

Submission by the Governments of Barbados, Bolivia and Suriname

September 2009

Comments on the Introduction and Criteria for Proposals Documents

The introduction and the criteria documents are clearly written, provide a useful explanation of the other documents distributed by the Expert Working Group on R&D Financing (EWG), and an adequate and concise description of disease, product, R&D types, and actors. Unfortunately, there are several important elements missing from the Introduction and Criteria for Proposals documents, and therefore in the methodology designed to examine and evaluate proposals.

.1 The broader context is missing

There is no reference to the WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) report or the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA61.21), even though the very existence of the EWG is based upon these documents. This is a serious flaw. This can be remedied by making reference to WHA61.21, and including in particular, the relevant parameters that have been set for the implementation of each element of the Global Strategy. These are summarized in paragraph 14 of the resolution WHA 61.21:

14. The elements of the global strategy, which are designed to promote innovation, build capacity, improve access and mobilize resources, will:

(a) provide an assessment of the public health needs of developing countries with respect to diseases that disproportionately affect developing countries and identify their R&D priorities at the national, regional and international levels

(b) promote R&D focusing on Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases

(c) build and improve innovative capacity for research and development, particularly in developing countries

(d) improve, promote and accelerate transfer of technology between developed and developing countries as well as among developing countries

(e) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, possible incentive schemes for R&D

(f) improve delivery of and access to all health products and medical devices by effectively overcoming barriers to access

(g) secure and enhance sustainable financing mechanisms for R&D and to develop and deliver health products and medical devices to address the health needs of developing countries

(h) develop mechanisms to monitor and evaluate the implementation of the strategy and plan

of action, including reporting systems.

These are the minimum standards against which all the proposals should be evaluated by the EWG, therefore the Criteria for Proposals document should be amended accordingly. It is unacceptable for any of these criteria to be excluded from the evaluation process.

.2 New thinking should be promoted

In creating the EWG, the WHO Global Strategy on Public Health, Innovation and Intellectual Property “**aims to promote new thinking on innovation and access to medicines.**” [Paragraph 13, The “aim”]. This needs to receive greater emphasizes.

For example, the Introduction and Criteria for Proposals do not include the core principle of de-linking R&D incentives from the prices of health care technologies, a fundamental precept underscored in WHO resolutions WHA 60.30 and WHA 61.21. This should be an independent criterion.

Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries. (Resolution WHA 61.21).

.3 Access and Affordability

There is insufficient recognition of the importance of access, affordability, product pricing or the relationship between the financing mechanisms and the management of intellectual property rights, even though the EWG was the product of two earlier initiatives, the CIPIH and the IGWG, both tasked with examining these issues.

It is useful to recall Albert Einstein's advice, “We can't solve problems by using the same kind of thinking we used when we created them.” For many years policy makers have designed systems to support medical R&D financing as if concerns about product pricing and access were unimportant details that would be left for others to address. Today we know this is not true.

The EWG is required by the Global Strategy to promote “access to medicines for all,” including in the application and management of intellectual property, the promotion of competition for generic manufacturers, and other measures to address the pricing of products. It is necessary to address access and affordability of products, right from the start. Proposals that address access effectively should be preferred over proposals that do not.

Some of the Bangladesh, Barbados, Bolivia and Suriname proposals include the obligation to grant open, reasonable and non-discriminatory licenses to patent pools (such as the UNITAID patent pool), licensing agencies or similar mechanisms in order to claim the rewards. Some also include Standards for Access to Technologies and proposals for price ceilings and market penetration tests. These are important components of our proposals.

In this regard, the Introduction and the Criteria for Proposals should remind reviewers that the proposals should be consistent with paragraph 24 of the Global Strategy, which in the section on

principles, states that the development of health products and medical devices should be:

- (i) developed in an ethical manner
- (ii) available in sufficient quantities
- (iii) effective, safe and of good quality
- (iv) affordable and accessible
- (v) used in a rational way

.4 Development of R&D capacity and technology transfer in developing countries

As set out in the CIPIH report and in Elements 3 and 4 of the Global Strategy, developing countries should play a role in supplying innovations, and should have the capacity to manufacture products. Some proposals before the EWG are sensitive to the need to building R&D and manufacturing capacity in developing countries. Others are not. For example, some of the Bangladesh, Barbados, Bolivia and Suriname Proposals have “set asides” for research teams working in developing countries and they promote open licensing to the developing world to facilitate local manufacturing capacity.

The documents distributed by the EWG do not adequately address the need for non-traditional actors to be involved in the R&D process, capacity building in developing countries, and to ensure the participation of disease-burdened countries. This is important and the Criteria for Proposals should be modified accordingly.

.5 Access to Knowledge and Promotion of Collaboration

The Introduction and the Criteria for Proposals do not recognize the importance of promoting collaborative and open R&D and better mechanisms to incentivize access to knowledge. Some of the Bangladesh, Barbados, Bolivia and Suriname proposals have open source/access dividends that provide incentives for collaboration and access to knowledge.

.6 Context for R&D involving Type I Diseases

The introduction provides an incomplete description of the R&D issues relating to Type I diseases, and an elaboration would be appropriate. There are two main areas where developing countries are concerned about R&D for Type I diseases. The first concern is that R&D for Type I diseases may sometimes focus on products that are inappropriate or not effective in a resource poor setting. For example, a product that requires cold storage or extensive medical infrastructure and trained personnel may not meet the needs of many persons living in developing countries. Second, the primary mechanism now used to stimulate R&D for Type I diseases is the granting of product monopolies, through patents and other intellectual property rights. These monopolies have led to high prices, and unequal access. For this reason, the EWG has been asked to look at alternative ways to contribute to R&D costs for Type I diseases, including mechanisms that de-link R&D incentives from product prices.

We note also that the introduction document uses a definition for Type I diseases that focuses on the fact that Type I diseases have substantial commercial markets. The definition used in the CIPIH report focuses on the incidence of the diseases, and underscores the importance of Type I diseases for developing countries, and the problems of access. See, for example, the definition of Type I diseases on page 13 of the CIPIH report:

Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable population in each. Examples of communicable diseases include measles, hepatitis B, and

Haemophilus influenzae type (Hib), and examples of noncommunicable diseases abound (e.g. diabetes, cardiovascular diseases, and tobacco-related illnesses). Many vaccines for Type I diseases have been developed in the past 20 years but have not been widely introduced into the poor countries because of cost.

We recommend that the EWG uses the CIPIH definition of Type I diseases, which is also consistent with the approach taken in resolution WHA61.21 and the EWG mandate.

In conclusion, the EWG should not anticipate on behalf of the WHA whether a proposed mechanism will be "acceptable" to governments. The evaluation should not prejudge governments willingness to support or not to support a proposal. The evaluation should be technical, objective and neutral. The methodology as currently presented has too much stress on assessing the likely performance of proposals in the R&D ecosystem of the North.

Comments on the Framework Document

The framework document presents an interesting structure to mapping the different proposals however it has some classification errors.

With respect to the Allocation Document and the Bangladesh, Barbados, Bolivia and Suriname proposals, for example:

- a) The Cancer Prize Fund, the Chagas Disease Prize Fund, the TB Diagnostic Prize Fund and the Prize Fund to support Innovation and Access for Donor Supported Markets proposals should be listed under every stage of research, product development, manufacturing and distribution, not just the basic research and early development stages.
- b) The Prize Fund to Support Innovation and Access for Donor Supported Markets proposal ranges over Type II and III diseases and should be included in both categories, accordingly.
- c) The Biomedical R&D treaty proposal should be included under both public and private sector funding because the proposal addresses ways to raise funds in the private sector in addition to the public sector.
- d) Some of the Bangladesh, Barbados, Bolivia and Suriname prize proposals should be included under both public and private funding source because they include the possibility of being privately funded. For example, the Chagas prize fund proposal.

With respect to the Fundraising Document, this document should include all the proposals emerging from the governments of Bangladesh, Barbados, Bolivia and Suriname, because they not only propose new allocation mechanisms but also propose mechanisms to raise new funds.

For example, the Chagas Disease Prize Fund proposal includes the following fundraising proposals:

- a) Voluntary contributions: Voluntary contributions to the CDPF, similar to contributions made to the Global Fund/TGF; Voluntary contributions from individual tax returns.
- b) Other Possible Funding Approaches: National contributions based upon domestic pharmaceutical marketing expenditures; Fees associated with the merger of pharmaceutical

companies, where at least one merging party employs more than 10,000 persons; Contributions based upon revenue from pharmaceutical royalty payments; Contributions based upon the trade in shares of pharmaceutical company stocks; Contributions based upon cross-border financial transactions.

Similarly, the TB Diagnostic Prize Fund Proposal includes fundraising proposals for how developed and developing countries could contribute to the prize fund, such as formulas based on proportion of GDP or country budget for the treatment of tuberculosis.

Comments to the Inventory Document

The Inventory is nearly complete in listing the proposals. However, it does not list three proposals that we consider to be very relevant:

1) The proposal for a Biomedical R&D Treaty as conceptualized in the submission by Bangladesh, Barbados, Bolivia and Suriname to the First Web-Based Public Hearing of the EWG is not included in the inventory.

The proposal for a WHO Biomedical R&D treaty has various proponents and has been conceptualized also by several others, including a specific proposal that was shared with the CIPIH in 2005, and apparently described in the inventory document. The Bangladesh, Barbados, Bolivia and Suriname proposal for a Biomedical R&D treaty needs to be added to the list, and described accurately.

2) The April 2008 Barbados and Bolivia proposal for a Priority Medicines and Vaccines Prize Fund, submitted to the the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (attached) should be added to the inventory.

3) The Patent Pool for Medicines that UNITAID is in the process of implementing.