

CEPI



COVAX no-fault compensation program for AMC eligible economies (the “Program”)

WHO - 25 February 2021

Purpose and Objectives

- Provide **fair no-fault lump-sum compensation in full and final settlement of any claims to** individuals who suffer a SAE resulting in permanent impairment or death associated with a COVID-19 vaccine procured or distributed through the COVAX Facility in any Gavi AMC eligible economy until 30 June 2022, or the administration of such a vaccine.
- **Inspire a high level of trust, be equitable, robust and transparent**
- **Reduce claims in court and reduce the need for indemnification by the Gavi AMC eligible economies.**
- **Promote fair and equitable access to COVID-19 vaccines in the poorest countries of the world.**

Covered vaccines

- COVID-19 vaccines procured or distributed through the COVAX Facility are vaccines that have received regulatory approval or an emergency use authorization to confirm their safety and efficacy.
- The Program covers **COVID-19 vaccine doses procured or distributed through the COVAX Facility to AMC eligible economies until 30 June 2022**, on which the **per dose levy to finance the capital of the Program** is charged.
- **Donations to the COVAX Facility of COVAX distributed vaccines** will be covered by the Program, provided that they are **for use in AMC eligible economies** and the **per dose levy is charged** on the vaccine doses in question.

Fair, robust, transparent and independent process

The Administrator:

- The Program will be managed and administered by an **independent claims administrator, pursuant to a services agreement with WHO.**
- **A world renowned company with over 30 years experience** in this field, who works with a world renowned partner, including for field investigations.
- Has **representation in all 92 AMC eligible economies.**

The Process:

- Designed **to inspire a high level of trust** with vaccine recipients.
- Based on a **detailed publicly available protocol and forms** for applications, evidence submission, notices of appeal, etc.
- **As easy as possible** for applicants, with full recognition of constraints in developing country settings. **Regional assistance will be offered, as well as helplines.**
- **Robust, transparent and fast** (while allowing applicants ample time to submit required documentation), and with a fair **level of compensation for eligible claimants.**
- The Administrator will make **“How to Submit an Application” instructions** available to MoHs of the AMC 92, so that they can provide these instructions to vaccination centers, vaccine adverse event casualty assessment committees, and registered healthcare professionals.
- There will be **no fee charged by the Administrator to applicants**

Program launch

- The Program will be **operational by the end of March**, with a **fully operational Web Portal**. Given the delays in the supply of the necessary vaccine-related shipment information, the Program cannot be operational sooner.
- **Eligible individuals** will have **ample time to apply for compensation** under the Program, even if a COVAX-distributed vaccine is administered to them **before** the Program becomes operational.
- **The Program's Protocol (procedure), Application and other Program forms, and other relevant Program information and resources** will be available in English, French and Spanish on the Program's Portal, including instructions on how to submit an application and **detailed FAQs** to guide interested applicants.

Eligibility

Eligibility of a patient (or his duly authorized representative) **to apply for compensation under the Program**, includes:

1. the patient is a resident or a citizen of, and has been administered a COVAX-distributed COVID-19 vaccine in, an AMC eligible economy, or is a beneficiary of the COVAX Facility humanitarian buffer in an AMC eligible economy; and
2. the patient has sustained an injury (i.e. permanent impairment or death) which, in the opinion of a registered health professional, is deemed to have resulted from a vaccine distributed through the COVAX Facility to an AMC eligible economy, or the administration of such a vaccine; and
3. the vaccine was administered before its Scope of Coverage Endpoint; and
4. the patient (or his duly authorized representative) has submitted an application, together with all supporting evidence, to the Administrator before the end of the Reporting Period.

Action that has been requested of the AMC 92

Before supply of vaccines of COVAX-distributed vaccines begins:

- To determine whether the acceptance by individuals of no-fault compensation under the Program in full and final settlement of any claims requires any implementing legislation within the country, i.e. so as to ensure that individuals who accept compensation in full and final settlement of any claims are precluded from seeking **further** compensation through national courts; **and**
- If such implementing legislation is required, take all necessary steps to draft and fully enact such legislation.

Once the Compensation Program has been established:

- Raise awareness about the Program in the country;
- Make the How to Submit an Application instructions available to vaccination centers, vaccine adverse event casualty assessment committees, and registered healthcare professionals within their country so that they can make these instructions available to recipients of COVAX distributed vaccines;
- Inform Registered Healthcare Professionals of the **need to carefully track and keep records of each COVAX-distributed vaccine and its diluent (if any)**, including: (1) the name of vaccine and name of its diluent (if any), (2) dose, (3) batch or lot number, (4) expiry date, (5) name of each individual to whom the vaccine is administered; and (6) date of administration to such individual;
- Work with the Program's Administrator to facilitate the submission and investigation of claims, as well as the exchange of safety information.



COVAX AMC

COVAX No-Fault Compensation Program for AMC Eligible Economies

[Home](#)

Welcome to the Web Portal for the COVAX No-Fault Compensation Program for AMC Eligible Economies

(This site is still under construction)

Thank you for your interest in the COVAX No-Fault Compensation Program for Gavi AMC eligible economies (the "Program"). The Program is expected to be operational by 31 March 2021.

The purpose of the Program is to provide no-fault lump-sum compensation in full and final settlement of any claims to eligible individuals who suffer a serious adverse event resulting in permanent impairment or death associated with a COVID-19 vaccine procured or distributed through the COVAX Facility in any Gavi **AMC eligible economy** until 30 June 2022, or the administration of such a vaccine. Gavi **AMC eligible economies** are the 92 low- and middle-income countries and economies eligible for support via the Gavi COVAX Advance Market Commitment (AMC) of the COVAX Facility. The Program is subject to the terms of its Protocol and applicable Program forms (see below).

The independent administrator of the Program is ESIS, Inc., a wholly-owned subsidiary of Chubb Limited.

While the Program's web portal is under construction, you may be interested to read some of the **Program's documents**.

Please note that, **until the Program is operational (which is expected to be on 31 March 2021)**:

1. The Program's documents made available through the link above are **for information purposes only**; and
2. Applications for compensation under the Program cannot be submitted to, nor be accepted by, the Administrator **until such time** (but please see the "Note" below).

NOTE: Eligible individuals may apply for compensation under the Program once the Program becomes operational, even if a COVAX-

www.covaxclaims.com

For information
purposes only until
Program is operational
by 31 March, 2021

THANK YOU



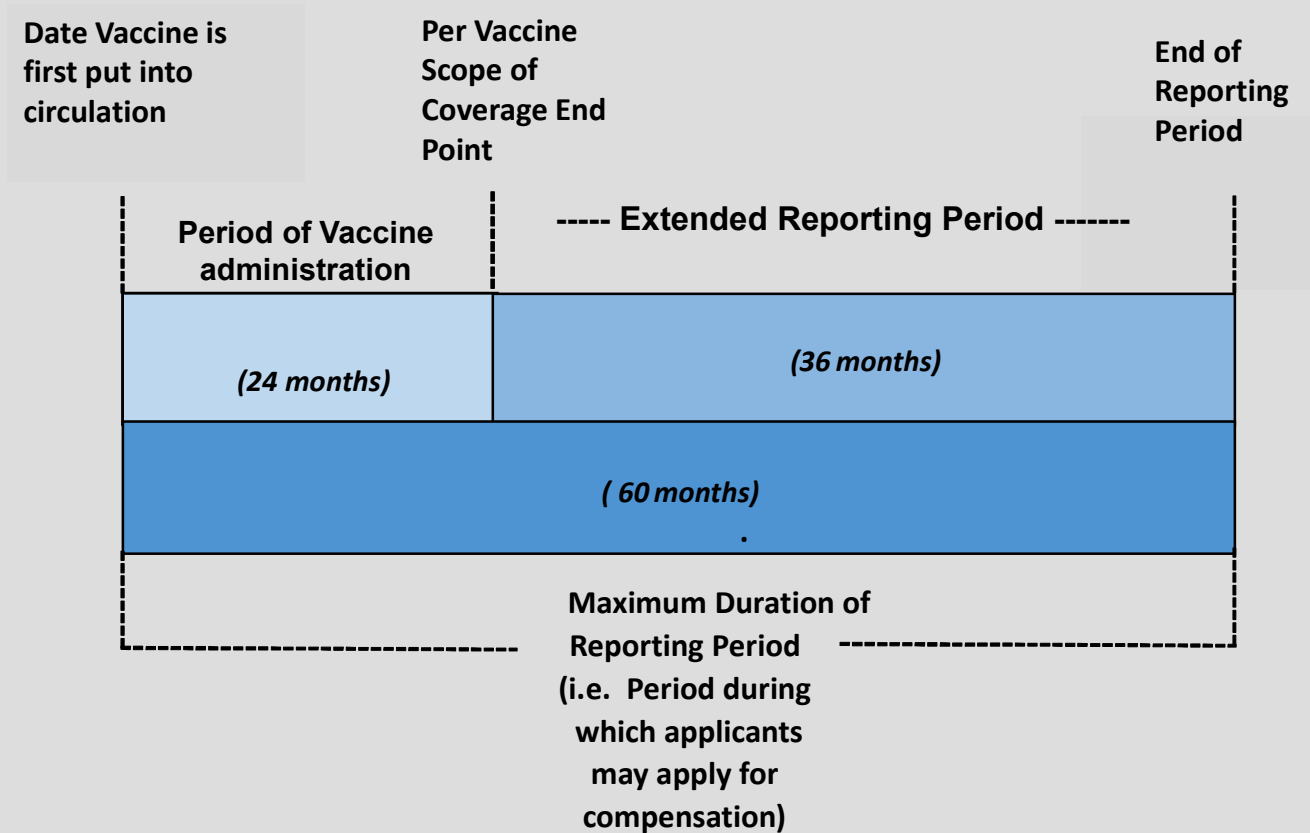
EXTRA SLIDES



Per Vaccine End Point and Extended Reporting Period

- Each vaccine distributed through the COVAX Facility to the AMC 92 will have a **Per Vaccine End Point** for coverage under the Program
- The Per Vaccine End Point is **24 months following the date on which the vaccine in question was first put into circulation by the manufacturer in any country** (under COVAX or otherwise), following regulatory approval or an emergency use authorization from any regulator.
- In addition, there will be an **Extended Reporting Period** for eligible individuals to submit applications for compensation under the Program. For as long as a COVAX distributed vaccine was administered to an eligible individual before the end of that vaccine's End Point, this individual will have a period which extends to **36 months following the end of that End Point, to submit an application for compensation under the Program.**
- **The End Point, particularly if taken together with the Extended Reporting Period for claims of 36 months:**
 - *significantly minimizes the risk of liability claims*
 - *is likely to cover the period of the pandemic to a large extent*
 - *is considered adequate to ensure that the safety profile of each vaccine is well understood and that credible new safety signals are unlikely to emerge by the time the coverage under the Program ends.*

Illustration of Per Vaccine End Point and Extended Reporting Period



**Level of Lump
Sum
Compensation
and
Average Pay-
outs (Per Claim)**

The level of compensation under the Program is based on the following formula:

GDP per capita of the Relevant AMC eligible economy x 12 x a harm factor based on the level impairment (ranging from 0.1 to 1.5 - expected average 1.0)

Where a payment is approved, a daily in-hospital benefit of \$100 per day will furthermore be paid for each day of hospitalization or prolongation of existing hospitalization, not to exceed a maximum payment period of 60 days.

Based on an average GDP per capita for AMC countries of \$2,500 adjusted up to \$3,333 to factor in a security margin and to include costs to be reimbursed for hospitalizations associated with valid claims, **the average pay-out is \$3,333 X 12 X 1.0= \$40,000**

Capacity of Fund and Estimated Incidence of SAEs

On the basis of a contribution of a per dose levy on the initially estimated 1,050,000,000 doses to be distributed to AMC countries through COVAX until 30 June 2022

The levy has been calculated as 0.10 USD cents per dose for two dose vaccines. Since the Program will provide compensation for SAEs arising from the distributed COVAX vaccines **per subject**, a levy of 0.20 USD cents would apply to one dose vaccines.

On this basis, an amount of approximately **\$105,000,000** represents the initial total funds that will be available for compensation payments under the Program.

Efforts are underway to add an insurance layer to the Program, which -if successful- may increase its capital to up to **\$200,000,000**.

Calculating the number of serious adverse events that will generate a compensable claim remains a guessing exercise, given also the magnitude of this endeavor.

Using an approximate view on the historic ratio of Claims/Vaccination from various Vaccine Indemnity Compensation Programs (VICPs), including the US VICP, the **projection** results in a range of **750 to 1,250 SAEs** covered by the Program for the population of 525,000,000 recipients of vaccines under COVAX in the 92 AMC eligible economies.

Using 1,000 claims, the mid-point, as a basis for the Program's projections, the Program will have **reasonable reserves** to cover **a higher incidence rate** than the estimated incidence rate (in addition to, of course, expenses and the fees of the Administrator, and insurance premium if insurance participation in the Program can be secured).