimed at recovering public goods from the private sector, thereby increasing public scrutiny over R&D performance. More importantly, it can produce a positively disrupting demonstration effect. It can operate to persuade governments that structural change is possible, and that, in fact, they can influence the direction of this change. Similar incremental approaches have patiently formed the bedrock of bilateral and multilateral negotiations for long time: building up confidence among relevant actors, so as to allow negotiators to move another step forward.

Table of contents

1. Trade and health: the long march in WHO since the essential medicines concept 2
2. Needs-driven innovation and access to essential drugs: Enduring hurdles & new policy opportunities 3
3. The WHO Global Strategy: An unparalleled opportunity to address both innovation & access 5
4. A broad range of commitments, and the challenge of implementation 6
5. Sustainability for essential innovation & access to medicines 7
6. Conclusions 8

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IQsensato

In Focus

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1. Trade and health: the long march in WHO since the essential medicines concept

In 1977, the adoption of the concept of essential medicines (EMC) introduced new principles of equity, cost-effectiveness, good governance and attention to the needs of the poor and disadvantaged in the field of pharmaceuticals. As a result, essential medicines were integrated as one of the major components in the primary health care package in 1978 - when the role of traditional medicine was recognized, too. The concept has been used as an inspiring principle to shape and develop national medicine policies and pharmaceutical programmes, especially in developing countries -- over 100 countries have developed national medicines policies based on the essential medicines concept. After thirty years, it has become part of the human rights-based approach dealing with an increasing web of innovative public health thinking and medicine policies initiatives in the field of access and quality standards, such as the WHO prequalification programme, the medicine price survey methodology, etc. The WHO remains the uncontested global conceptual and technical leader in this area and its constitutional mandate to develop and promote global standards and regulations on pharmaceuticals and biological is generally trusted.

As economic globalization and international trade agreements have progressively exerted a greater influence over national economies and regulatory policies, concern has mounted about their potential impact on public health, especially in the developing world. Although, for example, the global protection of intellectual property (IP) - touted as a critical incentive for innovation - has increasingly risen with developing countries undertaking major changes to implement the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), views on the subject have varied from those who believe increased global trade and enhanced IP protections naturally create public health benefits to those who fear that the failure to prioritize public health concerns in the process of trade liberalization will inevitably lead to public health harms. The globalisation of the pharmaceutical market, and of pharmaceutical knowledge that goes with it, could present unquestionable advantages for populations throughout the world. On the other hand, globalisation as the result of policies aimed at market control – the elimination of competition – through a rigid architecture of access[1], has extremely worrisome consequences for the health domain in general, and for access to medicines in particular.

The World Health Assembly, WHO's governing body, gave the Organization the mandate to work in this area *at least* since its resolution WHA.52.19 on the Revised Drug Strategy, in 1998[2]. This resolution noted that the impact of new international trade agreements on local manufacturing capacity and the access to essential drugs and prices of pharmaceuticals had scarcely been evaluated in most developing countries and that more initiatives were needed to research and develop drug policies *vis-à-vis* these agreements. Since then, a febrile political debate around issues of trade and health at the WHO –

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[1] Saul, J.R., *The Collapse of Globalism and the Reinvention of the World*, Atlantic Books, London, 2005, pp. 176-194.

[2] Resolution WHA52.19 on the Revised Drug Strategy, requested the Director-General, "*inter alia* to cooperate with Member States, at their request, and with international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements".

IQsensato

In Focus

Implementing the WHO Global Strategy on Public Health, Innovation & IP: An Opportunity that should not be Squandered by Poor Implementation

particularly in relation to the implementation of the TRIPs Agreement - has across years produced a considerable number of resolutions and initiatives, aimed at settling the question of how to ensure that patent protection for pharmaceutical products does not prevent people in poor countries from having access to medicines.

The lack of medicines that address diseases of the developing world poses a serious threat to fulfilment of the human right to health and is an impediment to the achievement of the Millennium Development Goals. Building up on previous negotiations, in 2003 the WHO Member States decided to set up an independent expert commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), to document the impact of IP protection on medical innovation and access to essential medicines, especially for diseases that affect the poor. The CIPIH, for the first time, managed to provide empirical evidence of the inherent limitations of the IP system with regard to the development, production and dissemination of medicines for diseases that mainly affect developing countries. In its 2006 Report[3], it made 60 recommendations requesting that policy-makers consider making adjustments to the current R&D system and developing new mechanisms to stimulate needs-driven medical innovation. It also recognized that governments have a crucial role to play with regard to the different interventions across disease areas - well beyond the most neglected tropical diseases[4] - needed to promote essential innovation and access to lifesaving medicines.

2. Needs-driven innovation and access to essential drugs: Enduring hurdles & new policy opportunities

Knowledge is, and has always been, central to all development in health. Knowledge and technology relevant for health cover a wide area, and include the following elements:

- Understanding health risks and patient characteristics;
- Preventive action, both individual and collective;
- Diagnostic procedures and practices;
- Curative procedures;
- Palliative interventions; and
- Delivery systems for all of the above.

If we look at the health and biomedical fields, these have witnessed major technological transformations leading to important breakthroughs over the last decades. The development of antiretroviral (ARV) therapy for the treatment of HIV/AIDS and the mapping of the human and other animal genomes, among other breakthroughs, have provided increasing hope for the realization of the right to health in developing and least developed

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[3] World Health Organization, *Public Health, Innovation and Intellectual Property Rights,* Report of the Commission on Intellectual Property Rights, Innovation and Public Health, WHO, Geneva, 2006. Available at *http://www.who.int/intellectualproperty/documents/ thereport/en/index.html*.

[4] Though the problem of lack of access to essential medicines is known through the example of infectious diseases, the challenges facing developing countries and LDCs with respect to non-communicable diseases have also become acute in the last few years: cancer, heart diseases and diabetes account for 16% of the disability adjusted life years lost in low and middle income countries – four times higher than the share of the total burden coming from malaria (see Lanjouw JO., "A Patent Policy Proposal for Global Diseases", *National Bureau of Economics*, April 2001). A case in point, cervical cancer kills more people in developing countries than all of the pathologies in the cluster of tropical diseases, including trypanosomiasis, Chagas disease, schistosomiasis, leishmaniasis, lymphatic filariasis, and onchocerciasis. Yet the vaccine is priced above the annual per capita health expenditure of most women who need it (see Outterson K., "A request for clarification concerning the proper scope of the IGWG's work to improve access to patented medicines", 2nd Public Hearing to WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights, 2007. Available at *http://www.who.int/entity/phi/public_hearings/second/contributions_section1/Section 1_Kevin_Outterson_Boston_Uni_Full_Contribution.pdf*

In Focus

Implementing the WHO Global Strategy on Public Health, Innovation & IP: An Opportunity that should not be Squandered by Poor Implementation

countries. Modern medical technologies have the potential to improve health even in countries at low levels of income. This is unlike the historical pattern in the now developed countries where health improvements were largely due to higher incomes[5]. Despite these significant scientific developments, there continue to exist shocking disparities in health, and unacceptable inequalities in the distribution of benefits between people in developed and developing countries, as well as within countries.

Although high drug prices have traditionally been justified as necessary to provide the incentive for R&D investment, there is a growing awareness of the associated access problems. High prices mean many people cannot afford essential medicines. In developing countries and least-developed countries (LDCs), the prohibitive cost of essential medicines is well known and documented[6]. High prices for medicines in developing countries have seriously compromised the ability of communities, governments and other players in the health sector to effectively manage infectious and communicable diseases, discouraging for example the stockpiling of drugs needed for health emergencies.

While a natural conflict exists between the need for low-cost medicines to promote access to treatment as a human right and the maintenance of a trade regime that seeks to finance medical R&D by allowing monopolists to charge high prices, reforms to the existing R&D system and a willingness to invest in promising new approaches are urgently needed to overcome the appalling lack of appropriate medicines to prevent and treat the causes of mortality and morbidity in developing countries[7]. Neglected tropical diseases kill 500,000 people every year. Existing medicines for diseases that are controlled in the rich world are often inappropriate for particular groups of patients with special needs, such as women and children.

Developed countries, which represent nearly 90% of the global pharmaceutical sales, account for only 10% of the 14 million plus global deaths that occur annually due to infectious diseases. Vice versa, developing countries represent 90% of the 14 million deaths, but only 10% of the global pharmaceutical sales: the so-called 10/90 gap[8]. It is in an effort to address the 10/90 gap and the emerging challenges with non-communicable diseases that the World Health Assembly (WHA) adopted the Global Strategy on Public Health, Innovation and Intellectual Property in May 2008. In particular, the Global Strategy aims to promote new thinking on innovation and access to medicines and to "*provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases which disproportionately affect developing countries*". This ambitious goal should not be defeated with poor implementation or lack of leadership at WHO.

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[5] Michael Kremer, "Pharmaceuticals and the Developing World" *Journal of Economic Perspectives*, Vol. 16, No. 4, Fall (2002), pp.67-90.

[6] See e.g., Médecins sans Frontières (MSF) Access to Essential Medicines Campaign *Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries*, 8th Edition, MSF, Geneva (June 2005).

[7] See the recent Oxfam report, *Ending the R&D Crisis in Public Health:* Oxfam Briefing Paper, November 2008.

[8] Although this gap was identified by the WHO Commission on Research and Development in 1990, no comprehensive action had been taken to address it. For detailed analysis of the problems relating to research into diseases that disproportionately affect developing countries see e.g., MSF Drugs for Neglected Diseases Working Group and the Campaign for Access to Essential Medicines, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*, MSF, Geneva (2001).

IQsensato

In Focus

Implementing the WHO Global Strategy on Public Health, Innovation & IP: An Opportunity that should not be Squandered by Poor Implementation

3. The WHO Global Strategy: An unparalleled opportunity to address both innovation & access

The Global Strategy is the harvest of the work of the Intergovernmental Working Group on Public Health, Innovation and IP (IGWG). The IGWG has been recognized as the most important WHO initiative on pharmaceuticals in the last few decades. It may not be a sheer coincidence that this two-year negotiation on essential health R&D and access to medicines overlapped with the 30th anniversary of the WHO's conception of essential medicines. For the first time, the report of a WHO independent commission - the CIPIH - has been translated into an intergovernmental platform through a member state-driven process. This is a new development, and one to be welcomed. At a time when many new actors and funding initiatives have emerged in the field of health R&D, the work of the IGWG – which ended with the adoption of the Global Strategy in May 2008 - could have great consequence. Negotiators were given the mandate to design a sustainable strategy and action plan intended not only to overcome the inequity in global expenditures on health research, but also to address the lingering mismatch between how research resources (in terms of scientific knowledge and human resources) are used and the burden of diseases affecting developing countries.

The Global Strategy contains consensus text on "the context", "the aim", "the principles" and specific actions under eight elements, namely: **(1)** Prioritizing research and development needs; **(2)** Promoting research and development; **(3)** Building and improving innovative capacity; **(4)** Transfer of technology; **(5)** Application and management of IP to contribute to innovation and to promote public health; **(6)** Improving delivery and access; **(7)** Promoting sustainable financing mechanisms; and **(8)** Establishing monitoring and reporting systems.

The Global Strategy definitely strengthens - and widens - the mandate of the WHO to undertake work on the interrelated issues of public health, research and development in the medical field, IP and access to medicines. It also denotes a significant advancement from previous instruments such as the Doha Declaration on IP and Public Health, insofar as:

- The Doha Declaration focused exclusively on access, whereas the Global Strategy significantly deals with innovation and access as intertwined elements;
- The Doha Declaration advocated for the use of primarily one of the TRIPs flexibilities, compulsory licenses, while the GS clearly confirms the options for Member States to resort to all flexibilities provided in the TRIPs Agreement (the Bolar provision, research exemption and patentability standards, only to name a few);
- The Doha Declaration's perspective hinged on the use of flexibilities for procurement purposes, whereas the debate has stretched further and the Global Strategy points to the use of TRIPs flexibilities to enhance upstream research and share health innovation and science, as well as to promote delivery of drugs to patients in need.

If backed with sufficient political, financial and technical support, the Global Strategy offers an unparalleled opportunity for addressing the twin challenges of incentivising and financing essential health R&D and promoting enhanced access to existing medicines. This possibility now exists because the Global Strategy provides a number of key parameters for success, namely it:

IQsensato

In Focus

Implementing the WHO Global Strategy on Public Health, Innovation & IP: An Opportunity that should not be Squandered by Poor Implementation

- **Establishes a Forum for Implementation and Monitoring:** For the first time governments have settled on a forum to address essential medical innovation and access, i.e. the WHO.
- **Provides a Framework for Action:** In the last 10 years the various resolutions on access to medicines and IP that have adopted by the WHA have not had a coherent framework for action. The Resolution on the Global Strategy (WHA61.21) establishes the strategy as the framework for the implementation of all these other resolutions including WHA52.19; WHA53.14; WHA54.10; WHA55.11; WHA56.27; WHA56.30; WHA57.14; WHA58.34 and WHA60.30.
- **Focuses on Sustainability:** The Global Strategy is premised on the idea that the implementation of the medium-term framework should result in establishing sustainable financing and incentive mechanisms for essential health research including a monitoring framework.

4. A broad range of commitments, and the challenge of implementation

The implementation of the Global Strategy will require the efforts of many stakeholders (particularly those identified in the Plan of Action) and concrete initiatives at international, regional and national/local level. The principal responsibility - about 90 actions of the Plan of Action - lies with governments as lead stakeholders to initiate actions that they have themselves negotiated.

The range of commitments is indeed broad. It pins down Member States to R&D priority setting - so that not only diseases that have captured donor and media attention receive funding, to the detriment of “championless” pathologies that still affect large number of people in developing countries. As a result, governments should be able to define their own R&D agenda and prioritise health financing accordingly, with the aim to integrate health research in the health system strengthening effort, at the national level.

Assessing needs and setting priorities is only the preliminary step, though. The Global Strategy has to do with designing and testing new pathways to innovation and access, complementary to the current IP system, as well as investigating new IP mechanisms to promote essential health innovation and access to lifesaving health tools, measuring their impact. In addition, it will entail improving the clinical trials and regulatory infrastructure in developing countries to facilitate introduction of adequate essential tools in resource poor settings. Finally, governments will have to adopt innovative financing mechanisms to grant provide and durable support to the development of, and access to, new and appropriate health technologies.

New legislations may be required, as well as coordination at the ministerial level, or even re-definition of government departments. Appropriate national policies remain absolutely essential to the implementation of any public health strategy which seeks to ensure that both medical public and commercial knowledge are made available to the public benefit. In particular, rich and poor countries must make investments in strengthening the scientific capacity of the developing world. The beneficial outcome would include the reduction in drug-development costs, the creation of new centres of innovation promoting local scientific capacity in universities, and therefore greater capacity to address issues of adaptation to local health needs (especially new combinations and formulations), and a shared stake in appropriate products for public health. South–South research collaboration provides unprecedented opportunities in this field, since it can promote health-related research on problems that have low priorities in the North, while allowing for shared

IQsensato

In Focus

Implementing the WHO Global Strategy on Public Health, Innovation & IP: An Opportunity that should not be Squandered by Poor Implementation

possibilities for capacity building. It also fosters political and economic links between countries, potentially helping them strengthen their position in the global arena.

At the international level, the main focus will be on the implementation efforts of the WHO governing bodies (the Executive Board and the WHA) and the WHO Secretariat, the WHO being the lead stakeholder for at least 48 actions. However, an important role will be played by other international organizations as well as various non-governmental actors and stakeholders including civil society, product development partnerships (PDPs) and funding agencies, as the resolution calls for international organizations and other stakeholders to give priority within their respective mandates and programs to the implementation the Global Strategy. Of course, it is important to notice that economic and political forces may affect the behaviour of the major players in the system. But in today's market mayhem, which could have serious implications for governments' ability to spend on the health and produce a decline in overseas development aid (ODA), it is imperative for policymakers and leaders in charge to recognize that the rarest of opportunities is emerging to institute reforms and end abuses in the pharmaceutical sector, for the benefit of all – rich and poor alike.

5. Sustainability for essential innovation & access to medicines

Resolution WHA 61.21, which incorporates the Global Strategy and the agreed parts of the Plan of Action, urges Member States to carry out the specific actions approved, to support actively the wide implementation of the Global Strategy and to consider providing adequate resources for implementation. Element 7 of the Global Strategy looks at how a sustainable funding basis for research and development could be secured, including the identification of funding gaps. To promote sustainable financing for R&D, and improving coordination of its use, the Global Strategy provides the establishment of a "*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 R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases*".

A number of recommendations on resource flows and coordination have been made in past years[9], and reiterated as recently as 2005 (Resolution WHA 58.34) for concrete implementation. No specific outcomes have yet resulted from such previous negotiations. The recent appointment of the Expert Working Group (EWG) potentially marks one of the most meaningful legacies of the IGWG, and an important requisite for inducing positive movement in the implementation of the Global Strategy. Just as greater public financing for medical innovation is urgent, innovative ideas are urgently required in the area of push and pull mechanisms to support needs-driven R&D and access to lifesaving medicines, focussing particularly on the de-linkage between the costs of R&D and the price of health products.

While fixing the funding problem will not be enough in an environment that hinges on ever-stricter imposition of IP rules, it appears that no single policy option is likely to provide the

[9] The 1990 Commission on Health Research for Development, recommending that governments should spend 2% of their health budgets on what it called essential national health research, and that donor nations should invest 5% of their aid for health in developing countries, on research and strengthening research capacity.

IQsensato

In Focus

Implementing the WHO Global Strategy on Public Health, Innovation & IP: An Opportunity that should not be Squandered by Poor Implementation

solution to the challenge of sustainability. There are, broadly, five ways in which societies can choose to promote socially desirable medical research-

- direct public funding and organisation of medical research;
- assignment of private rights for the commercial use of research, as in patent regimes;
- ensuring private profitability of investment and production through various means such as public pre-purchase agreements, and provision of fiscal incentives;
- reliance upon (or encouraging through fiscal and other means) private donor or charitable funds; and
- Statutorily requiring that those involved in medical businesses such as pharmaceutical companies and other health care providers reinvest a proportion of their revenues into non commercial health R&D.

The WHO expert working group on R&D financing should aim to articulate a richer menu of recipes for action. Indeed, the growing awareness of the limitations of IP rights to induce R&D for diseases that mainly affect the poor has already led to several proposals to address the question[10]. These include public-private partnerships, "sensible" patenting and social licensing strategies, patent pools, prize funds and open source pathways. This list should not be considered comprehensive, and new ideas should be advanced, leading to a scenario where developing countries feel motivated and ready to participate in a global system of innovation as equal partners, sharing the costs and benefits in new ways with the developed world. Contextual factors may shape policy decisions, and promoters of policy change will have to create their own policy space, sometimes by drawing on contextual features, and sometimes by other actions that create the opportunity to promote political innovation.

The choice of how and where the next new stream of finance is spent also needs to be similarly thought through. The Global Strategy could provide an invaluable platform to test the ability of developing countries to increase their contributions and scale up their own activities to foster innovation for health problems relevant to their own contexts. Even at a time of financial crisis, when aid revenues seem likely to stall at best.

6. Conclusion

The implementation of the WHO Global Strategy needs to be seen as an incremental endeavour. In fact, this mid-term strategy should provide the operational basis for a longer-term vision and systematic global approach to socially relevant health R&D. This incremental approach entails significant advantages. It can subtly shift the public/private balance by replacing poor policies with new devices aimed at recovering public goods from the private sector, thereby increasing public scrutiny over R&D performances. More importantly, it can produce a positively disrupting demonstration effect. It can operate to persuade governments that structural change is possible, and that, in fact, they can influence the direction of this change. Similar incremental approaches have patiently formed the bedrock of bilateral and multilateral negotiations for long time: building up confidence among relevant actors, so as to allow negotiators to move another step forward.

[10] "Innovation for Diseases that Mainly Affect Developing Countries: Issues and Ideas", Briefing note on Medical Innovation, WHO Regional Office for South-East Asia and Western Pacific Region, November 2006.