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Commentary

# COVAX no fault compensation program for COVID-19 vaccine injuries in 92 low and middle income countries

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COVID-19 vaccines play a key role in controlling the COVID-19 pandemic, as demonstrated by their various rates of effectiveness in preventing COVID-19 related death and disease in multiple countries [1]. However, even with rigorous attention to safety in vaccine development, regulation, manufacturing, distribution and administration, vaccines can cause adverse events [2]. The vast majority of such adverse events are mild and transient, but in rare cases, adverse events can be serious. While the benefits of immunization against COVID-19 (not only for vaccinated individuals, but also for society at large) greatly outweigh the limited risk of serious adverse events, solidarity requires that those who are seriously injured as a result of vaccination have access to fair and timely compensation.

Vaccine injury compensation programs provide a fair and efficient way to compensate individuals for injuries resulting from vaccination and are equitable for all stakeholders [3]. They also reduce the risk of tort liability for manufacturers, which may inhibit the wide supply of life saving vaccines [4]. To accelerate the availability and fair distribution of COVID-19 vaccines, COVAX (an initiative co-led by the World Health Organization, Gavi, the Vaccine Alliance, and the Coalition for Epidemic Preparedness Innovations) has established the world's first international no-fault vaccine injury compensation program [5]. The COVAX Program will provide no-fault, lump-sum compensation in full and final settlement of any claims to eligible individuals in the 92 low and middle income countries and economies, known as the Gavi COVAX Advance Market Commitment eligible economies [6] or the "AMC 92", who suffer a serious adverse event resulting in permanent impairment or death associated with a COVID-19 vaccine, or the administration of a COVID-19 vaccine, which is procured or distributed through COVAX until 30 June 2022.

The establishment of the COVAX Program contributes to the supply of life saving COVID-19 vaccines in the most resource constrained economies around the world and ensures that eligible individuals in these economies can receive compensation in an equitable, transparent and timely manner, if they suffer serious injuries following vaccination with a COVAX-distributed vaccine. The Program also reduces the financial burden to which the AMC92 may be exposed in the event of such injuries.

The Program is centrally managed by an independent, experienced claims administrator with representation in all AMC eligible economies. The Program's capital is financed by a donor funded levy on each vaccine dose distributed through COVAX to the AMC 92, and complemented with a robust insurance layer. While applying for compensation through the Program is voluntary, the Program aims to reduce the need for pursuing

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injury claims related to COVAX-distributed vaccines through national court systems, which can be a lengthy and costly process, with a higher burden of proof and a more uncertain outcome. As an international vaccine injury compensation program, the Program furthermore provides an equitable approach across countries through its uniformity.

All vaccines procured or distributed through COVAX will have received regulatory approval or an emergency use authorization to confirm their safety and efficacy. So far, possible associations have been identified between certain mRNA vaccines and anaphylaxis and, separately, myocarditis, as well as between certain vaccines using an adenovirus vector and rare blood clots with low platelets [7–9]. Since serious injuries arising from vaccination are generally rare and COVID-19 continues to cause widespread morbidity and mortality, the benefits of vaccination greatly outweigh the risks. If certain serious injuries nevertheless arise following the administration of COVAX-distributed vaccines in the AMC 92, the Program provides a way for eligible individuals to receive fair and equitable compensation.

Eligible individuals can submit applications for compensation, with supporting evidence provided by registered healthcare providers, using publicly available forms. No fee will be charged to submit an application, and eligible individuals will have ample time (through a long reporting period of up to 5 years) to submit an application after being administered a COVAX-distributed vaccine. Applications will be reviewed in accordance with a publicly available procedure. This includes the assessment of receivable claims by a central review panel and, as relevant, an appeals panel, both comprised of medical health care professionals. A scientific advisory panel of independent public health experts will provide guidance to the review and appeals panels in light of the evolving understanding of COVID-19 vaccine safety, particularly in respect of which, if any, types of injuries that manifest after vaccination are likely to have been caused by a vaccine and the characteristics of those injuries. Members of each of the panels are screened for potential conflicts of interest, and a process for managing such conflicts is in place.

In addition to the guidance provided by the scientific advisory panel, the review and appeals panels will also draw on available findings from investigations of serious adverse events following immunization (AEFI) by immunization programs and regulatory agencies and the conclusions of AEFI causality assessment committees. To maintain consistency in compensation decisions for applicants from different countries, the findings from such investigations and assessments will not by themselves determine whether or not a claim should be compensated, but the detailed information and on-the-ground insights from such investigations and assessments will be helpful in guiding such determinations.

Compensation will be provided if the review or appeals panel determines that a COVAX-distributed vaccine or its administration was the most probable cause of the claimed injury (obviating the need for injured individuals to demonstrate causality, as would be required in court litigation). Program compensation will be calculated per the following formula: GDP per capita of the relevant AMC eligible economy in which the claimant resides $\times$ 12 $\times$ a harm factor ranging from 1.5 to 0.1 dependent on the nature of the injury, and level of impairment, as evaluated based upon the most recently published edition of the American Medical Association's Guides to the Evaluation of Permanent Impairment [10]. This formula equitably reflects differences in cost of living across countries, and is aimed at providing a fair level of compensation. Applying for compensation through the Program is voluntary, but if a claimant accepts compensation, acceptance is in full and final settlement of any claims to ensure that the same injury is not compensated twice.

Although the Program is unprecedented in scale, it builds on decades of work on vaccine safety and vaccine injury compensation, including in the 25 jurisdictions worldwide that already have vaccine injury compensation programs [3]. For example, the per dose levy funding and scientific advisory panel are similar to elements of the U.S. Vaccine Injury Compensation Program [4], while the composition of the review panels is similar to the vaccine injury claim review system used in Quebec [11].

The range of capacities for evaluating the safety of vaccines through clinical trials, post-licensure safety monitoring, laboratory testing, etc., that have developed in many countries are critical for determining if a given vaccine can cause a given injury and are therefore important for decisions on which vaccine injury claims should be compensated [2]. Further improvements in global capacity to detect and assess vaccine safety signals, particularly in low and middle income countries, will help not only current, but also future vaccine injury compensation programs to operate fairly and efficiently.

Given its unprecedented geographic extent, the COVAX Program could provide an important opportunity to advance global efforts to maximize the benefits of vaccination. If the Program proves successful, it will not only be a major step forward in risk mitigation to make the response to the COVID-19 pandemic more equitable, but also serve as a potential model, including for use in global responses to future pandemics of new diseases.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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