COVID-19 Vaccination: Building Global Capacity

Q&A for Session 03: Indemnification and liability for COVID-19 vaccines

Tuesday, February 23, 2021

Thank you for attending the above session for National, regional and global stakeholders. Many questions were submitted by participants, either in the Zoom chat during the session itself, or in the two Telegram channels managed by Technet-21 supporting regions, countries, and partners in preparing for COVID-19 vaccine introduction. In this document, we share the answers from presenters to each question.

Links to the session recordings in all languages and presentations can be found on the Project ECHO website.

More information on COVID-19 vaccine introduction can be found in the resources listed below.

- General questions regarding the COVID-19 vaccines
- Preparing for COVID-19 vaccination
- WHO Coronavirus disease (COVID-2019) technical guidance
- TechNet-21 – The Technical Network for Strengthening Immunization Services
- OpenWHO COVID-19 vaccine trainings:
  - Orientation to national deployment and vaccination planning for COVID-19 vaccines

In addition, TechNet-21 manages two Telegram channels supporting regions, countries, and partners in preparing for COVID-19 vaccine introduction. In these two spaces - one anglophone and one francophone - you will be able to share your experiences, discuss key questions, and connect with experts from around the world. We'll also share new information and global guidance as it becomes available. Join us today:

- COVID-19 Vaccine Introduction – TechNet-21 (English)
- Introduction des vaccins contre la Covid-19 – TechNet-21 (Français)

You mentioned about the Georgetown University providing assistance regarding legislation for countries. How is it going to be made available for countries? How will it be shared? Will it be given to the participants from each country

The O'Neill center at Georgetown University has provided questions to go to countries, a list of experts that can provide assistance to countries and a collection of laws and regulations or executive orders that can serve as examples on how countries might proceed. We are also in discussions with the International Senior Lawyers Project and they will also be providing a list of experts to provide guidance to countries.

We (from Gavi) will be sending a set of questions to countries in the coming days. At the same time we will establish the mechanism whereby the consultants or attorneys willing to provide services to countries can be made available to countries that request it. We have also had discussion with regional intergovernmental organizations who also have an interest in participating in this work – including providing assistance and experts.

As we develop the specifics as to how these materials and assistance will be provided to countries, we will be circulating it more broadly.

Has anyone gone through the compensation process yet? If yes, what was the outcome?

The Program will become operational by 31 March 2021. Meanwhile, it should be noted that countries that have established national vaccine injury compensation mechanisms have seen a notable reduction in litigation against manufacturers. The reason for this is that such compensation mechanisms offer a faster, easier and considerably less expensive process for persons who suffer a serious adverse event following vaccination, to receive compensation.

Who exactly will be compensating the injured receipt? Is it the government?

The Program will be administered by an independent claims administrator, in accordance with the Program's Protocol (procedure). Applications for compensation will be evaluated for receivability by the independent claims administrator. If an application is receivable, it will then be assessed by a review panel of nurses (and where relevant, an appeals panel of nurses and physicians) established by the independent claims administrator to determine whether the COVAX-distributed vaccine was the most probable cause of the injury (i.e., the permanent impairment or death) in question; and if the answer is yes, then payment in respect of that injury will be approved. If a payment is approved, the compensation payment (calculated in accordance with the formula described under the question below) will be paid by the administrator directly to the injured individual (or, if the individual is a child, dead or disabled, to the person duly authorized to represent that injured individual), provided such individual (or the person representing him/her) has first returned a duly signed and notarized release agreement and a duly completed and signed payment method election form to the administrator in accordance with the terms of the Program's Protocol.

The capital of the Program will be financed by a per dose levy on the initially estimated 1,050,000,000 COVID-19 vaccines doses to be distributed to AMC Eligible Economies through the COVAX Facility until 30 June 2022.

How much money does this compensation represent? How much will the claimant get for a permanent impairment or in the case of death?

If it is determined that a COVID-19 vaccine supplied through the COVAX Facility or its administration was the most probable cause of the injury (i.e., permanent impairment or death), then the compensation payment will be calculated by the independent claims administrator based on the following formula, which is found in the Program's Protocol:

GDP per capita of the relevant AMC Eligible Economy times 12 times a harm factor.

The GDP per capita of the relevant AMC Eligible Economy will be as per the most recently published World Bank threshold at the time a payment is approved.

The harm factor (which is equal to 1.0 in the case of death, and ranges from 0.10 to 1.5 in the case of permanent impairment) is based on the level of impairment suffered by the individual concerned. This harm factor will be based upon the most recently published edition of the American Medical Association's Guides to the Evaluation of Permanent Impairment (AMA's Guides). Impairment percentages or ratings contained in the AMA's Guides have been developed by medical specialists and are consensus-derived estimates that reflect the severity of the medical condition and the degree to which the Impairment decreases an individual's ability to perform common activities of daily living.

The impairment rating is a percentage that represents the extent of a whole person impairment of an individual, based on the organ or body function affected by an injury.

This level of compensation is generous when compared to the level of compensation offered by existing (national) compensation mechanisms.

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.

Which groups of serious AEFI are eligible for COVAX compensation process NFC?

The purpose of the Program is to provide fair no-fault lump-sum compensation in full and final settlement of any claims to individuals who suffer a serious adverse event (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 economies until 30 June 2022, or the administration of such a vaccine.

A serious adverse event is a serious untoward medical occurrence that:

1. is sustained or suffered by an individual following the administration of a COVID-19 vaccine supplied through the COVAX Facility; and
2. results in a serious bodily injury or illness that:
    - requires hospitalization or prolongs an existing hospitalization; and
    - results in permanent total or partial impairment; or
    - is a congenital birth injury or illness in an unborn or new-born child of a woman who received a COVID-19 vaccine supplied through the COVAX Facility and results in permanent total or partial impairment; or
    - results in death.

How will the administrator decide if it is really an AEFI of COVID-19 vaccine, not related to any other underlying cause? How about in the case of death? How will it be determined if the vaccine is really responsible?

Receivable claims will be assessed by a review panel of nurses (and where relevant, an appeals panel of nurses and physicians) established by the independent claims administrator. The administrator will also have investigators to collect information related to claims locally. The review and appeals panels will be guided by an expert scientific advisory committee appointed with advice from WHO.

Receivable claims will be evaluated based on the evidence and information submitted by applicants, including through a supporting evidence form completed by one or more registered health care professionals. This will include detailed information on the administered vaccine, the injury, treatment for the injury, the registered health care professional's opinion about the cause of the injury, the functional impact of the injury, details of hospitalization, details of other known medication/vaccination (and in the case of birth defects, details of any medicines taken by, and/or any other vaccines administered to, the patient's mother during the pregnancy and/or 6 weeks before the start of the pregnancy), details of known previous long-term medication, details of any known pre-existing medical conditions of the patient or in the case of birth defects, of the patient's mother, whether the patient suffered any similar injury or illness before, medical history, etc.

The review process will take into consideration safety information and expert scientific advice provided by a scientific advisory committee. The role of this committee will be:

- to conduct a review of the evolving literature on COVID-19 vaccine safety; and
- to provide the administrator with updated information on the safety of the vaccines distributed through COVAX to the AMC 92 and relevant expert scientific advice to guide the process of the determination of receivable claims, including, but not limited to, advice on 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.

The injury will be assessed in accordance with the following general principles:

- The vaccine or its administration was the most probable cause of the claimed injury; and,
- The claimed injury was not present prior to the administration of the vaccine.

Most probable cause means the most likely cause (based on the balance of probabilities) that a vaccine or its administration resulted in the claimed injury (without making a determination who is at fault, nor establish actual causality).

Pre-existing conditions and injuries that are found not to have resulted from a vaccine or its administration, using the most probable cause standard, are excluded from compensation under the terms of the Program.