Defending the Status Quo, or Roadmap for Change?

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Comments of Knowledge Ecology International (KEI)
the Second Web-based Public Hearing
the Expert Working Group on R&D Financing.

1 The Draft Criteria for Proposals Lacks Useful Criteria, and Does Not Provide Sufficient Focus and Coherence with the WHO Global Strategy on Public Health Innovation and Intellectual Property

The draft criteria for proposals is surprisingly brief, and fails to describe or emphasize the essential policy guidance that was set out by the World Health Assembly (WHA) in WHA61.21, the resolution that created the Expert Working Group on R&D Financing. The EWG was created as part of a larger effort to change the way people think about innovation and access. In WHA61.21, the WHO has endorsed important new policies that collectively would provide fundamental reforms of the current system. There is little evidence this has been taken to heart by the EWG.

Without even mentioning the WHO Global Strategy, the draft criteria sums up all substantive policy issues relating to pricing, the management of intellectual property, technology transfer and capacity building in a single paragraph:

> **5. Effectiveness / impact** (NOTE: applies to allocation proposals only)
>
> Degree to which a proposal directs R&D towards developing country needs. This will differ at each stage of development e.g. proposals targeting health research could include degree to which they stimulate innovation capacity in developing countries; while early product development, could include degree to which R&D ensures product affordability through upfront agreements on price and distribution, or open licensing.

Even briefer, and devoid of content, is the discussion of governance.

> **16. Governance and ownership**
>
> Is there a governance structure and what does it look like? For example, is it a new or existing structure? Is it shared with other incentives, or parallel and autonomous?

It is hard to imagine a criteria document that offers so little in terms of criteria.

2 The Introduction and the Criteria Embrace the Status Quo

To the extent that the introduction and criteria documents set a tone for the evaluation of proposals, it is to encourage the most conventional thinking. Criteria 7, 9 and 10 are particularly pro-status quo:

> **Positive / negative interactions**
>
> Degree of compatibility or conflict between proposals, and their alignment or misalignment with existing financing mechanisms.

9. Acceptability

How acceptable the proposal is to relevant stakeholders. For example, whether it is likely / unlikely to secure support from government, community, regulatory bodies or target R&D groups.

10. Prior experience of it

Is the proposal based on a known approach; and has that approach been successful/ unsuccessful in raising/ allocating funds?

If a change in the status quo is to be considered, it may not be acceptable to all stakeholders, and change may challenge the existing order. By definition, innovations involve doing things that are new.

The introduction and criteria documents are being read by many as an effort to protect the status quo.

The Global Strategy calls for new thinking, for good reason. The existing systems have important flaws. R&D is often focused on products of limited medical need, follow-on innovation and access to knowledge is sometimes blocked by overly restrictive or poorly designed intellectual property mechanisms and incentive systems, and the linkage between R&D incentives and product prices has created barriers to access, and poorly served persons who live in poverty,

Influencing many economists and innovation experts are the revolutions in business models for telecommunications and software, including in particular the recognition in telecommunications that there are huge efficiency gains and social value in changing the way fixed costs are recovered, how knowledge is shared, and how follow-on innovation is enabled. These changes in business model have often been disruptive, but necessary for the transition to more modern, dynamic and useful systems.

3 Addition Criteria Are Needed to Refocus the EWG on the Reforms Set-out in The Global Strategy

The following examples, taken from the WHO Global Strategy, are illustrative of criteria that would reflect the norms embraced by the World Health Assembly, and promote change.

Does the proposal:

1. Provide a feasible mechanism to promote access for all?
2. Support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products?
3. Develop possible new mechanisms to promote transfer of and access to key health-related teclhnologies?
4. Use voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices?
5. Promote competition to improve availability and affordability of health products, including by supporting the production and introduction of generic versions of essential medicines in developing countries?

6. De-link of the costs of research and development and the price of health products?
7. Promote greater access to knowledge and technology relevant to meet public health needs of developing countries?
8. 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, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries?
9. Frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements?
10. Provide for transparency on research results and effective and appropriate management of possible conflicts of interest?
11. Improve access to, and promote use of, reliable, relevant, unbiased, and timely health information?
12. Support voluntary open-source methods to advance scientific discovery?
13. Promote and improve accessibility to compound libraries?
14. Frame and develop and support effective policies that promote the development of capacities in developing countries related to health innovation, including those relating to science and technology, and local production of pharmaceuticals?
15. Examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities?
16. Implement the recommendation made by the Commission on Health Research for Development in 1990 that "developing countries should invest at least 2% of national health expenditures in research and research capacity strengthening, and at least 5% of project and program aid for the health sector from development aid agencies should be earmarked for research and research capacity strengthening"?
17. Encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty?

4 Cost Effectiveness

Any document dealing with finance of health care products should be particularly sensitive and focused on issues about cost effectiveness. In this regard, methods of supporting R&D should be cost effective, not only in terms of producing medically important innovations, but also in terms of the life cycle costs of acquiring those technologies for use by patients.

18. Is the proposal the most cost effective mechanism for inducing medically important innovation, and acquiring access to that innovation?

5 Governance

As noted above, the existing criteria for governance is largely free of content, other than to ask if a governance mechanism exists. The following are some possible additional criteria for governance.

Is the governance structure:

19. Accountable to developing countries, donors and patients groups?
20. Transparent?
21. Free of conflicts of interest?

6 Sustainability

The issue of sustainability is quite important, both in terms of the sources of revenue for R&D, and the access to the products themselves. In this respect, it is important to recognize that there is a competition between different paradigms for supporting innovation, and not all of the paradigms can realistically be implemented. For example, given the limited resources that exist in developing countries, it is both unreasonable and unrealistic to expect adequate resources to be invested in the development of products of special relevance for developing counties, and to promote access to all medicines for all people, while at the same time endorsing unrestrained monopoly pricing of medicines. There are questions about the sustainability even of donor supported funding for the treatment of HIV/AIDS, TB and malaria, given the high prices of second generation medicines. Government funding of open source medical R&D or the funding of medical innovation prizes competes, at some level, with outlays on medicines that are super expensive because of the legal monopolies created to stimulate R&D. Choices will be made.

7 Concluding Remarks

One of the reasons why the EWG work is considered so controversial is that the WHO has been discussing changes in the medical R&D system that are potentially transformative, not only for a subset of diseases that primarily concern poor persons living in developing countries, but for the entire global systems for supporting medical R&D. For this reason, there are efforts to stop any innovation or change in medical R&D paradigms that pose risks even as models for future changes. The EWG should resist pressures to compromise in ways that are soley designed to protect the status quo.