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EDITORIAL

Drug prices

The United States of America (USA) spends almost 17% of its GDP on healthcare, whereas the average across the Organization for Economic Cooperation and Development (OECD) countries is about 9% (<https://www.oecd.org/unitedstates/health-at-a-glance-United-States-EN.pdf>). Despite spending so much, life expectancy in the US is almost four years lower than the OECD average. Prescription drug prices account for about 10% of the expenditure on health in the USA (<https://www.actuary.org/content/prescription-drug-spending-us-health-care-system#2>).

Let us look at one specific example of high-priced drugs. It is believed that about 8.5 million people in the US use insulin. The price of insulin was so steep that a documentary film, *Pay or Die*, was made about it. However, last year, the price dropped from upto US\$ 300 per vial to US\$ 30. Although one may start visualizing this phenomenon becoming widespread, a professor at Harvard University believes that the insulin price reductions were an anomaly, resulting from a constellation of factors, and would not be easy to replicate (doi:10.1001/jama.2023.5025).

The government in California not only capped the price of insulin but also announced that it would start manufacturing a drug that is used to reverse opioid drug overdoses. Public-sector manufacturing of drugs in the US! That has probably not happened for several decades. Any discussions of the government negotiating drug price discounts or imposing a tax to help implement universal healthcare can result in accusations of price controls, with connotations of socialism, an unpopular concept in the US (doi:10.1038/nbt.3748). Nevertheless, there is increasing discussion on the need for public manufacturing of drugs, partly due to an unprecedented shortage of cancer drugs. India is cited as one of the countries that brought down the price of drugs through public-sector manufacturing.

There has also been some progress in attempts to reduce the prices of some other drugs in the US. Medicare is a programme that is primarily meant for the 65 year and older citizenry and covers about 58 million people (<https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/>). Medicaid is a scheme that covers over 90 million low-income Americans

(<https://www.kff.org/mental-health/issue-brief/10-things-to-know-about-medicaid/>), although some enrollees are common to the two programmes. In 2003, the then President of US passed a law that prevented Medicare from negotiating drug prices with the pharma industry. Twenty years later, in 2023, the President of US signed into law the Inflation Reduction Act, which did the opposite. Between them, Medicare and Medicaid account for 45% of the prescription drug spending in the US today, so any reduction in drug prices in these programmes will have an impact on the nation's drug bill. The recently proposed reductions in drug prices will take place in a phased manner over several years. The first set of 10 drugs listed for price negotiation cover Crohn's disease, diabetes, heart failure, rheumatoid arthritis, some blood cancers and blood clotting that could lead to a stroke, and account for over US\$ 50 billion of spending in the US today. The ten drugs are brought out by ten different companies. Therefore, the impact will be spread across companies. Obviously, the pharma industry is not happy with these moves.

So, what are these drugs that cost so much? In 2023, the FDA approved 55 new drugs (<https://www.nature.com/articles/d41573-024-00001-x>). Large fractions are for cancer or orphan indications, with some overlap in these categories. The pharma industry likes to focus on cancer since patients need to use these medications long-term. The industry likes orphan drugs (for rare diseases) because the drugs serve very small populations, and therefore the industry can justify exorbitant prices. For both cancer drugs and orphan drugs, large revenues motivate the pharma industry to focus on them.

Let us come to a condition for which we may all, at some point, need a solution, that is anti-microbial resistance (AMR). AMR is now killing more than the 'three big ones', that is tuberculosis, malaria and HIV/AIDS combined and therefore has been described as the cause of a silent pandemic. The problem with antibiotics is that they are prescribed for short courses of a few days. Furthermore, their use is being restricted. Both of these are a headache for a company trying to increase its sales. So, one can expect that any novel antibiotic that is brought out will have an extremely high price tag.

Regarding drug discovery, we need to be concerned about two issues. First, which organizations develop new drugs? A recent invited commentary in *JAMA Internal Medicine* tells us that in the US, the National Institutes of Health have contributed to the development of every drug approved by the US Food and Drug Administration over a recent 10-year period (doi:10.1001/jamainternmed.2023.6256). Although most of this was through heavy investment in basic research, in at least 25% of the cases, it also included an involvement in later-stage drug development. Second, the industry does not spend as much on R&D as is sometimes portrayed. Leading companies, listed on the S&P 500 Index, have spent less on R&D than on dividends and buying back shares. Therefore, it is clear that public sector research institutions have a role to play in drug discovery and development. A recent study has also indicated that drugs developed with the involvement of academia are likely to have a greater therapeutic benefit than those developed solely by industry (doi:10.1001/jamainternmed.2023.6249).

Why do we, in India, need to concern ourselves with which drugs are developed in other countries or what their citizens pay for their drugs? The fact is that we have scant novel drug discovery in India. Therefore, high drug prices in the West result in high prices in India if there are no generic equivalents, that is, generic small molecule drugs or biosimilars. There have been recent accounts of some of these extreme drug prices. Occasionally, some patients were saved after the required funds were raised through crowdfunding, but crowdfunding cannot be a long-term strategy to cover healthcare costs. India accounts for approximately 1/6th of the world's population. It behoves us to do our own drug discovery and not be held hostage by high drug prices. Recently, it was reported that local drug discovery efforts brought down the price of four drugs, all

for rare diseases, by up to 100-fold. Actually, all four are generics, and one of them is not yet available on the market. Nevertheless, the original price of the drugs was eye-popping, the reduction breathtaking.

For many decades, India has had a strong non-profit sector, that works in various fields. Although there have been some non-profits that manufacture or distribute drugs in India (doi:10.1186/1744-8603-7-4), their numbers are minuscule. One wonders why there has not been more. More importantly, India has a venerable tradition of public-sector manufacturing of drugs and vaccines. It has been argued (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4055411) that during the COVID pandemic, India was largely dependent on two domestic vaccine manufacturers, both in the private sector, leaving the country's population vulnerable. Had the public-sector vaccine manufacturers that had been strong in earlier decades been supported and strengthened in recent years, they could have contributed to the battle against COVID. Given that we have to think of the health of over 1.4 billion people, there is a place for private- and public-sector manufacturing, and both should be enabled.

In summary, we need more new drugs coming out of India. Doubtless, our doctors and other experts would be delighted to do the necessary due diligence to develop drugs domestically. So, we need to see more translational research that takes laboratory findings to the clinic. We also need much-needed drugs to be manufactured locally. And we need them to reach all those who require them.

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