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IN FOCUS

August 19, 2021

Liability Issues Related to COVID-19 Vaccine Manufacturing and Global Distribution

Background

In March 2021, the United States announced efforts to donate Coronavirus Disease 2019 (COVID-19) vaccines abroad. In many high-income countries, vaccines and other medical countermeasures are playing a critical role in controlling the spread of COVID-19. Vaccine distribution efforts in low- and middle-income countries (LMICs) have been comparatively slow for a variety of reasons, raising concerns about how inequities may hinder pandemic control. Some vaccine manufacturers and others willing to donate COVID-19 vaccines are concerned about legal exposure should there be adverse health events arising from COVID-19 vaccination outside of the United States.

> In several countries, legal liability issues have slowed or entirely stalled vaccine roll-out.

For example, U.S. government vaccine donations to India reportedly remain in a Delhi warehouse because the Indian government has not agreed to indemnify vaccine manufacturers for vaccine-related injuries. Only a relatively small percentage of the Indian population is fully vaccinated against COVID-19; donated doses could potentially increase vaccination rates in the country. This In Focus discusses potential liability issues that vaccine manufacturers and donors may face, and options Congress might consider while deliberating vaccine distribution and liability issues.

Vaccine Distribution and Liability Concerns

Due to the novelty of the therapeutics used to control the COVID-19 pandemic, liability insurance is generally unavailable for COVID-19 vaccine manufacturers. Many pharmaceutical companies have expressed concern about the costs they may face from vaccine-related injury litigation, with some preventing governments from exporting vaccines to other countries without liability and indemnification agreements in place. In February 2021, the World Health Organization (WHO) and Chubb Limited, an insurance company, signed an agreement on behalf of COVAX—a multilateral initiative for global COVID-19 vaccine distribution—to create a No-Fault Compensation program for those who suffer serious adverse events associated with a vaccine administered through COVAX. For more on COVAX, see CRS In Focus IF11796, *Global COVID-19 Vaccine Distribution*.

In May 2021, the Task Force on COVID-19 Vaccines, Therapeutics, and Diagnostics for Developing Countries (the Task Force), composed of the International Monetary Fund, the World Bank Group, WHO, and the World Trade Organization, called for $50 billion in additional funding to support efforts to vaccinate 40% of all eligible people worldwide by the end of 2021. The Task Force cited liability issues and insufficient indemnification schemes as among the primary obstacles to achieving this goal.

According to COVAX, as of July 31, 2021, approximately 5% of COVID-19 vaccines that were pre-purchased by or for LMICs have been delivered to these countries. The Task Force indicated that the resolution of liability issues and negotiation of indemnification agreements through the No-Fault Compensation Program might incentivize additional donations to COVAX and mitigate acute near-term vaccine supply shortages.

Methods of Limiting Liability

Manufacturers may secure legal protection through a variety of means, including legislation and contracts (**Table 1**). Some legislation provides immunity for manufacturers or creates no-fault compensation funds that may apply to injuries related to vaccines. In addition, some governments and manufacturers have negotiated agreements to address distribution of COVID-19 vaccines, which vary by country and manufacturer. The relevant legal regimes involved may also vary depending on how vaccines are acquired and distributed, whether via COVAX or through other channels.

Table 1. Classification of Liability Regimes

Type	Description	Examples
Immunity	Prevents entities from being held legally liable and generally prevents individuals from receiving compensation	- U.S.: Public Readiness and Emergency Preparedness (PREP) Act - Philippines: COVID-19 Vaccination Programme Act
Indemnification	Requires a government to compensate entities for damages the entities owe to injured individuals	- Contractual provision between the EU and AstraZeneca - Contractual provision between the Dominican Republic and Pfizer
No-fault compensation	Individuals apply for compensation to a fund, and no liability attaches to the entities	- U.S.: National Vaccine Injury Compensation Program - COVAX mechanism

Source: Created by CRS.

Liability Issues for Doses Delivered via COVAX

To address liability and compensation issues related to serious adverse events, COVAX created the No-Fault Compensation program. Through the program, individuals who sustain qualifying injuries after being vaccinated through COVAX may apply for compensation through a centralized online portal. While their claims are pending, individuals may not file claims in courts or other fora. Applicants whose claims receive approval may obtain compensation from a centralized fund; if they accept the compensation offered, they must agree not to pursue any other claims in relation to the same vaccine-related injury. If an applicant's claim is rejected, the individual may then file a claim in a court or other forum. The Task Force hopes that the No-Fault Compensation program might avert a potentially burdensome caseload of COVID-19 vaccine-related claims, particularly in resource-limited countries.

Although this arrangement seeks to balance concerns about liability and responsibility to injured parties, there remain some concerns within the international community about claims settled outside of the COVAX program. In particular, WHO has raised concerns about whether lower-income countries will be able to pay indemnification costs owed to manufacturers under contracts or other agreements. COVAX is currently involved in ongoing discussions about the potential to provide loans to those countries through entities such as the Multilateral Investment Guarantee Agency, which is a member of the World Bank Group.

Vaccine Distribution in Humanitarian and Conflict Settings. In March 2021, COVAX agreed to set aside 5% of its vaccine doses to the COVAX Buffer for "high-risk groups in humanitarian settings," recognizing these groups may be hard to reach. According to the United Nations, 167 million people are at risk of exclusion from COVID-19 vaccination. The majority of those at risk are in COVAX Advanced Market Commitment (AMC)-eligible economies. AMC is a financial mechanism used by Gavi, the Vaccine Alliance, a multilateral public-private partnership that co-leads COVAX, to leverage high-income countries' large-scale purchases of COVID-19 vaccines to assure LMIC participation. However, roughly one-third of those in the high-risk group reside in areas not covered by COVAX's No-Fault Compensation Program. Humanitarian organizations have voiced concern about their ability to administer vaccines because they cannot afford to shoulder the cost of indemnification agreements. COVAX is reportedly in discussions with manufacturers to address these issues.

Bilateral Agreements

Outside of COVAX, doses are exported and distributed to recipient countries through several mechanisms. The United States and other countries have donated vaccine doses on a bilateral basis, and governments have purchased doses directly from manufacturers to be imported into their territories.

Unlike distributions made via COVAX, arrangements between governments and manufacturers are not part of a global legal regime that addresses vaccine manufacturers' potential liability. Instead, to limit their legal liability or financial responsibility, pharmaceutical companies generally have to rely on domestic immunity laws, no-fault compensation laws, or contractually negotiated provisions (although not all companies have sought indemnification clauses in their contracts).

Considerations for Congress

Some Members of Congress have raised questions about the variables affecting global distribution efforts for COVID-19 vaccines. Such questions include whether manufacturers can receive liability protection in the United States and abroad, and whether liability issues are restricting or delaying vaccine shipments. As described, there are international and bilateral efforts to address liability concerns in place. Some stakeholders remain concerned about whether countries receiving COVID-19 vaccines outside of COVAX will be able to cover future legal costs they may incur under indemnification clauses.

Congress may consider a variety of actions related to these issues, including

- whether to amend the PREP Act to address the scope of immunity provided to manufacturers for claims brought in the United States (for more on the PREP Act, see CRS Legal Sidebar LSB10443, *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures*);
- whether to authorize funds in future foreign assistance legislation to assist LMICs required to indemnify vaccine manufacturers, or provide technical assistance to governments working on laws or agreements addressing liability concerns;
- whether to encourage the Biden Administration to engage in additional efforts, bilaterally or multilaterally, to mobilize private investments, public-private partnerships, or other such agreements, to help countries cover potential costs associated with indemnification agreements; and
- whether to encourage the Administration to engage with other developed countries about how to contribute collectively to meet the financial needs of countries required to indemnify manufacturers, potentially through the Task Force, World Bank, the Group of 7 (G7), or Group of 20 (G20), to hasten the pace of vaccine distribution.

Sara M. Tharakan, Analyst in Global Health and International Development
Nina M. Hart, Legislative Attorney

IF11905

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