Middle East

Covid-19 Vaccine No Fault Compensation Schemes



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

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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Covid-19 Vaccine NFCSs in the Middle East

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Introduction

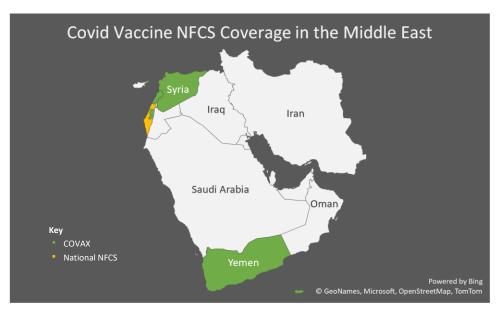
We have identified 29 national schemes that were offering no-fault vaccine compensation at the start of the pandemic in January 2020. Since then the number of jurisdictions with a no-fault compensation scheme which covers Covid-19 vaccines has increased almost five-fold. This is a rapid proliferation 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 Middle East¹ has a population estimated at 370 million. For the purposes of these reports Egypt is included in the Africa report, not the Middle East. Of the 16 countries that make up this region three quarters do not have any Covid Vaccine NFCS. Just under 20% of the population of the Middle East live in a jurisdiction with some form of Covid Vaccine NFCS.

Coverage of NFCSs

Geographical Coverage

The map below shows the distribution of the different NFCSs.



The only country with a national NFCS for Covid Vaccine Compensation is Israel.

Lebanon is one of three countries (Brazil, Lebanon and Tunisia) that have enacted legislation to create a national NFCS for COVID-19 vaccines, but have not actually implemented a national NFCS in practice. In Lebanon Law No. 211/2021 on Regulating the Emerging Use of Medical Products to Combat the COVID-19 Pandemic sets out a framework for a national NFCS for investigating compensation claims related to COVID-19 vaccination. This law sets out that a specialised Compensation Committee should have been set up by the Lebanese Ministry of Public Health to establish NFCS application procedure and to determine cases. We cannot find any evidence that this Compensation Committee has been established.

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¹ In this report the Middle East is taken to include Bahrain, Cyprus, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Palestine (West Bank & Gaza), Qatar, Saudi Arabia, Syria, Turkey, United Arab Emirates and Yemen. **Egypt has been included in the Africa report**.

The coverage for the remaining nations which have coverage (Palestine, the Syrian Arab Republic and Yemen Republic) comes from the COVAX multinational schemes. The diagram below illustrates which NFCSs each country participates in.



COVAX (3 from 92)

Palestine (West Bank & Gaza), Syrian Arab Republic, Yemen Rep.,

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, but both Israel's national NFCS and COVAX cover a number of different vaccines, full details can be found in the Israel and COVAX sections below.

Summary

The NFCS coverage in the Middle East is sparse, none of the Gulf states have a NFCS. Israel appears to have comprehensive coverage. Palestine, the Syrian Arab Republic and Yemen Republic have provision from COVAX in place, but this does not mean that there is coverage associated with every vaccination given in that country. In these three jurisdictions potential claimants will need to establish whether their vaccine was delivered under the COVAX framework. The percentage of vaccines delivered under the COVAX programs is likely to vary between different jurisdictions, so there is no simple way to quantify the overall level of NFCS cover across these three jurisdictions.

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

Detailed findings by Country

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

Israel

Introduction

Israel had an existing no-fault compensation scheme for vaccines created 5 December 1989. Covid Vaccines were added to the list of vaccines eligible for compensation on 4 February 2021, and cover was extended to vaccines administered from 20 December 2020.

This scheme was created under national legislation. The <u>Vaccine Injury Compensation Law 1989</u> (in Hebrew) and the <u>Insurance Regulations for Vaccine Victims 1992</u> (in Hebrew).

The NFCS insurance comes from the Internal Government Insurance Fund, a self-insurance fund for the Israeli government. The Internal Government Insurance Fund is managed by Inbal Insurance Company Ltd, a government owned body who act as the State insurer.

The funding for the covid vaccine compensation comes from central government. Funding for the other vaccines administered by the scheme comes from a levy on each vaccine dose.

Vaccines Covered

This NFCS covers nationally approved vaccines for a pre-specified list of diseases. Covid Vaccines were added on 4 February 2021 by Revisions 5555 into the 2018, 2018 (No. 2 Addendum) Section 1

It includes vaccines approved for emergency use and standard approvals.

Injuries Covered

This NFCS only covers permanent injuries.

Under this NFCS any injury is potentially covered, but this NFCS will only recompense injuries which cause permanent disablement. Section 6 of the Vaccine Injury Compensation Law Act 1989 specifies how disability is to be assessed. 'The degree of disability for the purposes of this law will be determined in accordance with the tests and principles established for determining the degree of disability according to section 61 of the National Insurance Law [combined version], 1968-5578.'

Charges for making a claim

There is nothing in the Act or the Regulations regarding a charge for making a claim under this scheme.

Although the law is silent on the procedures for claiming vaccine injury, in practice it is an adversarial process with legal representation from Inbal. In their 2021 article Kamin-Friedman & Davidovitch 2021 comment that the adversarial approach of this NFCS increases costs as it

'...requires claimants to prove their claims through a confrontation, with the State essentially a counterparty. As a result, the injured parties feel the need to employ legal counsel and pay for

medical opinion, which make the procedure more expensive. Cross-examination carried out by both parties prolong the legal procedure, which can then last as long as do tort litigations in court.'

Claimants

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

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

The Regulations set out the eligibility for compensation in the event of a claim for a death. Point 4 states that compensation for a death will be paid 'to the person who was the spouse of the beneficiary at the time of his death and his children; if the beneficiary was a minor, the insurance amount will be paid to the parent who had the minor under his care.'

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	Dependants of vaccine recipient	Estate/Representative of a deceased vaccine recipient
Compensation payments are		Compensation payments are
for general categories and are	No Compensation is provided	for general categories and are
not broken down into		not broken down into
economic and non-economic		economic and non-economic
losses.		losses.

Payments consist of a lump sum payment.

Funeral expenses are not available under this NFCS.

Compensation under this scheme consists of fixed sums. The 1992 Regulations define the following insurance amounts:-

- death of a minor, 10,000 Shekels;
- death of an adult 250,000;
- permanent disability 250,000.

The Regulations state that these values are index linked.

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 by the age of 21 if the vaccine recipient was a child.

Evaluating claims – standard of proof required

The Regulations specify at point 3 that when the insurer is notified of the occurrence of the insurance case and a claim, the insurer will contact the Minister of Health for the appointment of a committee of experts. The Regulations define the Committee of Experts as a three-member committee appointed by the Minister of Health: its chairman will be a judge appointed by the Minister of Health in consultation with the President of the Supreme Court, and its other two members will be doctors with expert degrees in the fields related to the insurance case.

The Role of the Committee of Experts is to discuss the claim and determine if there is a causal connection between the insurance case and the vaccine. If they have determined that the insurance case results from vaccination, the Committee then determines the percentages of the disability in accordance with the tests and principles established according to section 61 of the National Insurance Law [combined version], 1968-5778.

In the event of a death the Committee are tasked with determining whether the death of the beneficiary resulted from the vaccination.

There is no information provided on the standard of proof which the Committee are required to use.

In their 2021 article Kamin-Friedman & Davidovitch cite evidence that between 2008 and 2021 the Committee had never adjudicated compensation for claimants who claimed vaccine injury according to the Vaccine Injury Compensation law. When compensation was paid, it was given ex gratia as part of a settlement. This indicates that there may be significant divergence between the framework set out in the legislation and the practical application.

Appeals and the right to litigate

Section 7 of the Act specifies 'If a person files a claim under this law, he will not be allowed to file a claim under the Torts Ordinance [new version] due to the same injury, and vice versa. '

There is an external review process, the Expert Committee's decision can be appealed in the District Court.

Useful information and links

The scheme does not routinely publish data on claims.

Scheme website -

Vaccine Injury Compensation Law, Ministry of Health

Legislation (in Hebrew)

Vaccine Injury Compensation Law 1989

Insurance Regulations for Vaccine Victims 1992

Academic Articles

Kamin-Friedman S, Davidovitch N. **Vaccine injury compensation: the Israeli case.** Isr J Health Policy Res. 2021 Sep 13;10(1):54. doi: 10.1186/s13584-021-00490-w. PMID: 34517920; PMCID: PMC8436016.

Palestine (West Bank and Gaza)

Palestine (West Bank & Gaza) is a member of the COVAX NFCS.

Syrian Arab Republic

The Syrian Arab Republic is a member of the COVAX NFCS.

Yemen Republic

Yemen is a member of the COVAX NFCS.

Multinational Covid-19 NFCS

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	Legal heir(s) of a deceased vaccine
	vaccine recipient	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)