# **AFRICA**

Covid-19 Vaccine No Fault Compensation Schemes



This report examines the provision of No-Fault Compensation Schemes for injuries following Covid-19 vaccination across Africa.

These findings are part of a wider project looking at global No-Fault Compensation Scheme carried out at the Centre for Socio-Legal Studies, University of Oxford.

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https://www.law.ox.ac.uk/home-no-fault-compensation-schemes-covid-19-vaccines

# Covid-19 Vaccine NFCSs in Africa

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# Introduction

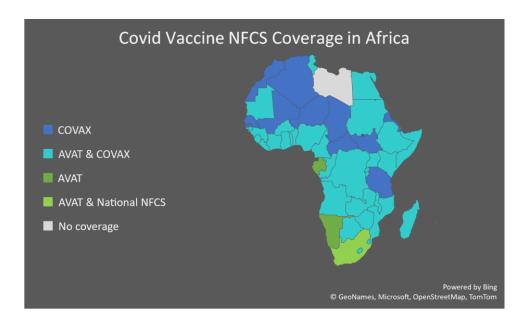
We have identified 29 national schemes that were offering no-fault vaccine compensation at the start of the pandemic in January 2020. Since then the number of jurisdictions with a no-fault compensation scheme which covers Covid-19 vaccines has increased almost five-fold. This is a rapid proliferation in NFCS which this project will research. The first stage of our research was to map NFCS landscape. This is one of a <u>series of reports</u> looking at global Covid-19 Vaccine No-Fault Compensation Schemes.

Africa is the second most populous continent after Asia with a population estimated at 1.4 billion. Of the 54 African countries recognised by the UN only three countries (Equatorial Guinea, Libya and the Seychelles) do not have some form of Covid Vaccine NFCS.

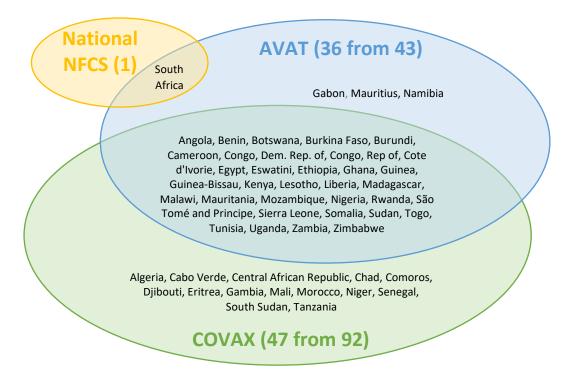
# Coverage of NFCSs

# Geographical Coverage

The map below shows the distribution of the different NFCSs.



The only country with a national NFCS for Covid Vaccine Compensation is South Africa. The coverage for the vast majority of the continent is due to the multinational schemes. The diagram below illustrates which NFCSs each country participates in.



#### Vaccines covered

The fact that a jurisdiction has a NFCS in place does not mean that all vaccinations given in that jurisdiction are covered. There are a number of restrictions in all of the NFCSs. Full details can be found in the AVAT, COVAX and South Africa sections below.

#### Summary

At a first glance the NFCS coverage in Africa looks impressive. However, the fact that a jurisdiction has some NFCS provision in place does not mean that there is coverage associated with every vaccination given in that country. Potential claimants will need to establish whether their vaccine was delivered under a program with an associated NFCS. The percentage of vaccines delivered under the AVAT and COVAX programs is likely to vary between different jurisdictions, so there is no simple way to quantify the overall level of NFCS cover across Africa.

We have summarised our findings from the publicly available information on NFCS. There may be additional options for some vaccine recipients which we have not summarised. We are not party to the bilateral supply agreements between nations and manufacturers, and therefore we do not know what provision, if any, they contain for compensation for vaccine adverse events.

# Detailed findings by Country

Detailed findings for each jurisdiction that has NFCS coverage can be found below.

# Algeria

Algeria is a member of the COVAX NFCS.

# Angola

Angola is a member of the AVAT NFCS and the COVAX NFCS.

# Benin

Benin is a member of the AVAT NFCS and the COVAX NFCS.

#### Botswana

Botswana is a member of the AVAT NFCS and the COVAX NFCS.

# Burkina Faso

Burkina Faso is a member of the AVAT NFCS and the COVAX NFCS.

#### Burundi

Burundi is a member of the AVAT NFCS and the COVAX NFCS.

# Cabo Verde

Cabo Verde is a member of the COVAX NFCS.

# Cameroon

Cameroon is a member of the AVAT NFCS and the COVAX NFCS.

# Central African Republic

Central African Republic is a member of the COVAX NFCS.

#### Chad

Chad is a member of the COVAX NFCS.

#### Comoros

Comoros is a member of the COVAX NFCS.

# Congo, Republic of.

The Republic of the Congo is a member of the AVAT NFCS and the COVAX NFCS.

#### Cote d'Ivoire

Cote d'Ivoire is a member of the AVAT NFCS and the COVAX NFCS.

# Democratic Republic of the Congo.

The Democratic Republic of the Congo is a member of the AVAT NFCS and the COVAX NFCS.

# Djibouti

Djibouti is a member of the COVAX NFCS.

# Egypt

Egypt is a member of the AVAT NFCS and the COVAX NFCS.

# Eswatini

Eswatini is a member of the AVAT NFCS and the COVAX NFCS.

# Ethiopia

Ethiopia is a member of the AVAT NFCS and the COVAX NFCS.

# Gabon

Gabon is a member of the AVAT NFCS.

# Gambia

Gambia is a member of the COVAX NFCS.

# Ghana

Ghana is a member of the AVAT NFCS and the COVAX NFCS.

#### Guinea

The Guinea is a member of the AVAT NFCS and the COVAX NFCS.

# Guinea-Bissau

Guinea-Bissau is a member of the AVAT NFCS and the COVAX NFCS.

# Kenya

Kenya is a member of the AVAT NFCS and the COVAX NFCS.

#### Lesotho

Lesotho is a member of the AVAT NFCS and the COVAX NFCS.

#### Liberia

Liberia is a member of the AVAT NFCS and the COVAX NFCS.

# Madagascar

Madagascar is a member of the AVAT NFCS and the COVAX NFCS.

# Malawi

Malawi is a member of the AVAT NFCS and the COVAX NFCS.

# Mali

Mali is a member of the COVAX NFCS.

#### Mauritania

Mauritania is a member of the AVAT NFCS and the COVAX NFCS.

# Mauritius

Mauritius is a member of the AVAT NFCS.

#### Morocco

Morocco is a member of the COVAX NFCS.

# Mozambique

Mozambique is a member of the AVAT NFCS and the COVAX NFCS.

#### Namibia

Namibia is a member of the AVAT NFCS.

# Niger

Niger is a member of the COVAX NFCS.

# Nigeria

Nigeria is a member of the AVAT NFCS and the COVAX NFCS.

#### Rwanda

Rwanda is a member of the AVAT NFCS and the COVAX NFCS.

# Sao Tome & Principe

Sao Tome & Principe is a member of the AVAT NFCS and the COVAX NFCS.

# Senegal

Senegal is a member of the COVAX NFCS.

#### Sierra Leone

Sierra Leone is a member of the AVAT NFCS and the COVAX NFCS.

#### Somalia

Somalia is a member of the AVAT NFCS and the COVAX NFCS.

# South Africa

South Africa has a national NFCS and is a member of the AVAT NFCS.

#### Introduction

South Africa introduced a no-fault compensation scheme for COVID-19 vaccines in 2021 through the National Department of Health Regulations No. 376 of 22 April 2021.

In addition to the 2021 Regulations, Directions on the establishment of a COVID-19 vaccine injury no-fault compensation scheme have been published in 2022 (see the <u>National Department of Health Directions 1987 of 4 April 2022</u>).

This scheme was created under national legislation, and its statutory basis is the <u>Disaster</u> Management Act 2002 (Act no. 57 of 2002).

The scheme is administered by the National Department of Health – see Regulations no. 376/2021, 90(1) and Directions no. 1987/2021, 3.1.

The funding for the scheme comes from Central Government and Donations – see Regulations no. 376/2021, 91(1):

'The funds of the Scheme consist of -

- (a) funds appropriated by an Act of Parliament to the vote of Health or from contingencies in terms of appropriation legislation or the Public Finance Management Act; and
- (b) funds donated to the Scheme.'

#### Vaccines Covered

The vaccines covered by this NFCS are those COVID-19 vaccines specified in Schedule 1 to the Directions no. 1987/2021, which are procured and distributed by the National Government (see Directions no. 1987/2021, 1.4).

Schedule 1 to the Directions lists as covered vaccines ('applicable vaccines' in the Schedule) the following COVID-19 vaccines approved by the South African Health Products Regulatory Authority (SAHPRA):

- Comirnaty and Pfizer-BioNTech COVID-19 vaccine;
- Johnson & Johnson's Janssen COVID-19 vaccine (JNJ-78436735)

that were donated to the National Department of Health, obtained by the Government of South Africa in terms of the COVAX facility, or which were procured by the Government of the Republic of South Africa through the National Department of Health in terms of specified previous agreements with Pfizer and Janssen Pharmaceutica (see Schedule 1, Directions no. 1987/2022).

To be covered by the NFCS, vaccines should be procured and distributed by the Government (see Directions no. 1987/2022, 1.4).

They should also have been administered at facilities in the Republic where COVID-19 vaccines are officially administered (Regulations no. 376/2021, 93(4)(c)).

#### Injuries Covered

Under this NFCS only eligible injuries are covered. Eligible injuries are 'severe injuries' resulting in permanent or significant injury, serious harm to a person's health, other serious damage or death as specified in directions issued in terms of subregulation (4)(a) – Regulations no. 376/2021, 93(3).

See also Directions no. 1987/2022, 8:-

'Vaccine injuries covered are injuries resulting in:

- Permanent physical or mental impairment
- Temporary physical or mental impairment
- Death.'

Disablement threshold: 5% for permanent impairment, 25% for temporary impairment (1 month minimum, up to a maximum of 6 months) - see Directions no. 1987/2022, Schedule 6.

A person may claim for both temporary and permanent disability where applicable.

# Charges for making a claim

It is not specified whether there is a charge for making a claim under this scheme.

#### Claimants

Under this scheme the following categories of individuals are permitted to make a claim:

- 'A person who has suffered harm, loss or damage caused by a vaccine injury ...'
- '...A dependant of a deceased person, who has suffered harm, loss or damage caused by the death of the deceased person whose death was caused by a vaccine injury ...'

See Regulations no. 376/2021, 93(1) and (2) and also Directions 1987/2022, 6.

Under this scheme the claimant is allowed to nominate a legal representative to make their claim (see Directions 1987/2022, 14.3.2). There is no specific funding for legal representation, however the Directions state that the Scheme Administrator should support claimants if they decide to formally lodge a claim (see Directions 1987/2022, Schedule 3).

# Losses covered

This scheme pays the following:

Live vaccine recipient	Dependents of vaccine	Estate of a deceased
	recipient	vaccine recipient
Compensation payments are	Compensation payments are	No Compensation is
for general categories and are not broken down into economic and non-economic losses.	for general categories and are not broken down into economic and non-economic losses.	specifically provided to the estate of the vaccine recipient.

Dependants are eligible for compensation only in the event the vaccinee is deceased.

Payments consist of a mixture of periodic payments and/or a lump sum payment.

A Death Benefit of R150,000 is available under this NFCS. This is to be divided between all dependants identified by the Adjudication Panel or the Appeals Panel within two months of the final determination of the claim.

Compensation under this scheme is calculated on an individual basis using tariffs/guidelines to assist with quantification. The quantum of compensation in the event of permanent disability is calculated by multiplying the Death Benefit amount by the specific harm factor depending on the severity of the disability.

The following harm factors are specified in Schedule 6 of the Directions:-

Harm Factor	Impairment following vaccination
0	No compensation will be paid if the impairment is below 5%
0.13	Impairment equal to or greater than 5% but below 10%
0.26	Impairment equal to or greater than 10% but below 20%
0.44	Impairment equal to or greater than 20% but below 30%
0.61	Impairment equal to or greater than 30% but below 40%
0.79	Impairment equal to or greater than 40% but below 50%
0.96	Impairment equal to or greater than 50% but below 60%
1.14	Impairment equal to or greater than 60% but below 70%
1.31	Impairment equal to or greater than 70% but below 80%
1.49	Impairment equal to or greater than 80% but below 90%
1.75	Impairment equal to or greater than 90%

In the event of temporary vaccine injury (in excess of 25% impairment), there is a temporary disability benefit of R5000 per month of disability up to a maximum of 6 months, with a minimum claim of one month. In order to be eligible for this benefit, a claimant should not be receiving a benefit for the same injury under <a href="COIDA">COIDA</a>.

A person may claim for both temporary and permanent disability where applicable.

# Time limits for claims

The scheme does not set a time limit between vaccination and the adverse event occurring.

According to the Directions 1987/2022, 11, the following time limits apply:

 An adverse event following immunisation (AEFI) must be reported to the National Immunisation Safety Expert Committee (NISEC) within 30 days of the onset of the AEFI. NISEC is a non-statutory, standing advisory committee of independent experts appointed by the Minister of Health (see Directions, 1.17). Note that reporting an AEFI is **not a claim for compensation**, but a prerequisite for an investigation into causality which may result in a claim (see Directions, Schedule 3);

 A claim for compensation must be filed within 30 days after the claimant or duly authorised person has been informed, in writing, of the outcome of the NISEC causality assessment by the NFCS Administrator.

Claims cannot be filed for vaccinations administered before 17 May 2021 or procured under the terms of an agreement entered into after 5 April 2022 – see Directions, 10.1 and 10.2.

The NFCS will not cease to operate or cease to be of force and effect merely because the State of National Disaster comes to an end (See Regulations, 101, on the duration and termination of the Scheme).

#### Evaluating claims – standard of proof required

NISEC must make an initial recommendation as to whether the claimant's reported vaccine injury meets the requirements of being causally linked to the applicable vaccine (Directions, 13.1.1).

When NISEC makes a determination of causality between a covered vaccine and an injury, it must inform the Department of Health, and the Department must then notify the Scheme Administrator within 28 days of the NISEC determination.

The Scheme Administrator must inform the eligible person, or the dependant, or parent or legal guardian in the case of a child, of the NISEC determination and assist with the lodging of a compensation claim. (Directions, 14.1 and 14.2).

The assessment on causality is made by NISEC (Directions, 14.5.3). To determine causality, NISEC shall apply the <u>WHO Methodology for Causality Assessment of AEFI</u> as may be published from time to time by the WHO (Directions, 14.5.4). The assessment on eligibility and quantum is made by the Adjudication Panel (see Directions, 15).

#### Appeals and the right to litigate

Court litigation and NFCS are mutually exclusive - see Regulations 376/2021, 96(1).

There is an internal review process to review the NFCS's decisions - see Regulations 376/2021, 100 and Directions 1987/2022, 16.

#### Useful information and links

It is not known whether the scheme produces an annual report including data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc).

Links to legislation:

https://www.gov.za/documents/disaster-management-act (Disaster Management Act 2002)

https://www.gov.za/sites/default/files/gcis\_document/202204/46196gon1987.pdf (Directions no. 1987 of 4 April 2022)

https://www.gov.za/sites/default/files/gcis document/202104/44485gon376.pdf (Regulations no. 376 of 22 April 2021)

#### South Sudan

South Sudan is a member of the COVAX NFCS.

#### Sudan

Sudan is a member of the AVAT NFCS and the COVAX NFCS.

#### Tanzania

Tanzania is a member of the COVAX NFCS.

# Togo

Togo is a member of the AVAT NFCS and the COVAX NFCS.

# Tunisia

Tunisia is a member of the AVAT NFCS and the COVAX NFCS.

# Uganda

Uganda is a member of the AVAT NFCS and the COVAX NFCS.

#### Zambia

Zambia is a member of the AVAT NFCS and the COVAX NFCS.

#### Zimbabwe

Zimbabwe is a member of the AVAT NFCS and the COVAX NFCS.

# Multinational Covid-19 NFCS

#### **AVAT**

#### Introduction

AVAT NFCS is a multi-jurisdiction compensation scheme for COVID-19 vaccine injuries received in any of the participating African Union (<u>AU</u>) or <u>CARICOM</u> States from vaccines deliver through the African Vaccine Acquisition Trust (AVAT) framework.

#### **AVAT Countries:**

**AU States** - Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Congo, Cote d'Ivoire, Dem. Rep. of Congo (DRC), Egypt, Eswatini, Ethiopia, Gabon, Ghana. Guinea, The Republic of, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mauritania, Mauritius, Mozambique, Namibia, Nigeria, Rwanda, São Tomé & Principe, Sierra Leone, South Africa, Sudan, Togo, Tunisia, Uganda, Zambia, Zimbabwe

**CARICOM States** - Antigua & Barbuda, Bahamas, Belize, Guyana, Jamaica, St Kitts & Nevis, Trinidad & Tobago

This scheme is a non-statutory scheme, governed by a Program Protocol.

It is administered by ESIS, Inc., who are a private body (private provider of managed claim services).

The funding for the scheme comes from financial reserves established out of an ad hoc fund based on a per dose levy charged on each covered vaccine procured or made available through the AVAT Facility for use in participating member States.

#### Vaccines Covered

This NFCS covers COVID-19 vaccines received in any Participating Member State through AVAT framework that:-

- i. 'either (A) has licensure or authorization from a stringent ("functional") regulatory authority or (B) has received WHO prequalification, following licensure or authorization from a stringent ("functional") regulatory authority, or (C) has been issued authorization for emergency use based on licensure or authorization by a stringent ("functional") regulatory authority; and
- ii. is included in Schedule 1, as updated from time to time; and
- iii. has received all required approvals and authorizations for importation, distribution and use in the relevant Participating Member State; and
- iv. has not reached its Scope of Coverage Endpoint.

As at February 2023 Schedule 1 includes just one vaccine, the Janssen Pharmaceutica NV vaccine.

For the Scope of Coverage endpoint see the Time Limits section below.

#### **Injuries Covered**

This NFCS only covers permanent injuries.

Under this NFCS only eligible injuries are covered. Eligible injuries are serious bodily injuries or illness that require hospitalisation and result in permanent total or partial impairment; or congenital birth injury resulting in permanent total or partial impairment; or injuries/illness resulting in death.

# Charges for making a claim

There is no charge for making a claim under this scheme.

#### Claimants

Under this scheme the following categories of individuals are permitted to make a claim.

- Vaccine recipients (see the definition of Claimant in the Program Protocol)
- an individual who is duly authorized to represent the vaccine recipient, in the event the vaccine recipient is a child, or is disabled or otherwise lacks the legal capacity to submit an Application for himself
- a duly authorised legal heir if the vaccine recipient has died

The Patient needs to have sustained an Injury which, 'in the opinion of a Registered Health Professional, is deemed to have resulted from a Vaccine or its administration'.

Under this scheme the claimant is allowed to nominate a legal representative to make their claim.

It is not known whether funding for legal representation is provided by the scheme.

#### Losses covered

This scheme pays the following

Live vaccine recipient	Dependants of vaccine recipient	Legal heir of a deceased vaccine recipient
Compensation payments are for general categories and are not broken down into economic and non-economic losses.	No compensation is provided specifically for Dependants	Compensation payments are for general categories and are not broken down into economic and non-economic losses.

Payments consist of a lump sum payment

It is not specified in the Program Protocol whether Funeral expenses are available under this NFCS.

Compensation under this scheme calculated on an individual basis using tariffs/guidelines to assist with quantification.

The amount that can be paid under this NFCS depends on the GDP per capita of the relevant country and the specific harm factor linked to the injury suffered by the vaccinee (GDP per capita of relevant country x 12 x harm factor) (see <a href="Program Protocol">Program Protocol</a> 9.a).

The following harm factors are specified in the protocol:-

Harm	Impairment following vaccination
Factor	
1.0	Death

1.5	Impairment equal to or greater than 75%
1.0	Impairment equal to or greater than 50% but below 75%
0.5	Impairment equal to or greater than 25% but below 50%
0.25	Impairment equal to or greater than 10% but below 25%
0.1	Impairment below 10%
1.5	Congenital injury/illness causing Impairment equal to or greater than 75%
1.0	Congenital injury/illness causing Impairment equal to or greater than 50% but below 75%
0.5	Congenital injury/illness causing Impairment equal to or greater than 25% but below 50%
0.25	Congenital injury/illness causing Impairment equal to or greater than 10% but below 25%
0.1	Congenital injury/illness causing Impairment below 10%

Hospital payments of \$100/day can also be awarded for a maximum of 60 days.

#### Time limits for claims

The scheme does not set a time limit between vaccination and the adverse event occurring. There is a minimum of 30 days between vaccination and making a claim, but no waiting time if the vaccinee is deceased.

**Vaccine Administration**. To be eligible for compensation the vaccine must have been administered before the 'Scope of Coverage Endpoint'. The 'Scope of Coverage Endpoint' is listed in Schedule 1 for each Vaccine; it is the date which is 36 months after the date on which a Vaccine was first put into circulation by the manufacturer within the AVAT Framework.

**Reporting a Claim.** To be eligible under the scheme a claim must also be brought within the 'Reporting Period' for that vaccine. The Reporting Period starts from the date on which the vaccine was first put into circulation by the manufacturer and terminates 36 calendar months after the 'Scope of Coverage Endpoint' listed in Schedule 1.

Schedule 7 Provides a schematic of the time limits for making a claim.

#### Evaluating claims – standard of proof required

The standard of proof required by the scheme is the 'most probable cause': the most likely cause (based on the balance of probabilities) that a vaccine or its administration resulted in a claimed Injury.

Claims are reviewed by a review panel of at least 5 nurses. Their work is informed by a Scientific Advisory Committee. This is an expert panel who review the evolving literature and provide the Administrator, Review Panel and Appeals Panel with advice to guide the claims determination process, 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.

# Appeals and the right to litigate

Use of the scheme and litigation are mutually exclusive and a claimant must choose which one they take. By making a claim under the NFCS a claimant agrees not to make any other claim for compensation for the injury while their application is pending with the NFCS.

In the Protocol under the definition of 'claimant' it states that claimant may not use this NFCS if they have a pending lawsuit or if they have received any prior payment from any other source, including, court awards, settlements and insurance payments, as compensation for the Injury. If a claimant is eligible for compensation for the injury from other source(s) they are required to disclose the nature and extent of their eligibility.

There is an internal appeals process where the NFCS itself reviews the decision. A claimant can file a Notice of Appeal and the claim is then examined by a three-person Appeals Panel consisting of 2 doctors and a nurse who determine whether the denial of the claim should be upheld or reversed.

#### Useful information and links

It is not known whether the scheme produces an annual report including data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc).

Links to the scheme website etc:

**African Union** 

**CARICOM** 

Home - AVAT No-Fault Compensation Scheme (avatclaims.com)

AVAT-Compensation-Program-Protocol.pdf

AVAT-Compensation-Program-Vaccine-List.pdf (avatclaims.com)

AVAT-Compensation-Program-Ilustrative-Diagram-of-the-Reporting-Period.pdf (avatclaims.com)

# COVAX – COVAX No-Fault Compensation Program for AMC Eligible Economies Introduction

COVAX is a multi-jurisdiction compensation scheme for COVID-19 vaccine injuries received through the COVAX Facility in the 92 low- and middle-income AMC Eligible Economies.

COVAX Countries: Afghanistan, Algeria, Angola, Bangladesh, Benin, Bhutan, Bolivia, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroon, Central African Republic, Chad, Comoros, Congo Dem. Rep, Congo Rep., Côte d'Ivoire, Djibouti, Dominica, Egypt, El Salvador, Eritrea, Eswatini, Ethiopia, Fiji, Gambia, Ghana, Grenada, Guinea, The, Guinea-Bissau, Guyana, Haiti, Honduras, India, Indonesia, Kenya, Kiribati, Korea, Dem, People's Rep, Kosovo, Kyrgyz Republic, Lao DPR, Lesotho, Liberia, Madagascar, Malawi, Maldive Islands, Mali, Marshall Islands, Mauritania, Micronesia, Federated States of, Moldova, Mongolia, Morocco, Mozambique, Myanmar, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papau New Guinea, Philippines, Rwanda, Samoa, São Tomé & Principe, Senegal, Sierra Leone, Soloman Islands, Somalia, South Sudan, Sri Lanka, St Lucia, St Vincent & the Grenadines, Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Timor-Leste, Togo, Tongo, Tunisia, Tuvalu, Uganda, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank & Gaza, Yemen Rep., Zambia, Zimbabwe

This scheme is a non-statutory scheme, governed by a Program Protocol.

It is administered by ESIS, Inc., who are a private body (private provider of managed claim services).

The funding for the scheme comes from financial reserves established out of an ad-hoc fund based on a per dose levy charged on each covered vaccine procured or made available through the COVAX Facility for use in AMC Eligible Economies.

#### Vaccines Covered

This NFCS covers COVID-19 vaccines procured through COVAX facility to AMC eligible economies.

These 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)' (see <a href="Program Protocol">Protocol</a>, 2.z.i).

The covered vaccines also have to be included in Schedule 1 to the Program Protocol and have 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' (2.z.ii), have 'received all required approvals and authorizations for importation, distribution and use in the relevant AMC Eligible Economy' (2.z.iii) and have not reached its 'Scope of Coverage Endpoint' (2.z.iv), see 'Time Limits' section below).

#### **Injuries Covered**

This NFCS only covers permanent injuries.

Under this NFCS only eligible injuries are covered. Eligible injuries are serious bodily injuries or illness resulting in permanent total or partial impairment, congenital birth injury resulting in permanent total or partial impairment, or injuries/illness resulting in death.

#### Charges for making a claim

There is no charge for making a claim under this scheme.

#### Claimants

Under this scheme the following categories of individuals are permitted to make a claim:

- Vaccine recipients ('Patient', see Program Protocol 2.f.i and 2.o):
- Individuals who are duly authorized to represent the vaccine recipient if the vaccine recipient has died, is a child or otherwise lacks legal capacity (see 2.f.i).

The 'Patient' needs to have sustained an injury that 'in the opinion of a Registered Health Professional is deemed to have resulted from a Vaccine or its administration' (2.f.ii).

Under this scheme the claimant is allowed to nominate a legal representative to make their claim.

It is not known whether funding for legal representation is provided by the scheme.

#### Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of a vaccine recipient	Legal heir(s) of a deceased vaccine recipient
Compensation payments are for	No Compensation is	Compensation payments are for
general categories and are not	provided specifically	general categories and are not
broken down into economic and	for Dependants	broken down into economic and
non-economic losses.		non-economic losses.

Payments consist of a lump sum payment.

It is not specified in the Program Protocol whether funeral expenses are available under this NFCS.

Compensation under this scheme calculated on an individual basis using tariffs/guidelines to assist with quantification.

The amount that can be paid under this NFCS depends on the GDP per capita of the relevant country and the specific harm factor linked to the injury suffered by the vaccinee (GDP per capita of relevant country x 12 x harm factor) (see PP 9.a). Hospital payments of \$100/day can also be awarded for a maximum of 60 days.

The following harm factors are specified in the Protocol:-

Harm	Impairment following vaccination
Factor	
1.0	Death
1.5	Impairment equal to or greater than 75%
1.0	Impairment equal to or greater than 50% but below 75%
0.5	Impairment equal to or greater than 25% but below 50%
0.25	Impairment equal to or greater than 10% but below 25%
0.1	Impairment below 10%
1.5	Congenital injury/illness causing Impairment equal to or greater than 75%
1.0	Congenital injury/illness causing Impairment equal to or greater than 50% but
	below 75%
0.5	Congenital injury/illness causing Impairment equal to or greater than 25% but
	below 50%
0.25	Congenital injury/illness causing Impairment equal to or greater than 10% but
	below 25%
0.1	Congenital injury/illness causing Impairment below 10%

Hospital payments of \$100/day can also be awarded for a maximum of 60 days.

#### Time limits for claims

The scheme does not set a time limit between vaccination and the adverse event occurring. There is a minimum of 30 days between vaccination and making a claim, but no waiting time if the vaccinee is deceased.

**Vaccine Administration.** To be eligible for compensation the vaccine must have been administered before the 'Scope of Coverage Endpoint'. The 'Scope of Coverage Endpoint' means, for each covered vaccine, the date which is 24 months following the date on which the vaccine was first put into circulation by the manufacturer in any country.

**Reporting a Claim.** To be eligible under the scheme a claim must also be brought within the 'Reporting Period' for that vaccine. The Reporting Period starts from the date on which the vaccine was first put into circulation by the manufacturer and terminates 36 to 24 calendar months after the 'Scope of Coverage Endpoint' for the vaccine considered (see COVAX Program Protocol, 2t and 2w, and also Schedule 1).

<u>Schedule 6</u> provides a schematic of the time limits for making a claim.

The Reporting Period for any Patient can in no event extend beyond 30 June 2027.

#### Evaluating claims – standard of proof required

The standard of proof required by the scheme is the 'most probable cause': the most likely cause (based on the balance of probabilities) that a vaccine or its administration resulted in a claimed Injury.

#### Appeals and the right to litigate

Use of the scheme and litigation are mutually exclusive, and a claimant must choose which one they take.

There is an internal appeals process where the NFCS itself reviews the decision.

#### Useful information and links

It is not known whether the scheme produces an annual report including data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc).

Link to NFCS website: <a href="mailto:covaxclaims.com">covaxclaims.com</a>

Program Protocol Link: <a href="https://covaxclaims.com/program-protocol/">https://covaxclaims.com/program-protocol/</a>

Schedule 1 (List of vaccines): <a href="https://covaxclaims.com/wp-content/uploads/2021/03/COVAX-Compensation-Program-Vaccine-List.pdf">https://covaxclaims.com/wp-content/uploads/2021/03/COVAX-Compensation-Program-Vaccine-List.pdf</a>

Schedule 6 (Reporting Period illustrative diagram): <a href="https://covaxclaims.com/wp-content/uploads/2021/03/COVAX-Compensation-Program-Illustrative-Diagram-of-the-Reporting-Period.pdf">https://covaxclaims.com/wp-content/uploads/2021/03/COVAX-Compensation-Program-Illustrative-Diagram-of-the-Reporting-Period.pdf</a>

AMC Eligible Economies list available here: COVAX CA COIP List COVAX PR V5.pdf (gavi.org)

