

**PROTOCOL FOR
COVAX NO-FAULT COMPENSATION PROGRAM FOR AMC ELIGIBLE
ECONOMIES**

(Version dated 8 December 2023)

1. Purpose and Scope; No Fees; General Information about the Program’s Forms

- (a) Purpose of the Program: The purpose of the COVAX No-Fault Lump-Sum Compensation Program for AMC Eligible Economies as detailed in this Protocol and its Schedules (the “**Program**”) is to provide a mechanism to compensate those persons who suffer a Serious Adverse Event following the administration of a COVID-19 Vaccine which has been received through the COVAX Facility within any of the GAVI AMC Eligible Economies¹.
- (b) Scope of the Program: For clarity, the Program will not provide compensation for any **non-Serious** Adverse Events. Any such **non-Serious** Adverse Events are outside the scope of the Program. In addition, the Program will not provide compensation for any serious or non-serious adverse events arising from any COVID-19 vaccine which has not been received through the COVAX Facility or has been administered in any country, territory or economy which is not an AMC Eligible Economy. Furthermore, in the event a government of any AMC Eligible Economy authorizes, recommends or permits the use of a Vaccine in a manner other than in accordance with that Vaccine’s label (as approved by the functional or stringent regulatory authority of reference, as applicable), then Serious Adverse Events arising from such use of the Vaccine shall only be eligible for compensation under the Program (subject to and in accordance with this Protocol), if and to the extent such use of the Vaccine complies with the recommendations of the WHO Strategic Advisory Group of Experts on Immunization (SAGE) and WHO guidance relating to the implementation of such recommendations.
- (c) Waiting Period: A waiting period of 30 days following the administration of the Vaccine dose that is deemed to have resulted in the Injury to the Patient (or, in the case of birth defects, to the Patient’s mother) must be observed, before any steps towards initiating an Application for compensation under this Program can be taken (see Schedules 2 and 3 attached to this Protocol for more information). This waiting period does not apply in case the Patient has died following the administration of a Vaccine dose and the death is considered by a Registered Healthcare Professional to have been caused by this Vaccine or its administration.
- (d) Funds for Compensation Payments and Capacity of the Administrator: Payments for compensation as provided in this Protocol will be made from financial reserves established out of a fund specifically created for this purpose, based on a per dose levy charged on each Vaccine procured or made available through the COVAX Facility for use in AMC

¹ “**AMC Eligible Economies**” are the Advance Market commitment (AMC) eligible economies that can be found here: https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_V5.pdf

Eligible Economies. When the aforesaid financial reserves are no longer, or may no longer be, sufficient to make any further compensation payments beyond those already projected, then: (i) no further Applications will be accepted by the Administrator; (ii) the review of all or part of submitted Applications for receivability under the Program will be suspended or closed (on the basis of first come, first served); and (iii) the Program will be suspended or closed. When relevant, a notice to that effect will be posted by the Administrator on the dedicated Program web portal at www.covaxclaims.com and the Administrator will notify affected Applicants thereof in writing.

The Administrator has the capacity to review up to twenty-five thousand (25'000) Applications and Receivable Claims within any consecutive thirty day period. In the unlikely event that during any thirty day period, the number of Applications and Receivable Claims under the Program exceeds 25'000, the Administrator may (without prejudice to the first paragraph of this [Section 1 \(d\)](#) and without prejudice to [Section 1 \(i\)](#) below) temporarily suspend the intake of any new Applications until such time as the Administrator is again able to process new Applications within the limits of the Administrator's capacity and in the chronological order in which they were received. The purpose of this temporary suspension is to ensure that the Administrator is able to review Applications and Receivable Claims with the least possible disruption to the needs of the Program. When relevant, a notice to that effect will be posted by the Administrator on the dedicated Program web portal at www.covaxclaims.com and the Administrator will notify affected Applicants thereof in writing.

- (e) **No Fees:** There is no fee for any individual to file an Application for compensation under the Program. Similarly, there is no fee for any Applicant to file an appeal of a rejected Application (deemed not receivable) or for any Claimant to file an appeal of a denied Receivable Claim under the Program.
- (f) **Program Forms; Accepted Languages:** The Program forms contained in [Schedules 2, 3, 4 and 5](#) and accompanying instructions on how to complete and submit them are made available by the Administrator in downloadable format in the English, French and Spanish languages on the Program's website at www.covaxclaims.com. The Application form ([Schedule 2](#)), the Supporting Evidence form ([Schedule 3](#)), the Notice of Appeal of Rejected Application ([Schedule 4](#)), the Notice of Appeal of Denied Receivable Claim ([Schedule 5](#)), the Release Agreement described in [Section 11](#) below and the Payment Method Election Form described in [Section 2g](#) below must be completed and submitted to the Administrator in either English, French or Spanish, in order to be accepted and considered by the Administrator under the Program. Any forms completed and submitted in other languages will be rejected.
- (g) **Global Telephone Hotline:** A global telephone hotline has been established by the Administrator to assist Applicants who have questions about the Program, an Application or any of the Program forms. The telephone number for the Global Telephone Hotline may be toll-free or at-cost to the Applicant, depending on which AMC Eligible Economy the Applicant is calling from. Applicants should verify whether or not any calling charges apply

before calling the Global Telephone Hotline. The telephone number for the Program's Global Telephone Hotline (including a list of the AMC Eligible Economies for which this Global Telephone Hotline is toll-free), as well as the direct (at-cost) telephone numbers for the Program's Regional Centers, can be found on the Program's website at www.covaxclaims.com. The telephone numbers for the Program's Global Telephone Hotline and for the Program's Regional Centers can also be found in the "How to Submit an Application" instructions that will be made available by the Administrator to Ministries of Health in the AMC Eligible Economies and, in so far as the COVAX Facility humanitarian buffer is concerned, to the organizations responsible for distributing and/or administering the doses in this humanitarian buffer to beneficiaries in AMC Eligible Economies.

- (h) Means of Submitting the Program's Forms: The means through which the Program's forms can and must be submitted to the Administrator are described on the Program's website at www.covaxclaims.com and in the above mentioned "How to Submit an Application" instructions. If Schedules 2, 3, 4 and/or 5 are submitted to the Administrator via email or other allowable electronic means (e.g. the Program's web portal), then the Administrator and the Program shall be entitled to rely on the signatures and certifications appearing on such electronically submitted forms as if the original signature/certification had been received. The Release Agreement described in Section 11 below and the Payment Method Election Form described in Section 2g below cannot be submitted to the Administrator via email or other electronic means, and must be submitted to the Administrator via registered mail only.
- (i) End of the Program's application process: The Program's application process will come to an end on 30 June 2027. Notwithstanding any provision to the contrary in the present Protocol, including any of its Schedules, and/or in other documents issued or information provided by the Administrator in connection with the Program, and without prejudice to Section 1 (d) above, **no Applications will be accepted by the Administrator after 30 June 2027.**

2. Definitions

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 this Protocol 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) above 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 details 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 below, 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)² 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 below, 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.
- 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.

² 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 \(interagencystandingcommittee.org\)](https://interagencystandingcommittee.org).

- 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 below.

- s. **“Registered Health Professional”** or **“Registered Healthcare Professional”** means any healthcare professional, including physicians, surgeons, nurses, midwives, nurse practitioners, physicians’ assistants, 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)³; 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 the 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:

³ 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.

- (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**
- (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) above, 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.

3. Procedure for Filing an Application

- (a) An Applicant seeking a Payment under the Program and who considers that he meets all the requirements set forth in Section 2(f) above must submit a duly completed Application and

all Supporting Evidence required pursuant to this Protocol, using the Application form and the Supporting Evidence form, as contained in Schedule 2 and Schedule 3, respectively.

- (b) The Application and all Supporting Evidence must be submitted by the Applicant to the Administrator before the end of the Reporting Period.

4. Review of Applications for Receivability

- (a) The Administrator shall review each Application within 7 days of its receipt to confirm whether: (i) the Applicant meets all the requirements of a Claimant, as set forth in Section 2(f) above, (ii) the Application is complete and accompanied by the required Supporting Evidence, (iii) the Application has been filed by the Applicant with the Administrator before the end of the Reporting Period, and (iv) the Application thus constitutes a Receivable Claim.
- (b) Applications that are incomplete, or are filed by Applicant who does not meet the requirements of a Claimant as set forth in Section 2(f) above, or are filed after the end of the Reporting Period, shall be returned by the Administrator to the Applicant, together with an indication of the additional documents required or the reasons why the Applicant's Application is not a Receivable Claim, as the case may be. In the case of incomplete Applications, the Applicant shall be provided with a period of 90 days from the date of the Administrator's notification, to submit any missing documentation to the Administrator.
- (c) All Applications that are found by the Administrator to be Receivable Claims shall be accepted and submitted by the Administrator to the Review Panel as soon as possible after the Application has been deemed to be a Receivable Claim and no later than 7 days thereafter.
- (d) All Applications that are found by the Administrator not to be Receivable Claims shall be rejected.
- (e) The Administrator will promptly send written notice to the Applicant of whether such Application: (i) has been accepted as a Receivable Claim, or (ii) has been rejected because it does not constitute a Receivable Claim. If the Application has been rejected because it does not constitute a Receivable Claim, the Administrator's notice to the Applicant shall include the grounds therefor and a notification of the Applicant's right to appeal this decision pursuant to Section 7 below, together with a copy of the Notice of Appeal of Rejected Application form (Schedule 4). The Administrator shall send the aforementioned notice as soon as possible, but not later than 7 days after the Administrator has determined whether or not the relevant Application constitutes a Receivable Claim.
- (f) An Applicant who has submitted an Application that has been rejected because it does not constitute a Receivable Claim may appeal such decision, subject to and in accordance with the procedure and deadlines set forth in Section 7 below.

5. Requests for further information and documentation

- (a) At any time during the process of evaluation of an Application or Receivable Claim (as applicable), the Administrator, taking into consideration any safety information and/or expert scientific advice that may have been previously provided by the Scientific Advisory Committee and/or a determination by the Review Panel or Appeals Panel, as the case may be, has the right to ask for further information and/or documentation from either the Applicant, Claimant, the Registered Healthcare Professional(s) providing medical and/or other evidence, and/or from any other relevant persons and/or bodies. By making the Application, the Applicant provides the Administrator consent to contact those aforementioned Registered Healthcare Professional(s), persons and/or bodies for the purposes of the determination of the Application and/or Receivable Claim, as applicable.
- (b) Any information and/or documentation so requested pursuant to Section 5(a) above shall be provided in writing to the Administrator within 90 days from the date of the Administrator's written request to the Applicant, Claimant, the Registered Healthcare Professional and/or the other relevant persons/bodies, as applicable. Pending the receipt of such additional information and/or documentation, the process shall be suspended in respect of the determination of the Application by the Administrator, or of the Receivable Claim by the Review Panel or the Appeals Panel, as applicable.

6. Determination of Receivable Claims – Review Panel

- (a) The Administrator shall submit each Receivable Claim, together with the Supporting Evidence and any further information and/or documentation which the Administrator may have requested, to the Review Panel as soon as possible after the corresponding Application has been deemed to be a Receivable Claim in accordance with the terms of Section 4 or Section 7 of this Protocol, but no later than 7 days thereafter.
- (b) The Review Panel shall make its determination within 30 days after a Receivable Claim, the Supporting Evidence and all additional information or documentation, if requested by the Administrator and/or the Review Panel, has been submitted to it.
- (c) In reviewing and evaluating Receivable Claims, the Review Panel will take into consideration any safety information and/or expert scientific advice that may have been previously provided by the Scientific Advisory Committee; and where appropriate, shall request the Scientific Advisory Committee to provide it with advisory opinions.
- (d) Pre-existing conditions and Injuries that have been found not to have resulted from the Vaccine or its administration, using the Most Probable Cause standard, are excluded from compensation under the terms of this Program. In addition, in the event a Vaccine has been used in a manner other than in accordance with that Vaccine's label (as approved by the functional or stringent regulatory authority of reference, as applicable), then Serious Adverse Events arising from such use of the Vaccine shall only be eligible for compensation under the Program (subject to and in accordance with this Protocol), if and to the extent

such use of the Vaccine complies with the recommendations of the WHO Strategic Advisory Group of Experts on Immunization (SAGE) and WHO guidance relating to the implementation of such recommendations.

- (e) Injury shall be assessed by the Review Panel in accordance with the following general principles:
 - (i) The Vaccine or its administration was the Most Probable Cause of the claimed Injury; and
 - (ii) The claimed Injury was not present prior to the administration of the Vaccine.
- (f) The Review Panel shall communicate its determination to approve or deny a Receivable Claim (including the grounds for such determination) in writing to the Administrator as soon as possible after the determination has been made, but not later than 7 days thereafter.
- (g) The Administrator shall notify the Claimant in writing of the Review Panel's determination as soon as possible, but not later than 7 days after receipt of the determination from the Review Panel. If the Receivable Claim was denied by the Review Panel, the notification shall include the grounds for the determination and notification of the Claimant's right to appeal pursuant to the terms of Section 8 below, together with a copy of the Notice of Appeal of Denied Receivable Claim form (Schedule 5).
- (h) A Claimant whose Receivable Claim has been denied by the Review Panel may appeal such decision, subject to and in accordance with the procedure and deadlines set forth in Section 8 below.

7. Appeals to Rejected Applications (deemed not receivable)

- (a) Any Applicant whose Application has been rejected by the Administrator on the grounds that such Application does not constitute a Receivable Claim has the right to file an appeal of the rejection by following the procedure described in this Section 7. For the avoidance of doubt, this Section 7 does not apply to appeals to denied Receivable Claims, for which the procedure under Section 8 below shall exclusively apply.
- (b) In order to commence an appeal under this Section 7, the Applicant must complete, sign and submit to the Administrator a written Notice of Appeal of Rejected Application, using the form set forth in Schedule 4, which form will be provided to the Applicant by the Administrator with the Application rejection notification. The Notice of Appeal of Rejected Application must be filed with the Administrator within 90 days from the date of the Administrator's Application rejection notification.
- (c) Bearing in mind that pursuant to Section 4(b) above, in the case of incomplete Applications, the Applicant shall be provided with a period of 90 days to submit any missing documentation to the Administrator, the Applicant who submits a Notice of Appeal of Rejected Application shall not be permitted to provide any further documents in connection with the appeal. Only the Application and the Supporting Evidence which was submitted to

the Administrator as of the date of the Application rejection notification shall be considered for purposes of the appeal of Rejected Application under this Section 7, and no other documentation.

- (d) The Administrator shall submit all Notices of Appeal of Rejected Application, together with the original Application and Supporting Evidence, to the Administrator's Vice President of Risk Consulting as soon as possible after receipt, but no later than 7 days thereafter.
- (e) The Administrator's Vice President of Risk Consulting shall make his determination to uphold or reverse a prior rejection of an Application, within 30 days after the Notice of Appeal of Rejected Application, together with the original Application and Supporting Evidence, has been submitted to him.
- (f) The Administrator's Vice President of Risk Consulting shall communicate his determination to uphold or reverse a prior rejection of an Application (including the grounds for such determination) in writing to the Administrator as soon as possible after the determination has been made, but not later than 7 days thereafter.
- (g) All decisions of Administrator's Vice President of Risk Consulting pursuant to this Section 7 shall be final and cannot be appealed by any Applicant.
- (h) The Administrator shall send the Applicant written notice of the determination whether to uphold or reverse a prior rejection of an Application, including the grounds thereof, as soon as possible after the Administrator's Vice President of Risk Consulting has submitted this determination to the Administrator, but no later than 14 days thereafter.

8. Appeals to Denied Receivable Claims

- (a) Any Claimant whose Receivable Claim has been denied by the Review Panel has the right to file an appeal of the denial by following the procedure described in this Section 8. For the avoidance of doubt, this section does not apply to appeals to Rejected Applications, for which the procedure under Section 7 above shall exclusively apply.
- (b) In order to commence an appeal of a denied Receivable Claim under this Section 8, the Claimant must complete, sign and submit to the Administrator a written Notice of Appeal of Denied Receivable Claim, using the form set forth in Schedule 5, which form will be provided to the Claimant by the Administrator with the claim denial notification. The Notice of Appeal of Denied Receivable Claim must be filed with the Administrator within 90 days from the date of the Administrator's claim denial notification.
- (c) At the time of filing a Notice of Appeal of Denied Receivable Claim, the Claimant must also provide any further documents he wishes to submit in support of the appeal.

- (d) The Administrator shall submit all Notices of Appeal of Denied Receivable Claims and all accompanying documentation, as well as the original Application and Supporting Evidence, to the Appeals Panel as soon as possible after receipt but no later than 7 days thereafter.
- (e) The Appeals Panel shall make its determination of whether or not the denial of the Receivable Claim in question should be upheld or reversed, within 30 days after the Notice of Appeal of Denied Receivable Claim, the accompanying documentation submitted by the Claimant and any additional information or documentation that may have been requested by the Review Panel, has been submitted to the Appeals Panel. In making its determinations, the Appeals Panel shall take into consideration any safety information and/or expert scientific advice that may have been previously provided by the Scientific Advisory Committee and, where appropriate, request the Scientific Advisory Committee to provide it with advisory opinions.
- (f) The Appeals Panel shall communicate its determination to uphold or reverse a prior denial of a Receivable Claim (including the grounds for such determination) in writing to the Administrator as soon as possible after the determination has been made, but not later than 7 days thereafter.
- (g) The Appeals Panel may reverse a prior denial of a Receivable Claim if:
 - (i) There has been a material change in circumstances since the determination to deny the Receivable Claim was made; and/or
 - (ii) The Review Panel's determination was made without knowledge of relevant facts; and/or
 - (iii) The Review Panel failed to properly consider relevant medical evidence; or
 - (iv) The Review Panel failed to properly apply the Most Probable Cause standard.
- (h) All decisions of the Appeals Panel shall be final and cannot be appealed by any Claimant.
- (i) The Administrator shall send the Claimant with written notice of the Appeals Panel's determination of whether to uphold or reverse a prior denial of a Receivable Claim, including the grounds thereof, as soon as possible after the Appeals Panel has submitted the determination to the Administrator, but no later than 14 days thereafter.

9. Payments

- (a) In the event that a Payment is approved either by the Review Panel or the Appeals Panel then, subject to Section 9(b) below, the sum to be paid shall be calculated by the Administrator with reference to the following methodology:

GDP per capita of the Relevant AMC Eligible Economy x 12 x the harm factor resulting from the Vaccine or its administration 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, if any, not to exceed a maximum payment period of 60 days.

Where:

- (i) The GDP per capita of the relevant AMC Eligible Economy is as per the most recently published World Bank threshold as at the time of the Payment is approved; and
 - (ii) The harm factors resulting from the Vaccine or its administration are:
 - a. 1.0 if death
 - b. 1.5 if the Impairment is equal to or greater than 75%
 - c. 1.0 if the Impairment is equal to or greater than 50% but below 75%
 - d. 0.5 if the Impairment is equal to or greater than 25% but below 50%
 - e. 0.25 if the Impairment is equal to or greater than 10% but below 25%
 - f. 0.10 if the Impairment is below 10%
 - g. 1.5 if congenital injury or illness causing Impairment is equal to or greater than 75%
 - h. 1.0 if congenital injury or illness causing Impairment is equal to or greater than 50% but below 75%
 - i. 0.5 if congenital injury or illness causing Impairment is equal to or greater than 25% but below 50%
 - j. 0.25 if congenital injury or illness causing Impairment is equal to or greater than 10% but below 25%
 - k. 0.10 if congenital injury or illness causing Impairment is below 10%
- (b) Notwithstanding the provisions of Section 9(a) above or any other provision of this Protocol, in the event that: (1) a Payment is approved for the Claimant, and (2) the Claimant has received any prior payment from any other vaccine injury compensation program(s) as similar compensation for the same Injury, then the following provisions will apply:
- (i) the Administrator shall have the right to deduct the Other Prior Compensation Amount (as defined below) from the Program Amount (as defined below). As used in this section, the following terms have the following meanings:
 - 1. **“Other Prior Compensation Amount”** means an amount (stated in United States Dollars at the then applicable currency exchange rate) equal to the amount of all prior payment(s) which the Claimant received from any other vaccine injury compensation program(s) as similar compensation for the same Injury, *except however* for any payment(s) for the reimbursement of hospital and/or other medical expenses (which reimbursement shall be deemed by the Administrator *not* to be included in the Other Prior Compensation Amount); and
 - 2. **“Program Amount”** means the amount calculated pursuant to the formula in Section 9(a) above.

- (ii) in the event the Administrator exercises the right described in Section 9(b)(i) above, the Claimant shall—subject to the terms of Sections 9(c) to 9(h) below—only be entitled to receive from the Program a Payment in an amount equal to the Program Amount *minus* the Other Prior Compensation Amount; it being understood that if the Other Prior Compensation Amount exceed the Program Amount, then no Payment shall be due under the Program.
- (c) The Administrator’s written notice of determination approving the Payment shall be accompanied by (i) the Release Agreement described in Section 11 below, which must be signed by the Claimant as a precondition to receiving the Payment, (ii) the Payment Method Election Form described in Section 2g above, and (iii) if applicable, an indication showing how the Payment amount was calculated in accordance with Section 9(b) above.
- (d) Within 90 days from the date of the Administrator’s written notice of determination approving the Payment, the Claimant shall return to the Administrator: (i) the Release Agreement, duly signed and dated and duly certified by Notary Official, and (ii) the Payment Method Election Form, duly completed and signed. Upon receipt of the Payment Method Election Form and the duly signed, dated and certified Release Agreement, the Administrator shall proceed to make the Payment to the Claimant, within 28 days.
- (e) Subject to any restrictions imposed by applicable laws and regulations, the Administrator shall effect Payment - at the Claimant’s election - through any of the following means:
 - i. by wire transfer directly to a bank account in the name of the Claimant. If necessary, the Administrator will use reasonable endeavours to assist the Claimant in setting up such a bank account; or
 - ii. by making a wire transfer to Western Union, allowing the Claimant to retrieve cash; or
 - iii. by securely mailing a hard copy check to the Claimant, if feasible.
- (f) If and to the extent a Payment has not been collected and/or cashed by the Claimant within six (6) months after the issuance of such Payment, the Administrator shall credit the funds back to the Program in the amount of such uncollected and/or uncashed Payment.
- (g) Any Payment under the Program shall be in full and final settlement of any and all claims in respect of the Injury in question, whether known or unknown, now or in the future, which the Claimant may otherwise be entitled to bring in any jurisdiction.
- (h) There shall be only one Payment under this Program in respect of the same Injury.

10. Fraud and misrepresentation

- (a) If, whether fraudulently or otherwise, any person who falsifies or misrepresents any material information or fails to disclose any material fact and, in consequence of the falsification,

misrepresentation or failure, a Payment is made, then the person to whom the Payment was made shall be liable to repay the amount of that Payment to the Administrator.

(b) Any person who, for the purpose of obtaining any Payment under the Program, whether for himself or some other person:

1. knowingly makes any false statement or representation, or
2. produces or furnishes, or causes or knowingly allows to be produced or furnished, any document or information which he knows to be false in a material particular,

shall have committed an offence punishable to the extent the law permits within the relevant country.

(c) For purposes of this section, the term “person” includes, but is not limited to: (1) the Patient, Applicant or Claimant, as the case may be, (2) the author of any evidence in support of any Application, any Supporting Evidence and/or any Notice of Appeal hereunder, or (3) the Notary Official certifying the Release Agreement).

11. Release Agreement

It shall be a condition that, prior to any Payment being made, the Claimant shall first sign, have certified by a Notary Official, and return to the Administrator a Release Agreement which will be provided to the Claimant by the Administrator and which provides, among other things, that:

- (a) the Payment and/or the Release Agreement does not constitute, and shall not be construed, at any time and for any purpose as an admission or evidence of any fault, liability, wrongdoing or responsibility of any kind on the part of any of the following persons: (i) the manufacturer(s) of the Vaccine in question, (ii) any organization co-leading COVAX (e.g., GAVI, the World Health Organization (WHO) and/or the Coalition for Epidemic Preparedness Innovations (CEPI)); (iii) the donors of Vaccines and/or of funds to the COVAX Facility, (iv) other entities participating in the COVAX Facility including, without limitation, the Pan-American Health Organization (PAHO), the United Nations Children’s Fund (UNICEF), and all persons involved in the supply, distribution and/or administration of the Vaccine to the individual who suffered a serious adverse event that resulted in the Injury in respect of which the Payment will be paid subject to the terms of the Release Agreement; (v) the Administrator in respect of the Payment, and/or (vi) any and all subsidiaries, affiliates or successors of any of the persons mentioned in this section, and any of their respective officers, directors, employees, contractors, agents and/or representatives; and
- (b) the Claimant accepts the Payment subject to and in accordance with the terms of the Release Agreement and this Protocol, and agrees that the Payment will be: (i) in full and final consideration of the Injury in question; (ii) in full and final consideration for the Claimant’s signature of and compliance with the Release Agreement, and (iii) in full and final settlement of any and all actions, claims, demands or other proceedings of any kind against the persons mentioned in Section 11(a) above in any jurisdiction; and

- (c) the Claimant fully and finally releases the persons mentioned in Section 11(a) above from any actions, claims, demands or other proceedings of any kind in any jurisdiction in relation to the Injury in respect of which the Payment will be made to the Claimant; and
- (d) the Claimant fully and finally waives the right to seek and/or obtain compensation in respect of the Injury in question from or through any other compensation program or through any other means.

12. Failure by an Applicant or Claimant to meet deadlines set forth herein

If an Applicant or Claimant fails to meet any deadlines set forth in this Protocol or any of its Schedules, then the Administrator may deny, terminate and close the process in respect of the Applicant's Application or Claimant's Receivable Claim, as the case may be (including any pending review and/or appeal).

13. Sharing of data

The Applicant, in making any application for compensation under this Program, provides consent, insofar as such consent is necessary, for the sharing of sensitive personal data (including, for the avoidance of doubt, data relating to the Injury) between the Administrator and relevant persons and bodies, for the purposes of administering the Program, the review of the Application and Receivable Claim and any appeal, as the case may be, for the collection of data to assess the risk profiling of the Vaccines, for the prevention and detection of any criminal activity, and for any other reasonably proportionate purpose permitted by law.

14. Reference Law

Any matter relating to the interpretation and application of this Protocol and/or any of its Schedules which is not covered by their respective terms, shall be resolved by reference to English law.

15. Complaints and Settlement of disputes

- (a) All complaints and disputes arising out of or relating to the interpretation or application of this Protocol shall be submitted in writing to the Administrator. The Administrator will acknowledge the complaint and/or dispute in writing, and the Administrator's Vice President of Claims will conduct an investigation into the complaint or dispute within 30 days of receipt. Following the investigation, the Vice President of Claims will provide a written response to the Patient, Applicant or Claimant, as the case may be. If the Patient, Applicant or Claimant is dissatisfied with the decision, the Patient, Applicant or Claimant has the option to submit the matter to binding arbitration as provided hereinbelow.
- (b) Any dispute relating to the interpretation or application of this Protocol shall, unless amicably settled, be shall be settled by arbitration. The arbitration shall be conducted in accordance with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final and binding on them.

16. Amendments

- (a) This Protocol and/or any of its Schedules may be amended from time to time by the Administrator. The revised version of the Protocol and/or its Schedules, as so amended, shall be made publicly available by the Administrator on the Program's website, as soon as reasonably possible after their effective date.
- (b) Notwithstanding the foregoing, any amendments to the Protocol and/or any of its Schedules shall be without prejudice and shall not apply to any Applications which have been received by, or any Receivable Claims which are under consideration by, the Administrator prior to the effective date of such amendment.

17. Conflicts

In the event of any conflicts between the terms of the Protocol, any of its Schedules, the Release Agreement described in Section 11 above, the Payment Method Election Form described in Section 2(q) above and/or any other documents issued or information provided by the Administrator in connection with the Program, the following order of precedence shall apply (from highest to lowest precedence):

1. the Release Agreement
2. This Protocol, Schedule 1 (List of Vaccines) and Schedule 6 (Illustrative Diagram of the Reporting Period);
3. Schedules 2, 3, 4 and 5 and the Payment Method Election Form; and
4. any other documents issued or information provided by the Administrator.

18. Prevailing Language

This Protocol and its Schedules has been prepared in the English language, and shall be translated into the French and Spanish languages. In the event of any conflict or inconsistency between the English language version of this Protocol and/or any of its Schedules, on the one hand, and any translations hereof, on the other hand, then the English language version(s) shall control and prevail in all respects.

List of Schedules to this Protocol

The following Schedules are incorporated into this Protocol by this reference, and constitute an integral part hereof:

Schedule 1: List of Vaccines

Schedule 2: Application Form (incl. certifications and waiver of medical secrecy and confidentiality)

Schedule 3: Supporting Evidence

Schedule 4: Notice of Appeal of Rejected Application (deemed not receivable)

Schedule 5: Notice of Appeal of Denied Receivable Claim

Schedule 6: Illustrative Diagram of the Reporting Period

[END OF PROTOCOL]