Drug costs: Patent delinkage no panacea

Leaving drug development to the public sector will not help improve access to medicines; rather, it could impede it

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THE COST OF medicines is on the agenda this week at the World Health Organisation's annual policy meeting, the World Health Assembly, in Geneva. NGOs and certain middle-income countries continue to argue that market-based drug development—reliant on intellectual property rights (IPRs) as its primary incentive—makes medicines too expensive. It fails, they say, to provide cures for those most in need but who can't pay, such as people in developing countries.

The premise that patents jack up drug prices is particularly relevant for a country like India. National Sample Survey Office survey points out that 86% of the rural population and 82% of the urban population are yet to be covered by any health insurance scheme (public or private). Moreover, millions are pushed into poverty every year to meet their medical expenses. 70% of India's population, who reside in rural India, has to borrow more (25%) in comparison to their urban counterpart (18%) to meet their healthcare needs.

On the fringes of the assembly, NGOs and academics talk excitedly about a new model for drug development, in which R&D costs are "de-linked" from the final price of a drug. In practice, this would gradually erode IPR, and expand the role of academia and the public sector in drug R&D. Resulting taxpayer funded drugs could be distributed free or very cheaply and policymakers could prioritise research on the most pressing diseases. Would publicly-funded R&D usher in a new era of cheap medicines?

The idea's proponents say that most new medicines already come from the public sector. In a 2015 commentary in the *New York Times*, Nobel Laureate economist Joseph Stiglitz wrote, "As it is, most of the important innovations come out of our universities and research centres, like the National Institutes of Health, funded tutes of Health, which disperses grants to universities and other research institutions for early stage research. But it is a leap to argue that because publicly-funded universities play an important role in early research, they also have the skills, resources and motivation to undertake commercialisation of that research.

Taking a drug through clinical trials to regulatory approval takes on an average a decade and costs between $1.2 billion and $2.6 billion. It's a risky business: only one in 10,000 promising drug compounds ends up as a marketed medicine.

Universities simply don't have the specialist skills and facilities—such as chemical formulation and toxicity testing—to navigate a drug through the clinical trials required by regulators to approve a drug as safe for the market.

Navigating the drug regulatory approval process is costly and demands technical and commercial skills concentrated in the private sector. Around 80-90% of recently approved drugs were developed entirely in the private sector, according to the *New England Journal of Medicine*.

Those drugs with publicly-funded origins typically come from universities taking advantage of intellectual property laws (such as the Bayh–Dole Act in the United States) to licence their early discoveries to the private sector for commercialisation. Countries, such as China, now also have such legislation, hoping it will bolster local innovative industries, while similar proposals are under discussion in India.

But asking universities to move from basic research into fully-fledged drug commercialisation would require enormous subsidies to build technical and commercial capacity, and manufacturing and distribution systems. Universities would be diverted from their core purpose, to advance knowledge.

As it stands, private industry rightly they can fund risky projects while standing a good chance of getting a return.

They are just important for small R&D companies as they are for large: evidence shows that a patent signals to VCs that an early drug idea has potential, helping them make investment decisions.

Given that early stage biomedical research is highly risky, patents, therefore, ensure a continued stream of investment. Removing patents from the equation sans a replacement would be disruptive. The damage would be worse with policymakers committed to a "delinkage" agenda pinning their hopes on an ill-equipped public sector and academia to conduct considerably more R&D.

In fact, the premise that patents lead to higher drugs price are unfounded. Researchers checked national patent registries in developing countries and found that 95% of the medicines on the list has expired. Instead of trying to nationalise drug R&D, policymakers must focus on practical solutions. The mandatory clinical trials process is where most drug development costs are incurred, for instance, but regulators have overseen an unwelcome increase in complexity in recent years.

Import tariffs and taxes on drugs remain high in many countries. Higher costs can also emanate from inefficient supply-chain management, cartelisation, and dysfunctional public healthcare systems. Therefore, citizens from many countries particularly in Asia and Africa have to shoulder higher healthcare costs. Rather than blaming patent protection, a better health outcome can be achieved through an effective national health policy. In India, the National Health Policy 2017 aims at capping prices of essential medicines and increasing public expenditure on health from the current 1.4% of GDP to 2.5% by 2025. This is aimed at providing free drugs, diagnostics and emergency care services in

the National Institutes of Health, funded by government and foundations."

It is certainly true that in the US, the federal government is the biggest funder of basic research, via the National Insti-

As it stands, private industry rightly shoulders most of the financial burden and risk of drug development. IPRs—particularly patents—are the key incentive, because they give investors certainty that

diagnostics and emergency care services in all public hospitals. These are all areas that await reforms. The delinkage agenda under discussion in Geneva this week, while well-intentioned, is a distraction.