Multi-national schemes

Covid-19 Vaccine No Fault Compensation Schemes



This report examines the provision of No-Fault Compensation Schemes for injuries following Covid-19 vaccination made by multi-national scheme.

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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Multi-national Covid-19 Vaccine NFCSs

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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.

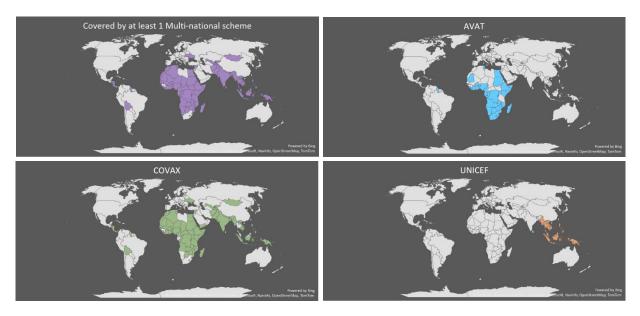
The national NFCS that were in place prior to the pandemic were in high and high-middle income nations. Very few low- and middle-income countries had any vaccine NFCS provision. Since the start of 2020 three multi-national Covid-19 Vaccine NFCS have been created which redress this balance.

- AVAT The African Union Vaccine Acquisition Trust
- COVAX Covid-19 Vaccines Global Access, which is a WHO initiative
- UNICEF UNICEF Covid-19 Response

Coverage of NFCSs

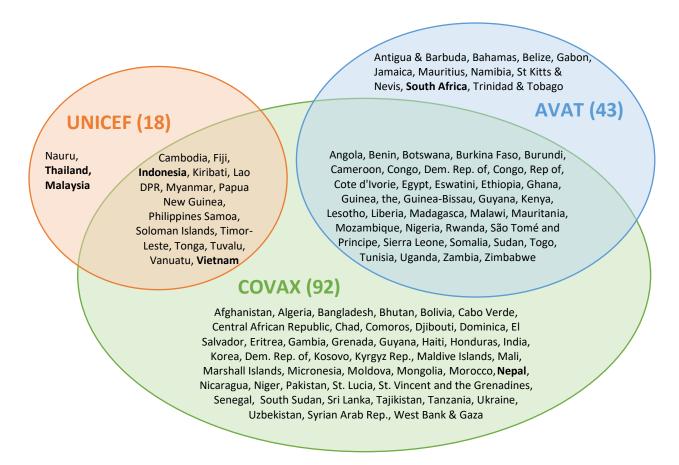
Geographical Coverage

The maps below shows the distributions of the different NFCSs. COVAX coverage extends to low and middle income countries in Africa, the Americas, Asia Pacific, Europe and the Middle East. There is geographical overlap between the coverage provided by COVAX and the other two multinational schemes. There is no overlap between the coverage offered by AVAT (which is focussed in Africa and the Caribbean) and UNICEF (which is focussed in Asia).



Between them these three schemes cover 98 countries; AVAT - 43 countries, COVAX - 92 countries, UNICEF - 18 countries. 48 countries are members of more than one multinational scheme (AVAT & COVAX or COVAX & UNICEF).

The diagram below illustrates which multinational NFCS each country participates in. Countries that also have a national NFCS are shown in **bold**.



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 UNICEF sections below.

Summary

The multinational schemes are funded by levy, the majority of the national schemes we researched were funded by governments rather than by levy. Given the multi-national nature of the schemes a levy per does provides a workable funding mechanism.

The multinational schemes have provided coverage to a large number of countries which did not have any NCFS provision prior to the pandemic. However, the fact that a jurisdiction has some NFCS provision in place does not mean that there is coverage for every vaccination given in that country. Potential claimants will need to establish whether their vaccine was delivered under one of these three programs and that their jurisdiction has signed up to be part of the associated NFCS. The percentage of vaccines delivered under the AVAT, COVAX and UNICEF programs is likely to vary between different jurisdictions, so there is no simple way to quantify the overall level of NFCS cover.

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Detailed findings by 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 <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

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 <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 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: 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/wp-content/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)			
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UNICEF

Introduction

UNICEF is a multi-jurisdiction compensation scheme covering COVID-19 vaccines which have been either procured and/or delivered by UNICEF on a <u>Participating Country</u>'s behalf; donated to a Participating Country through UNICEF; or formally included into the Scheme (but otherwise procured and/or delivered but not by or through UNICEF).

This scheme is a non-statutory scheme, governed by a <u>Program Protocol</u>.

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.

Vaccines Covered

This NFCS covers COVID-19 vaccines 'received in any Participating Country that [are] either: (i) procured and/or delivered by UNICEF on a Participating Country's behalf; (ii) donated to a Participating Country through UNICEF; or (iii) formally included into the Scheme (but otherwise procured and/or delivered but not by or through UNICEF, that:

- (i) either (A) [have] licensure or authorisation from a stringent ("functional") regulatory authority or (B) [have] received WHO prequalification, following licensure or authorisation from a stringent ("functional") regulatory authority, or (C) [have] been issued authorisation for emergency use based on licensure or authorisation by a stringent ("functional") regulatory authority; and
- (ii) is included in <u>Schedule 1</u>, as updated from time to time; and
- (iii) has received all required approvals and authorisations for importation,

distribution and use in the relevant country; and

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

(see Program Protocol, 2 "Vaccine").

For more on the 'Scope of Coverage Endpoint', 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 requiring hospitalisation or prolonging an existing hospitalisation and resulting in permanent total or partial impairment; or congenital birth injuries or illness in an unborn or new-born child of a woman who received a covered vaccine resulting in permanent total or partial impairment; or serious 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 recipient (see PP 2 'Patient'), or individual who is duly authorised to represent the vaccine recipient if the vaccine recipient has died, is a child or otherwise lacks legal capacity (duly authorised legal heir in case of death).

The 'Patient' or 'duly authorized' representative of 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' (PP 2 'Claimant').

Under this scheme claimant legal representation is allowed.

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

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependents of	Estate/Legal heirs of a deceased
	vaccine recipient	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
	for dependants	

broken down into economic and	broken down into economic and
non-economic losses.	non-economic losses.

Payments consist of a lump sum payment.

It is not specified 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). Hospital payments of \$100/day can be awarded for a maximum of 60 days (see PP 9).

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 36 calendar months after the 'Scope of Coverage Endpoint' for the specific vaccine considered (see Schedule 1 to the Program Protocol), provided always that the vaccine was administered before the 'Scope of Coverage Endpoint' (which is 24 months after the relevant vaccine had first been put into circulation). There is also a mimimum of 30 days that need to have passed between vaccination and making a claim, but no waiting time if the vaccinee has deceased.

Evaluating claims – standard of proof required

The standard of proof required by the scheme is that of 'Most probable cause': the most likely cause (based on the balance of probabilities) that a covered 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: https://c19vaccinenfc.com/

Program Protocol Link: https://c19vaccinenfc.com/wp-content/uploads/2021/10/Covid-19-vaccine-Facillity-No-Fault-Compensation-Scheme-Protocol.pdf

Schedule 1 (List of vaccines): https://c19vaccinenfc.com/wp-content/uploads/2021/10/Covid-19-Vaccine-Facillity-No-Fault-Compensation-Scheme-Vaccine-List.pdf

Schedule 6 (Reporting Period illustrative diagram): https://c19vaccinenfc.com/wp-content/uploads/2021/10/Covid-19-Vaccine-Facillity-No-Fault-Compensation-Scheme-Illustrative-Diagram-of-the-Reporting-Period.pdf

List of Participating Countries: https://c19vaccinenfc.com/wp-content/uploads/2021/10/Covid-19-Vaccine-Facillity-No-Fault-Compensation-Scheme-List-of-Participating-Countries.pdf