

Q&A on the R&D Resolution

prepared by the Campaign for Access to Essential Medicines, Médecins Sans Frontières

What is this Resolution?

In November 2005, Kenya submitted a draft Resolution for discussion at the World Health Organization's Executive Board (WHO EB) meeting in January 2006. This resolution, subsequently co-sponsored by Brazil, is entitled "Global framework on essential health research and development". Members of the EB could not reach agreement on the final wording of the Resolution; a bracketed version was therefore referred to the World Health Assembly in May 2006, where it will be finalised, and hopefully adopted.

You can help push this resolution by spreading the word about it. Read more about the resolution, its implications, and what you can do, below.

What does the Resolution call for?

The proposal calls for a group of countries to meet within WHO in a Working Group, and for them to examine the different mechanisms or incentives that would encourage health research and development activities that answer the world's health problems.

The WHO would then be required to give feedback on the group's progress, culminating in a final report with concrete proposals to be submitted to the Executive Board at its 121st session in January 2008 and to the World Health Assembly in May 2008.

Médecins Sans Frontières believes that countries should support the Resolution at the WHA for two key reasons:

- firstly, because it represents an important step to ensure that medical R&D is driven by and prioritised according to real health needs, and not solely by commercial concerns;
- secondly, because it is a valuable opportunity to ensure long-term, secure financing of health R&D that is equitably shared around the world and that ensures patients' access to products that are developed.

The current system for health R&D is inadequate in that it fails to deliver on both of the points above.

How will the Resolution change this picture?

If the World Health Assembly adopts the Resolution, it will enable countries to examine the benefits of a variety of different mechanisms and incentives that could bring responses to the problems outlined above – problems in terms of priority setting, and in terms of sustainable funding. It would signal a willingness to address, in line with numerous pledges from governments and in the spirit of the Millennium Development Goals, the vast problem of access to medicines that blights an increasing percentage of the world's population's health. It will put governments more firmly in the picture and shift the main responsibility for prioritising essential health research from the commercial sector to the public sector. The resolution also will force WHO to play a more proactive role in essential health R&D and in helping design policies that ensure that the essential medicines of the future are actually developed.

On the contrary, if the World Health Assembly fails to pass this Resolution, it will be a clear sign of countries' and WHO's reluctance to consider the health needs of the world's poor as something meriting formal attention under the auspices of the UN health body.

What would the “framework” look like?

The idea behind a framework for essential health R&D is simply that a system or structure is needed to address these issues in a coherent and sustainable way. It is an attempt to involve the WHO in a new role of proactively re-shaping policies at the international level regarding the support for essential health R&D. This could take many forms. For example, it could set a target for countries to allocate a defined percentage of their GDP to essential health R&D – this could be on a voluntary basis, or a more formalised agreement. For example this process could lead to an international agreement on R&D that is broader and creates rights and obligations for countries to support needs driven essential health R&D. This would be entirely up to the countries participating in the Working Group created by the Resolution to decide. The Resolution only opens the door for these discussions to begin.

What are the different mechanisms envisaged in the Resolution?

A framework could include a wide variety of mechanisms. It is important to stress that the Resolution merely outlines the issues and calls on the WHO to facilitate and host discussions between countries on the different mechanisms that could provide practical solutions. It does not restrict countries by stating what these discussions should focus on, or what these mechanisms could be. Nor does the Resolution advocate for one mechanism in particular – each has strengths and weaknesses.

Mechanisms that might be considered include ways to identify the areas of greatest need, or benefit, or opportunity, for health R&D so that priorities are set. The Working Group would also look at methods to create incentives or obligations so that these priorities are addressed.

It is also important to note that the Resolution does not challenge existing initiatives or ongoing discussions around these issues. On the contrary, it serves to bring them forward. For example, the Resolution is complementary to recent fundraising proposals from the French government to levy a tax on airline tickets, and calls from a number of European countries including the UK and Italy to set up an International Finance Facility. These fundraising methods could be included as a part of this framework, so that they be scaled up globally, or so that the money that is raised is channelled towards R&D addressing the most urgent needs.

Finally the Resolution does not challenge or conflict with the Commission on Intellectual Property Rights, Innovation, and Public Health (CIPRH) report. This was a concern for some countries during the WHO EB in January. The CIPRH was established by the 2003 World Health Assembly and charged with looking at mechanisms that could stimulate, and steer, innovation. Their report ~~is expected~~ was published on 3rd April 2006 and ~~could~~ will feed into (and not rival) the Working Group's discussions – particularly as among its recommendations are that the WHO and its Member States examine precisely these problems and find sustainable solutions that address them.

What does the Resolution say about patents, intellectual property rights and international trade?

Intellectual property rights (IPR) are another one of the different mechanisms that would be examined by a working group of countries if the Resolution were passed. It is important to note that the Resolution does not put intellectual property rights into question, it recognises them as “one of several important tools to promote innovation, creativity, and the transfer of technology”. But it does challenge the current patent system prescribed in the TRIPS agreement as the predominant mechanism for prioritising and financing R&D.

What are the problems the Resolution could overcome?

- Global spending on health R&D reaches US\$ 106 billion. 90% of this money is spent on the health problems of less than 10% of the world's population.¹
- In 2003, WHO noted that less than 1% of new drugs addressed diseases that primarily afflict the poor and for which new treatments would have the greatest effect on world healthcare.²
- If a disease primarily afflicts the poor, then there is no viable commercial market for any diagnostic test, drug or vaccine that addresses it. There is therefore little incentive to invest vast sums into research for new health tools for these diseases. This explains why, between 1975 and 2004, of the 1,556 new chemical entities marketed globally, only 20 new drugs - a mere 1.3% - were for tropical diseases and tuberculosis, diseases which account for 12% of the total disease burden.³
- Northern patients are also affected. A breakdown of the 1,035 new drugs approved for American patients by the US Federal Drug Administration between 1989 and 2000 revealed that more than three quarters are classed as having no therapeutic benefit over existing products.⁴ Profitability, not therapeutic benefit, remains the driving force behind medical innovation.
- When innovation is undertaken by pharmaceutical companies, the costs of R&D are recouped by the firm through higher prices for the products developed which they can ask as a result of patent monopolies. This is then at the detriment of poorer patients' access to new medicines.
- Recent initiatives have shown that it is possible to separate the cost of R&D from the price of the drug. For example, a number of pharmaceutical companies have invested on a no-profit no-loss basis in neglected disease R&D. However, the pharmaceutical firms' initiatives are miniscule when compared to marketing costs or to their overall R&D budget, and are by no means big enough to respond to all the needs. A Fortune Magazine survey in April 2002 showed how drug companies allocate only 12.5% of their revenue to R&D, compared with over 30% for marketing and administration.
- Drug development partnerships such as the Medicines for Malaria Venture (MMV), the Global Alliance for Tuberculosis Drug Development (GATB), or the International AIDS Vaccine Initiative (IAVI), have also been established to develop new drugs, diagnostics and vaccines for such diseases. These have yearly unmet funding needs estimated at US\$200 million per year.⁵ Without secure longer term funding, new drug, diagnostic, and vaccine candidates will stay where they are – in the pipeline. Today, it is unclear where this money will come from, when the vast majority (or 79%) of their existing resources are provided by philanthropic foundations, with governments contributing barely 16%.⁶
- Today there is no equitable solution for health R&D. The investments into health R&D, which benefits everyone, vary enormously from government to government.

What happens now?

During the World Health Assembly (22nd-26th May 2006), interested countries will meet in a drafting group to finalise the wording of the Resolution. It will be crucial for the different MSF sections to actively lobby for support to the Resolution. If you contact a delegation or a government that is a keen supporter of the Resolution, please encourage them to participate in the drafting group, and to contact the Kenyan delegation. Also consider contacting other stakeholders that may support the Resolution, such as the scientific and research community – prominent scientists, including 5 Nobel laureates, have already written an open letter calling for support for the Resolution – this can be accessed at www.whoscientistsletter.org

Groups that are involved in advocating for this Resolution include CPTech, DNDi, Health Action International, BukoPharma Campagne, Medico international.

I would like to become an expert on the essential health R&D. How do I do that?

You can start with reading the following articles:

- MSF R&D briefing document, January 2006
- Background document to the Resolution submitted by Kenya to WHO, November 2005
- Article by Nathan Ford, MSF and Nicoletta Dentico, DNDi “The Courage to Change the Rules: A Proposal for an Essential Health R&D” published in PloS February 2005
- Jamie Love (Director of CPTech)’s contribution on “Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D” presented at WIPO, March 2006
- Open letter by scientific community to WHO EB www.whoscientists.org

If you have trouble tracking any of these down, ask james.arkinstall@msf.org

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March 2006

¹ *Monitoring Financial Flows for Health Research 2004* Global Forum for Health

² World Health Assembly 56 Resolution 17 on Intellectual Property Rights Innovation and Public Health (2003)

³ *Drug Development for Neglected Diseases: a Deficient Market and a Public-Health Policy Failure* Patrice Trouillier et al. 359 *Lancet*, 2188 (2002). [updated figures by Chirac P, Torreele E, 2005, submitted for publication]

³⁴ *Changing Patterns of Pharmaceutical Innovation*, National Institutes for Health Care Management Foundation, May 2002

⁴⁵ *Fatal Imbalance: the Crisis in Research and Development for Drugs for Neglected Diseases*. Médecins Sans Frontières/Drugs or Neglected Diseases Working Group, 2001

⁵⁶ *The New Landscape of Neglected Disease Drug Development* London School of Economics and Political Science / Wellcome Trust, September 2005