Americas

Covid-19 Vaccine No Fault Compensation Schemes



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

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 the Americas

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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 the NFCS landscape. This is one of a <u>series of reports</u> looking at global Covid-19 Vaccine No-Fault Compensation Schemes.

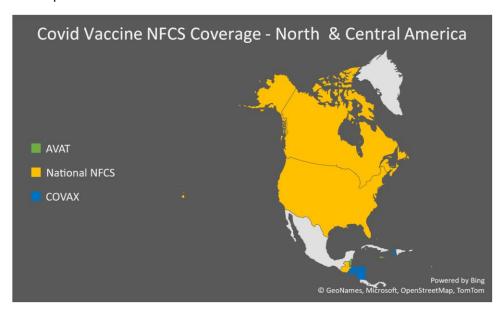
The Americas have a population estimated at 1.014 billion, and contain 35 heterogenous countries from the US with a population estimated at 333 million to St Kitts & Nevis with just 53,000 people. Two thirds of the population of the Americas are from three counties; US, Brazil and Mexico. Of the 35 countries that make up this region 16 (including Brazil and Mexico) do not have any Covid Vaccine NFCS. Brazil passed Law 14.125/2021 which sets out a framework for a national NFCS for investigating compensation claims related to COVID-19 vaccination, but this was never implemented and has been repealed on 15 June 2022 by Provisional Measures (Government Law) 1.126/2022.

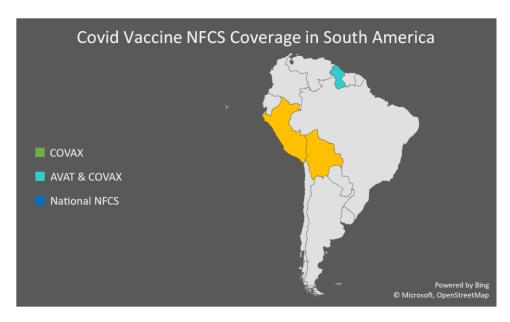
Colombia, the fourth most populous country (estimated population of 52 million) has established the Covid-19 Evaluation Council which functions as an autonomous, independent body within the Institute for the Evaluation of Health Technologies. This is not a NFC scheme *per se*; the Council is a precursor to conciliation/litigation which establishes causation, but it does not award any compensation.

Coverage of NFCSs

Geographical Coverage

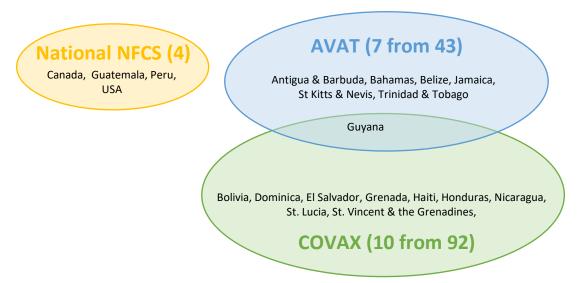
The map below shows the distribution of the different NFCSs.





It is immediately obvious that there is a significant difference in coverage between North America and Central & South America. North America has complete geographical coverage from national schemes. In contrast the geographical coverage in Central and South America is patchy and comes partially from national NFCSs and partly from 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 National, AVAT and COVAX sections below.

Summary

The NFCS coverage in the Americas is patchy. North America is completely covered by national NFCSs, but in Central and South America coverage is sparse. The majority of people in the Americas live in a nation with no Covid –19 Vaccine NFCS coverage.

A number of Central and South American nations have provision from multinational schemes in place. Ten are members of the COVAX NFCS, Seven have coverage from the AVAT NFCS, with Guyana being double covered. The fact that there is a NFCS in that nation does not mean that there is coverage associated with every vaccination given in that country. In the countries covered by the multinational schemes potential claimants will need to establish whether their vaccine was delivered under the relevant framework. 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 coverage across Central and South America.

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 can be found below.

Antigua & Barbuda

Bolivia is a member of the AVAT NFCS.

Bahamas

The Bahamas is a member of the AVAT NFCS.

Belize

Belize is a member of the AVAT NFCS.

Bolivia

Bolivia is a member of the COVAX NFCS.

Canada - Quebec

Introduction

The only part of Canada which had an existing no-fault vaccine compensation scheme was Quebec. This scheme started in November 1987 and covid vaccines were covered from 22 April 2021.

Details on the Canadian Scheme for covid vaccines for all of Canada except Quebec which was announced on 8 December 2020 can be found below.

The Quebec scheme is a statutory scheme under Chapter VII, Division III, Sections 70-78 of the Public Health Act 2001 and the regulation under the Public Health Act in effect since August 2003, division II sections 4-28.

It is administered by the Institut National de Sante Publique du Quebec (INSPQ), who are a public body. The funding for the scheme comes from the Quebec State government.

Vaccines Covered

This NFCS covers covid vaccine administered in Quebec under the Quebec Immunization Program. To date these have been nationally approved (Health Canada approved) vaccines approved for emergency use and standard approvals.

Injuries Covered

This NFCS covers serious permanent physical or mental injury, or death. Under this NFCS any type injury is potentially covered.

Charges for making a claim

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

Eligible Claimants

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

- Live vaccine recipient/their authorised representative
- Beneficiaries of a vaccine recipient/their authorised representative
- The estate/representative of a deceased vaccine recipient

Under this scheme the claimant is allowed to nominate a legal representative to make their claim. Funding for legal representation is not provided by the scheme.

Losses covered

This scheme pays the following

Live vaccine recipient	Dependents of vaccine recipient	Estate of a deceased vaccine recipient
Both eligible economic and eligible non-economic losses are compensated	Both eligible economic and eligible non-economic losses are compensated	Both eligible economic and eligible non-economic losses are compensated

The following categories of benefits and reimbursements are available.

- Income replacement
- Bodily injury
- Personal assistance benefits
- Death benefits, including funeral expenses
- Reimbursement of eligible economic losses such as medical expenses,
- Rehabilitation costs

Benefits and reimbursements are quantified according to the Automobile Insurance Act. Payments consist of a mixture of periodic payments and a lump sum payment. Periodic payments are indexed to take into account cost of living increases.

Funeral expenses are available under this NFCS.

Compensation for non-economic losses under this scheme calculated on an individual basis using tariffs/guidelines set out in the Automobile Insurance Act to assist with quantification. There is a top cap of \$175,000 Canadian dollars.

Compensation for economic losses are individualised and claimants are expected to provide receipts/documents required for reimbursement.

Loss of earnings/income replacement are paid under this scheme. They are quantified on an individual basis but with a top cap which is updated annually.

There is no de minimis threshold for claims to this NFCS.

Time limits for claims

The scheme does not set a time limit between vaccination and the adverse event occurring. A claim under the scheme must be brought within 3 years of the vaccination, or death for claims for death benefits. If an injury starts gradually the 3 years starts from the date the injury first became apparent or the date when a likely causal relationship with the vaccine is established.

The claimant's medical situation must be stable before an assessment can take place to determine if the injury is permanent. It may take some time for the medical situation to stabilise.

Evaluating claims – standard of proof required

INSPQ collect all the relevant medical records (with the claimant's permissions). Claims are reviewed by a three-person expert panel. The panel are all medical professionals. One of the panel is appointed by the claimant, a second by the minister and the third (who chairs the panel and writes the report) is appointed by the other two panel members. The standard of proof required by the scheme is that on the balance of probabilities there is a likely causal relationship between the injury and the vaccine. This requires a majority decision by the three person panel.

If causality is established the panel undertake an assessment of the degree of injury according to the Schedule of Injuries of the Societe de l'assurance automobile du Quebec (SAAQ). The Minister considers the recommendations in the report from the panel and a written decision to compensate or not is made. SAAQ quantifies the compensation as per the Automobile Insurance Act and makes the payment.

Appeals and the right to litigate

The right to litigate is not affected by use of the scheme - A claimant has a free choice to use the scheme or to litigate. If an individual successfully litigates after they have used the scheme they have to pay back any payments the scheme has awarded them from their court-awarded damages.

There is an external process. If a claimant is dissatisfied with either the decision of the Minster or the quantification of their claim they can appeal to the Tribunal Administratif du Quebec within 60 days of the date of notification of the scheme decision. The appellant must pay their own costs. There is also the choice to litigate.

Useful information and links

The scheme publishes data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc)

Vaccine Injury Compensation Program | Gouvernement du Québec (quebec.ca)

S-2.2 - Public Health Act (gouv.qc.ca)

S-2.2, r. 1 - Regulation under the Public Health Act (gouv.qc.ca)

A-25 - Automobile Insurance Act (gouv.qc.ca)

Canada other than Quebec

Introduction

The only part of Canada which had an existing no-fault vaccine compensation scheme was Quebec. Details on the Quebec scheme can be found above. This page describes the scheme for covid (and other) vaccines for all of Canada except Quebec which was announced on 8 December 2020, and which incorporated covid-19 vaccines from that date.

This scheme is a non-statutory scheme. It is administered by Raymond Chabot Grant Thornton Consulting Inc, who are a private body. The funding for the scheme comes from the Federal government.

Vaccines Covered

This NFCS covers nationally approved (Health Canada approved) covid vaccine administered anywhere in Canada other than Quebec. This includes vaccines approved for emergency use and standard approvals.

Injuries Covered

This NFCS only covers permanent injuries.

Under this NFCS any type injury is potentially covered. This NFCS will only recompense Serious and Permanent injuries. This is defined as a Severe, life-threatening or life-altering injury that may require in-person hospitalization, or a prolongation of existing hospitalization, and results in persistent or significant disability or incapacity, or where the outcome is a congenital malformation or death.

Charges for making a claim

There is no charge for making a claim under this scheme. However, the claim must include a form completed by a doctor. If the doctor charges the claimant the scheme is able to reimburse this cost.

Eligible Claimants

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

- Live vaccine recipient/their authorised representative
- Beneficiaries of a vaccine recipient/their authorised representative
- The estate/representative of a deceased vaccine recipient

Under this scheme the claimant is allowed to nominate a legal representative to make their claim. Funding for legal representation is not provided by the scheme.

Canadian citizenship is not required to be eligible under the scheme.

Losses covered

This scheme pays the following

Live vaccine recipient	Dependents of vaccine recipient	Estate of a deceased vaccine recipient
Both eligible economic and eligible non-economic losses are compensated	Both eligible economic and eligible non-economic losses are compensated	Both eligible economic and eligible non-economic losses are compensated

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

Funeral expenses are available under this NFCS.

Compensation non-economic losses under this scheme are calculated on an individual basis using tariffs/guidelines to assist with quantification. There is a top cap of \$175,000 Canadian dollars.

Loss of earnings are paid under this scheme. They are quantified on an individual basis but with a top cap which is updated annually.

There is no minimum claim value under this NFCS.

Time limits for claims

The scheme does not set a time limit between vaccination and the adverse event occurring. A claim under the scheme must be brought within 3 years of the vaccination or becoming aware of the injury.

Evaluating claims – standard of proof required

Claims are evaluated by a three person expert panel. The standard of proof required by the scheme is that on the balance of probabilities the vaccination did cause the adverse event. This requires a majority decision by the three person panel using the WHO causality assessment "Causality assessment usually will not prove or disprove an association between an event and the immunization. It is meant to assist in determining the level of certainty of such an association. A definite causal association or absence of association often cannot be established for an individual event."

Appeals and the right to litigate

The right to litigate is not affected by use of the scheme - A claimant has a free choice to use the scheme or to litigate. If an individual successfully litigates after they have used the scheme they have to pay back any payments the scheme has awarded them from their court-awarded damages.

There is an internal appeal process where the NFCS itself reviews the decision. The original decisions is reviewed by a different three person panel. There is also the choice to litigate.

Useful information and links

The scheme publishes data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc)

Vaccine Injury Support Program

https://vaccineinjurysupport.ca/en

Colombia Covid Vaccine partial-NFCS

Introduction

Colombia does not have a full no-fault compensation scheme for covid-19 vaccines. Instead they created the Covid-19 Evaluation Council as a mechanism to establish causation as a precursor to conciliation/litigation. This was established on 20 November 2020, and it covers Covid-19 vaccines given from 2 June 2020.

This Council was created under national legislation, Laws 333 of 2022, Law 2064 of 2022 and Decree 601 of 2 June 2021.

The Covid-19 Evaluation Council functions as an autonomous, independent body within the Institute for the Evaluation of Health Technologies, who are a public body.

The Covid-19 Evaluation Council Panel consists of five members with the following expertise

- Medical/nursing with expertise in epidemiology or pharmacology;
- Pharmaceutical chemist/expert in pharmacology or pharmacovigilance
- Medical professional with expertise in immunology/allergology;
- Medical professional with expertise in internal medicine/infectious diseases;
- Medical professional specialising in pathology.

The sole function of the Council is to evaluate causation.

The funding for the Council comes from Central Government.

Vaccines Covered

It covers vaccines supplied by the State of Colombia. Article 5 of Law 2064 of 2022 infers that it includes vaccines approved for emergency use and standard approvals.

Injuries Covered

The types of injuries covered is not specified.

The Covid-19 Evaluation Council and the right to litigate

There is a restricted right to litigate - A claimant must use the Covid-19 Evaluation Council before they can commence litigation or conciliation.

In claims that follow a positive causation finding by the Council eligibility, quantification, limit periods, etc, all follow standard litigation/conciliation rules.

Charges for applying to the Covid-19 Evaluation Council

There is no charge for applying to the Council, but the applicant must provide medical records and a diagnosis.

Time limits for applying to the Covid-19 Evaluation Council

The legislation does not specify any time limits on when an application to the Council can be brought.

Evaluating claims – standard of proof required

The standard of proof required by the Council is that on the balance of probabilities the vaccination caused the adverse event.

Conclusion

This is not a full NFCS as there is no quantification/payment mechanism.

Dominica

Dominica is a member of the COVAX NFCS.

El Salvador

El Salvador is a member of the COVAX NFCS.

Grenada

Grenada is a member of the COVAX NFCS.

Guatemala

Introduction

Guatemala created a no-fault compensation for COVID-19 vaccines in 2021 through the passing of the Congress of the Republic of Guatemala Decree 8-2021 ('Decree 8-2021'), which entered into force on 7 July 2021. The scheme is further regulated by the Acuerdo Ministerial 149-2021 of 23 July

<u>2021</u> ('Acuerdo Ministerial 149-2021') and the <u>Acuerdo Ministerial 150-2021 of 26 July 2021</u> ('Acuerdo Ministerial 150-2021').

The scheme is administered by the Ministry of Public Health and Social Assistance (Ministerio de Salud Publica y Asistencia Social). The Decree 8-2021 provides that a Comité de Evaluación de Reacciones Adversas Serias a la Vacunas (Committee for the Evaluation of Serious Adverse Reactions to Vaccines), a supporting expert body of the Ministry of Public Health and Social Assistance, is set up to assess compensation claims relating to COVID-19 injuries under the scheme (Decree 8-2021, Article 7, and also Acuerdo Ministerial 149-2021).

The funding for the scheme comes from central government (see Decree 8-2021, Article 10).

Vaccines Covered

This NFCS covers nationally approved vaccines purchased by or donated to the state within 24 months from the entry into force of the Decree No. 8-2021 (see Decree 8-2021, Article 2).

As the title of the Decree refers to emergency use vaccines and the scheme is operational only for 24 months from the entry into force of the Decree, it seems this NFCS might cover vaccines approved for emergency use only, although this is not specified in the Decree.

The scheme is not retroactive, therefore only vaccines administered before entry into force of the law are covered by this NFCS.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS only eligible injuries are covered. Eligible injuries are serious adverse reactions to a covered vaccine resulting in a significant impact on the injured person's bodily functions. More specifically, these are injuries involving:

- Hospitalisation or prolonging of hospitalisation of a vaccinated person;
- Persistent or significant disability;
- Death of the vaccinated person.

See Acuerdo Ministerial 150-2021, Article 2(g) and (h); see also Decree 8-2021, Article 3(e) and (f).

Charges for making a claim

It is not known whether there are any charges for making a claim under this scheme.

Claimants

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

- Vaccinated person who suffered a serious adverse reaction following a vaccine administered by the health sector of the State of Guatemala, or legal representative of the vaccinated person;
- A family member within a legally recognised degree of kinship.

See Acuerdo Ministerial 150-2021, Article 2(h); see also Decree 8-2021, Article 3(f).

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

Funding for legal representation is not specifically provided by the scheme.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Surviving family members of a deceased vaccine recipient
Compensation payments are for	No Compensation is	Compensation payments are for
general categories and are not	specifically provided	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 mixture of periodic payments and a lump sum payment.

Different types of compensation apply to those who are beneficiaries of social security and those who are not beneficiaries of social security (Decree 8-2021, Article 9).

If the vaccinated person whose claim for compensation is successful is a beneficiary of Guatemalan social security, the relevant social security legislation of the Guatemalan Institute of Social Security (Instituto Guatemalteco de Seguridad Social) will apply to their case.

If the claimant is not a beneficiary of Guatemalan social security, compensation consists of a lump sum payment equal to ten (in the event of serious or persistent disability) or fifteen (in the event of death) monthly minimum wages for non-agricultural activities.

Hospital treatment is also covered and compensation equal to the daily minimum wage for non-agricultural activities for each day of hospitalisation and subsequent rehabilitation for serious injuries is offered to those who are not beneficiary of social security.

Funeral expenses are not specifically available under this NFCS.

Loss of earnings are not paid under this scheme.

While there does not seem to be a general cap on compensation set out in statute, the Decree 8-2021 sets out at Article 9 a maximum quantum of fifteen monthly minimum wages for non-agricultural activities in the event of death of vaccinated people who are not social security beneficiaries.

There does not appear to be a minimum claim value under this NFCS.

Time limits for claims

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

There is a time limit of 30 days from the date of vaccination for the vaccinated person to inform her Vaccination Centre or appropriate health institution that an adverse event allegedly attributable to vaccination has occurred (see Acuerdo Ministerial 150-2021, Article 4).

There is also a time limit of 30 days from the notification of the decision of the Expert Committee (the Comité de Evaluación de Reacciones Adversas Serias a la Vacunas) on whether a vaccine has caused a serious adverse event to file a claim for compensation with the competent 'Dirección de Área de Salud'.

It should be noted that a claim for compensation may only be filed with the Dirección de Área de Salud following a decision of the Committee finding a causal link between a covered vaccination and a serious adverse reaction (see Decree 8-2021, Article 8 and Acuerdo Ministerial 150-2021, Article 11).

Evaluating claims – standard of proof required

The standard of proof required by the scheme is Based on the Bradford Hill Criteria (see the Manual para la vigilancia de eventos supuestamente atribuibles a la vacunación o inmunización (ESAVI) Guatemala, <u>here</u> at Annex 7).

Appeals and the right to litigate

There seems to be a restricted right to litigate claims covered by this NFCS.

There is an exemption of liability for those involved in the development, manufacture, commercialization, acquisition, and distribution of an eligible COVID-19 vaccine, however this does not apply when fraudulent actions or omissions occur or when serious injury or death is caused and it can be demonstrated that this is the result of intentional or wilful misconduct (see Decree 8-2021, Articles 4 and 5).

Prior to receiving compensation, a statement from the claimant is required which declares acceptance of NFCS compensation and exempts the state of Guatemala and the Ministry of Public Health and Social Assistance from any responsibility in relation to the compensated adverse event (see Acuerdo Ministerial 150-2021, Article 16).

No information is available on an appeal processes.

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:

Congress of the Republic of Guatemala Decree 8-2021:

 $\frac{https://legal.dca.gob.gt/GestionDocumento/VisualizarDocumento?verDocumentoPrevia=True\&versionImpresa=False\&doc=106270$

Acuerdo Ministerial 149-2021 of 23 July 2021:

https://legal.dca.gob.gt/GestionDocumento/VisualizarDocumento?verDocumentoPrevia=True&versionImpresa=False&doc=109643

Acuerdo Ministerial 150-2021 of 26 July 2021: https://www.mspas.gob.gt/acuerdos-ministeriales-2021?task=download.send&id=2654&catid=274&m=0

Other resources:

Lexology press release: https://www.lexology.com/library/detail.aspx?g=372762fd-195c-404d-892b-48b0a2de9948

Manual para la vigilancia de eventos supuestamente atribuibles a la vacunación o inmunización (ESAVI) Guatemala:

https://medicamentos.mspas.gob.gt/phocadownload/Farmacovigilancia/MANUAL%20ESAVI.pdf

Guyana

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

Haiti

Haiti is a member of the COVAX NFCS.

Honduras

Honduras is a member of the COVAX NFCS.

Non-implemented National Covid Vaccine NFCS

Decree 193-2020, the Special Law for the Guarantee of Care for Serious Adverse Events Attributed to the Application or Use of the Vaccine Against COVID-19 and if Applicable for Compensation Without Fault, sets out provisions for no-fault compensation. Article 6 of the Decree states that the Care Unit for Persons Vaccinated against COVID-19 is created under the subordination of the Director-General for Surveillance of the Regulatory Framework. Article 19 of the Decree states that the Secretary of State in the Health Office must issue the respective Regulations to this law within 120 days. We cannot find any evidence of the Care Unit for Persons Vaccinated against COVID-19 nor any Regulations.

Jamaica

Jamaica is a member of the AVAT NFCS.

Nicaragua

Nicaragua is a member of the COVAX NFCS.

Peru

Introduction

Peru created a no-fault compensation for COVID-19 vaccines in 2021 through the passing of the <u>Decreto de Urgencia No. 031-2021</u> on 10 March 2021. The scheme is further regulated by the <u>Decreto Supremo No. 012-2021-SA of 21 April 2021</u>.

The scheme is administered by the Ministry of Health (Ministerio de Salud, or 'MINSA'). The Decreto de Urgencia No. 031-2021 provides that a specialised Committee, the Comité Asesor Nacional de los Efectos Supuestamente Atribuidos a la Vacunación o Inmunización del Ministerio de Salud ('Comité Asesor de ESAVI', where ESAVI stands for 'Effect Supposedly Attributed to Vaccination or Immunization') is tasked with the production of the final report determining the existence of a causal link between any of the COVID-19 vaccines acquired by the Ministry of Health and alleged serious adverse events (Decreto de Urgencia No. 031-2021, Article 3.2).

The funding for the scheme comes from central government.

It should be noted that the Decreto de Urgencia No. 031-2021 was valid until 31 July 2022.

Vaccines Covered

This NFCS covers vaccines against COVID-19 acquired by the Ministry of Health and administered within the Peruvian territory.

It is not specified whether this scheme includes both vaccines approved for emergency use and standard approvals.

Injuries Covered

This NFCS only covers permanent injuries.

Under this NFCS only eligible injuries are covered. Eligible injuries are alleged severe adverse reactions resulting from a covered COVID-19 vaccination causing a total permanent disability, a permanent partial severe disability, or death. (see Decreto Supremo No. 012-2021-SA, Article 3.

Charges for making a claim

There is no charge for making a claim under this scheme (see Decreto de Urgencia No. 031-2021, Article 6)

Claimants

This scheme provides for an *ex officio* procedure, which is started by public and private health service providers who have to immediately notify the Direcciones de Redes Integradas de Salud (local agencies of the Ministry of Health), Direcciones Regionales de Salud (regional health directorates), and the Gerencias Regionales de Salud (regional health management bodies) of the occurrence of a case of possible severe adverse reaction to a COVID-19 vaccination acquired by the Ministry of Health.

Under this scheme the following categories of individuals are entitled to compensation:

- A vaccinated person who has suffered a possible serious adverse reaction following vaccination;
- The legal heirs of a vaccinated person.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Legal heirs of a deceased vaccine recipient
Compensation payments are for	No Compensation is	Compensation payments are for
general categories and are not	specifically provided	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.

Funeral expenses are not specifically provided under this NFCS.

Compensation under this scheme calculated on an individual basis using tariffs/guidelines to assist with quantification and is based on 100% of the Remuneración Vidal Minima ('RVM'), that is the legal minimum wage, at the time of the NFCS decision, in the amount specified by the Decreto Supremo No. 012-2021-SA, Article 9:

35 times the RMV in the event of death;

Up to 25 times the RMV in case of severe permanent total disablement;

Up to 15 times the RMV in cases of severe permanent partial disablement.

Loss of earnings are not paid under this scheme.

Compensation under this scheme does not have an explicit cap, but the maximum quantum that can be awarded seems to be 35 times the RMV in the event of death of the vaccinated person.

There is no specified minimum claim value under this NFCS.

A person who has been found to have suffered an eligible injury also has the right to continuity of the coverage by the relevant public IAFA Health Insurance Fund Administrator Institution, or by the private IAFA according to the current regulatory framework. People who do not have health insurance are immediately enrolled in the Comprehensive Health Insurance (SIS) – see Decreto de Urgencia No. 031-2021, Article 3.4(a).

Time limits for claims

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

There are no specific time limits for people eligible for compensation to file claims, as this NFCS sets out an *ex officio* compensation procedure. However, Article 4 of the Decreto Supremo No. 012-2021-SA provides that public and private health service providers have to immediately notify the appropriate administrative health bodies (see 'Claimants' section above) of the occurrence of a

possible case of serious adverse reaction following a covered COVID-19 vaccination for NFCS proceedings to be commenced.

Evaluating claims – standard of proof required

The decision on causality between serious adverse events and covered COVID-19 vaccinations is made by the Comité Asesor de ESAVI based on the published scientific evidence (Decreto de Urgencia 031-2021, Article 3.2).

The decision on compensation quantum for eligible disabling injury found to be causally linked to vaccination is made through subsequent evaluations in the NFCS procedure involving other administrative bodies, with the Comité Nacional de Ponderaciones being the entity responsible for determining the amount to be paid to the vaccinated person – for further detail on these stages of the compensation procedure see Decreto Supremo No. 012-2021-SA, Articles 6, 7 and 8.

Appeals and the right to litigate

There is a restricted right to litigate - a final report ('informe final') from the relevant NFCS authority (the Comité Asesor de ESAVI) is required before starting court proceedings. A second-instance administrative decision on the compensation quantum is required before starting litigation to challenge the amount of compensation awarded. See Decreto de Urgencia 031-2021, Articles 3.3 and 3.5.

There is an optional internal NFCS review process to challenge the compensation amount decision made by the Comité Nacional de Ponderaciones. There is also an external review process where NFCS decisions can be challenged through administrative court litigation.

Useful information and links

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

Links to legislation:

Decreto de Urgencia No. 031-2021 on 10 March 2021: https://www.gob.pe/institucion/pcm/normas-legales/1971982-031-2021

Decreto Supremo No. 012-2021-SA of 21 April 2021:

https://cdn.www.gob.pe/uploads/document/file/1850579/Decreto%20Supremo%20N%C2%B0%20012-2021-SA.pdf

St Kitts & Nevis

St Kitts & Nevis is a member of the AVAT NFCS.

St Lucia

St Lucia is a member of the COVAX NECS.

St Vincent & the Grenadines

St Vincent & the Grenadines is a member of the COVAX NFCS.

Trinidad & Tobago

Trinidad & Tobago is a member of the AVAT NFCS.

United States

Introduction

The US had an existing no-fault compensation scheme for standard vaccines including childhood vaccines, the <u>National Vaccine Injury Compensation Program</u> (VCIP).

Covid Vaccines were not included in VCIP. Instead, they were included the <u>Countermeasures Injury Compensation Program</u> (CICP). The provisions to create the CICP were effective from 30 December 2005, and Covid-19 vaccines were incorporated from 17 March 2020.

The CICP was created under federal legislation; the Public Readiness and Emergency Preparedness Act, or <u>PREP Act</u>, (as defined in section 319F-3(i)(2) of the Public Health Service Act (PHS Act)). The PREP Act established the CICP to provide compensation to eligible individuals for serious physical injuries or death directly caused by the administration or use of pandemic, epidemic, or security countermeasures identified in declarations issued by the Secretary pursuant to section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d).

It is administered by the Health Resources & Services Administration, who are an Agency of the U.S. Department of Health and Human Services.

The funding for the scheme comes from the Federal Government.

Vaccines Covered

This NFCS includes vaccines approved for emergency use and standard approvals. To be a covered countermeasure a vaccine must be:-

- 1. administered in the US, and
- 2. must be
 - a. approved or cleared under the Food Drug & Cosmetics Act;
 - b. licensed under the Public Health Service (PHS) Act; or
 - c. authorized for emergency use under Sections 564, 564A, or 564B of the Food Drug & Cosmetics Act

Injuries Covered

This NFCS covers both temporary and permanent injuries. Under this NFCS only eligible injuries are covered. Eligible injuries are serious physical injuries or death. A serious physical injury is defined as an injury that (a) is life threatening; (b) results in permanent impairment of a body function or

permanent damage to a body structure; or (c) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure (section 319F-3(i)(10) of the PHS Act (42 U.S.C. 247d-6d(i)(10)).

The PREP Act makes provision for a Table of injuries where a rebuttable presumption of causation exists. As at February 2023 there is not a <u>Countermeasures Injury Table</u> for Covid-19 vaccines. All non-table injuries require that the injury must be a direct result of the administration of the vaccine. Proof must be based on compelling, reliable, valid, medical and scientific evidence.

Charges for making a claim

There is no charge for making a claim under this scheme. It is the responsibility of the claimant to provide medical records to the scheme, no funding is provided for this.

Claimants

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

- Live vaccine recipient/their authorised representative
- Eligible Survivors/Beneficiaries of a deceased vaccine recipient/their authorised representative
- The estate of a deceased vaccine recipient

Under this scheme the claimant is allowed to nominate a personal or a legal representative to make their claim. Funding for the personal or legal representation is not provided by the scheme.

The priority order for Eligible survivors is:-

Priority	Category
1	Spouse and no surviving child(ren) of the vaccine recipient -
	A spouse will qualify for CICP benefits if he or she qualifies as a spouse under the Public
	Safety Officers' Benefits (<u>PSOB</u>) Program
2	Spouse, child(ren), and minor dependent(s) - if there is at least one surviving child of
	the vaccine recipient and a surviving spouse: The spouse may receive 50% of the death
	benefit and the child(ren) and minor dependent(s) may receive a percentage. A
	surviving child will qualify under this category if he or she is a natural, illegitimate,
	adopted, or posthumous child, or stepchild of a vaccine recipient who, at the time of the
	vaccine recipient's death, is:
	18 years old or younger, or
	 between 19 and 22 years of age and a full-time student, or
	 incapable of self-support due to a physical or mental disability, regardless of age
3	Child(ren) and no surviving spouse - If there is at least one surviving child (as defined in
	category two above) but no surviving spouse, the surviving child (or surviving children in
	equal shares) receives the death benefit.
4	Named Beneficiary and no surviving spouse or child(ren) – If the vaccine recipient dies
	without a spouse, child, or dependent minor, then the person(s) named in a beneficiary
	designation form supplied by an employer or, if no such form exists, the most recently
	executed insurance policy may be eligible for death benefits. The individual(s) may
	receive the entire death benefit.
5	Parents and no spouse, no child, no minor dependent, and no named beneficiary - If
	there is no spouse, no child, no minor dependent, and no named beneficiary, then the

	two parents may divide the death benefit into equal shares. If there is only one surviving
	parent, then he or she would receive the entire benefit.
6	Legal guardian of a deceased minor without surviving parents - If the deceased vaccine
	recipient was a minor, then his or her legal guardian if other than a parent (such as a
	grandparent) may receive the death benefit if there are no other survivors as listed
	above under the standard calculation.
7	Adult Children - if none of the above: If there is no spouse, no child as defined under
	category two above, no minor dependent, no named Beneficiary, and no surviving
	parent, then the death benefit may be paid to the individual(s) who would qualify as
	surviving child(ren) under category two above, but for age
There	is an additional category of survivors who may be eligible for the alternative calculation of
the de	ath benefit.
1	Dependent(s) younger than the age of 18: A person whom the Internal Revenue Service
	would consider to be the deceased vaccine recipient's dependent at the time the
	covered injury was sustained and who is younger than the age of 18 at the time of the
	filing of the Request Form. This category may include individuals who would also qualify
	as a surviving minor child (as defined under category two in the section above) as well as
	dependents other than the decedent's children, such as nieces, nephews, foster
	children, or other minors. Surviving dependents younger than the age of 18 under this
	category have the same priority as surviving children as described under category two in
	the section above (2. Spouse, child(ren), and minor dependent(s)).
	the section above (2. spouse, child(len), and millor dependent(s)).

Losses covered

This scheme is secondary of other collateral sources of payment, such as health insurance and other statutory entitlements. Collateral sources should be exhausted before a claim will be paid by the scheme.

The scheme pays the following

Live vaccine recipient	Survivors/Beneficiaries of	Estate of a deceased vaccine
	vaccine recipient	recipient
Only eligible economic losses	Compensation payments are	Only eligible economic losses
are compensated	for general categories and are not broken down into	are compensated
	economic and non-economic	
	losses.	

The following categories of benefits and reimbursements are available.

Live Vaccine recipients

- medical expenses where reasonable and necessary and not paid by insurance/Government programs such as Medicaid or Veterans Benefits
- **Lost income** this is only available for those who have been unable to work for more than five days.

Survivors of a deceased vaccine recipient

- **Death Benefits** – these are capped at the standard maximum death benefit under the Public Safety Officers' Benefits program (this is updated annually, for eligible deaths and disabilities that occurred on or after 1 October 2022 it is \$422,035).

Estate of a deceased Vaccine recipients

- **medical expenses** If an individual injured as a result of a covered vaccine dies (regardless of the cause of death) before CICP has paid all medical and/or lost employment income benefits due, the individual's estate may be eligible to receive those benefits
- **Lost income** as per medical expenses above.

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

Funeral expenses are not available under this NFCS.

Compensation for live vaccine recipients and Estates is fully individualised under this scheme.

Loss of earnings are paid under this scheme. They are quantified on an individual basis set out in <u>Section 239d(a)(B)</u>. Lost earnings calculated at 66.67 % of their income at the time of the injury. If the injured vaccine recipient has one or more dependents this is augmented by 8.33%.

The total value of benefits paid has a top cap of \$50,000 a year and a lifetime cap equivalent to the standard maximum death benefit under the Public Safety Officers' Benefits. Section 239d(c)(3)(A)(ii) states that the lifetime cap does not apply to those under a disability as defined in section 416(i) of the Public Health and Welfare Act. Section 416(i) defines a disability as (A) inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or has lasted or can be expected to last for a continuous period of not less than 12 months, or (B) blindness; and the term "blindness" means central visual acuity of 20/200 or less in the better eye with the use of a correcting lens. An eye which is accompanied by a limitation in the fields of vision such that the widest diameter of the visual field subtends an angle no greater than 20 degrees shall be considered for purposes of this paragraph as having a central visual acuity of 20/200 or less.

There is no minimum claim value under this NFCS, but loss of earnings cannot be claimed for the first five work days of lost employment. This does not apply if the individual is claiming for lost employment for 10 or more work days. Lost earnings can only be claimed until the vaccine recipient reaches the age of 65.

Time limits for claims

For Table injuries an injury will only be eligible for compensation if it occurs within a set time of the vaccination, which is specified on the Table. There is currently no table for Covid-19 vaccine injuries.

A claim under the scheme must be brought within 1 year from vaccination.

Evaluating claims – standard of proof required

Claims are assessed using an administrative process described in the:-

- Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule (A Rule by the Health and Human Services Department on 21 October 2010), and
- <u>Countermeasures Injury Compensation Program (CICP): Administrative Implementation,</u> <u>Final Rule</u> (A Rule by the Health and Human Services Department on 7 October 2011),

Briefly, it is the responsibility of the claimant to ensure that CICP has received the information required in the **Request for Benefits package**, which includes:-

- Request for Benefits form
- **Authorisation for Use or Disclosure of Health Information Form** (a separate form is needed for each healthcare provider who treated the vaccine recipient)
- **Proof of administration of a covered vaccine**, for example a Covid-19 vaccine card.
- **Medical records**. These can be submitted either by the claimant/their representative or the health care provider(s). The CICP prefers that medical records are sent directly to the program by the health care provider(s). Medical records must include:-
 - All medical records documenting medical visits, procedures, consultations, and test results that occurred on or after the date of administration of the Covid-19 Vaccine.
 - All hospital records, including the admission history and physical examination, the discharge summary, all physician subspecialty consultation reports, all physician and nursing progress notes, and all test results that occurred on or after the date of administration of the Covid-19 Vaccine.
 - All medical records for one year prior to the Covid-19 vaccination, as necessary, to show any pre-existing medical history.

The Request for Benefits Package must be submitted either via the HRSA Injury Compensation Programs Website or by mail. Once received the Request for Benefits Package is reviewed by CICP medical staff to determine eligibility for benefits. The standard of proof required by the scheme varies depending on whether the injury is a Table Injury or a non-Table injury.

For injuries included in the Table of injuries a rebuttable presumption of causation exists. As at February 2023 there is not a <u>Countermeasures Injury Table</u> for Covid-19 vaccines.

All non-table injuries require that the injury must be a direct result of the administration of the vaccine. Proof must be based on compelling, reliable, valid, medical and scientific evidence.

Appeals and the right to litigate

This scheme is a removes the right to litigate.

There is an internal appeals process where the NFCS itself reconsiders the decision. Requests for reconsideration must be received in writing within 60 days of the CICP's decision that the claim was not eligible for compensation. Judicial review of the NFCS decision is not permitted.

Useful information and links

The scheme produces data on claims (claim numbers, payments, claim processing timeframes, etc)

Statutes

Public Readiness and Emergency Preparedness (PREP) Act

Definition of serious physical injury - section 319F-3(i)(10) of the Public Health Service Act

Definition of disability - Section 416(i) of the Public Health and Welfare Act

Scheme website and Scheme rules

<u>Countermeasures Injury Compensation Program</u> (CICP).

- Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule (A Rule by the Health and Human Services Department on 21 October 2010), and
- <u>Countermeasures Injury Compensation Program (CICP): Administrative Implementation,</u> <u>Final Rule</u> (A Rule by the Health and Human Services Department on 7 October 2011)
- <u>Countermeasures Injury Table</u> for Covid-19 vaccines

Vaccine Injury Compensation Program website for comparison between CICP and VCIP

National Vaccine Injury Compensation Program (VICP)

- Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP) | HRSA.

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	Legal heir of a deceased
	recipient	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 <u>Program Protocol</u> 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

<u>Home - AVAT No-Fault Compensation Scheme (avatclaims.com)</u>

AVAT-Compensation-Program-Protocol.pdf

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

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

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 <u>92 low- and middle-income AMC Eligible Economies</u>.

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 Protocol, 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).

Schedule 6 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

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: covaxclaims.com

Program Protocol Link: https://covaxclaims.com/program-protocol/

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

Schedule 6 (Reporting Period illustrative diagram): https://covaxclaims.com/wpcontent/uploads/2021/03/COVAX-Compensation-Program-Illustrative-Diagram-of-the-Reporting-Period.pdf

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