



Make Medicines for People Not for Profit

Towards an Agreement on Biomedical Research and Development for the Public Benefit: Academia's Urgent Call to Action

As members of the international academic and scientific community, we call upon the member states of the World Health Organisation (WHO) to negotiate a much overdue global research and development (R&D) agreement to ensure innovation and access to affordable vaccines, medicines and life-saving technologies for all.

In an open letter in 2008, leading academics, researchers and scientists, including many of us, urged universities and research institutes to set policies for research and technology transfer that serve the public good, while calling on the WHO's Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property to find new mechanisms to address a failing system of R&D on medicine and health technologies.

In 2012, the WHO's Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) stated that the way to truly address the systemic issues causing the crisis in global health today would be to work towards a legally binding global biomedical R&D agreement. This recommendation was supported by many member states. However, opposition by a few led to the 66th World Health Assembly postponing the discussions of an agreement until 2016.

After over 10 years of debate at WHO, a number of initiatives have been developed and put into practice proving that a different way of implementing biomedical R&D is possible. Projects like the Drugs for Neglected Diseases Initiative have shown that patient-driven innovation is possible at affordable cost and show that claims that it takes \$2.56 billion to produce a drug are a myth. The Medicines Patent Pool has shown that a collaborative approach to intellectual property can speed up the availability of affordable HIV medicines in resource poor settings.

Yet the current system continues to fail people. New Hepatitis C cures are marketed at an exorbitant \$1,000 per pill. A generic drug treating toxoplasmosis saw a price increase of 5,000% overnight. Breast cancer patients in the UK are unable to access treatment and we are proving unable to stimulate real innovation to combat antimicrobial resistance. The current biomedical R&D system is no longer just failing the poor, it is failing us all.

There is a lack of sufficient research funding for neglected tropical diseases (such as sleeping sickness, and Chagas' disease), chronic diseases, and diseases for which return on investment

cannot be guaranteed (such as multi-drug resistant tuberculosis). The international system is going in the wrong direction by strengthening intellectual property rights - with the Trans Pacific Partnership Agreement as a lead example - that further advance corporate control over biomedical R&D. Preserving patent monopolies as the primary incentive for medical R&D results in exorbitant prices for medicines and medical technologies which endanger public health budgets and impoverish families.

Innovation has slowed as the overproduction of “me too” drugs has been incentivised, and legal restrictions have proliferated impeding the free flow of information for scientific progress. Patent monopolies increasingly enable rising drug prices, without any corresponding increase in innovation. We have witnessed stagnation in the face of public health emergencies. In the case of the tragic Ebola epidemic, governments and private companies allowed potential vaccines and treatments to remain in preclinical development for over a decade prior to the outbreak because there was no market incentive to invest in treatments for diseases limited to poor countries. As noted by the WHO-commissioned Report of the Ebola Interim Assessment Panel in July 2015, it was “a defining moment for the governance of the entire global health system.”

A different system, based on principles of open access, open knowledge, open sharing and fair price, as well as incentives and mechanisms to encourage research and development of essential medicines according to needs of people worldwide, is possible. There are mechanisms being used that show great potential including prize funds, patent pools, and open collaborative approaches. However, the initiatives are fragmented and lack coherence. A global agreement for an equitable biomedical R&D system can provide a much needed structure. It can provide guiding principles which can move us to a system that incentivizes research and technology transfer based on global health needs and recognizes the human right to health.

Now, more than ever, we must act. As academics, researchers and scientists it is our responsibility to generate and transmit knowledge. We have a unique role to promote innovation in many fields and to ensure that our innovations are used to benefit the public. In no field are the moral imperatives to do so as clear as they are in medicine. At a time of huge progress in scientific research we are deeply concerned about the ability of the existing system to translate investment into better global health.

We are therefore calling on WHO member states to ensure the open-ended meeting of WHO member states on May 2-4¹, 2016 in Geneva seriously addresses this urgent situation. We believe the meeting must include a broad range of civil society actors. The meeting should advance and inform member states discussions on an agreement that will support a coherent, sustainable and needs-driven agenda for a new approach to biomedical research and development for all.

¹ The original dates were March 21-22 and they have been changed as WHO announced new meeting dates.

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