



# **Jan Swasthya Abhiyan**

**(Peoples Health Movement – India)**

**Health for All - Now!**

**Health is a Basic Human Right**

May 19, 2020

To,

Shri Narendra Modi  
Hon'ble Prime Minister of India  
South Block, Raisina Hill  
New Delhi 110011

**Re: Government of India's Negotiations with Pfizer on supply of the mRNA vaccine to India  
Concerns regarding Pfizer's demand for indemnity**

Dear Prime Minister,

We are writing to you as Jan Swasthya Abhiyan over a matter of public and national interest. There are current shortages of COVID-19 vaccines across the country. The government has been trying to invite big U.S pharmaceutical corporations like Pfizer and Moderna to supply their mRNA vaccines to India.

## **The facts:**

For months, Pfizer, Moderna put pressure on the Central Drugs Standard Control Organisation (CDSCO) and the Indian government to waive specific requirements such as local clinical trials and to demand broad indemnity clauses in the Government of India contract for purchase in exchange for registration dossier submission and to supply their vaccines to India. [[ET, April 16, 2021](#);

Earlier, the government rejected the demand from vaccine manufacturers for indemnity from any liability that may arise due to severe side-effects/adverse reactions due to the dispensation of their vaccines. [[First Post, January 11, 2021](#)].

In April 2021, the CDSCO introduced a regulatory pathway to provide emergency use approval to Covid-19 vaccines in India, approved for emergency use by drug regulators in the U.S., U.K., Japan, or listed in the WHO Emergency use listing. The changed rules made the mRNA vaccines from Moderna and Pfizer immediately eligible for emergency approval without necessitating the otherwise mandatory local clinical trials [[CDSCO, Public Notices, April 15, 2021](#)]

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### **Addresses for Correspondence:**

#### **National Secretariat:**

c/o **Delhi Science Forum**, Khasra No.275, West End Road, Saidulajab, New Delhi – 110030

c/o **Public Health Resource Network**, First Floor, 2/42, Sarvapriya Vihar, New Delhi- 110016

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However, U.S. corporations have been pressing for more concessions through indemnity against all legal liabilities. According to the media reports, we understand that the discussions are at a very advanced stage between the government and Pfizer. The news report implies that the government may agree to their demands to supply India. [[May 15, 2021, 2021](#)].

### **What is Pfizer asking from countries in exchange for the supply of the mRNA vaccine?**

Many governments have been reluctant to sign the indemnity clauses, a pre-condition for Pfizer Inc to supply its vaccine that goes far beyond the demands of the other vaccine manufacturers. According to a recent report, Pfizer asked Latin American countries for wide-ranging indemnity from civil cases before supplying the life-saving vaccine. In simple words, the U.S. Corporation will not be responsible for paying any compensation for any adverse effects arising out of the vaccine, and shall be exempt from any liability resulting from any legal action. In a nutshell, it would not itself have to pay up for legal problems at any step of its vaccine supply chain or its acts of negligence, shifting the burden entirely to governments. A government official in Latin America described the demands as “high-level bullying” and said the administration felt “held to ransom” over access to life-saving vaccines. [[Bureau of Investigative Journalism, February 10, 2021](#)]

### **Concerns**

- The agreement between Pfizer and the Government of India lacks transparency, in the absence of which would be akin to trading away the rights of people who could be affected by serious adverse events and other acts of negligence of the pharmaceutical corporation in the future.
- For countries who receive vaccines under the COVAX (COVID-19 Vaccines Global Access) facility, the WHO has set up a mechanism for compensation for people who suffer severe but rare adverse events associated with COVID-19 vaccines. However, a careful perusal of indemnity [agreements](#) with the U.S corporation show that Pfizer’s demand for indemnity is not limited to severe adverse events. If accepted, such indemnity clauses may undermine currently available protections and safeguards available to people in India under various laws and court decisions against the acts of negligence that arise from the unethical practices of the pharmaceutical industry. A recent example is the finding of an expert committee set up by the Health Ministry that Johnson & Johnson (J&J) was “suppressing” key facts on the harmful effects of the company’s “faulty” hip replacement systems [[Indian Express, August 30, 2018](#)]. Some patients were able to claim compensation directly from J&J.

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The Government must refrain from entering into any agreement with Pharmaceutical corporations, which shall jeopardize patient's right to claim compensation for the harm they suffer.

- Even if the government is thinking of providing indemnity to Pfizer for just serious adverse events, other companies would also claim such protection from liability to introduce their vaccines into India. Therefore, any framework for exemption from liability must be discussed and published for public comments before deciding.
- Immediately put in place a mechanism for no-fault compensation, ensuring that persons affected by adverse effects from any of the COVID-19 vaccine may receive appropriate redressal of their grievance.

The supply of the mRNA vaccine to the developing world has been a trickle, and Pfizer has completely rejected calls for sharing technology and know-how. By agreeing to the indemnity that Pfizer is demanding, India will set a dangerous precedent. Allowing pharmaceutical corporations to bully a government in exchange for supplying COVID-19 vaccines amid a humanitarian crisis is unethical.

**We request** that all details of the current negotiations with Pfizer on the pricing of the mRNA vaccine, quantities, indemnity, and other public interest issues be made public immediately. Such demands for indemnity from pharmaceutical corporations should be rejected if Pfizer is genuinely interested in addressing the Indian effort to address the COVID-19 pandemic. In that case, it must do so in good faith and without such pre-conditions that harm public interest.

Sincerely,

Amitava Guha, Amulya Nidhi

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### **Copy to:**

1. P K Mishra, Principal Secretary to Hon'ble Prime Minister, PMO
2. Shri P. K. Sinha, Principal Advisor to Hon'ble Prime Minister, PMO
3. Harsh Vardhan, Hon'ble Minister, Ministry of Health and Family Welfare (MOHFW)
4. Shri Rajesh Bhushan, Secretary, MOHFW
5. Arti Ahuja, Additional Secretary (Health), MOHFW
6. Shri Lav Aggarwal, Joint Secretary, MOHFW
7. Vinod K. Paul, Member, Niti Aayog
8. Dr Somani, DCGI, CDSCO
9. Ms. S. Aparna, Secretary, Department of Pharmaceuticals

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