› Research for change

WHO to debate global R&D "framework"

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SUMMARY • *Square brackets – to enclose controversial text – now litter a resolution from Kenya and Brazil for May's World Health Assembly. The resolution calls for debate on a radical proposal to transform global health R&D, but the organization's Executive Board is pulling the punches. Nevertheless there could still be significant developments.*

On 27January, 2006, the World Health Organization Executive Board – a small group of states that prepares the programme for the coming World Health Assembly in May – agreed to forward for debate a resolution concerning a new "Global Framework on Essential Health Research and Development." The debate over this resolution is an attempt to involve the WHO in a new role of pro-actively re-shaping global policies regarding the support for R&D for new medicines. It is controversial.

First submitted by the governments of Kenya and Brazil, the original version of the resolution touched on a number of different aspects of the global system for supporting medical R&D, including topics such as the equitable sharing of the costs of R&D; the need for better priority setting ("needs-driven R&D"); the importance of both access and innovation, including follow-on innovation; various problems concerning intellectual property rights and trade agreements; and the promise of new "open models" for the development of medical science.

It called for the creation of a group of member states to consider proposals to establish a global framework for supporting needs-driven research, consistent with appropriate public interest issues, and for a variety of other measures that were designed to promote access to medicines and a needs-driven R&D agenda.

The 1 200 word version of the resolution that emerged from the WHO EB (EB117.R13) contained most but not all of the original ideas, but also a number of proposed modifications, including several that would weaken or change the direction of the resolution. There are now 32 areas where the text of the resolution is bracketed, including even the words "Global Framework" in the title, indicating divisions among the WHO EB members on the most important issues.

The existence of so many areas of disagreement raises questions about the degree to which the WHA members – the world's governments, represented by their ministers of health – can reach consensus on the proposal at all, or if they do, what the final product of negotiations will look like. Nevertheless it is a remarkable effort to fashion the landscape for financing R&D on new medicines, and if it is embraced, it could open the way for a new and important way of addressing medical R&D at the global level.

A Global Framework for Essential Health R&D

But what would a "global framework" for needs-driven health R&D actually look like? By definition, a framework is a "basic structure underlying a system." This could take many different shapes.

Brazil and Kenya's proposal for the creation of a working group of member states to consider the global framework would be a first step – a step toward multilateral negotiations, open to any interested country, to discuss and set norms about the appropriate level of support for medical R&D, and the creation of new mechanisms to address priority setting for R&D.

It could be a simple set of 'soft' norms, such as a suggestion, without enforcement, that a certain percentage of a country's global GDP or health care budget supports essential medical R&D.

It could also be a more formal obligation, such as an agreement or treaty that required members to directly or indirectly support medical R&D.

It could also include news mechanisms to identify priority R&D in areas of greatest need, opportunity or benefit, and incentives or obligations to address these priorities.

It could address issues of technology transfer and capacity building in developing countries.

Such a framework could be completely outside of and separate from other frameworks that support medical R&D, like existing provisions in trade agreements such as the WTO's TRIPS agreement or the many bilateral accords that touch on drug patents or drug prices.

But it could also be a model for an alternative and competing paradigm, based upon public health perspectives, that could eventually replace the older agreements, in terms of

determining who will pay for the costs of R&D for new medicines. The choice of the word 'framework' is general enough that any of these outcomes are possible. The resolution simply opens the door for discussions on these topics to start. It does not say how they will conclude.

The need for a new framework to support innovation

The resolution notes a number of areas where medical R&D is inadequate. Much of the emphasis is on areas of particular relevance to persons living in poverty, singling out for example the need for new vaccines, diagnostics, and medicines, including microbicides, for the treatment of AIDS, Tuberculosis and Malaria, as well as other illnesses that disproportionately affect persons living in poverty in developing countries.

But the resolution also addresses other concerns, such as the importance of the development of treatments for diseases that have small client populations (often referred to as 'orphan' diseases in the US or Europe), and more broadly, it notes that more than 70% of all new drug approvals are for medicines that do not provide incremental benefits over existing ones.

The resolution also makes reference to the importance of global public goods, such as the Human Genome Project, and other "open and accessible public research in advancing science and the transfer of technology."

The resolution recognizes the importance of both public and private investment in the development of new medical technologies. It states that intellectual property rights are one of several important tools to promote innovation, creativity, and the transfer of technology, but also notes the importance of "providing for a proper balance between intellectual property rights and the public domain," and "the need to implement intellectual property rules in a manner that is consistent with the fundamental right of every human being to the enjoyment of the highest attainable standard of health and the promotion of follow-on innovation." Concerns about access to medicine are mentioned several times.

Reconciling access and innovation

The resolution notes the need to "reconcile the public interest in accessing the products derived from new knowledge, with the public interest in stimulating invention."

Civil society supporters of the proposed resolution, which include a large number of public health, development and public interest NGOs, hundreds of well-known scientists, including several Nobel Prize winners, and many economists and other experts, see the resolution as a first step in a new approach to globalization that addresses the issue of R&D for new medicines as a public health matter, rather than strictly commercial concern.

The TRIPS accord of the WTO and the plethora of new bilateral and regional trade agreements that deal with drug patents and other measures that raise drug prices are seen as:

- raising barriers for access to medicine everywhere
- ineffective in promoting certain types of medical R&D, including investments in global public goods, or the development of medicines that are most relevant to persons living in poverty.

A new approach of focusing directly on the need to support R&D, with a realistic discussion of who will pay, is seen as a necessary step in addressing the legitimate concerns that the globalization mechanisms provide sustainable sources of finance for R&D.

By recognizing the importance of both public and private sector investments, and the need to also address market failures and priority setting, the new framework can be a better mechanism – one that helps rather than hurts consumer interests.

In the January debate over the resolution, most developing countries on the WHO EB supported the resolution. Unfortunately, most countries with annual per-capita incomes greater than US$ 10 000 were less supportive. The United States, Japan and the European Union (which acted on behalf of its member states) all sought a number of changes that would cumulatively reduce the resolution to a highly general appeal to provide more incentives for pharmaceutical companies to invest in neglected diseases.

These countries insisted on brackets on virtually every mention of global public goods, the public domain, open research projects, public sector financing of research, or market failures outside of infectious diseases, and they also put brackets around every mention of the need to provide for global mechanisms that would ensure equitable sharing of the costs of essential medical R&D.

Without support from the US, Japan and the EU, there will not be a new global framework – only an increasing emphasis on more and more bilateral and regional trade agreements that raise drug prices.

The high-income countries, particularly the United States, should reconsider their initial negative reaction to this important initiative. For years the United States government has claimed it is looking for new ways of getting its trading partners to share the costs of medical R&D. This is of course the rationale for the many new global trade agreements, such as the US/Australia Free Trade Agreement (FTA), or the many similar agreements recently negotiated with developing countries.

The US has also made several announcements at recent G8 meetings, calling for broader participation in global open source projects to develop new vaccines for AIDS and other public health threats, like SARS or avian influenza. If they reject this effort, it will appear as though they are more interested in getting higher prices for the products US companies sell, than on actually doing something Continuing on page 16 >

> constructive and positive with regard to the sharing of R&D costs. Europe should also reconsider its position on the new global framework. Like the US, Europe is facing a growing crisis of access to the newest medicines for severe illnesses, like cancer. If Europe continues to back only those globalization initiatives to boost drug prices at the expense of access, its own consumers, including in particular the new members of Europe, will face their own access problems.

The Kenya/Brazil proposal, which will be debated in May 2006, should not be seen as a North/South fight, but rather as a positive measure – one that takes a balanced look at the R&D issue, and calls for serious negotiations on the core issues of who will pay for R&D, and what type of R&D do we really need? This can be an example of good globalization. ■

READ ON

WHO Executive Board draft resolution EB117.R13: [Global framework on] essential health research and development
http://www.who.int/gb/ebwha/pdf_files/EB117/B117_R13-en.pdf

The draft text of an experts' proposal for a Medical R&D Treaty
http://www.cptech.org/workingdrafts/rndtreaty.html

A February 2005 experts letter to the EB, proposing evaluation of a Medical R&D Treaty
English http://www.cptech.org/workingdrafts/24feb05WHOen.pdf
Français http://www.cptech.org/workingdrafts/24feb05OMSfr.pdf
Español http://www.cptech.org/workingdrafts/24feb05OMSes.pdf

Open letter from scientists in support of World Health Organisation resolution proposed by Brazil and Kenya
http://www.whoscientistsletter.org/

Neglected Diseases R&D Appeal
http://www.researchappeal.org/

End of page 5 > In fact we did the first needs assessment in collaboration with them, and we are discussing the way forward with them and other partners.

We deal sometimes with NASCOP, sometimes the Divison of Reproductive Health, both under the Ministry of Health, and NAC, the National AIDS Commission, a completely independent body.

> RHN: I understand NASCOP is rather a strong programme, but what about other parts of the bureaucracy? I was just attending a two day meeting of the World Economic Forum here in Nairobi which was demonstrating the weakness of the health systems and bureaucracies in Africa, and trying to galvanise new solutions. You seem to be dealing with quite an active, responsive bureaucracy. Or do you face these problems too?

NK: You do, but you have to willing to negotiate and navigate around them! And perhaps that is one of the challenges of policy-oriented research, because where do you draw the line between engagement with health policy, and actually using research results? To what extent are you an advocate, and to what extent are you a researcher who's getting your research used? It's a very delicate grey area.

> RHN: But you really have to understand the bureaucracy.

NK: Certainly. I think you have to be local, to be honest with you, and have a keen sense of the underlying dynamics and politics.

> RHN: So you become a politician as well...

NK: Gosh! I would never ever see myself as a politician!

> RHN: Changing the activities of government, that's political! But of course you are doing it through evidence... that's a different game.

NK: Certainly it is! **RW** ■

End of page 11 > production within weeks, as it will be produced in cells in the lab, rather than chicken eggs.

But it would be a new vaccine, normally requiring a full series of clinical trials, lasting months or years. But for a world in the midst of a pandemic, that would be too late. So there would be a difficult decision by the US Food and Drug Administration and other such bodies approving pharmaceuticals and vaccines on what tests – if any – should be applied before the vaccine would be approved for use. ■

READ ON

Protection of Mice and Poultry from Lethal H5N1 Avian Influenza Virus through Adenovirus-Based Immunization
Journal of Virology, February 2006, vol 80(4): 1959-64

US Centers for Disease Control - Pandemic influenza
http://www.cdc.gov/flu/pandemic/

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