Seize this opportunity to institutionalise accountability

The discourse on an indemnity waiver for COVID-19 vaccines is a hidden moment for India to act

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The Drugs Controller General of India granted Emergency Use Authorisation (EUA) to the COVID-19 vaccines manufactured by Moderna and by Johnson & Johnson, in end June and early August 2021, respectively. In addition, India has an opportunity to receive 5 crore to 10 crore doses of Pfizer-BioNTech's mRNA-based vaccine, including through the COVAX mechanism co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the World Health Organization, before the end of 2021.

What it covers

Despite granting EUA for two vaccines and a third (that of Pfizer-BioNTech) being eligible for approval, uncertainty on supply and availability remains. One of the primary reasons for this is the Indian government's indecision on requests for indemnity from these manufacturers. Indemnity translates to protection from legal proceedings and liabilities, against claims from people who may experience rare and serious Adverse Events Following Immunisation (AEFI).

COVID-19 vaccines are given EUA by the regulatory authorities after a thorough review of their safety and efficacy. However, even though vaccines meet safety parameters, as an immuno-biological substance, a vaccine can be associated with rare and serious AEFIs, some of which – such as vaccine-induced immune thrombotic thrombocytopenia (VITT) and Myocarditis – are known. Other long-term impacts can only be known over a period of time.

There is a need for increased and sustained vaccine supply in India. The country's COVID-19 vaccination drive has been underperforming, and in the seven-and-a-half months since the drive was initiated, only 11% of the total population has been fully vaccinated, and 35.5% has received a single dose. A reason for this is the insufficient supply, which has consistently been less than the projected vaccine availability. The situation persists in spite of the certain regulatory modifications enacted by the Government to increase availability, including: fast track authorisation of COVID-19 vaccines approved by regulatory authorities in the United States, the United Kingdom, Japan and Europe, and those included in the World Health Organization (WHO) emergency use listing; waiving off requirements for bridging trials; and doing away with mandatory batch testing for vaccines manufactured abroad. Though these steps have led to the EUA of two additional vaccines, there is a lack of clarity on the definitive timeline on their availability in India. A key bottleneck is demand from manufacturers to grant indemnity. The core argument of the manufacturers is that they have been granted indemnity in their country of origin and have supplied vaccines to other countries only when granted indemnity. Vaccines under COVAX programme, further have an effective waiver of indemnity, through a separate mechanism that has been established.

The existing provisions

The idea of not granting indemnity is to hold vaccine manufacturers accountable. The manufacturers of the three vaccines currently being administered in India (Covishield, Covaxin, and Sputnik V) have not been granted indemnity.

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There seem to be two key thoughts that are delaying the Government's decision on indemnity. First, the supply from these manufacturers is likely to be a very small proportion of total vaccine availability in the country. Second, it is likely that once foreign manufacturers are granted indemnity, manufacturers currently supplying vaccines might make similar demands citing the fair play rule.

What do the existing rules and regulations suggest? The rules governing clinical trials in India specify that compensation must be granted in case of injury or death of a trial subject. However, though a similar compensation mechanism does not exist for AEFIs reported under the Government's routine immunisation programme in the country or for any other vaccine-related injury; the legal responsibility for any vaccine-related injury, in the existing Indian regulations, lies with the manufacturers. Therefore, if manufacturers are granted indemnity for any COVID-19 vaccine, there has to be an alternative mechanism for people to make a legal claim for compensation. That essentially would mean the Government has to accept responsibility to provide compensation for any such proven injury or harm. Second, indemnity must not be construed as blanket protection for deliberate acts, fraud or instances of negligence. Third, if foreign vaccine manufacturers are granted indemnity, then manufacturers of the vaccines currently in use are likely to demand similar protections.

Though at a broader level, the stand and unwillingness of these manufacturers to supply COVID-19 vaccines to any country unless granted indemnity is too rigid. However, beyond indemnity, India does have mechanisms in the current legal framework to ensure safety and legal remedy for any harm. First, the Drugs Controller General of India while granting registration certificates is empowered to take action against companies found to be in violation of the Drugs and Cosmetics Act, 1940. Second, any individual seeking compensation after experiencing AEFI may directly file petitions before consumer courts and the High Courts. Third, recent amendments to the Consumer Protection Act, 1986 disallow individuals but permit the regulatory bodies to initiate class action suits (cases representing groups of people who have suffered from the same loss) based on individual complaints.

Opportunity in the crisis

Requests for indemnity must be contextualised within the larger public interest. For citizens, as long as mechanisms to tackle and compensate for a potential harm are effective, it makes a marginal difference if they come from the Government or a manufacturer. Moreover, even in cases where manufacturers hold legal liability, the Government and regulators cannot wash their hands of their responsibility to protect public health.

Therefore, India should examine safeguards instituted by countries which have granted indemnity to manufacturers, such as America's Countermeasures Injury Compensation Program (CICP) and similar schemes in the U.K., Canada, the European Union, and Singapore. The COVAX has underwritten the compensation burden to protect vaccine manufacturers and distributors.

This discourse clearly needs a recalibration and provides the Indian government a valuable opportunity to institutionalise legal safeguards from vaccine injuries and possibly, at a larger level, improve overall patient and healthcare safety in the country. Such institutional mechanisms need to be supplemented with dedicated funding from the Government. Such systems can then be applicable to any licensed vaccines in India.

One of the characteristics of India's response to the COVID-19 pandemic has been delaying decisions till a point of crisis has emerged. Situations such as the novel coronavirus pandemic demand proactive and decisive problem-solving instead of burying our heads in the sand, hoping the problem will disappear. However, the debate on indemnity has far-reaching consequences. It must be seen as an opportunity far beyond the quantum of vaccines, to review legal provisions and create long-term mechanisms for protection from vaccine harm and making health services safer and accountable. It is a high time that a decision on granting (or not) indemnity to COVID-19 vaccines manufacturers is taken, before the situation morphs into another crisis and then a decision is rushed. The approach has to be to safeguard the interest of the citizen and convert this as an opportunity to reduce vaccine 'licensing to availability gap', increase vaccine availability, and establish institutional mechanisms.

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