DEFINITIONS UNDER
THE COVAX NO-FAULT COMPENSATION PROGRAM FOR AMC ELIGIBLE ECONOMIES

(Version dated 8 December 2023)

Note: The definitions of words in singular shall apply to such words when used in the plural, and vice versa. Reference to the male pronoun throughout should be read as reference to the male or female pronoun, as the context requires.

a. **"Administrator"** – means ESIS, Inc., the claims Administrator appointed to manage and administer the Program, including, but not limited to, the receipt and registration of Applications, distributing acknowledgements of receipt of Applications, setting financial reserves for Receivable Claims, review of Applications, Supporting Evidence and other documents to assess receivability, assessing Receivable Claims, and approve or deny, as the case may be, Payment for compensation, in accordance with the terms of this Protocol.

b. **"Appeals Panel"** – a three-member panel (i) that is comprised of 2 duly licensed physicians and 1 duly licensed nurse, who shall be appointed by the Administrator from a roster of 6 such physicians and nurses and (ii) that will review all Notices of Appeal of Denied Receivable Claims filed by Claimants and determine – in accordance with the terms of this Protocol—whether the Review Panel's denial of the relevant Receivable Claim should be upheld or reversed.

c. "**Applicant**" – means, as the context requires, either:

   (i) the Patient who directly submits an Application for compensation under the Program for himself; or

   (ii) in the event the Patient has died, is a child, or is disabled or otherwise lacks the legal capacity to submit an Application for himself, then the Applicant must be a person who is a duly authorized legal heir (in the case of death), parent, legal guardian, or other legal representative of the Patient.

d. **"Application"** – a written claim for compensation completed by an Applicant on the application form approved by and provided by the Administrator, as set forth in Schedule 2 attached to this Protocol, which must be accompanied by all Supporting Evidence as defined below.

e. **"COVAX"** – the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator collaboration, convened by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi The Vaccine Alliance (Gavi), and the World Health Organization (WHO), whose aim is to accelerate the development, manufacture and equitable access to COVID-19 vaccines. The **"COVAX Facility"** is the global procurement mechanism of COVAX.

f. **"Claimant"** – any Applicant, who meets all of the following requirements:

   (i) Is a Patient (or is an individual who is duly authorized to represent such a Patient, in the event the Patient has died, is a child, or is disabled or otherwise lacks the legal capacity to submit an Application for himself); and

   (ii) Is or is duly authorized to represent a Patient who has sustained an Injury which, in the opinion of a Registered Health Professional, is deemed to have resulted from a Vaccine or its administration; and

(iii) the Vaccine was administered before its Scope of Coverage Endpoint (as indicated in Schedule 1); and

(iv) Has submitted an Application for compensation, using the prescribed form in Schedule 2, together with all Supporting Evidence, using the prescribed form in Schedule 3 to the Administrator, following the procedures described in this Protocol, and provided that this Application is submitted: (a) in full observance of the waiting period of 30 days referred to in Section 1(c) of the Program's Protocol and in Schedules 2 and 3; (b) before the end of the Reporting Period; and (c) otherwise within the time limits set forth in Section 4, ; and

(v) Either (A) has not received any prior payment from any other source, including, but not limited to, awards from any courts or arbitral tribunals, settlements and payments from any other vaccine injury compensation program, as compensation for the Injury, or (B) if any such prior payment has been received, discloses to the Administrator the nature, amount and full details of such payment; and

(vi) Either (A) is not eligible to receive any payment from any other vaccine injury compensation program as compensation for the Injury, or (B) if eligible to receive such payment, discloses to the Administrator the nature and full extent of such eligibility; and

(vii) Has no pending legal proceedings, demands or claims for compensation for the Injury, including no pending claims for the Injury before any other vaccine injury compensation program; and

(viii) Agrees not to initiate any legal proceedings or make any demands or claims for any other compensation for the Injury, including any claims for the Injury before any other vaccine injury compensation program, for as long as the Application and/or Receivable Claim, as applicable, is pending with the Program; and

(ix) Is not and does not represent a Patient in respect of whom the Administrator is by any applicable sanctions regime, including any UN Security Council sanctions regime, precluded from accepting an Application and/or paying compensation under the Program.

g. **"Hospital"** – means a public or private institution which: (1) is licensed or otherwise formally recognized as a hospital, clinic or other healthcare facility by the Government of the AMC Eligible Economy where it is located; (2) provides 24-hour medical, surgical and/or nursing care or treatment under the supervision of licensed physicians, surgeons, nurses and/or other healthcare professionals; and (3) has the capacity to provide room and board to patients resident overnight.

h. **"Hospitalization"** means the admission of the Patient to a Hospital for more than 24 consecutive hours of resident overnight medical, surgical and/or nursing care.

i. **"Impairment"** – means a significant deviation, loss, or loss of use of any body structure or body function in an individual with a health condition, disorder or disease.

The evaluation of an Impairment as provided in this Protocol 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 (as defined in this Protocol).

j. **"Injury"** – serious bodily injury or illness suffered or sustained by a Patient that:

(i) results in permanent total or partial Impairment; or

(ii) 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

(iii) results in death.

An Injury may (but shall not necessarily) have required Hospitalization or prolongation of an existing Hospitalization. In accordance with Section 9 of the Protocol, in the event of such a Hospitalization or prolongation of an existing Hospitalization, and where a Payment for death or Impairment is approved, a daily in-Hospital benefit of $100.00 per day will be paid for each day of Hospitalization or prolongation of existing Hospitalization, not to exceed a maximum payment period of 60 days.

k. **"Most Probable Cause"** – the most likely cause (based on the balance of probabilities) that a Vaccine or its administration resulted in a claimed Injury.

l. **"Notary Official"** – a notary public or other public official legally authorized to provide notarization and/or legalization services within the AMC Eligible Economy in which the Patient, or Applicant or Claimant, as the case may be, resides, or in which the Vaccine was administered to the Patient or in the case of birth defects, to the Patient's mother.

m. **"Notice of Appeal of Denied Receivable Claim"** - an appeal filed by a Claimant, following the denial of his Receivable Claim by the Review Panel, in accordance with the procedure described in Section 8 of this Protocol and using the form in Schedule 5.

n. "**Notice of Appeal of Rejected Application (denial of receivability)**" – an appeal filed by an Applicant, following the denial of receivability of his Application by the Administrator, in accordance with the procedure described in Section 7 of this Protocol and using the form in Schedule 4.

o. **"Patient"** means an individual: (i) who is a citizen, resident, or person within the populations of concern to the COVAX Humanitarian Buffer, as defined and updated from time to time by the Inter-Agency Standing Committee (IASC)[1] in an AMC Eligible Economy; (ii) who was administered a Vaccine in an AMC Eligible Economy; and (iii) who claims or in respect of whom it is claimed that he has suffered or sustained a Serious Adverse Event which is associated with a Vaccine or its administration, and which, in turn, has resulted in an Injury.

p. **"Payment"** – the no-fault, lump-sum payment which in respect of a Receivable Claim (i) has been approved by the Review Panel or the Appeals Panel, as applicable, (ii) is calculated utilising the mechanism detailed in Section 9 of the Program's Protocol, and (iii) is to be paid (subject to and in accordance with the conditions set forth in this Protocol and its Schedules) to a Claimant in full and final settlement and compensation of all claims arising from or relating to the Injury.

[1] The definition of populations of concern to the COVAX Humanitarian Buffer as at 8 June 2021 can be found at: Frequently Asked Questions: The COVAX Humanitarian Buffer | IASC (interagencystandingcommittee.org).

q. "**Payment Method Election Form**" – the written form to be provided by the Administrator, in which the Claimant will elect the means through which the Claimant will receive the Payment, out of the list of possible Payment means set forth in Section 9(e) of this Protocol.

r. **"Receivable Claim"**– any duly completed Application for compensation (i) that is accompanied by all Supporting Evidence, (ii) that is filed/submitted by an Applicant prior to the end of the Reporting Period with the Administrator, and (iii) that is found by the Administrator and/or by the Administrator's Vice President of Risk Consulting to be receivable as provided in Section 4 or Section 7 of the Program's Protocol.

s. **"Registered Health Professional"** or **"Registered Healthcare Professional"** means any healthcare professional, including physicians, surgeons, nurses, midwives, nurse practitioners, physicians' assistants, psychiatrists, psychiatrists, physical therapists, occupational therapists, dentists and pharmacists, who is duly licensed or legally authorized to practice the profession in the AMC Eligible Economy in which the Patient resides and received the Vaccine, or in the case of birth defects, where the Patient's mother resides and received the Vaccine.

t. **"Reporting Period"** means, on a per Vaccine basis, the period during which an Applicant may file an Application for compensation under this Program in respect of such Vaccine. The **maximum** Reporting Period for each Vaccine extends from:

(a) the date on which such Vaccine was first put into circulation by the manufacturer (whether within or outside the framework of the COVAX Facility), following regulatory approval or an emergency use authorization of such Vaccine by any regulator (as indicated in Schedule 1)[2]; and

(b) **terminates** on the date which is **36 to 24 calendar months** immediately after the Scope of Coverage Endpoint for such Vaccine (as indicated in Schedule 1), provided always that the Vaccine was administered **before** this Vaccine's Scope of Coverage Endpoint (as defined in Section 2w and indicated in Schedule 1). See the illustrative diagram of the Reporting Period attached to this Protocol as Schedule 6.

For each Patient, the Reporting Period depends on the date the Vaccine was administered to the Patient. To calculate the Reporting Period that applies to the Patient, the Patient (or a person who is a duly authorized to represent the Patient as provided in Section 2c above) needs to:

1. Determine (through Schedule 1) what is the date of the Scope of Coverage End Point that applies to the Vaccine that was administered to Patient; and
2. Calculate the number of months and days from the vaccination date (i.e. date that the Vaccine was administered to the Patient) until the date of the Vaccine's Scope of Coverage End Point, and:
   (i) if the Vaccine was administered to the Patient before 30 June 2024, add another 36 months to establish the Reporting Period that applies to the Patient; **or**

[2] For the purposes of the Program, the date on which a Vaccine was first put into circulation by the manufacturer (whether within or outside the framework of the COVAX Facility), following regulatory approval or an emergency use authorization of such Vaccine by any regulator, means the date on which this Vaccine (whether received within or outside the framework of the COVAX Facility) was first administered to any individual in any country of the world, following regulatory approval or an emergency use authorization of such Vaccine by the regulatory authority in that country.

(ii) if the Vaccine was administered to the Patient between 30 June 2024 and 30 June 2025, the Reporting Period that applies to the Patient ends on 30 June 2027.

As provided in Section 1 (i) of the Program's Protocol, the Program's application process will come to an end on 30 June 2027. This means that the Reporting Period for any Patient can in no event extend beyond 30 June 2027, and the Administrator will not accept any Applications for compensation after this date.

u. **"Review Panel"** – a panel appointed by the Administrator comprised of 5 duly licensed nurses, selected from a roster of 11 such nurses, who will review all Receivable Claims submitted by Claimants and determine – in accordance with the terms of this Protocol – whether Payment for compensation should be approved or denied.

v. **"Scientific Advisory Committee"** – an advisory panel of experts appointed by the Administrator, comprised of at least 3 duly qualified public health experts with relevant expertise and experience (which experts may include licensed physicians, epidemiologists and/or statisticians) that will conduct a review of the evolving literature on COVID-19 Vaccine safety and will provide the Administrator, Review Panel and Appeals Panel with updated information on the safety of the Vaccines and with 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.

w. **"Scope of Coverage Endpoint"** or **"Scope of Coverage End Point"** means, for each Vaccine, the date which is 24 months following the date on which a Vaccine was first put into circulation by the manufacturer in any country (whether within or outside the framework of the COVAX Facility) following regulatory approval or an emergency use authorization of such Vaccine by any regulator. Such date is indicated on Schedule 1.

x. **"Serious Adverse Event"** means a serious untoward medical occurrence that (i) is sustained or suffered by a Patient following the administration of a Vaccine, and (ii) results in an Injury, as defined in this Protocol.

y. **"Supporting Evidence"** means the supporting evidence, using the form in Schedule 3, that is required to evaluate an Application and that shall include:

(i) Detailed medical documentation from a Registered Healthcare Professional describing the Injury and medical treatment required as a result of the Injury, together with details of any Hospitalization or prolonged Hospitalization, including but not limited to admission and discharge records.

(ii) A description of the nature, extent, functional impact and prognosis of the Injury, as assessed by the Registered Healthcare Professional.

(iii) A statement from the Registered Healthcare Professional that the Injury was, in the Registered Healthcare Professional's opinion, the result of the Vaccine or its administration.

(iv) Certification from a Registered Healthcare Professional of when, where and which Vaccine was administered.

(v) In the case of death, a death certificate and any other documentation available from a Registered Healthcare Professional of the cause and manner of death.

(vi) Any further evidence that the Administrator may deem necessary to adjudicate the Application and/or Receivable Claim, as applicable, guided, as appropriate, by the Scientific Advisory Committee, the Review Panel and/or the Appeals Panel.

z. **"Vaccine"** – a COVID-19 vaccine that:

(i) has been received in any AMC Eligible Economy through the COVAX Facility (COVID-19 vaccines received through the COVAX Facility are COVID-19 vaccines that either (A) have received a WHO Emergency Use (EUL) recommendation or prequalification (if applicable), following authorization from a functional or stringent national regulatory authority of reference for vaccines, or under exceptional circumstances (B) have received either a standard or a conditional marketing authorization, or emergency use authorization, from a stringent regulatory authority of reference for vaccines); and

(ii) is included in Schedule 1, as updated from time to time, and has been earmarked for delivery through the COVAX Facility to the relevant AMC Eligible Economy, or to a Humanitarian Agency for use in the relevant AMC Eligible Economy, up to and inclusive of 30 June 2023; and

(iii) has received all required approvals and authorizations for importation, distribution and use in the relevant AMC Eligible Economy; and

(iv) has not reached its Scope of Coverage Endpoint.

For the purpose of this Protocol, a Vaccine is considered *"earmarked for delivery through the COVAX Facility to an AMC Eligible Economy, or to a Humanitarian Agency for use in the relevant AMC Eligible Economy"* once, in the context of the COVAX Facility, either a purchase order issued for such Vaccine has been accepted, or a donation agreement in respect of such Vaccine is in place, whichever occurs first.

For the avoidance of doubt, Vaccine doses which have been redeployed by an AMC Eligible Economy or another country to an AMC Eligible Economy without the explicit agreement of the COVAX Facility shall not be considered as falling within the present definition of "Vaccine". Applications from Applicants having received such doses shall not therefore be deemed to constitute a Receivable Claim.

* * * * *