

Balancing patents and drug prices

A debate on drug policy is vital in light of growing concerns about access to medicines and apprehensions about the financial sustainability of healthcare systems around the world. Affordable drugs are indeed necessary. But what happens when there are no drugs to treat the new diseases that continue to confound pathologists? What happens when new drugs are not created to treat existing diseases more effectively due to increasing resistance to antibiotics? The question of affordability, then, becomes moot.

India's health sector, until last year, was allocated only a little over 1% of our nation's gross domestic product (GDP) compared to the world average of 6%. There is a need to better understand determinants of drug prices, in order to identify exactly which measures can be most effective in terms of affordability and access.

Why Indian patients wait longer for treatment

A general scepticism and gloom-ridden predictions based on an incomplete understanding of intellectual property rights (IPRs) often obfuscate the real issues facing India's drug industry. Patents are critical in innovative sectors, because they provide incentives for companies to invest in the creation of new solutions.

Currently, only 5% of medicines used in India are said to be patent-protected. What must link medical innovation and affordable treatment is a supportive role of the state. India has over three million cancer patients, which means one in every 13 of the world's cancer patients is Indian. Then why only seven new cancer drugs were introduced in India in the last few years, despite the fact that over 50 breakthrough therapies were made available in other countries? Scholars Iain Cockburn and Ernst Berndt of Boston University and the Massachusetts Institute of Technology provide an answer. They examined 184 US Food and Drug Administration-approved innovative drugs sold in India and found that 50% of these drugs encountered delays in marketing approval of more than five years after their global launch.

Even once approved for marketing, over 50% that became newly available in India was produced and sold as generic versions by multiple follow-on Indian manufacturers within one year of their introduction. The scholars claim that such delays combined with rapid appearance of generic versions of innovator drugs in India could be an indication of a lack of faith in the patent regime and enforcement environment. If their findings are to be believed, it is bad news not just for manufacturers facing uncertainty, but, more importantly, for our patients.

The World Health Organization (WHO) announced earlier this year that the world is running out of antibiotics in the face of multi-drug-resistant infections, and that the speed of increasing resistance will outpace the slow drug development process. Major drug companies are closing their labs dedicated to antibiotics research, perhaps to pursue research on drugs for diseases, including diabetes, hypertension and cancer. But why are they closing antibiotic research labs when bacterial resistance is increasingly rendering the current stock of antibiotics ineffective and the pipeline of backup drugs is running dry?

Academicians from the University of British Columbia addressed this important question in their research. Combining theoretical economics and molecular biology, they find that the problem of cross-molecular resistance may necessitate stronger intellectual property protection with broader and longer patents. This may sound odd to some but governments must not erode incentives to innovation and fight the very real threat of humankind returning to pre-penicillin days.

How do medicine prices build up?

According to WHO and Health Action International, more than 50% of the end price of medicine is contributed by components other than the manufacturer's selling price.

Drug price regulation, such as the one instituted by the National Pharmaceutical Pricing Authority (NPAA) recently, is ineffective if the design of the price-control mechanism is detached from all the other components identified by WHO and implementation is poor. Scholars have empirically established that Eastern Europe countries should focus more on containing the distribution costs, which form an integral part in the medicine value chain. Economic theory tells us that price controls may deter entry into the market, resulting in perverse welfare effects. China followed a different strategy to tackle the issue of affordability of patented drugs.

Earlier this year, China slashed prices of patented drugs by 70% as a precondition for eligibility for government insurance schemes, but without tampering with grant of patents. This made the drugs eligible for state co-payment, making them affordable to patients while protecting the revenue stream of pharmaceutical companies.

Policy re-routing can bring rewards

Based on 2015 *Bloomberg* data, it was found that the monthly unit drug prices in India for hepatitis C, asthma and diabetes were 2%, 3% and 4%, respectively, of prevailing US prices. In terms of comparison, patients in China and Brazil pay substantially more for the same drugs. However, this lowered price has come at the cost of time, with excessive delay in the availability of essential medicines in India and weak incentives for our own industry to innovate. Along with reducing uncertainty in IPR, India can also deploy policy tools to strengthen its fragile health sector. India needs to follow-up on the commitments it laid down in the National IPR Policy to bring about a congenial environment for innovation to take place. The bright promise of a forward-looking bio-pharmaceutical industry in India will only be fulfilled if we work to build an ecosystem that promotes medical innovation. I hope this was one of the outcomes of the recently concluded world conference on medicines held in New Delhi. Our government needs to actively create an enabling environment for this to happen. We must achieve a balance between the current and future needs of patients and the timely introduction of existing and new pharmaceutical drugs.

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