Indemnity Waiver for COVID-19 vaccines

What is the issue?

Despite DCGI granting Emergency Use Authorisation (EUA) for two vaccines, uncertainty in vaccine availability remains because of the government's indecision in granting indemnity.

What is a EUA?

- It is a mechanism to facilitate the availability and use of medical countermeasures (like vaccines), during public health emergencies.
- It allows the use of unapproved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met

What is the status of India's vaccine program?

- Drugs Controller General of India granted EUA to COVID-19 vaccines manufactured by Moderna and by Johnson & Johnson.
- In addition, India has an opportunity to receive about 10 crore doses of Pfizer-BioNTech's mRNA-based vaccine by the end of 2021.
- Yet, only 11% of the population has been fully vaccinated and 35.5% has received a single dose.
- Major reason for the underperformance is the **insufficient supply of vaccines**, which in turn is due to the demand from the manufacturers to grant indemnity.

What is indemnity?

- Vaccines are given EUA after a thorough review of their safety.
- However, there can be rare and serious Adverse Events Following Immunisation (AEFI) like vaccine-induced immune thrombotic thrombocytopenia and Myocarditis.
- Grant of indemnity by the government means that the manufactures **cannot be sued** in those countries by people who may experience AEFIs.
- However, it does not always mean beneficiaries cannot seek compensation for adverse events at all.
- But the bar to seek compensation is very high.

What is the International Practice?

- **U.S -** Pfizer and Moderna were granted immunity from liability.
- This protects them, until 2024, from lawsuits arising out of any foreseen and unintentional medical complications as a result of vaccination.
- WHO - In February, the WHO started a "No-Fault compensation program" for 92 low- and middle-income countries.
- This is the only global vaccine injury compensation mechanism and is funded by a small levy on each dose supported by the Gavi COVAX Advance Market Commitment.
- It is available for rare but serious adverse events associated with COVAX-distributed vaccines

until June 2022.

What is the situation in India?

- The manufacturers of the three vaccines currently being administered in India (Covishield, Covaxin, and Sputnik V) have not been granted indemnity.
- Pfizer and Moderna have supplied their Covid-19 vaccines only to the countries that granted indemnities.

Why is the government hesitant on granting indemnity?

- **Accountability -** Indian regulations provide for compensation in case of injury or death of a trial subject.
- The idea is to hold the manufacturers accountable.
- **Additional Burden -** The legal responsibility for any vaccine-related injury in India lies with the manufacturers.
- Therefore, if manufacturers are granted indemnity, this would mean the Government has to provide compensation.
- **Misuse -** Indemnity might be misused as blanket protection for deliberate acts, fraud or instances of negligence.
- **Demand -** If some foreign manufacturers are granted indemnity, then manufacturers of the vaccines currently in use are likely to demand similar protections.

What are the existing safety mechanisms?

- Even if indemnity is granted, India has several safety mechanisms.

    1. DCGI is empowered to take action against companies violating the Drugs and Cosmetics Act, 1940.
    2. Any individual seeking compensation may directly file petitions before consumer courts and High Courts.
    3. Recent amendments to the Consumer Protection Act, 1986 disallow individuals but permit the regulatory bodies to initiate class action suits based on complaints.

Class action suits - cases representing groups of people who have suffered from the same loss

What should the government do?

- Examine initiatives such as America's Countermeasures Injury Compensation Program in granting indemnity.
- Institutionalize legal safeguards from vaccine injuries supplemented by government funding.
- Utilize this opportunity to reduce vaccine 'licensing to availability gap' and to increase the vaccine availability

Source : The Hindu



SHANKAR
IAS PARLIAMENT
Information is Empowering