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Towards a needs-based medical R&D system

Loon Gangte & Leena Menghaney

India has an unprecedented opportunity at the international level to influence a change in the global rules of medical R&D to prioritise people's health over profit.

Amit (name changed), our friend and colleague, died this year. His passing, heartbreaking as it was, had been all the more distressing because he did not receive the treatment that he needed to save his life.

Amit was HIV-positive and also infected with tuberculosis (TB). In India, as in the rest of the developing world, doctors are struggling to treat and diagnose new strains of drug resistant TB. The medical and clinical response is falling hopelessly short of the needs. Doctors and patients are helpless because effective medicines and diagnostic tools are just not available.

There is a simple reason for this: the way the development of new medicines, diagnostics and vaccines is funded at present.

Today, the medical research and development (R&D) system relies heavily on pharmaceutical companies recovering their investments through maximising profits, by charging high prices, and protecting them through patent monopolies. As a result, essential drugs are priced out of the reach of people and governments.

Of equal concern is that diseases such as TB or paediatric HIV that affect people in developing countries do not get adequate attention and investment into research as compared to diseases that have more lucrative markets. The statistics speak volumes: only one per cent of the drugs reaching the market between 1975 and 2006 were developed for neglected diseases like kala-azar, malaria and TB; diseases that affect us. It has been evident for some time now that the intellectual property system does not encourage R&D into diseases prevalent in developing countries, and rather focusses on drugs for those illnesses such as diabetes and heart disease, for which there is a large market in the developed world.

Moreover, medicines and diagnostics that have been developed in wealthy countries are often ill-suited for use in resource poor settings in developing countries. Treating and diagnosing HIV and AIDS in children is a clear example of this. As developed countries have been successful in preventing parent-to-child transmissions of HIV, there was no need felt to develop paediatric formulations and diagnostic tests for children living with HIV. This has meant that medical practitioners and caregivers of these children in India and the rest of the developing world have little option but to split adult tablets.

This practice often results in children getting the wrong dosage of a medicine that is in any case too bitter and difficult to swallow.

India now has an unprecedented opportunity at the international level to influence a change in the global rules of medical R&D to prioritise people's health over profit. Representatives of governments from all over the world including the Indian delegation from the Ministry of Health and Family Welfare have gathered at the United Nations in Geneva to discuss, negotiate and reach an agreement to stimulate R&D for neglected diseases.

Facilitating this process is a body set up by the World Health Organisation. Its long name notwithstanding, the 'Intergovernmental Working Group on Public Health, Innovation and Intellectual Property' is path-breaking as it is the first political body to consider the problems of pricing barriers and the failure of current market driven incentives for R&D on pharmaceuticals, at the same time.

The discussions in Geneva offer an extraordinary chance for developing countries to set a global agenda for a needs-based R&D agenda that addresses both medical innovation and access to medicines in a manner that does not pit one interest against the other. In other words, countries are now looking at ways to ensure that medical R&D is tailored to the needs of their citizens in a way that also makes the results of the R&D available and accessible for them. The international community also has a chance to debate key issues such as funding, sharing technology and addressing intellectual property barriers for conducting R&D on neglected diseases.

The intergovernmental working group's mandate is one of the first steps at the international level towards de-linking the cost of R&D from the price of the medicines, diagnostics and vaccines.

The stakes are high for people in India. It is hoped that the Indian government will make the best use of this opportunity to prioritise and contribute resources, knowledge and technology to build an alternative incentive system for pharmaceutical R&D, thus fulfilling the vast medical needs of India's growing population.

For the first time, developing and least developed countries through their official submissions and negotiations have the potential to own the mandate to set research priorities and design financing mechanisms that reward R&D – but do not rely on charging high prices.

The awakening of the global community to our health needs has come too late for Amit. That the lives of those of us living with HIV, TB and hepatitis and a myriad of other illnesses depend on this process is surely not lost on our Government. It is important that governments like those of Brazil, African countries, Thailand and India join hands in Geneva, as they have done so often in the past, to protect public health. For medicines to be judged and invested in based on their ability to prevent millions of avoidable deaths rather than the quantum of price they can command is an idea whose time has come and it is with great hope that we look forward to the success of this process.

(Loon Gangte is President, Delhi Network of Positive People & Leena Menghaney is campaigner, Medecins Sans Frontieres, Campaign for Access to Essential Medicines.)

Please contact communications@field.amsterdam.msf.org for any correspondence.