The promise of a free-Covid vaccine! Is it achievable?

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PM Modi is keen about delivering Covid-19 vaccine free of cost to the people of India. At the state-level, governments of Bihar, Madhya Pradesh and Tamil Nadu promised delivery of free vaccines. Noble promise but is it doable? Read on.

Research on vaccines for Covid-19 has reached Phase 3 trail (that is, testing an experimental drug in human). Although the private companies developing the vaccines are getting public grants, the price of vaccines are likely to vary between $3 (with a price cap) to $30 a dose, depending on the drug manufacturers. AstraZeneca, for instance, in a deal with the Euro Commission has agreed to sell vaccines between $3 and $4, a dose. Moderna is promising a delivery with a price tag of $37, per piece. Sinovac, the Chinese vaccine maker, is selling vaccines for its emergency program in select cities in China at $60 for two shots of vaccine. The vaccine, jointly developed by Sanofi and GlaxoSmithKline, comes with a price tag of $10, a piece. Ergo, for the Indian consumers, the first best option is to go for the vaccine developed by the Pune-based Serum Institute of India (SII), with a price cap of $3 per dose. Under circumstances, when imports become necessary, the price will be on the higher side.

Assuming India's population size of 1.3 billion, this means the government needs to shell out $3.9 billion or around INR 30,000 crore Indian rupees to foot the bill for the vaccine. Then there is distribution, transportations and logistics costs for delivering the vaccines. For medicines, this cost amounts to 10-14%. However, for vaccines, as it requires transporting and storing in refrigerated containers, this cost will increase further. Therefore, there is a merit when SII is asking for INR 80,000 crore from the government.

A quick look at the budgetary documents over the last few years, indicate for the fiscal 2019-2020, the Central Government allocated INR 61398 crore for health. During the last fiscal, public expenditure on health as a percentage of GDP was 1.29% of GDP – an improvement from around 1.15% of GDP, an average figure clocked over the last four years. However, with India's GDP likely to contract by 10.3%, from $2.87 trillion in 2019-2020 to $2.58 trillion in 2020-2021, even if the government spends what did during the previous years, there is going to be a shortfall from the stated INR 80,000 crore.

So how to ensure that the government achieves better health outcomes. Fortunately, there are a number of simple reforms that will make a real difference. These reforms will have benefits that last beyond the current pandemic, increasing access to medicines for all. These reforms will ensure greater access to medicines, including those in the process of being developed for the Covid-19.

Consider tariffs. Import tariffs, sales taxes and other levies are applied by many countries – including India – on medicines and vaccines, driving up prices and reducing availability. At an average of 10%, India has the highest levels of medicine tariff in the world, worse globally only by Pakistan and Nepal (14.7% and 11.3%), according to a recent study. The cumulative impact of these tariffs cost patients in India $737m per year and increased their final price by up to 80% of the original sales price ex-factory. Although, the effective rate of protection is falling, there are instances of increase in non-tariffs barriers. India should commit to permanent and legally binding duty-free medicines, preferably by joining the 34 other jurisdictions that are members of the WTO's Pharmaceutical Zero Tariffs Agreement.

Then there are other domestic taxes standing in the way of patients, notably the 12% GST levied on most pharmaceuticals in India. These raise relatively little revenue and pose a significant financial burden to patients, most of whom pay for medicines directly from their own pocket. Of the total money spent on healthcare, around 64% comes out-of-pocket, of households.

Customs red tape in India is a major barrier to access to medicines, holding up medicines and raising costs. Examples include inefficient customs procedures, cumbersome export and import procedures, administrative red-tape, hidden taxes, congestion fees and a generally sub-optimal trade infrastructure. Research has identified 3958 different examples of these "non-tariff measures" in India in 2016.

New therapeutics and vaccines for Covid-19, many of which will be manufactured abroad, will be needed rapidly. The state governments should therefore examine the existing stock of these barriers to eliminate superfluous regulations and ensure that medicines can enter the country quickly.

Another factor that forces patients in India to wait extra time for access to new medicines is poor regulation, notably the fact that the Central Drugs Standard Control Organisation(CDSCO) does not accept as evidence data from Phase 1 studies generated overseas. As a result if these and other bureaucratic wrinkles, patients in India have to wait on average 500 days for drugs that have already been approved elsewhere.

The government could easily reduce regulatory bottlenecks by obliging the regulator to accept clinical trials data generated overseas throughout the drug approval process.

Other measures recommended include asking governments to update their national formulary lists more frequently to take account of new medicines, and an end to protectionist measures that prioritize local companies, for example during procurement. Such “localised barriers to trade” reduce the number of medicines suppliers, leading to higher prices, fewer choices, shortages, and produce output that are of questionable qualities. Take for instance, the ventilators manufactured in India. As there is no requirement for obtaining licence from Drug Controllers of India and other mandatory quality control certificates, there are prevalence of fake and low-quality ventilators flooding the market. Even in the case of personal protective equipment, which are manufactured by the domestic firms, there is no requirement of certification marks or standard quality accreditation, such as GS1 standards.

As new treatments and vaccines for Covid-19 become available it is imperative they are made available globally as quickly as possible. In India’s case, the 2012 Nexavar compulsory licensing case saw the Controller General of Patents, Designs and Trademarks set a precedent of requiring foreign innovators to manufacture in India as a condition of “working the patent” in order to avoid forced licensing of their inventions to third parties. This could force innovators to manufacture in India in order to avoid being forced to license an invention to third parties – if invoked in the case of Covid-19 therapies, this would add unnecessary time and cost for access to the India market.

Trade and regulatory barriers stand in the way in many countries, including India. Fortunately, many of these barriers are easy to address.

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