June 30, 2009

To: Members of the WHO Expert Working Group on R&D Financing

Dear members of the WHO Expert Working Group on R&D Financing

The WHO Expert Working Group on R&D financing (EWG) was created as the third stage of a longer process to address important flaws in the current system of financing medical R&D. The EWG follows the CIPIH and the IGWG. The overall objective has been to reform and change the current system. We are writing to express our views regarding transparency, conflicts of interest and EWG outcomes.

1. **Transparency and balance**

There are no publicly available procedures outlining how EWG will conduct itself. For example, there are no rules for the conduct of meetings and those invited to attend.

The WHO Expert Working Group is this week holding its second non-public meeting. The first meeting in January 2009 was held without advance notice, was not open to the public, and featured attendance and presentations from selected stakeholders, including the pharmaceutical industry, the Gates Foundation and several groups funded by the Gates Foundation – groups that generally share similar views, and which collectively can be said to represent the status quo. There has not been any opportunity for those holding other views to address the EWG meetings directly.

The mode for evaluating proposals is highly secretive. There is little known about which consultants have been hired. The EWG should identify which WHO staff or consultants have been hired to evaluate proposals, and be more open about the proposed criteria, as well as its own meeting schedules and agendas.

While we recognize the need for the EWG to hold non-public sessions, the approach to obtaining stakeholder input should be transparent, participatory and reflective of all views.

There are a number of alternative models to address these concerns for example the public sessions held by the CIPIH.

2. **Conflicts of Interest**

There are no public procedures on how EWG will address conflicts of interest. This is a critical issue as there are many opposing views.

The pharmaceutical industry, product development partnerships (PDPs) and academic and other non-profit research institutions all will be vying to be recipients of new money for medical R&D. As such, there will be incentives to skew EWG outcomes to favor their institutions. The EWG needs to recognize this, and adopt policies to manage the risks presented by conflicts of interest.

There is also an unusual set of conflicts of interest presented by the Gates Foundation. Today the Gates Foundation is the primary source of funding for many important areas of research and development for neglected diseases, and is also active in setting R&D priorities and norms for a wide range of R&D activities, including the management of intellectual property.

While recognizing and applauding the tremendous good that the Gates Foundation does in many areas, it is also necessary to address openly the fact that in the area of norms for intellectual property, priority setting, and sustainable financing mechanisms, the Gates Foundation is known for supporting proposals and policies that are at odds with some of the most controversial reforms explored in the CIPIH and IGWG processes.

Another recent example of the need for clarity on process and conflicts is the proposal to engage the George Institute to undertake a comparative review of alternative incentives, which will include the establishment of a stakeholder network . In at least one draft, this network would consist of 9 pharmaceutical companies and trade associations, 8 organizations that consist of the Gates Foundation or research organizations funded by the Gates Foundation, 7 government agencies from OECD countries, 5 government agencies from developing countries, and only one NGO critical of the status quo. Such a network would incorporate an unacceptable lack of balance, have many conflicts of interest, lack legitimacy, and be highly unlikely to recommend anything that would represent significant changes.

In addition the proposal mixes into one process, on the one hand core functions of the EWG and stages of review -- e.g identification of incentives, establishing the framework for review of submissions, review and short listing; and, on the other the desire to obtain buy-in from certain stakeholders. As a result it gives certain stakeholders privileged prior input into the thinking of the EWG and a key role in setting the parameters for discussion.

3. **Substantive Outcomes**

It is our view that any proposals in the EWG process should meet the following standards, particularly in light of the recommendations of the CIPIH report and the Global Strategy and Plan of Action.

Sustainable systems of finance for medical R&D, including both sources of funding and possible incentive mechanisms, should be:

1) transparent
2) cost effective, and
3) ambitious enough to address real needs for innovation, and
4) include government funding,
5) require, when possible, open licensing of inventions and other IPR in developing country markets,
6) encourage or require open access to data, material and knowledge,
7) foster the transfer to and development of technology in developing countries,

8) condition financing to requirements for access requirements,
9) promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products,
10) when possible ensure sustainable and competitive supply of products from generic producers in developing countries, and be
11) accountable to governments and democratic processes.

4. **The biomedical R&D Treaty**

The recent World Health Assembly, agreed that the EWG should appropriately consider this issue, and report to the WHO. It is very important that the EWG review the proposals made for future discussions regarding a biomedical R&D treaty, including whether to consider recommending that the WHA revisit the question of the WHO role as a stakeholder in discussions about a biomedical R&D Treaty.

Concluding comments

Thank you for considering our comments on these issues and we look forward to your response.

(Groups listed in alphabetical order)

Sincerely:

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cc: Sir George Alleyne, Chair, WHO Expert Working Group on R&D Financing
cc: Dr. Elil Renganathan, WHO Executive Secretary for Public Health, Innovation and Intellectual Property.