



COVAX Facility:

No-fault compensation mechanism

AMC Participating Economies

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Context

- COVID-19 pandemic requires the **fastest and largest deployment of a novel vaccine in history**
- Vaccine deployment must be global and ensure equitable access across SFPs and AMC92 Participants
- Even under normal circumstances, vaccines that are approved for general use may nevertheless, in rare cases, cause unexpected serious adverse events (SAEs)
- Given the unprecedented nature and scale of the COVID-19 pandemic, **normal risk transfer solutions (insurance or self-insurance) will not be available to manufacturers from the outset**
- Without addressing this risk, manufacturers are reluctant to deliver COVID-19 vaccines, **threatening timely access to life-saving vaccines**
- The **COVAX Facility is doing everything possible to find a practical solution that:**
 - can be **implemented rapidly before deployment,**
 - is **equitable for all stakeholders,** and
 - **mitigates anticipated financial risks to AMC92 Participants**
- COVAX will **not compromise on safety and efficacy of COVID-19 vaccines** supplied through the COVAX Facility
- In addition to the rigorous processes that will be followed by COVAX, the COVAX Facility will rely on regulatory authorities to ensure the safety and efficacy of COVID-19 vaccines

Serious Adverse Events

A serious untoward medical occurrence that (i) is sustained or suffered by an individual following the administration of a Vaccine, and (ii) results in a serious bodily injury or illness that:

(i) requires hospitalization or prolongs an existing hospitalization; and

(ii) results in permanent total or partial impairment; or

(iii) is a congenital birth injury or illness in an unborn or new-born child of a woman who received a Vaccine and results in permanent total or partial impairment; or

(iv) results in death.

Proposed solution

Limited in Scope Limited to COVID-19 vaccine doses to be procured or distributed through COVAX – all of which will have received approval or Emergency Use Licensure

Limited in Time Applies until end of June 2022

Equitable and Fair Solutions to mitigate liability should be equitable for all stakeholders: manufacturers, Participants and recipients of vaccines that incur a serious adverse events (SAE) arising from a vaccine procured or distributed through COVAX

Description

Participants indemnify manufacturers and other relevant stakeholders

Guarantees to backstop indemnity obligations

Compensation mechanism to cover SAEs arising from COVAX vaccines

Scope

All COVAX participants

AMC Group Participants only

AMC Group Participants only

Compensation mechanism – scope and objectives

No fault, lump sum compensation in full and final settlement of any claims for **expected and unexpected serious adverse events** (SAEs) arising from vaccines procured or distributed through the COVAX Facility or their administration in **AMC Participating Economies. This includes the humanitarian buffer.**

Aim:

- To **disincentivize claims in court** and **reduce the need for indemnification** by the AMC 92
- To establish the compensation mechanism with **sufficient reserves to respond to twice the estimated number of compensable claims**

Process:

- To be managed and administered by an **independent claims administrator with representation in all 92 AMC eligible economies**
- **Robust, transparent** and **fast** process for determining if a claim should be compensated
- Fair **level of compensation** for eligible claimants

Compensation mechanism – scope and objectives

Designed to inspire a high level of trust with vaccine recipients.

- Process to be based on a **detailed publicly available protocol** with publicly available forms
- The process to include a **review panel of nurses** and an **appeals panel of nurses and physicians** at the independent claims administrator, both of which will be guided by a **scientific advisory committee of physicians appointed in consultation with WHO**
- **Process for claimants to be as easy as possible**, with recognition of constraints in developing country settings
- **Regional assistance and helplines in multiple languages**
- **Instructions** on how to submit an application to be **made available to Ministries of Health and humanitarian buffer partners** for distributions to persons suffering a SAE following the administration of Vaccines

Thank you



COVAX

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