Terms and Conditions for the Indemnity Fund for Adverse Events Following Immunization with Coronavirus Disease-2019 (COVID-19) Vaccines (AEFI Fund)

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1. Background

- 1.1 The Government has set up the Indemnity Fund for Adverse Events Following Immunization with Coronavirus Disease-2019 (COVID-19) Vaccines (AEFI Fund) to cover the indemnities offered to vaccine manufacturers under bilateral purchase agreements, and to provide financial support to eligible individuals who have proof of suffering unexpected serious adverse events (SAEs) associated with a COVID-19 vaccine administered under the Government's COVID-19 Vaccination Programme.
- 1.2 The Government has set up an Expert Committee on Clinical Events Assessment following COVID-19 Immunization (Expert Committee) to provide independent assessment of potential causal link between Adverse Events Following Immunization (AEFIs) and the COVID-19 vaccines.
- 1.3 After a report arising from an SAE falling under the AEFI and Adverse Events of Special Interest (AESI) lists is received and upon completion of causality assessment by the Expert Committee, the affected individual may be eligible for a lump-sum payment under the AEFI Fund if the below two conditions are met:
 - (a) there is certification by a Registered Medical Practitioner of the SAE; and
 - (b) the evaluation outcome of the Expert Committee cannot rule out that the event is not associated with the administration of a vaccine under the Government's COVID-19 Vaccination Programme.
 - For (a), as an additional safeguard, the affected individual may be required to undergo medical examination by public sector doctors if necessary.
- 1.4 The Government has appointed AXA Hong Kong, as the Third-Party Administrator (Administrator) to manage the application, enquiry, complaint handling as well as devise severity assessment scheme to advise the Government for the appropriate payment tier of payout from the AEFI Fund for individual SAE as set out below.

2. Defined terms

ADL (Activity of Daily Living)

ADLs means the following activities:

- dressing the ability to put on and take off clothing without assistance
- toileting the ability to use the toilet, including getting on and off without assistance
- mobility the ability to get in and out of a bed or a chair without assistance
- continence the ability to control bowel and bladder function

- feeding the ability to get food from a plate into the mouth without assistance
- bathing and showering the ability to bathe and shower without assistance

AEFI Fund Refers to the Indemnity Fund for Adverse Events Following

Immunization with Coronavirus Disease-2019 (COVID-19) Vaccines

AEFI List Refers to the List of Serious or Unexpected Adverse Events

Following Immunization of COVID-19 Vaccines endorsed by the

Expert Committee

AESI List Refers to the List of Adverse Events of Special Interest of COVID-19

Vaccines endorsed by the Expert Committee

Age This means the age of the affected person as at the date of last

dose of COVID-19 vaccination under Government Programme (and

the expression "Aged" shall be construed accordingly)

AXA Hong Kong Refers to AXA China Region Insurance Company Limited

COVID-19 Refers to Coronavirus Disease-2019

COVID-19 vaccine Refers to COVID-19 vaccines authorized by the Secretary for

Health, under a state of public health emergency, which fulfil the criteria of safety, efficacy and quality for the purpose of vaccination programmes conducted by the Government on the advice of an advisory panel appointed by the Chief Executive in accordance with the Prevention and Control of Disease (Use of

Vaccines) Regulation (Cap. 599K)

Expert Committee Refers to the Expert Committee on Clinical Events Assessment

following COVID-19 Immunization appointed by the Director of

Health

Health Bureau Refers to the Health Bureau of the Government of Hong Kong

Special Administrative Region

Government Refers to the Government of the Hong Kong Special Administrative

Region

Hong Kong Refers to the Hong Kong Special Administrative Region of the

People's Republic of China

Registered Medical Practitioner

(RMP)

Refers to a person who is duly qualified by a degree in western medicine and is legally authorized by the government of the geographical area of his or her practice to render medical or

surgical services

Serious Adverse Event (SAE) Refers to a serious clinical situation identified under either the AEFI

list or AESI list

Administrator Refers to the contractor appointed by the Government to process

applications of the AEFI Fund

3. Eligibility of Application

An affected individual, who has proof of suffering unexpected SAE certified by a Registered Medical Practitioner (RMP) (certification of SAE) arising from any dose of the COVID-19 vaccine of any kind under the Government's COVID-19 Vaccination Programme, is eligible to apply for the AEFI Fund.

The AEFI Fund does not cover COVID-19 vaccination administered by private doctors outside the Government's COVID-19 Vaccination Programme.

- 3.2 The time limit of which an applicant can apply for the AEFI Fund is within two (2) years after the last dose of the COVID-19 vaccine under Government Programme was received.
- 3.3 For individuals who received COVID-19 vaccination both under Government Programme and in private market AND possessed certification by a RMP of the SAE, their eligibility for applying AEFI Fund will be subject to case-by-case examination of individual circumstances.

4. Application

- 4.1 An applicant for AEFI Fund could be:
 - 1. An individual who received the COVID-19 vaccine under Government Programme and possessed certification by a RMP of the SAE; or
 - A parent or legal guardian of an individual under 18 or disabled adult who
 received a COVID-19 vaccine under Government Programme and
 possessed certification by a RMP of the SAE; or
 - 3. A legal representative of the estate of a deceased person who received the COVID-19 vaccine under Government Programme and possessed certification by a RMP of the SAE.
- 4.2 Application form for the AEFI Fund (<u>Appendix 1</u>) can be obtained via one of the following methods:
 - 1. Download the application form for AEFI Fund from the following link:

https://www.axa.com.hk/en/aefi-fund

- 2. Contact hotline at 2894 4699 (service hours: Mon-Fri 09:00 17:30, except Saturday, Sunday and public holidays in Hong Kong) for obtaining the form via email or fax; or
- 3. Collect the application form at one of the Administrator's Hong Kong Service Counters
- 4.3 All applicants of the AEFI Fund are required to submit the following documents:
 - 1. Completed application form;
 - 2. Copy of Identity document including one of the followings:
 - a. Hong Kong Identity Card (HKID) or Passport;
 - b. Consular Corps Identity Card (CCIC); or
 - c. An acknowledgement of application for an identity card;
 - d. Certificate of Exemption; or
 - e. Exit-entry permit with landing slips or extension of stay labels issued by the Immigration Department
 - 3. Paper or electronic vaccination record of receiving the COVID-19 vaccine issued by the Government;
 - 4. Proof of suffering from SAE certified by a RMP (Certification of SAE). This shall include but not limited to hospital discharge summary, certification letter by attending doctor, medical certificates, etc. Sick leave certificate alone however, is not acceptable as a certification proof;
 - 5. For certification of SAE provided by RMP from the private medical sector in Hong Kong, or outside Hong Kong, a copy of the completed COVID-19 Vaccine Adverse Event Report submitted by the reporting RMP through the pharmacovigilance platform under the Drug Office of the Department of Health of Hong Kong (DH); https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html;
 - 6. For the application of death payout only:
 - Death Certificate AND
 - Grant of Letter of administration on Deceased's estate; and
 - 7. In certain circumstances, more information may be required to substantiate the application.
- 4.4 Completed application forms with all required documents can be returned to the Administrator via means as specified in <u>Appendix 4: Contact information</u>.
- 4.5 If the application is submitted on behalf of a deceased person or is filed by an individual other than the injured person or the parent of an injured minor, the application must also be accompanied by documents establishing the authority to submit the application in a representative capacity or, supplemented with a statement explaining when such documentation will be available.

- 4.6 For all applications that are completed and with all necessary documents submitted, the Administrator shall issue an acknowledge receipt to the applicant within two (2) working days from the date of receipt of the application.
- 4.7 The time limit of which an applicant can apply for the AEFI Fund is within two (2) years after the last dose of the COVID-19 vaccine under Government Programme was received. Application submitted beyond this time limit will not be processed and the Administrator shall notify the applicant within five (5) working days from the date of receipt of the application.
- 4.8 If the certification of the SAE provided by the RMP does not fulfil the requirement of the AEFI Fund, the application will be declined and the applicant will be informed of the result within five (5) working days from the date of receipt of the application.
- 4.9 If the applicant's case has not yet been submitted to the Expert Committee for assessment, the Administrator shall inform the applicant that the application cannot be proceeded. Upon confirmation from the Secretariat of the Expert Committee that no case was received, the Administrator will advise the applicant to request the attending RMP to issue certification of the SAE concerned through reporting the case in the pharmacovigilance platform under the Drug Office of DH, by which the case will be filed to the Expert Committee.

5. Enquires

- 5.1 Enquires can be made in person, by mail, by email or by post to the Administrator by means as stated in Appendix 4: Contact Information.
- 5.2 Enquiries related to coverage of AEFI Fund; its application, progress, results and decision will be answered by the Customer Service Team of the Administrator with Cantonese, Mandarin and English capability.

6. Complaint and Review

- Any complaints regarding the performance and service provided by the Administrator and review request of the AEFI Fund will be handled seriously.
- 6.2 Any complaint regarding the application process and review request regarding the decision on the AEFI Fund application and payout amount will be handled by the

Administrator. Complainant can file the complaint in writing and provide the following information:

- Name
- Hong Kong Identity Card Number, or passport number
- Application number OR copy of the application form if available
- Contact details
- Details of the allegations
- Relevant supporting documents required by the Administrator, if any
- 6.3 Upon receipt of the complaint, the Administrator will issue an acknowledgement to the complainant within 2 (two) working days and inform the complainant of the result as soon as practicable upon completion of the investigation.
- 6.4 Complaints and review request can be sent to the Administrator through the following means:
 - By Email: feedback@axa.com.hk
 - By Mail: Mail to 5/F AXA SouthSide, 38 Wong Chuk Hang Road, Wong Chuk Hang, Hong Kong
 - In person: at any of the service centers from the Administrator (as listed in Appendix 4)
 - By phone: (852) 2894 4699

7. Certification of Serious Adverse Events (SAE)

- 7.1 Evidence for certification provided by a RMP from either the public or the private medical sector in Hong Kong, or outside Hong Kong are acceptable.
- 7.2 Acceptable evidence for certification include but not limited to hospital discharge summary, certification letter by attending doctor, and medical certificates. Sick leave certificate alone however, is not acceptable as a certification proof.

8. Severity Assessment

- 8.1 It is understandable that suffering and damages perceived by an individual is subjective and cannot be quantified, hence the justification of any amount of payout is somewhat arbitrary. This said, the relativity of severity between different degrees of harm is objective. Under this backdrop, the guiding principles of severity assessment include:
 - Fairness to applicant
 - Prudent use of public funding
 - Transparent to public

- Based on medical science
- 8.2 The conditions listed in the AEFI and AESI list are classified into different categories:
 - I. Conditions not entitled for payout
 - II. Conditions with severity assessment table constructed as broad principles
 - III. Conditions that require individual assessment
- 8.3 The severity assessment will be classified into four (4) levels :
 - i. Pain and Suffering
 - ii. Long Term Damage
 - iii. Disablement
 - iv. Death
- 8.4 The assessment of disability will take reference to well-established compensation schemes within the insurance industry, such as the assessment for total and permanent disability (TPD) using limitation in activities for daily living (ADL). The broad principles on severity assessment are set out below. Severity of individual cases are subject to case-by-case assessment according to their circumstances.
- 8.5 Pain and Suffering
- 8.5.1 Pain and suffering refers to a state of which a person sustained a period of sickness with physical and /or psychological trauma.
- 8.5.2 The condition is reversible, and the applicant has recovered within a certain time frame, with no foreseeable long term sequalae.
- 8.5.3 Range of payout for eligible cases: up to 10% of corresponding maximum payout for injuries. Examples:

Facial paralysis for 7 days or more, but less than 26 weeks that recovered: up to 4% of corresponding maximum payout

Anaphylaxis requiring resuscitation with no long-term consequences: up to 10% of corresponding maximum payout

Thromboembolism for 2 weeks or more AND require medical treatment with no long-term consequences: up to 2% of corresponding maximum payout

- 8.6 Long Term Damage
- 8.6.1 Persistent damage to the body that extend beyond a certain time frame; and requires prolonged period of time of medical care and follow up.
- 8.6.2 The condition however does not affect the ability for a person to perform activities of daily living or causes disability.

8.6.3 Range of payout for eligible cases: up to 50% of corresponding maximum payout for injuries. Examples:

Facial paralysis for 26 weeks or more, with noticeable facial asymmetry, eye (corneal) damage, and /or side effects of treatment such as that of corticosteroids: up to 50% of corresponding maximum payout

Thromboembolism for 8 weeks or more, but less than 26 weeks AND require long term medical treatment: up to 20% of corresponding maximum payout

- 8.7 Disablement
- 8.7.1 A state of which a medical condition affects the ability of a person to look after oneself or impacts on his earning capacity after a defined period of time.
- 8.7.2 Applicant will be assessed by the number of ADL he failed to perform as a result of the disablement. A person who fails to perform 1 or more out of 6 ADL will be classified as partially disabled and entitled to 60% of corresponding maximum payout. A person who fails to perform 3 or more out of 6 ADL will be classified as totally disabled and entitled to 100% of corresponding maximum payout. The 6 ADL commonly used in the insurance industry for assessment is listed below:

Activities of Daily Living (ADL) Dressing – the ability to put on and take off clothing without assistance Toileting – the ability to use the toilet, including getting on and off without assistance Mobility – the ability to get in and out of a bed or a chair without assistance Continence – the ability to control bowel and bladder function Feeding – the ability to get food from a plate into the mouth without assistance Bathing and showering – the ability to bathe and shower without assistance

8.7.3 Range of payout for eligible cases: up to 100% of corresponding maximum payout for injuries. Examples:

Anaphylaxis requiring long term medical treatment for 26 weeks or more AND loss of up to 1 or more ADL / 3 or more ADL: up to 60% / 100% of corresponding maximum payout respectively

Thromboembolism for 26 weeks or more AND loss of up to 1 or more ADL / 3 or more ADL: up to 60% / 100% of corresponding maximum payout respectively

8.8 The maximum payout level for death and injuries associated with listed SAEs are as below:

Age of deceased individual (as at the date of last dose of vaccination under Government Programme)	Amount of payout (per individual)
Under 40	HKD\$2,500,000
40 or above	HKD\$2,000,000

Age of injured individual (as at the date of last dose of vaccination under Government Programme)	Maximum amount of payout (per individual)
Under 40	HKD\$3,000,000
40 or above	HKD\$2,500,000

- 8.9 It should be noted that for injuries, a severity assessment will be conducted to further classify the severity of individual event to determine the eligibility and corresponding level of payout, and therefore it is not necessary that the maximum amount of payout will be issued to the applicants.
- 8.10 The SAE eligible for severity assessment can be found in the following lists that were endorsed by the Expert Committee albeit not all SAEs in the two lists will be included for assessment. The conditions to be covered in the lists shall be subject to revision from time to time and the Administrator shall update the corresponding lists accordingly.
 - List of Serious or Unexpected Adverse Events Following Immunization of COVID-19 Vaccines (AEFI List) (<u>Appendix 2</u>)
 - List of Adverse Events of Special Interest of COVID-19 Vaccines (AESI List)
 (Appendix 3)
- 8.11 For cases where the Expert Committee cannot rule out the death was not associated with the administration of a COVID-19 vaccine under the Government's COVID-19 Vaccination Programme, the death payout will be issued. The amount of payout depends solely on the age of the deceased, as at the date of receiving the last dose of vaccination under Government Programme. These conditions include:
 - I. AEFI condition 5: Death when associated with COVID-19 vaccine adverse event
 - II. AESI condition 16 (level 4): Death during a hospitalization for COVID-19 (any cause)
 - III. AESI condition 17: Death (any causes)
 - IV. AESI condition 26: Maternal death
 - V. AESI condition 42: Sudden death

9. Special Considerations

- 9.1 In the event where the applicant had been confirmed by the Expert Committee of more than one SAE arising from COVID-19 vaccination under Government Programme, and that it is the opinion of the attending medical practitioner that the SAE had led to the occurrence of another SAE, the condition with the higher percentage calculated would be entitled for payout from the AEFI Fund. For the avoidance of doubt, a person would not be entitled to more than 100% of the maximum amount of payout for injuries associated with listed SAEs of the corresponding age category in any circumstances (i.e. in any event no more than the maximum payout for injuries for that individual as stated under paragraph 8.8).
- 9.2 In the event where the applicant had been confirmed by the Expert Committee of two or more SAEs arising from COVID-19 vaccination under Government Programme simultaneously, and that it is the opinion of the attending medical practitioner that there is no association between the conditions, then all SAEs will be entitled for payout by the AEFI Fund. For the avoidance of doubt, an applicant would not be entitled to more than 100% of the maximum amount of payout for injuries associated with listed SAEs of the corresponding age category in any circumstances (i.e. in any event no more than the maximum payout for injuries for that individual as stated under paragraph 8.8).
- 9.3 In the event where the applicant had been confirmed of one or more SAEs arising from COVID-19 vaccination under Government Programme, and who subsequently succumbed within two (2) years of vaccination of the last dose of the COVID-19 vaccine under Government Programme, then the applicant would be entitled to the death payout if this amount is more than that the injury payout the applicant received. If the injury payout has already been issued, then a top-up amount will be made to make up to the death payout. Any injury payout made exceeding death payout will not be recovered.
- 9.4 In the event where the applicant had been confirmed of one or more SAEs arising from COVID-19 vaccination under Government Programme, and who subsequently succumbed within two (2) years of vaccination of the last dose of the COVID-19 vaccine under Government Programme, then the applicant would not be entitled to the death payout if the death payout is less than the injury payout the applicant received. In other words, NO further payout for death will be issued on top of the injury payout received, yet no exceeding payout will be recovered.
- 9.5 In the event where the applicant had been confirmed of one SAE condition arising from COVID-19 vaccination under Government Programme and issued an injury payout, the applicant is still entitled to a higher payout if his / her condition deteriorates. The application however, needs to be submitted within two (2) years after the last dose of the COVID-19 vaccine under Government Programme received and subject to another severity assessment. For the avoidance of doubt, an applicant would not be entitled to more than 100% of the maximum amount of payout for injuries associated with listed

SAEs of the corresponding age category in any circumstances (i.e. in any event no more than the maximum payout for injuries for that individual as stated under paragraph 8.8).

10. Interpretation

10.1 The Health Bureau shall have the final right to determine the interpretation of the Terms and Condition for the AEFI Fund.

Appendix 1: Application Form

https://axa.com.hk/aefi-application-form

Appendix 2: List of Serious or Unexpected Adverse Events Following Immunization of COVID-19 Vaccines as of July 2021 (AEFI List)

- 1. Acute peripheral facial paralysis (Bell's Palsy)
- 2. Anaphylactoid reaction
- 3. Anaphylaxis
- 4. Any other severe and unusual events that are thought by health workers or the public to be related to immunization
- 5. Death when associated with COVID-19 vaccine adverse event
- 6. Disability when associated with COVID-19 vaccine
- 7. Encephalomyelitis
- 8. Encephalopathy
- 9. Guillain Barre Syndrome
- 10. Hospitalization when associated with COVID-19 vaccine adverse event
- 11. Myocarditis / Pericarditis
- 12. Sepsis
- 13. Septicaemia
- 14. Thrombocytopenia / Thrombosis with thrombocytopenia syndrome (TTS)
- 15. Toxic shock syndrome
- 16. Transverse myelitis

Appendix 3: List of Adverse Events of Special Interest of COVID-19 Vaccines as of April 2021 (AESI List)

- 1. (Idiopathic) Thrombocytopenia
- 2. Acute aseptic arthritis
- 3. Acute cardiovascular injury
- 4. Acute disseminated encephalomyelitis (ADEM)
- 5. Acute kidney injury
- 6. Acute liver injury
- 7. Acute pancreatitis
- 8. Acute respiratory distress syndrome
- 9. Anaphylaxis
- 10. Anosmia, ageusia
- 11. Arrhythmia
- 12. Bell's Palsy (Acute peripheral facial paralysis)
- 13. Chilblain like lesions
- 14. Coagulation disorders
- 15. Coronary artery disease
- 16. COVID-19 disease (by levels of severity)
 - Level 1: Hospitalization for COVID-19 (confirmed or suspected),
 - Level 2: ICU admission in those with COVID-19 related admission;
 - Level 3: Acute respiratory distress requiring ventilation (ARDS) during a hospitalization for COVID-19;
 - Level 4: Death during a hospitalization for COVID-19 (any cause)
- 17. Death (any causes)
- 18. Erythema multiforme
- 19. Fetal growth restriction
- 20. Generalized convulsion
- 21. Gestational Diabetes
- 22. Guillain-Barré Syndrome
- 23. Haemorrhagic disease

- 24. Heart failure
- 25. Major congenital anomalies
- 26. Maternal death
- 27. Meningoencephalitis
- 28. Microangiopathy
- 29. Microcephaly
- 30. Multisystem inflammatory syndrome in children
- 31. Myocarditis
- 32. Narcolepsy
- 33. Neonatal death
- 34. Preeclampsia
- 35. Preterm birth
- 36. Rhabdomyolysis
- 37. Single Organ Cutaneous Vasculitis
- 38. Spontaneous abortions
- 39. Stillbirth
- 40. Stress cardiomyopathy
- 41. Subacute thyroiditis
- 42. Sudden death
- 43. Termination of Pregnancy for Fetal Anomaly
- 44. Thromboembolism
- 45. Transverse myelitis
- 46. Type 1 Diabetes

Appendix 4: Contact information

Contact information of AXA Hong Kong, the Administrator for the AEFI Fund

By phone:

Hotline number:

- 2894 4699
- Monday to Friday 09:00 -17:30 except Saturday, Sunday and public holidays in Hong Kong.

In-Person:

Visit our Service Counters at

- Times Square: Suites 2001, 20/F, Tower Two, Times Square, 1 Matheson Street, Causeway Bay, Hong Kong
- China Hong Kong City: Unit 1715-19A, 17/F, Tower 3, China Hong Kong City, 33 Canton Road, Tsim Sha Tsui, Kowloon
- AXA Tower: Room 4202, 42/F, AXA Tower, 100 How Ming Street, Kwun Tong, Kowloon

Service Hours:

 Monday to Friday 09:00 – 17:30, Saturday 09:00 – 13:00, except Sunday and public holidays in Hong Kong.

By mail:

 Mail to 5/F AXA SouthSide, 38 Wong Chuk Hang Road, Wong Chuk Hang, Hong Kong

By Fax:

• Fax to 3009 4608

By Email:

• Email to fund administrator@axa.com.hk

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