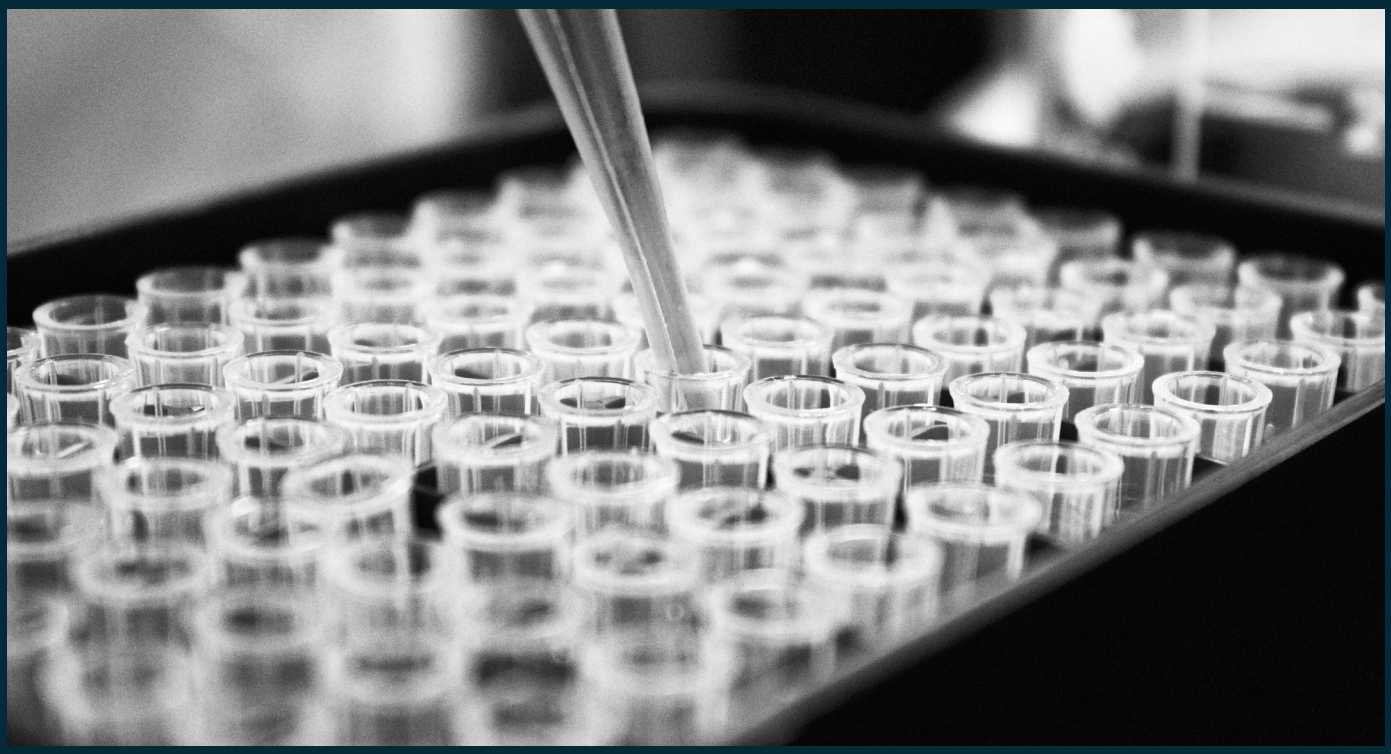

WORKING DRAFT UNDER DISCUSSION

BRIEFING NOTE

ADDITIONAL INFORMATION ON INDEMNIFICATION FOR COVAX AMC PARTICIPANTS

COVAX

NOVEMBER 2020

How the COVAX Facility will address potential liability, and compensation in the event of unexpected serious adverse events (SAE), arising from the manufacture, storage, transportation and administration of COVID-19 vaccines for AMC Countries

BACKGROUND

Following accelerated development, the delivery of COVID-19 vaccines at virtually the same time in hundreds of countries and territories will be the fastest and the largest deployment of a novel vaccine in history. All vaccines made available or procured through the COVAX Facility will have received regulatory approval or an emergency use authorization, allowing their general availability (the "Vaccines"). However, even under normal circumstances, vaccines that are approved for general use may nevertheless, in rare cases, cause unexpected serious adverse events (SAEs). Those involved in their manufacture, distribution and administration can normally get insurance to cover this risk.

Given the unprecedented nature and scale of the COVID-19 pandemic, however, normal insurance will not be available from the outset. The lack of such coverage may limit or delay global access to lifesaving Vaccines as manufacturers are reluctant to deliver COVID-19 Vaccines if this risk is not addressed. They are also, in the first instance, looking to countries receiving and deploying the Vaccines – including via bilateral deals – to indemnify them against product liability claims (as was the case at the time of the H1N1 pandemic). Equally, people receiving Vaccines who suffer unexpected SAEs associated with a Vaccine or its administration deserve compensation.

The COVAX Facility is doing everything possible to find a practical solution to make sure this indemnification requirement is not a barrier to access, particularly to low and middle-income countries. This solution has to be one that can be implemented within the short time frame available before deployment of Vaccines, is equitable to all stakeholders and mitigates the anticipated financial risks to AMC countries. The COVAX Facility is developing a system to provide compensation to those individuals in any of the 92 economies to be supported by Gavi, the Vaccine Alliance (Gavi) under the COVAX Advance Market Commitment (the "AMC Group")[1] that suffer unexpected SAEs associated with such Vaccines or their administration. In addition, recognizing that countries and territories will be required to indemnify the manufacturer, the COVAX Facility is exploring backstopping guarantees for these indemnification obligations for the 92 participants in the AMC Group .

It is critical to note that COVAX will not compromise on safety and efficacy of COVID-19 Vaccines supplied through the COVAX Facility, and will, in addition to all the rigorous processes that will be followed by COVAX, rely on regulatory authorities to ensure that is the case.

Against the background provided above, this document provides an overview of how the COVAX Facility will address potential liability and compensation to Vaccine recipients in the event they suffer unexpected serious adverse events, arising from the manufacture, storage, transportation and administration of Vaccines for countries in the AMC Group.[2]

INDEMNIFICATION

In light of the fact that normal liability insurance coverage will not be available to manufacturers from the outset, each country receiving COVID-19 Vaccines through the COVAX Facility, whether distributed under an emergency use authorization or recently licensed will be required to indemnify manufacturers, donors, distributors, and other stakeholders (the "Indemnified Entities") against any losses they incur from the deployment and use of those Vaccines (as was the case at the time of the H1N1 pandemic) .[3] That is, each country participating in the COVAX Facility will be required to pay any legal awards in that regard against the Indemnified Entities. This will apply regardless of whether the country is a high or upper-middle income country supplied with Vaccines through the COVAX Facility, or a country in the AMC Group.

COMPENSATION

In order to promote that people receiving Vaccines allocated and distributed under the COVAX Advance Market Commitment and that suffer unexpected SAEs associated with such a Vaccine or its administration can receive compensation, a no-fault compensation mechanism will be established whereby any person receiving a Vaccine in any of the 92 countries in the AMC Group, who suffers an unexpected SAE found to be associated with such Vaccine will receive a no-fault, lump-sum compensation for that event in full and final settlement of any claims. The level of compensation will be (i) established based on the nature and severity of the harm or injury and adjusted in accordance with the GDP per capita of the country where the unexpected SAE occurs, and (ii) designed to disincentivize claims in court to the greatest extent possible. Payment will be from a fund (or a combination of a fund and insurance) established by a per dose levy on the Vaccines distributed to the AMC countries and territories, possible contributions from the manufacturers that would benefit from the indemnification, and possible small contributions from AMC countries that would benefit from the compensation mechanism, as well as possible other financing options if needed.

The compensation mechanism would not preclude persons suffering harm or injury from bringing a case under their local laws. For example, if they are not satisfied with the compensation provided through the no-fault mechanism, they may decline that compensation and seek a remedy through the local courts. The compensation mechanism, however, will be designed to significantly reduce instances where such cases are brought. It is intended that claims resolved through the no-fault, lump-sum compensation will be in full and final settlement of all claims for the unexpected SAE in question and will thus not require any indemnification by countries.

BACKSTOPPING GUARANTEES

For those cases where: (a) claimants bring a successful claim under local law (which -as noted above- are expected to be limited if a no-fault compensation mechanism is in place) and (b) the AMC country is not able or willing to pay the award made by the court, the COVAX Facility is exploring arrangements through which a third party would initially pay the award made by the court on behalf of the country. It is contemplated that the third party would then have the right to seek reimbursement of that payment directly from the country. For example, the COVAX Facility is in discussions with MIGA (The Multilateral Investment Guarantee Agency) to establish a vehicle to pay indemnification obligations on behalf of an AMC country or territory as required and separately work out a way for the MIGA payment to be reimbursed to them.

SCOPE OF COVERAGE END POINT AND EXTENDED REPORTING PERIOD FOR CLAIMS

The compensation mechanism will operate to provide no-fault, lump sum compensation for unexpected SAEs found to be associated with a vaccine administered prior to the point at which it is deemed by the COVAX Facility that either adequate insurance is available to the manufacturer in the market, or the manufacturer can self-insure, but in any event no later than 30 June 2022, which date may be extended by the COVAX Facility based on periodic reviews (the "Scope of Coverage End Point").

For a Vaccine administered after the Scope of Coverage End Point for that Vaccine, coverage for unexpected SAEs under the compensation mechanism will no longer apply. In addition, for a Vaccine put into circulation after the Scope of Coverage End Point for that Vaccine, there will no longer be an indemnification requirement, and the manufacturer in question will either need to obtain the necessary liability insurance or self-insure against injuries which may be found to be caused by the Vaccine.

With respect to claims for a Vaccine administered prior to the Scope of Coverage End Point for that Vaccine, the compensation mechanism will allow a period of time immediately following the Scope of Coverage End Point for claims to be made and notified to the compensation mechanism (the "Extended Reporting Period").

1 The AMC-eligible economies are listed here: https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_V5.pdf.

2 High and upper-middle income economies are considered to have the financial means to provide adequate compensation to individuals who sustain unexpected SAEs and to adequately indemnify manufacturers and other stakeholders.

3 Economies will not be required to provide indemnification for losses that result from e.g. the wilful misconduct, or gross negligence of the Indemnified Entities or for losses that result from a defect in the Vaccine which occurred because of the manufacturer's failure to comply with the terms of the marketing authorization or emergency use authorization, as applicable, and/or cGMP requirements, and/or failure of the manufacturers to properly store, handle and/or transport the Vaccines.