



**Comments of Spring Gombe
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**Draft Global Strategy on Public Health, Innovation and Intellectual Property
WHO Doc A/PHI/IGWG/2/2**

I submit the following comments with a view to strengthening the draft global strategy and plan of action, and for the consideration of member states during their negotiations in November.

I look forward to further public discussion subsequent to the conclusion of the negotiations in November, through to the end of the 61st World Health Assembly when the results of the submissions are presented to member states.

The guiding principles:

The right to health is universal and inalienable.

The convention on the rights of the child, the convention to end all forms of discrimination against women, the right to development, the International Covenant on Economic, Social and Cultural rights and the Universal Declaration on Human Rights cement the moral basis of the work of the IGWG

The moral is not subsidiary to the economic or the technical. Indeed the scientific technical, economic and social are means to achieving the moral end, and must remain coherent with the right to health.

To recapitulate from the CIPIH Report:

“ Although much of this report is couched in the language of science, medicine, economics or law, it should not be forgotten that there is an underlying moral issue.”... “The moral obligation is backed by a legal imperative. Most governments have committed to take steps ensuring that various fundamental human rights are fulfilled. Human rights have an authority that is not trivial; most countries have already acknowledged the primacy of human rights by signing and ratifying the international agreements in which they are enshrined, and many have further made provision in national constitutions and legislation (25). In this context, the relevant human right agreed in the International Covenant on Economic, Social and Cultural Rights (article 12.1) is “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”(26). This language reflects the overarching objective in WHO’s Constitution, which is “the attainment by all peoples of the highest possible level of health”(27).“

And further, from the Doha Declaration on TRIPS and Public Health:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

These principles form the basis for the work of the IGWG.

The context

In the service of the principles, the context is set by WHA resolution WHA 59.24. The burden of communicable disease, which accounts for half of the disease burden of developing countries, is a matter for urgent action, but attention must also be paid to the increasing impact of non-communicable disease, and taking into account the effects on poverty on access to health.

Resolution WHA 60.30 the World Health Assembly encouraged the development of proposals for health-needs driven research and development that include a range of incentive mechanisms, including those that address the relation between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product.

Advances in science and technology, the right to the enjoyment of which are enshrined in the International Convention of Economic Social and Cultural Rights, offer opportunities for innovation of medicines. Proprietary rights and the policies for their management should not constitute an impediment. Science, technology, and the policies for management of these should be more effectively harnessed of the public good.

The GSPOA must address both innovation and access, together.

The aim

The GSPOA should provide a medium term (and this should be defined in number of years) framework based on the recommendations of the CIPIH, as mandated in WHA Resolution 59.24, to secure *inter alia* an enhanced and sustainable basis for needs-driven, essential research and development relevant to diseases that disproportionately affect developing countries and estimating financing needs. .

The agenda for research and development depends on the needs of developing countries. Needs assessment and gap identification for priority must be given in all regions to the capacity for undertaking such research and development – given that capacity according to stage of the research and development process, and the resources for the same vary widely. The existing capacity must be mapped and redirected to achieve this end.

Attention to financing is part of the mandate of the IGWG and cannot be sidestepped. The draft GSPOA failed to address this part of its mandate. This should be addressed in the

intervening period to the negotiations.

As part of its plan of Action the IGWG (or a body identified/resulting therefrom) must clearly assume a leadership role in securing financing for R&D.

The focus

The draft plan states the focus comprises R&D for diseases or conditions of significant public health importance in developing countries and related health technologies. This wording is problematic, if it will be used to limit in any way the provisions of the draft plan that address access to medicines to only some diseases or conditions. The draft plan should state that it will address the measures needed to promote access to medicine for all, without limitations on the diseases or conditions.

The importance of access to medicine for all diseases is emphasized in many of the CIPIH recommendations. For example:

- 4.7 "For non-communicable diseases, governments and companies should consider how treatments, which are widely available in developed countries, can be made more accessible for patients in developing countries."
- 4.9 states: "Governments of low and middle income countries where there are both rich and poor patients should formulate their funding and price regulation with a view to providing access to poor people."
- 4.10 states: "given the leverage to determine prices that patents confer, [Governments] should adopt measures to promote competition and ensure that pricing of medicines is consistent with their public health policies. Access to drugs cannot depend on the decisions of private companies but is also a government responsibility."

While the provisions in the draft plan dealing with access to medicines should be very broad, it is appropriate to consider measures relating to R&D that focus on the special problems facing developing countries. The special R&D needs for developing countries include not only diseases and conditions that have significant incidence in developing countries, but disproportionate impact in developing countries, but also for adapting products to address the needs of developing countries, including the R&D needed to ensure that treatments are effective and available resource poor settings. In this regard, there can also be no justification for the limitation of the scope of disease, as attempted in footnote 1 on page 4 of the GSPOA. This limitation should be removed from the negotiating documents.

The elements

The elements outlined in the draft global strategy and plan of action form together the basis for a coordinated global response. The comments that follow do not address all elements, but that is not indicative.

Element 1: Prioritizing research and development needs

The draft documents prepared by the Secretariat should have provided member states with models for their consideration for **gap identification** and **priority setting** exercises that they might undertake, with an assessment of the relative merits of each in regard to the protection and advancement of the right to health, but also taking into consideration their technical and economic components.

The capacity to assess health needs, which are not universally available, forms the necessary basis for establishing and sustaining developing countries health needs, and their determinants, and is essential to drive sustainable research and development.

Whatever tools are developed to assist countries in gap identification and priority setting, these **must necessarily include some estimate of the financial implications** for countries, which are already resource constrained, and should give guidance as to how this fits in with the other elements here. CIPIH Recommendation 4.5: Policies for biomedical innovation must take account of the fact that health systems in many developing countries remain resource-constrained. Policies must emphasize affordable innovations adapted to the realities of healthcare delivery in developing countries, and covering appropriate technologies for the diagnosis, prevention and treatment of both communicable and diseases. Mechanisms for promoting such adaptive research in a systematic way must be improved.

The Secretariat should play a bridging role in working with funders to help them appreciate the need for such tools, and in allowing them to champion those they favour.

Element 2: Promoting research and development

The context for the work of the IGWG in promoting research and development should be safeguarding the public domain. This includes the promotion of public access to the results of government funded research, 2.12 Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to R&D outputs relevant to the health concerns of developing countries and to products derived therefrom, are facilitated through appropriate licensing policies and practices.

A prerequisite for research and development is access to knowledge. The Secretariat should have provided resource documents for member states on the implication of lack of openness on science, innovation and eventually access, and make proposals for means to maximize openness. Some examples should be tabled for discussion in November. The CIPIH Recommendation that applies is 3.7: Practical initiatives that would motivate more scientists to contribute to this field through “open source” methods should be supported.

Member states will need to make binding and enforceable commitments to funding for the promotion of research and development. The constant simmer of the existing private public partnerships for product development point to this need. The Secretariat should not have been afraid to be explicit in this regard. Whether the norms initially adopted are soft or hard is a matter for member states. Some poor countries have already indicated their interest in advancing work in this regard, and some rich countries have expressed their dissatisfaction at being the primary payers for research and development. Common ground therefore exists for

new solutions to the satisfaction of all actors, including new frameworks for research and development. Enforceable norms keep all actors honest and accountable. The Secretariat should now act as a convenor of such discussions, remaining unafraid, and unashamed, to be the advocate first of the right to health. The mandate for this is already given in WHA resolution 56.27.

Other submissions by Knowledge Ecology International will address the issue of the policy development of a new framework for essential research and development, including the possible elements of a treaty on research and development, consistent with Recommendation 3.6 of the CIPIH.

Element 3: Building and improving innovative capacity

The context for this is access to knowledge and policies that facilitate such access in all areas with an implication for innovation of and access to medicines and related technologies for diseases that disproportionately affect developing countries. These include policies in education (especially tertiary education in science and technology), research, industry, health, and information management, to name a few. As mentioned before, all this is premised on harnessing knowledge for the public good.

Element 5: Management of Intellectual Policy

The setting of the context, and the discussion in this section represent departure and to an extent regression from agreements already taken and recommendations already made. The CIPIH report goes much further than the text; **the relevant CIPIH recommendations are 2.10, 4.5-4.27 and 5.3.** These are not adequately captured in the text. It is also important that the context takes full account of the exemptions to Least Developed Countries, and also the question of IP for those countries members of WHO, but not of WTO.

The section should deal with **public policies in intellectual property that affect the right to health.** The title of this element should be accordingly changed. The context should derive from the recommendations of the CIPIH report, and the emphasis from the Doha Declaration on TRIPS and Public Health, which has implication for all areas of trade and subsequent trade policy at the bilateral or multilateral level.

The WHO Secretariat is not obliged to be passive in this regard. Indeed as the primary agent for the “attainment by all people’s of the highest possible level of health” it is **compelled to be proactive.** As such the plan of action should reflect the measures that WHO in collaboration with other actors in a position to assist, and especially sister organizations and bodies of the UN system will take to provide the needed technical assistance to developing countries in this regard, as in others.

Specific concern arises in this section from the approach to data exclusivity. The CIPIH Report in its **Recommendation 4.20 is clear:** Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS agreement, would benefit public health, weighing the positive effects against the negative effects. A public

health justification should be required for data protection rules going beyond what is required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.

This forms an integral part of the context for the development of a plan of action, and should be better reflected in the negotiating text.

Further concern arises from the conflation of the roles of regulatory agencies and patent offices. Patent offices assess the extent to which a drug meets standards for grant of exclusive rights. What the CIPIH Report recommends is that Governments should take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria and, if appropriate, consider changes to national patent legislation. (Recommendation 4.27)

National drug regulatory offices assess the quality, safety and effectiveness of a drug. Attempts to link the functions of the two offices are neither warranted nor necessary to stimulate innovation and access. For them, **the CIPIH recommends:** developing countries need to assign a higher priority to improving the regulation of medical products. Developed countries, and their regulatory institutions, should provide greater financial and technical assistance to help attain the minimum set of regulatory standards needed to ensure that good quality products are available for use. This assistance should also support infrastructure developments within a country, to ensure that good manufacturing practice and supply chain management standards are implemented and sustained. (Recommendation 5.6)

The text in Element 5 should recognize the separation of function of patent offices and regulatory agencies and be accordingly revised.

Element 7: Ensuring sustainable financing mechanisms.

New mechanisms for rewarding innovation that separate this function from the high prices of medicines are badly needed. These must necessarily be that are long term, sustainable, explicit and predictable are badly needed. Such mechanisms must be clear in their targets. The context is as set out in the CIPIH report (Recommendation 3.3 on page 95): WHO should initiate a process to devise mechanisms that ensure the sustainability and effectiveness of public-private partnerships by attracting new donors, both from governments and the private sector, and also to promote wider participation of research institutions from developing countries. However, governments cannot passively rely on what these partnerships could eventually deliver; there is a need for a stronger commitment on their part for an articulated and sustainable effort to address the research gaps identified in this report.

The impetus for innovation and access must come from governments and the Secretariat alike. Governments should bring to the negotiating table in November explicit proposals for models they favour and wish to test.