I. Introduction

It is widely acknowledged that there is a serious crisis with regard to R&D in diseases of developing countries as well as access to appropriate and affordable treatments for patients of the developing world.

To address this crisis a process was begun in WHO in 2003 which resulted in the Report of the Commission on Intellectual Property, Innovation and Public Health (hereinafter known as the “CIPIH Report”) eventually leading to the adoption of the Global Strategy and Plan of Action (GSPOA) in May 2008 through WHA 61.21.

The CIPIH report and the GSPOA have set the stage for concrete action by governments towards resolving the R&D crisis. In particular 5 key observations made by those documents are worth recalling in this submission, as they are fundamental to any action to enhance R&D.

1. Few R&D resources are directed to the health needs of developing countries as the private sector lacks incentives to invest; and the majority of publicly funded R&D takes place in developed countries and reflects its priorities.\(^7\)

That calls for more investment has had limited success while at the same time recognizing that more sustainable funding is a necessity to support long-term R&D effort.\(^8\)
2. That few or no available mechanisms exist to advise on appropriate priorities for resource allocation between R&D on different diseases, the balance between resources needed for R&D and delivery for each disease or the means to monitor and evaluate the impact of resources devoted to treatment and delivery.9

3. In the longer term the development of innovative capacity for health research in developing countries will be the most important determinant of their ability to address their own health care needs.10

4. Patents are not a relevant factor or effective in stimulating R&D and bringing new products where the market has very limited purchasing power as is the case for diseases affecting people in developing countries. In fact the monopoly costs associated with patents limit the affordability of patented health-care products required in developing countries as well as could be a barrier to further R&D efforts.11

5. New products are of no value if they are not available and accessible to those who need them.12

It is apparent from these observations that there is an urgent need for mechanisms for prioritization, coordination, sustainable financing of R&D as well as for R&D models (push and pull mechanisms) that inter alia ensure availability of affordable treatments suitable for developing country conditions; that promote further research and generic competition as well as that strengthens and builds the R&D and production capacity of developing countries.

For this to happen a systematic and transparent global approach to R&D is urgently required under the auspices of WHO that is mandated by its constitution “to act as the directing and coordinating authority on international health work.”

For a successful Global Framework on R&D, the framework must be supported with predictable and sustainable financing, a dynamic R&D architecture and guiding principles that prioritizes sharing of knowledge, access to affordable treatments, building capacity in developing countries and generic competition. These elements are central components of the GSPOA and the CIPIH Report.

Each of the components are addressed below.

II. Sustainable Financing

The CIPIH report called for “urgent need for action to generate more and sustainable funding for R&D to address the health needs of developing countries, and to engage governments more in

9 See pg. 206, CIPIH report
10 See pg. 161, 204, CIPIH report. See also para 22 of GSPOA, which states: “The strengthening of innovative capacity of developing countries is essential to respond to the needs of public health”.
11 See pgs. 35 and 196, CIPIH Report. See also para 25 of the GSPOA, which states: “Intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain”.
12 See pg. 115, CIPIH report.
this endeavor…..” 13 It also noted that in the absence of such funding new players with innovative capacity such as developing countries will not be able to participate in R&D.14 The GSPOA also notes in paragraph 40 that “further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries.”

The call for “sustainable financing” reaffirms the imperative for predictable funding at a certain rate or level. Previous calls for sustainable financing for R&D has had limited effect resulting in funding of R&D on an ad-hoc basis according to the values of the funder in a limited number of diseases.

What is needed is solidarity for financing of R&D under the auspices of the WHO.

Towards this end, it is proposed that a fund be established. Such a fund would work to achieve collection of a specific amount of funds. The primary source of financing for the fund would be from government contributions according to targets set out taking into account their level of development.15 To generate their respective contributions to the fund governments could use mandatory levies on certain products and tax-based systems as feasible nationally. Government funding can be supplemented with other contributions such as donor funding.

Several developing country governments have successfully used mandatory levies to raise funds to support national public health measures. For example the Thai Health Promotion Foundation established in 2001 raises approximately US $35 million per year from a 2% Government excise tax on tobacco and alcohol. The funds are used to provide grants for a range of health promotion projects.16

The WHO World health report on health financing (2010) cites several other examples.17 Gabon imposed a 1.5% levy on the post-tax profits of companies that handle remittances and a 10% tax on mobile phone operators. Between them, the two taxes raised the equivalent of US$ 30 million for health in 2009. UNITAID’s successful financing mechanism is tax on airline tickets.18

III. Dynamic R&D Architecture

The second critical component of a successful Global Framework on R&D is a dynamic R&D Architecture that guides and supervises the funding of R&D.

The R&D architecture would engage in needs assessments, priority setting and determine which activities and R&D is to be funded as well as the model of R&D including incentives that should be the basis of the conduct of R&D.

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13 See pg. 209
14 See pg. 199, CIPIH report
15 CIPIH report noted: “We seek a new approach that involves governments on a sustainable basis in the financing of health related research relevant to developing countries” (See pg. 207)
Needs Assessment

Needs assessment under the architecture would aim to identify at the country/regional/international levels the health problems, the determinants, severity, and availability of affordable and appropriate treatments, R&D gaps and resources available for research. The process of assessment should be transparent, member driven and involve all other relevant stakeholders.

Priority Setting

Priority setting is another important element in order to better use financial and human resources available, as well as to focus efforts on where needs are most demanding and on products/technologies which if not for the funding made available would not see any R&D activity.

Funding R&D & Determining Appropriate Model including incentives for R&D

The process of narrowing the broad list of needs identified through needs assessment into a relevant R&D agenda that would be funded by the fund should be transparent, inclusive and based on a scientific methodology.

We are of the view that the R&D agenda should not be limited to diseases where no appropriate health products (e.g. medicines/vaccines/diagnostic tools) exist but should also include gaps where health products need to be further improved (e.g. where the side effects of existing products are problematic); or where products exist but need to be adapted to suit the conditions of developing countries (e.g. heat resistant treatments); or that meet the special needs of patients (e.g. the need for pediatric formulation, fixed dose combinations).

The R&D architecture should also engage in determining which R&D is to be funded based on the needs assessment and priority setting as well as the model of R&D including incentives that should be the basis of the conduct of R&D.

On the funding of R&D, it is generally envisaged that the R&D architecture would make a call for proposals based on the R&D gaps identified, evaluate applications and fund the appropriate applicants on a step-wise basis.

On the matter of model for R&D there are many mechanisms that either involve push or pull mechanisms or both. Some of these mechanisms are already being implemented for example advance market commitments, priority review voucher, product development partnerships.

However several reports on these mechanisms have revealed fundamental shortcomings in the delivery of R&D outcomes for developing countries such as the emerging products may not be affordable to middle income developing countries; limited or no sharing of knowledge generated from the R&D; the mechanisms do not promote generic competition nor aim to strengthen capacity in developing countries.

See para 27 of the GSPOA which states: “A better understanding of the developing countries’ health needs, and their determinants is essential to drive sustainable research and development on new and existing products”.

For example see Oxfam (2008), “Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation”; See also http://www.msfaccess.org/main/medical-innovation/advance-market-commitments/
We are of the view that the model of R&D most suited for the development of pharmaceutical product/technology very much depends on the gap that has been identified.

Providing grants to conduct R&D is important to ensure participation of developing country entities in the R&D. Having said this it is also important to explore other mechanisms that can also facilitate R&D. For instance, there may be situations where a specific targeted technical challenge has been identified, and “prizes” may work either as a stand alone mechanism or together with a grant. There could also be R&D gaps where collaborative research along the lines of an “open source” approach could be considered.\(^2\)

Hence, different push and pull mechanisms can be used but these mechanisms should be guided by the principle of delinking the cost of R&D from the price of the product and other guiding principles elaborated below in Part IV.

**Scope of Activities of the Architecture**

It is envisaged that funding under the architecture will be provided for all aspects of R&D including for conducting relevant clinical trials. Funding should also be provided for the purpose of strengthening regulatory capacity and ethical standards of clinical trials in developing countries. As building capacity of developing countries is critical, funding should also be provided to build the local research capacity in developing countries as well as for promoting transfer of technology to developing countries. Towards this end a network of developing country R&D institutions can be established and sustained using the resources of the fund.

What is critical is that funding for R&D is provided to conduct R&D in accordance with certain guiding principles elaborated upon below in Part IV.

**Intellectual Property**

An important issue that needs to be resolved is what is the proprietary status of the research outcomes including product, technologies and data that is generated from the R&D that has been funded. The failures of the patent system to generate R&D for the problems of developing countries are well-known. Thus R&D mechanisms that rely on IP protection and result in monopolization of research outcomes do not adequately address public health problems of developing countries. In this regard, it is important to move away from this “business as usual” paradigm that is obsessed with monopolization of research outcomes even where R&D is publicly funded.

As a general principle the following is proposed: Under the R&D fund and architecture when funding is provided, the research outcomes should not be monopolised by the researcher/research entity through the use of intellectual property protection. The R&D architecture must allow others to build on the R&D outcomes that has emerged as a result of the efforts of the R&D fund and architecture.

**Coordinating, Monitoring & Evaluating R&D**

A key objective of the Global Framework will be to develop mechanisms to coordinate R&D

efforts as far as possible including develop appropriate networks, facilitate periodic assessments of these efforts, provide guidance and direction to these efforts at national, regional and international level as it would have the knowledge and expertise following the needs assessment and priority setting phase; advise on appropriate priorities for resource allocation between R&D on different diseases; the balance between resources needed for R&D and delivery for each disease.

Accordingly the architecture will develop mechanisms to monitor and evaluate R&D efforts generally including those undertaken with funds provided under the architecture as well as the impact of resources devoted to treatment and delivery.

IV. Guiding Principles for R&D

If the global fund for R&D is to work to address diseases of developing countries then the architecture of such a fund would have to address the weaknesses in the current system for funding R&D and to spend money more responsibly. Accordingly we have identified some key guiding principles that should underpin the funding and architecture for R&D.

(1) The R&D fund and architecture must not be limited to Type 3 diseases but should also address other R&D gaps prevailing in developing countries. The fund and architecture should extend to R&D of medicines, diagnostic tools and medical devices.

(2) R&D efforts should be focused on the development of health products that are adapted to the needs of developing countries and patients of all ages.....simple (in terms of use, prescription and storage), accessible (in terms of availability & affordability), safe and of quality.

(3) There must also be emphasis on strengthening the regulatory capacity regarding the safety and quality of medicines and ethical standards of clinical trials in developing countries as well as full disclosure of clinical trial data.

(4) Prices of products/technologies produced should be fixed on the basis that it is affordable to all who need those products/technologies including in middle income countries.

Towards this end R&D mechanisms (push and pull mechanisms) for the conduct of R&D should be designed to de-link the cost of R&D from the price.

(5) The R&D models should be designed to ensure that outcomes and data generated from the R&D are not monopolised.

R&D funded and done under this architecture should be widely disseminated for other researchers to engage in follow-on health research on condition that such follow-on R&D will also be readily accessible for others to build on.

(6) R&D models including incentive mechanisms for the conduct of R&D should be designed to ensure that as a condition of receiving funding the full ownership of research outcomes including products/technologies emerging from R&D will remain with the R&D fund and architecture to further promote research and generic competition.

(7) Activities should also aim to build and strengthen research and local capacity of developing countries. Thus where possible such research and production should be undertaken in developing
countries by the locals or in collaboration with locals in developing countries. For this purpose, effective measures to promote transfer of technology should also be set up.

(8) Where a product results from the genetic resource and/or associated knowledge of indigenous peoples and local communities the principles of prior informed consent and fair and equitable benefit sharing should be adhered to at all stages of research, development and commercialisation.22

(9) High standards of governance and transparency are essential elements for the proper functioning of the R&D fund and architecture. For example there should be transparency with regard to R&D funding provided and the cost of R&D incurred.

(10) R&D fund and architecture should ensure sufficient and meaningful representation and participation of public and private institutions and researchers from developing countries. This includes providing developing countries an equal voice in decision-making processes.

(11) Conflicts of interest must be disclosed and properly managed.

V. Institutional Setup

This submission will not venture to make a specific proposal on the issue of governance of the fund and architecture as there are many ways of setting up the governance, once there is an understanding of the components that are important for delivery R&D. We have highlighted above the components we believe to be important.

However we would stress that it is important that the fund and architecture be managed by structures that are guided by the principles of transparency, inclusiveness that stresses effective participation of developing countries in decision-making processes, equity and high governance standards.

VI. A Global Framework on R&D: The way forward

A successful Global R&D Framework must be able to prioritise R&D, coordinate R&D supported with predictable and sustainable financing, a dynamic R&D architecture and guiding principles that focuses on sharing of knowledge, access to affordable treatments, building capacity in developing countries and generic competition. All of these elements have been elaborated above.

This proposal differs from other proposals pertaining to a fund in that our proposal offers a more comprehensive approach to R&D beginning with needs assessment, aims to fund different R&D gaps that are prioritised, stresses knowledge sharing and strengthening capacity of institutions in developing countries.

We are of the view that the elements (i.e the fund, architecture and guiding principles) could form components of an international framework instrument on R&D.

22 The CIPIH report observed at pgs. 187 that: “We support the principles contained in the Convention on Biological Diversity, i.e. that there should be fair benefit sharing with the providers of that knowledge” and recommended that “All countries should consider how best to fulfill the objectives of the Convention on Biological Diversity”
Such an instrument could also additionally contain general norms/standards with regard to R&D and access that WHO member states would have to follow and that would guide R&D initiatives such as:

1. Norms to facilitate access to government funded research
2. Norms/standards that promote transparency in global medical innovation such as: that call for disclosure of the costs of the different stages of R&D; that establish standards for reporting and sharing information on resource flows used to support R&D;
3. Norms to facilitate and promote R&D incentives that de-link prices from the cost of the product and that promote further research, generic competition, and affordability
4. Norms for monitoring and evaluating global R&D efforts, including implementation of the framework.
5. Ethical standards of clinical trials in developing countries as well as full disclosure of clinical trial data.

VII. Conclusion: Compatibility with CEWG Criteria

The aim of this proposal is to propose the development of a framework instrument on R&D that addresses issues of financing, prioritization, conduct of R&D, coordination, monitoring and evaluation of R&D as well as that sets certain norms/standards in relation to R&D

In Part II the issue of sustainable financing is addressed. It is a feasible proposal as it envisages financing of R&D to be obtained primarily from government contributions. And governments that are unable to contribute the amount could put in place certain levies to generate their contributions. It also envisages that the fund will receive supplementary financing from other sources.

Overall, it is hoped that this proposal will put in place a comprehensive approach to the R&D problems of developing countries. The proposed solutions on financing should address financing issues, while the proposed R&D architecture as well as the guiding principles elaborated on in Part III and IV explicitly address inter alia issues of affordability of R&D outcomes, building capacity of developing countries, IP management issues as well as delinking of R&D costs from the price of products. Thus we believe that the public health impact on developing countries of the above proposal is bound to be positive.

The above proposal should also result in rational and equitable use of resources. Under the R&D Architecture, it is proposed that needs assessment and priority-setting exercises be undertaken and accordingly a relevant R&D agenda be established to be taken forward under the architecture. At the same time, the architecture is also generally to undertake coordination, monitoring and evaluation of R&D efforts and provide general direction on the needs and priorities that should be financed. This approach will ensure that critical R&D gaps are properly funded and there is proper use of the limited resources that are available.

On the criteria of accountability and participation in governance and decision-making, see Part V on Institutional Setup where it stresses that the fund and architecture be managed by structures that are guided by the principles of transparency, inclusiveness that stresses effective participation of developing countries in decision-making processes, equity and high governance standards.

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