

## **BIO-IFPMA Comment on COVAX No-Fault Compensation Program for COVAX Advance Market Commitment Eligible Economies**

Geneva, 9 April 2021 - We commend COVAX on the launch of its [Web Portal](#) for the no-fault compensation program (NFC) for the 92 low- and middle-income countries eligible for support under the COVAX Advance Market Commitment (AMC). The development of this international NFC system is a historic achievement, and the program will play a crucial role in advancing the prompt, equitable, and responsible administration of COVID-19 vaccines. We recognize the immense challenges the World Health Organization (WHO) faced in designing this first-of-its-kind international system, and we appreciate that the program incorporates many of the critical design elements associated with highly-effective NFC systems. We recommend two refinements that will maximize the effectiveness and success of this impressive program.

**First, we support the WHO's decision to limit compensation to serious adverse events but suggest that the COVAX NFC program cover all serious adverse events, not just permanent serious adverse events.** Doing so would align with successful national NFC systems, and would also align with the [definition of "serious adverse event" adopted by International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use \(ICH\)](#).

***Why is this refinement important to the effectiveness and success of the program?*** Serious adverse events of any kind have only rarely been associated with vaccines, but those few that do occur even more seldom result in permanent injuries. For example, anaphylaxis is a very rare but serious event that, with proper treatment, is normally resolved within a relatively short time. It clearly fits the standard ICH definition of a serious adverse event, yet it would not always be eligible for compensation under the WHO program as currently designed. Excluding people who experience such events would deprive them of fair compensation and could undercut public confidence in the NFC program.

**Second, COVAX should ensure that the COVAX program is agile enough to respond to rapidly-changing global developments—such as the rise of new COVID-19 variants—including through potential extensions of the program's coverage term.** We understand that the COVAX NFC program currently has an eligibility cutoff date of June 30, 2022 and includes additional coverage limitations tied to the date upon which vaccines receive initial regulatory authorization and the date upon which countries first receive vaccine doses.

***Why is this refinement important to the effectiveness and success of the program?*** While these coverage term restrictions may currently be appropriate, the rise of new variants and other global developments could require the introduction of new and/or modified vaccines and may significantly alter the timelines for global vaccine distribution. Given the unpredictability of these developments, we request that the COVAX acknowledge its willingness to extend the program's coverage term as necessary in the coming months and years.

Effective NFC systems should advance two core goals:

- They should provide vaccine recipients with access to prompt, fair, and transparent compensation for any serious adverse events associated with vaccinations. By achieving this goal, well-designed systems can greatly enhance vaccine confidence and expedite vaccine uptake.
- NFC systems should mitigate the risks of time-consuming and resource-intensive vaccine liability litigation. Reducing costly litigation provides governments and other stakeholders with the financial security necessary to carry out robust vaccination programs, while still providing vaccine recipients with timely access to compensation. This goal is particularly important in low- and middle-income countries, where the financial risks posed by liability litigation can severely limit the implementation of vaccination programs. By implementing the above refinements, COVAX will best be able to ensure that its program advances both of these goals.

We again commend COVAX on the announcement of its historic NFC program. By implementing the above recommendations, the COVAX will be able to best ensure that this program plays an effective role in enhancing global vaccination efforts for the duration of the COVID-19 pandemic. We look forward to further collaborating with the COVAX partners to advance our shared public health goals, and we welcome any opportunity to further discuss these recommendations.