

EUROPE

Covid-19 Vaccine No Fault Compensation Schemes



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

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 NFCs in Europe

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Introduction

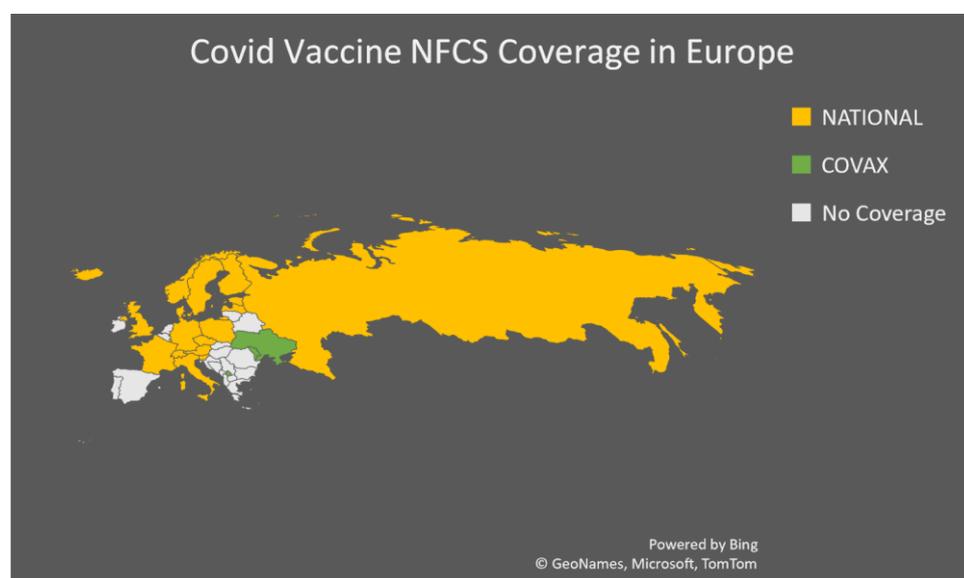
We have identified 29 national schemes that were offering no-fault vaccine compensation at the start of the pandemic in January 2020. Since then the number of jurisdictions with a no-fault compensation scheme which covers Covid-19 vaccines has increased almost five-fold. This is a rapid proliferation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

Europe is the third most populous continent after Asia and Africa. Europe has the highest GDP of any of the continents. Of the 44 countries in Europe¹ around half have some form of Covid Vaccine NFCS.

Coverage of NFCSs

Geographical Coverage

The map below shows the distribution of the different NFCSs.



Coverage is almost entirely due to national NFCS for Covid Vaccine Compensation. Kosovo, Moldova and Ukraine are members of the COVAX NFCS. Ukraine passed a Resolution to create a national scheme, but this was subsequently repealed.

Hungary had an existing compensation scheme for vaccine injuries. We have not been able to find any information to indicate that Covid vaccines have been added to this scheme, therefore Hungary is listed as having no coverage.

¹ We have used the countries recognised by the United Nations: Albania, Andorra, Austria, Belarus, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holy See (Vatican City), Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Monaco, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, UK

National NFCS (18)

Austria, Czech Rep., Denmark, Estonia, Finland, France, Germany, Iceland, Italy, Latvia, Luxembourg, Norway, Poland, Russia, Slovenia, Sweden, Switzerland, UK,

Kosovo, Moldova,
Ukraine

COVAX (3 of 92)

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 COVAX and National NFCS sections below.

Summary

The coverage across Europe is mainly existing National vaccine injury NFCS. There is a distinction between East and Western Europe. Coverage is less common in Eastern Europe, but there are a number of Western European nations that do not have and Covid Vaccine NFCS provision in place. The discrepancies between Covid Vaccine NFCS provision in EU member states is potentially surprising as they took a more collective approach to the pandemic, including the EU Covid-19 Procurement arrangements. The multinational NFCS approach that accompanied the AVAT, COVAX and UNICEF facilities has not been adopted by the EU. This may be a reflection of fact that the EU is comprised of economically stronger national than the economies of AVAT, COVAX and UNICEF members.

The fact that a jurisdiction has some NFCS provision in place does not mean that there is coverage associated with every vaccination given in that country. Potential claimants in Kosovo, Moldova and Ukraine will need to establish whether their vaccine was delivered under the COVAX framework or under another program.

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.

Austria

Introduction

Austria introduced a no-fault compensation scheme for vaccine injuries through the passing of the Vaccine Damage Act of 1973 ('Bundesgesetz vom 3. Juli 1973 über die Entschädigung für Impfschäden or Impfschadengesetz'). The Act was amended in 1991 to cover damages caused by all government-recommended vaccinations (it originally applied to damages caused by smallpox vaccination). There is no specific COVID-19 start date, but it seems the scheme has covered COVID-19 vaccines since the start of the vaccination campaign in the country in December 2020.

The main administrative body is the Sozialministeriumservice (Ministry of Social Affairs). The decision-making body on compensation claims is the Federal Office for Social Affairs and Disability.

The funding for the scheme comes from the Austrian government.

Vaccines Covered

This NFCS covers smallpox vaccination (prescribed until 1980), vaccinations mentioned in the 'Mother-Child Passport', vaccinations administered based on an administrative order referring to persons engaged in medical occupations, vaccinations for border guards, vaccinations recommended by decree of the Ministry of Health - all of which must have been carried out in Austria (though non-Austrian citizens are also entitled to compensation) – see Vaccine Damage Act 1973, § 1, § 1a and § 1b.

Although not specifically indicated in the law, it seems this scheme includes vaccines approved for emergency use and standard approvals.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS only eligible injuries are covered. Eligible injuries those which result in death, disability or serious bodily harm - see Vaccine Damage Act 1973, §2 and §2a. Serious bodily harm covers non-permanent injuries causing adverse health effects/inability to work lasting longer than 24 days.

Charges for making a claim

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

Claimants

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

- Injured vaccinated person;
- Surviving family of an injured vaccinated person.

It is not known whether under this scheme the claimant is allowed to nominate a legal representative to make their claim.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Estate 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 specifically provided for the dependants of injured vaccinated people.	Compensation payments are for general categories and are not broken down into economic and non-economic losses.

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

The quantification of vaccine-related damage is based on tariffs (care allowance), individual assessment (disability pension, widow's pension, orphan's pension) or fixed sum (non-permanent injuries). Medical expenses incurred by victims can also be covered by NFCS (it is up to the applicant to provide evidence regarding such expenses). For disability pension eligibility only, there is a requirement that capability to work of an injured person above the age of 15 is reduced of at least 20%. Funeral expenses are available under this NFCS.

Loss of earnings do not appear to be covered under this NFCS.

The maximum quantum that can be awarded under this scheme depends on the nature of the injury and is determined by reference to tariffs/guidelines established by law.

Time limits for claims

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

There is no information on specific time limits to file a claim under this compensation scheme.

Evaluating claims – standard of proof required

The standard of proof required by the scheme is that on the balance of probabilities - the injury has likely been caused by vaccination.

Appeals and the right to litigate

The right to litigate seems to be unaffected by the NFCS - according to § 5 of the Vaccine Damage Act, other claims that go beyond the benefits under this federal law based on other legal provisions remain unaffected.

There is an external review process where the Federal Administrative Court reviews the decision of the Federal Office for Social Affairs and Disability.

Useful information and links

This scheme produces a periodic report including data on claims & financial performance - Key figures related to the operations of the Ministry of Social Affairs and vaccine NFCS are available online. For data referring to 2021, see:

https://sozialministeriumservice.at/Ueber_uns/News_und_Veranstaltungen/News/Geschaeftsbericht_2021.de.html.

Links to legislation:

Vaccine Damage Act 1973:

<https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010356>.

Other resources:

Ministry of Social Affairs website:

<https://www.sozialministeriumservice.at/Finanzielles/Sozialentschaedigungen/Impfschaeden/Impfschaeden.de.html>

Czech Republic

Introduction

The Czech Republic introduced a no-fault compensation scheme for vaccine injuries in 2020, which is regulated under the Act No. 116/2020 Coll. on Compensation for Damage Caused by Compulsory Vaccination of 8 April 2020. The scheme was extended to COVID-19 vaccination in December 2020, though the passing of the Act No. 569/2020 Coll of 23 December 2020.

The administrator of this scheme is the Czech Ministry of Health (Ministerstvo zdravotnictví) – see Act No. 116/2020, §4(1). The Ministry may establish an independent expert commission to assess complex cases (§6).

The funding for the scheme comes from the Czech government.

Vaccines Covered

This NFCS covers compulsory vaccines and Covid-19 vaccines acquired by the Czech Republic on the basis of Commission Decision C(2020) 4192 final of 18 June 2020.

Although not specifically indicated in the law, it seems this scheme includes vaccines approved for emergency use and standard approvals.

Injuries Covered

It is unclear whether this NFCS covers temporary injuries or whether it only covers permanent injuries.

Under this NFCS only eligible injuries are covered. Eligible injuries are particularly serious injuries to the vaccinated person's health causing pain and suffering, loss of earnings and 'deteriorated social position' – see Act No. 116/2020, § 2.

Charges for making a claim

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

Claimants

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

An injured vaccinated person;

Those who have incurred costs associated with the care of the injured vaccinated person, their health or their household;

A person close to someone who has died or suffered a serious injury following vaccination.

Note that, according to CMS (<https://cms.law/en/int/expert-guides/cms-expert-guide-to-vaccine-compensation-regimes/czech-republic>), it is unclear whether third parties compensation provisions in Act No. 116/2020 also apply to COVID-19 vaccines or only to damage caused by compulsory vaccinations.

It is not known whether under this scheme the claimant is allowed to nominate a legal representative to make their claim.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Person close to a deceased vaccine recipient
Both eligible economic and eligible non-economic losses are compensated	No Compensation is specifically provided for the dependants of injured vaccinated people.	Only eligible non-economic losses are compensated

It is not known whether NFCS payment consists of periodic payments, lump sum payments, or a mix of periodic payments and lump sum payments.

The Czech NFCS compensates claimants who have been injured by an eligible vaccine (compulsory vaccines and certain Covid-19 vaccines procured by the Czech Republic) in case of particularly serious injury to the vaccinated person's health, pain and suffering, loss of earnings and 'deteriorated social position' – see Act No. 116/2020, § 2. Compensation is also offered to cover costs associated with the care of the vaccinated person, their health or their household. This latter

type of compensation is awarded to the person who has incurred these costs. Following the death or serious injury of a vaccinated person, the state also offers compensation to 'a person close to the vaccinated person for mental suffering'.

However, as stated above, it is important to note that it is unclear whether compensation provisions related to third parties also apply to COVID-19 vaccines or only to damage caused by compulsory vaccinations, as Act No. 569/2020 does not expressly refer to Act No. 116/2020 regarding damage suffered by third parties (see CMS page [here](#)).

It is not specified whether funeral costs are covered under this NFCS.

Damages appear to be assessed on an individual basis – however, it should be noted that there are guidelines published by the Supreme Court of the Czech Republic for calculation of compensation for non-property damage which, although non-binding, are routinely followed by court (see <https://next.codexis.cz/judikatura/JD209965#L1>). It is unclear whether the Ministry of Health follows these guidelines in its assessment of vaccine injury claims.

Loss of earnings are covered under this NFCS. They seem to be quantified on an individual basis (Act No. 116/2020, § 5(2)).

There is no specified maximum quantum that can be awarded under this scheme.

Time limits for claims

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

There is no information on specific time limits to file a claim under this compensation scheme.

Evaluating claims – standard of proof required

Adverse reactions likely linked to a specific vaccine are listed in an implementing decree for the NFCS - for such reactions, a presumption of causality exists (therefore, the applicant will not have to offer proof of causation when an adverse reaction is among those listed in the decree). As of March 2021, no adverse reactions to Covid-19 vaccines have been included in the decree (see <https://ceelegalmatters.com/czech-republic/16149-czech-republic-to-compensate-for-harm-suffered-as-a-result-of-covid-19-vaccination>).

Appeals and the right to litigate

There is a restricted right to litigate - The NFCS-implementing legislation does not exclude the obligation of the state to compensate for damage according to other laws. For cases covered by the NFCS, exercising the right to compensation through NFCS is a condition for the eventual exercise of the right to compensation for damage in court. (see §1(2) and §5(6) Act no. 116/2020).

There is an external review process where the decision of the Ministry of Health can be challenged through litigation in court.

Useful information and links

It is not known whether the scheme produces periodic reports including data on claims & financial performance.

Links to legislation:

Act No. 116/2020 Coll.: <https://www.zakonyprolidi.cz/cs/2020-116>

Act No. 569/2020 Coll.: <https://www.zakonyprolidi.cz/cs/2020-569>

Denmark

Introduction

Denmark had an existing no-fault compensation scheme for vaccines created 8 March 1978, and which incorporated covid-19 vaccines from 27 December 2020.

This scheme was created under national legislation. It is now governed by the [Complaints and Compensation Act LBK No 9 of 04/01/2023](#).

It is administered by the Danish Patient Compensation Association ([Patientserstatningen](#)), who are a public body.

The funding for the scheme comes from central government funds.

Vaccines Covered

This NFCS covers EU approved vaccines administered in Denmark on the free National Vaccination Program.

This includes vaccines approved for emergency use and standard approvals.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS any injury is potentially covered.

Charges for making a claim

There is no upfront charge for making a claim under this scheme, but a deductible is taken from successful claims. The deductible is set out at Section 46 clause 2 of the Act, it is uplifted each year and the 2023 value is 8,305 DKK.

Claimants

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

- Vaccine recipient/their representative
- Estate of a deceased vaccine recipient

Under this scheme the claimant is allowed to nominate a legal representative to make their claim. There is no funding for direct legal representation within the scheme, but there is provision for the scheme to arrange for the examination of witnesses in the district court where they live funded by the state under s33 paragraph 3.

Losses covered

This scheme pays the following

Live vaccine recipient	Dependants 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

Quantification of loss is set out under the [Promulgation of the Act on Liability Act law 1070 of 24/08/2018](#). The figures set out below are from 2018 and will have been subject to annual increases.

It includes the following claim types

Payments for the vaccinated individual

- **Lost earnings.** Lost earnings is intended to cover a temporary period until the vaccine recipient can return to work. It is not paid if the reduction in earning capacity is less than 15%.
- **Pain and Suffering.** This is paid at a daily rate, is capped at 50,000 DKK.
- **Lasting harm.** This is a fixed lump sum calculated taking into account the medical nature and extent of the injury and the disadvantages caused to the claimant's personal life. For 100 per cent disability the compensation to DKK 573,500. In case of lower degrees of disability, the amount is reduced proportionately. In special cases, the disability allowance may be set at a higher amount, but not more than DKK 687,500. No compensation is paid if the degree of disability is less than 5 per cent.
For claimants who are over 40 at the time of the injury the compensation is reduced by 1 per cent for each year that claimant was older than 39 years. If the claimant had reached the age of 60, the compensation is reduced by a further 1 per cent for each year that they were older than 59. However, the allowance shall not be further reduced after the age of 69.
- **Loss of future earning capacity.** If there is a permanent reduction in the vaccine recipient's ability to work then the loss of earning capacity is calculated taking into account:- the vaccine recipient's pre-injury earnings/earning potential; the percentage reduction in their earning capacity; and their age. If the loss of earning capacity is less than 15 percent then no payment will be made. If the vaccine recipient had reached the age of 30 at the time of the injury, the compensation is reduced by 1 per cent for each year that they were older than 29. If the vaccine recipient had reached the age of 55, the compensation is reduced by a further 2 per cent for each year in which they were older than 54. However, the compensation is not further reduced after the age of 69. Loss of future earning capacity is capped at 6,020,000 DKK.

Survivors Payments

- **Funeral expenses/transitional payments.** For deceased claimants either funeral expenses or a transitional payment to a spouse/cohabiting partner are available. The transitional payment is 108,000 DKK. If the deceased person does not leave behind a spouse or cohabiting partner, then in exceptional circumstances the transitional payment may be granted to another surviving person.
- **Compensation for spouse or cohabitant.** This is 30 per cent of the compensation for complete loss of earning capacity. Unless there are special circumstances this compensation will be at least DKK 644,000. If the breadwinner had reached the age of 30, the compensation is reduced in the same way as it is for loss of earning capacity.
- **Loss of dependency compensation for children.** This is fixed at an amount equal to the sum of the maintenance contributions which the deceased would have been liable for under the Child Support Act at the time of the injury if the deceased had been liable to pay contributions. If the deceased was a single parent, the compensation is increased by 100 per cent.

Payments consist of a lump sum payment.

Funeral expenses are available under this NFCS, but only if the transitional payment is not claimed.

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

Loss of earnings are paid under this scheme. They are quantified on an individual basis/on an individual basis using a tariff/individualised but with a top cap of 6,020,000 for loss of earning future capacity .

Compensation under this scheme is capped, with a top value that depends on which elements of the compensation an individual receives.

There is no minimum claim value under this NFCS, but there is a deductible. It is not worth making a claim for an amount below the deductible value, which is 8,305 DKK in 2023.

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 becoming aware of the injury, with a ten year longstop.

Evaluating claims – standard of proof required

Section 45 of the Act places a requirement on any Health Care Professional who during their work becomes aware of injuries that are likely to give rise to compensation under the Act to inform the injured party and to help the injured party to fill in the claim form. Claims are investigated Patienterstatningen, the standard is to judge is set out in the Act and is that 'the damage is most likely caused by the use of the medicinal product'.

Appeals and the right to litigate

If a claimant disagrees with the decision reached they have 30 days to appeal to the Appeals Board of Patient Compensation. Alternatively, an appeal can be made to the Patient Ombuds Board.

There is a restricted right to litigate. There is also a subrogation clause in s 53 of the Act which means the Ministry of Health will be subrogated into a patient's subsequent Product Liability Act claim against a manufacturer. Under paragraph 2 of S53 it is clear that the State may incur the costs of legal proceedings for recovering compensation for s53 claims, and that any recovered compensation from such claims will be paid to the State to the extent to which the State has provided compensation or incurred expenses.

Useful information and links

The scheme produces an annual report including data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc)

Danish Patient Compensation Association ([Patientserstatningen](#))

Legislation

[The Complaints and Compensation Act LBK No 9 of 04/01/2023.](#)

[Promulgation of the Act on Liability Act law 1070 of 24/08/2018](#)

Estonia

Introduction

Estonia created a no fault compensation for covid-19 vaccines on 1 May 2022, effective immediately and covering Covid Vaccines administered from 27 December 2020.

This scheme was created under national legislation. It is governed by the [Medicines Act](#) RT I, 20 June 2022, 75 as amended by the [Health Care Provider's Compulsory Liability Insurance Act](#) RT I, 29 April 2022, 1.

It is administered by Estonia Health Insurance Fund ([Eesti HaigeKassa](#)), who are an independent public body who organise national health insurance to provide insured people with access to healthcare services.

The funding for the Covid vaccine compensation awarded under the scheme comes from central government funds. Fundings for compensation from adverse events caused by other vaccines come from a levy of €0.15 per dose.

Vaccines Covered

This NFCS covers EU approved vaccines, which are used in Estonia. As at March 2023 the covered Covid-19 vaccines are:

- Pfizer Comirnaty, Pfizer Comirnaty (children);

- Moderna Spikevax; Moderna Spikevax (children);
- AstraZeneca Vaxzevria;
- Janssen;
- Novavax NUVAXOVID;
- VLA2001 Valneva

It includes vaccines approved for emergency use and standard approvals.

The vaccine must have been given in Estonia.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS only eligible injuries are covered. Eligible injuries are those where:-

- the person has suffered severe injury which has lasted at least four months, or the person dies;
- the person's treatment is documented in the health information system;
- the State Agency of Medicines has established an association between the vaccination and the subsequent injury caused to the person.

The scheme specifies that there must be a 'severe' injury, but this is not defined and there is no specified disablement threshold in this scheme.

Charges for making a claim

There is nothing in the statute about whether there is a charge for making a claim under this scheme.

Claimants

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

- Injured individual
- Authorised legal representative or guardian of a vaccine recipient who is a child or an adult ward
- An heir to a deceased vaccine recipient

All individuals who have been vaccinated in Estonia are able to apply; there is no requirement for the person claiming to hold health insurance in Estonia.

Under this scheme the claimant is allowed to nominate a legal representative to make their 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	Heir of a deceased vaccine recipient
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Compensation payments are for general categories and are not broken down into economic and non-economic losses.	No compensation is specifically provided for dependants of the vaccine recipient	Compensation payments are for general categories and are not broken down into economic and non-economic losses.
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Payments consist of a lump sum payment.

Funeral expenses do not seem to be specifically provided under this NFCS.

Compensation under this scheme calculated on an individual basis using tariffs to assist with quantification. The sum insured and the benefits increase annually based on the consumer price index. The rates for 2022 and 2023 are set out below.

Injury Severity	Vaccinated 31/12/2022 or before	Vaccinated 01/01/2023 – 31/12/ 2023
Serious injury of moderate severity	€2 000	€2 390
Serious injury of medium severity	€10 000	€11 940
Serious injury	€25 000	€29 850
Very serious injury	€50 000	€59 700
Extremely serious injury or death	€100 000	€119 400

Loss of earnings are not paid under this scheme.

Compensation under this scheme is capped, for 2023 the top value available under the scheme is €119 400 for extremely serious injury or death.

There is a minimum claim value under this NFCS, in 2023 this is €2 390 for a serious injury of moderate severity.

Time limits for claims

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

Ordinarily a claim under the scheme must be brought within a year from the occurrence of the insured event. There is an exception for compensation of Covid-19 vaccine injuries. Applications for Covid-19 vaccine injury claims may be submitted retroactively from the beginning of administration thereof (27 December 2020) until 1 May 2023.

Evaluating claims – standard of proof required

The standard of proof required by the scheme is that on the balance of probabilities the vaccination caused the adverse event/ there is a preponderant probability that the vaccination caused the adverse event/other – specify

Appeals and the right to litigate

The application is submitted to the Estonian Health Insurance Fund who verify whether the application is potentially eligible for compensation. Claims can be submitted on a portal, by email or on paper. Claims which are potentially eligible for compensation are passed to the State Agency of Medicines, who assess whether there is a probable causal link between the vaccine and the reported injury or the death. The State Agency of Medicines report back to the Estonian Health Insurance Fund, who issue a decision to the applicant.

There is a restricted right to litigate - Compensation awarded through NFCS does not limit the right of the entitled person to submit a civil claim against the manufacturer or distributor of the vaccine to the extent that the Health Insurance Fund has not compensated the damage. Furthermore, the extent of compensation for damages to the entitled person by the Health Insurance Fund is reduced to the extent that the damage has been compensated by the manufacturer of the vaccine.

There is an internal appeals process where the NFCS itself reviews the decision. An application for an internal review must be submitted within 30 days of the delivery of the NFCS decision. There is also an external review process, an appeal can be filed with the administrative court under the Code of Administrative Court Procedure.

Useful information and links

The scheme does not appear to data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc)

Administrator

Estonia Health Insurance Fund ([Eesti HaigeKassa](#))

[Scheme information](#)

Legislation

The [Medicines Act](#) RT I, 20 June 2022, 75

The [Health Care Provider's Compulsory Liability Insurance Act](#) RT I, 29 April 2022, 1

Finland

Introduction

Finland had an existing no-fault compensation scheme for vaccines created 1 May 1987, and which incorporated covid-19 vaccines from 21 December 2020.

This scheme is a non-statutory scheme, it consists of insurance for members of the Finnish Cooperative for Pharmaceutical Injury Indemnities. Membership of the cooperative is voluntary. The vast majority of manufacturers, importers, marketers and sellers are members of the Finnish Co-Operative for Pharmaceutical Injury Indemnities. This means that the insurance covers nearly all medicines sold in Finland.

The Scheme ordinarily only covers medicines purchased in Finland. Section 3 of the Medicines Act ([lääkelaki, 395/1987](#)) states that all medicines that are sourced or obtained from Finland and intended for human use fall within the scope of pharmaceutical insurance if their manufacturer, importer, marketer or seller is a member of the Finnish Co-Operative for Pharmaceutical Injury Indemnities.

The Pharmaceutical insurance covers covid vaccines that have been procured in Finland via the EU common procurement mechanism. All of the covid vaccines either currently or previously administered in Finland were procured via the EU common procurement mechanism and so are covered by insurance.

The scheme is administered by the [Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities](#), who are a captive owned by the Finnish Co-Operative for Pharmaceutical Injury Indemnities.

The funding for the scheme comes from insurance contributions levied on members of the Finnish Co-Operative for Pharmaceutical Injury Indemnities. For Covid vaccine claims there was a significant unknown and reinsurance was not available. Therefore, the Finnish Government granted an insurance guarantee to the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities. A charge is levied for this guarantee in the same way as for reinsurance. The guarantee applies to coronavirus vaccines that are procured in Finland through the EU procurement mechanism.

Vaccines Covered

This NFCS covers EU approved vaccines, it therefore includes vaccines approved for emergency use and standard approvals. To be eligible under this NFCS the vaccine must have been:-

- administered in Finland and
- procured in Finland via the EU common procurement mechanism.

Injuries Covered

This NFCS covers both temporary and permanent injuries. To be eligible for compensation the vaccine recipient must have

- suffered an incapacity to work or otherwise impaired bodily functions for not less than 30 consecutive days, or
- sustained a permanent physical injury or illness, or
- died.

Charges for making a claim

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

Claimants

This is an insurance and the Insured is defined in the [Terms and Conditions](#) at point 3 as

'The Insured shall denote the users of Pharmaceutical Products.'

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

- Vaccine recipient/their representative if the vaccine recipient is a child or incapacitated
- A beneficiary of the estate of a deceased vaccine recipient
- Survivor of a deceased vaccine recipient

Under this scheme the claimant is allowed to nominate another person, including a legal representative, to make their claim. Funding for legal representation is not provided by the scheme, but each health service has a patient ombudsman who can provide assistance with submitting the claim forms.

Losses covered

This scheme pays the following

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

All payments in this scheme are secondary to other sources of compensation such as a social security payments and benefits. Quantification of claims is carried out according to the provisions of the Finnish Tort Liability Act ([vahingonkorvauslaki, no. 412 of 1974](#)) and any applicable norms and guidelines of the Traffic Accident Board. The following categories of payment are available.

Live Vaccine Recipients.

- **Costs incurred from pharmaceutical product damage.** The includes necessary extraordinary medical expenses caused by the damage, such as hospitalisation and outpatient fees, medical fees, laboratory tests, the costs of medicines and physical therapy. Other eligible costs include travelling expenses incurred for extraordinary treatment.
- **Temporary incapacity.** Compensation for temporary harm compensates the injured party for the pain, suffering and other temporary harm caused by the injury, seeking to make up for the associated loss of quality of life. The size of this compensation will depend on the nature and severity of the damage, the type and duration of treatment required, and the duration of the harm suffered. Compensation for temporary harm covers the time between the incidence of the personal injury until the state of health of the injured party has either been restored or has otherwise stabilised.
- **Permanent harm.** Pharmaceutical insurance will pay compensation for any permanent functional disability caused by pharmaceutical product damage. This compensation is determined according to a decision of the Ministry of Social Affairs and Health (incapacity categories 1-20), and depends on such factors as the nature of the disability and the age of the injured party.
- **Permanent cosmetic harm.** Compensation for cosmetic harm is payable for any permanent disfigurement, such as scarring due to pharmaceutical product damage. This compensation is determined in accordance with the guidelines of the Traffic Accident and Patient Injury

Board, and depends on such factors as the size, shape, colour, location and visibility of the scar or other cosmetic harm. It also varies according to the age of the injured party.

- **Loss of earnings.** Insurance compensation may be payable for a loss of earnings suffered by an injured employee or self-employed person. This compensation for lost earnings may be transitory or permanent. Transitory compensation for lost earnings may be payable for a period during which the injured party was unable to work normally. Permanent compensation for lost earnings may be payable if the pharmaceutical product damage has caused the injured party to suffer a permanent reduction in capacity to work. Compensation for lost earnings is payable from pharmaceutical insurance only insofar as the injured party does not receive statutory compensation. This means that any per diem allowances and pensions payable pursuant to such statutes as the Health Insurance Act ([sairausvakuutuslaki, no. 1224 of 2004](#)), the Traffic Insurance Act ([liikennevakuutuslaki, no. 460 of 2016](#)), the Workers' Compensation Act ([työtapaturma- ja ammattitautilaki, no. 459 of 2015](#)) earnings-related pensions legislation, the National Pensions Act ([kansaneläkelaki, no. 347 of 1956](#)) and the Patient Injuries Act ([Potilasvahinkolaki, no. 585 of 1986](#)) will be deducted from the compensation payable under pharmaceutical insurance.

Deceased Vaccine recipients

- **Maintenance for survivors.** The beneficiaries potentially eligible for maintenance are a surviving spouse and minor children, in certain cases children under 21 years of age and in education will also be eligible. This compensation is only payable insofar as other income and statutory benefits of the beneficiary, such as survivors' pension, do not meet the minimum necessary maintenance levels.
- **Funeral costs.** The reasonable funeral costs and associated expenses of the injured party may be reimbursed in the event of death. This insurance compensation may cover such items as the costs of a burial plot, coffin, gravestone, funeral service, flowers, obituary notice and mourning clothes. The costs of compiling the estate inventory are not covered. Funeral costs are reimbursed to the death estate or to the person who incurred the said costs out of pocket.

Payments consist of a lump sum payment.

Funeral expenses are available under this NFCS.

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

Loss of earnings are paid under this scheme. They are quantified on an individual basis.

Compensation under this scheme is capped, with a top lifetime claim value of €4 million.

There is a minimum claim value under this NFCS of €85.

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 1 year of becoming aware of the injury, with a ten year longstop.

Evaluating claims – standard of proof required

Claims are submitted to the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities, who collect the required information from the healthcare organisations. A claim settler examines the claim to see if it meets the eligibility requirements set out in the [Terms and Conditions](#). This involves clarifying if the symptoms suffered could be due to the vaccine. This usually requires obtaining the opinion a specialist doctor. The standard of proof required by the scheme is that on the balance of probabilities the vaccination caused the adverse event. If there are multiple possible causes of the injury the vaccine must be the most likely cause.

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. However, if a claimant succeeds in their NFCS claim they sign over their rights to compensation from any other source (except state benefits) to the NFCS, as specified in the [Terms and Conditions](#) 9.2

Dissatisfied claimants have various options open to them. There is an internal appeals process where the NFCS itself reviews the decision and there is an external review process where another organisation reviews the decision. A claimant can contact the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities and request a correction, any new information should be included in this request.

Claimants can also request a recommendation from the Finnish Financial Ombudsman Bureau ([FINE](#)). There are no formalities involved in submitting such a request. FINE processes settlement recommendation requests either in-house or by referring them to the Finnish Insurance Complaints Board. Requests concerning pharmaceutical insurance are generally referred to the Finnish Insurance Complaints Board. Either FINE or the Finnish Insurance Complaints Board will issue a substantiated written settlement recommendation for the case. This procedure is free of charge to applicants. A request to FINE must be submitted within three years after receiving notification of the decision of the insurance company.

There is also the option to issue legal proceedings by bringing an action against the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities. This action must similarly be brought no later than three years after receiving notification of the decision of the insurance company.

Useful information and links

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

Scheme website

[Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities](#)

[Terms and Conditions](#)

Appeals

Finnish Financial Ombudsman Bureau ([FINE](#)).

Legislation

Earnings-related pensions legislation, the National Pensions Act ([kansaneläkelaki, no. 347 of 1956](#))

The Patient Injuries Act ([Potilasvahinkolaki, no. 585 of 1986](#))

Medicines Act ([lääkelaki, no. 395 of 1987](#))

Finnish Tort Liability Act ([vahingonkorvauslaki, no. 412 of 1974](#))

The Health Insurance Act ([sairausvakuutuslaki, no. 1224 of 2004](#))

The Workers' Compensation Act ([työtapaturma- ja ammattitautilaki, no. 459 of 2015](#))

The Traffic Insurance Act ([liikennevakuutuslaki, no. 460 of 2016](#))

France

Introduction

France had an existing no-fault compensation scheme for vaccines created in 1964 (through the passing of the [Law n°64-643 of 1 July 1964](#)), which covered injuries resulting from compulsory vaccinations (see [Borghetti 2016](#)). The French vaccine NFCS is now regulated under the code de la santé publique (the Code of Public Health), [L. 3111-9](#), and is part of a broader administrative no-fault system of compensation for medical accidents (see [Looker and Kelly 2011](#)). COVID-19 vaccinations administered in the course of the vaccination campaigns established by article 55-1 of decree 2021-1262 of 16 October 2020 and by the article 53-1 of decree 2020-1310 of 29 October 2020 were incorporated into the system in December 2020 (see [here](#)).

The scheme is administered by ONIAM (Office National d'Indemnisation des Accidents Médicaux), which is a public body under the authority of the Ministry of Health.

The scheme is funded through different sources, including:

- A payment from the compulsory health insurance schemes, determined by decree and each year by the Social Security Financing Act;
- The revenue from the reimbursement of expert assessment fees, provided for in Articles L. 1142-24-4, L. 1142-24-11, L. 1221-14, L. 1142-14 and L. 1142-15;
- The revenue of penalties set out in articles L. 1142-14, L. 1142-15, L. 1142-24-6, L. 1142-24-7, L. 1142-24-16 and L. 1142-24-17 of the Code of Public Health;
- The revenue of subrogation actions under articles L. 1221-14, L. 1142-15, L. 1142-17, L. 1142-24-7, L. 1142-24-16, L. 1142-24-17, L. 3131-4, L. 3111-9 and L. 3122-4 of the Code of Public Health;
- Grants paid by the French State under articles L. 3111-9, L. 3131-4, L. 3135-1, and sections 4bis and 4ter of this chapter (Chapter II) of the Code of Public Health.

See Code of Public Health, [L.1142-23](#).

Vaccines Covered

This NFCS covers mandatory vaccines and vaccines introduced as a health emergency measure (H1N1 and Covid-19 vaccines). The Covid-19 vaccines covered are those administered in the course of the vaccination campaigns established by article 55-1 of decree 2021-1262 of 16 October 2020 and by the article 53-1 of decree 2020-1310 of 29 October 2020 (see ONIAM website, [here](#)).

It is not specifically stated whether the scheme includes vaccines approved for emergency use and standard approvals. However, since COVID-19 vaccines started receiving standard marketing approvals by the EMA in 2022 it is assumed that both categories are covered.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS any injury is potentially covered.

Note that a threshold of disability is provided for medical accidents compensation under ONIAM, but this does not apply to compulsory vaccination or emergency health measures compensation.

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:

- Vaccinated person or legal representative of the injured vaccinated person;
- Close relatives of a vaccinated person (only if the injured vaccinated person or their legal representative is also filing a claim with ONIAM)
- Legal heirs of a deceased vaccinated person or their legal representative.

See the compensation form available on ONIAM's website ([here](#)).

Under this scheme the claimant is allowed to nominate a legal representative to make their claim. There appears to be some funding for legal counsel (as well as expert medical advice), with a maximum cap of 700€.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Legal heirs of a deceased vaccine recipient
Both eligible economic and eligible non-economic losses are compensated.	No Compensation is specifically provided for dependants, however relatives of a vaccinated person can be eligible for compensation for	Both eligible economic and eligible non-economic losses are compensated.

	economic and non-economic losses.	
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It is not known whether payments consist of periodic payments, a lump sum, or a combination of the two.

Funeral expenses are available under this NFCS.

Compensation under this scheme is individualised, however there are non-binding compensation standards set out by ONIAM, which can be adapted by scheme assessors in individual cases (see ONIAM website [here](#)). The damages eligible for compensation are listed in a set of comprehensive guidelines known as DINTILHAC nomenclature (see [here](#)).

Compensation for loss of earnings is available under this scheme. It is quantified on an individual basis.

Compensation under this scheme is not capped and 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. It also does not seem to specify any time limits on when a claim can be brought.

Evaluating claims – standard of proof required

The decision on causality is made by one or more appointed experts, with the burden of proving a causal link between vaccination and damage falling on the claimant.

Appeals and the right to litigate

There is a restricted right to litigate - if a compensation offer from ONIAM is accepted, no further recourse to the court system is available. If ONIAM's offer is refused by the claimant, it is possible to seek compensation in court. ONIAM has developed a preliminary offer system in which partial offers are made while a claimant's case is still being investigated – courts have considered these acceptance of these partial offers as also barring further legal action.

There is also an external review process where an appeal against ONIAM's decision may be filed with the Administrative Court (Tribunal Administratif).

Useful information and links

The scheme produces an annual report including data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc) – for more information, see: <https://www.oniam.fr/indemnisation-accidents-medicaux/rapport-d-activite>

Link to the scheme website:

<https://www.oniam.fr/accidents-medicaux-indemnis%C3%A9s/vaccination-contre-la-covid-19>

Links to legislation:

Law n°64-643 of 1 July 1964: <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000000684954/>

Code de la santé publique (the Code of Public Health):

https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000036393284

Academic literature:

Looker, C. and Kelly, H. No-fault compensation following adverse events attributed to vaccination: a review of international programmes. *Bull World Health Organ* 89:371–378 (2011).

doi:10.2471/BLT.10.081901. Available at:

<https://apps.who.int/iris/bitstream/handle/10665/270902/PMC3089384.pdf?sequence=1&isAllowed=y>.

Borghetti, J. 2016. Causation in Hepatitis B. Vaccination Litigation in France: Breaking Through Scientific Uncertainty?, *Chi.-Kent L. Rev.* 91:543-566 (2016). Available at:

<https://scholarship.kentlaw.iit.edu/cklawreview/vol91/iss2/7>.

Additional resources:

ONIAM - Référentiel indicatif d'indemnisation: <https://www.oniam.fr/procedure-indemnisation/bareme-indemnisation>

Commission des Affaires Sociales - PROJET DE LOI DE FINANCES POUR 2023 MISSION «SANTÉ»: <https://www.senat.fr/rap/a22-118-4/a22-118-4-syn.pdf>

Germany

Introduction

The introduction of no-fault vaccine injury compensation in Germany followed a 1953 decision of the German Supreme Court relating to smallpox vaccination ruling that people suffering damage to health caused by compulsory vaccination were entitled to compensation (see [Looker and Kelly 2011](#)). Initially, laws were introduced regulating vaccine injury compensation at a state level. State regulations were replaced in 1961 by federal legislation (Bundesseuchengesetz - 'German Federal Epidemic Act').

The Federal Epidemic Act was in turn replaced in 2001 by the '[Infektionsschutzgesetz](#)' ('IfSG'), ('German Infection Protection Act') which, in conjunction with the Federal Law on War Pensions

([‘Versorgung nach dem Bundesversorgungsgesetz’/‘BVG’](#)), regulates the current no-fault compensation scheme for vaccine injuries in Germany. There is no specific COVID-19 start date, but it appears the scheme has covered COVID-19 vaccines since the start of the COVID-19 vaccination campaign in Germany.

Claims for compensation are filed with the Social Affairs Offices (Versorgungsämter). The Public Health Departments of the respective Federal States (Länder) are also responsible to produce reports assessing potential causal links between vaccination and damage to health, and can offer assistance with the initiation of compensation claims (see the section on vaccine injury on the Robert Koch Institute website, [here](#)).

The funding for the scheme comes from the relevant federal state (Land), according to Section 66 IfSG.

Vaccines Covered

This NFCS covers any publicly recommended vaccinations (which includes both compulsory and non-compulsory vaccines) – see Section 60 IfSG.

Although not specifically indicated in the law, it seems this scheme includes vaccines approved for emergency use and standard approvals.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS only eligible injuries are covered. Eligible injuries are defined as ‘...the health-related and economic consequences of a health impairment due to vaccination the degree of which exceeds that of a normal post-vaccinal reaction’ – see Section 2, 11 IfSG.

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:

- Injured vaccinated person;
- Surviving dependants of an injured vaccinated person.

See Section 60 IfSG, paragraphs 1 to 4.

It is not known whether under this scheme the claimant is allowed to nominate a legal representative to make their claim.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Estate of a deceased vaccine recipient
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Only eligible economic losses are compensated	Compensation payments are for general categories and are not broken down into economic and non-economic losses.	No Compensation is specifically provided for the estate or legal heirs of injured vaccinated people.
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Payments consist of a mixture of periodic payments and lump sum payments.

The main elements of compensation are listed in Section 9 of the BVG and further defined in following sections of the BGV. They include the following:

- Medical expenses;
- Disability pension and care allowance;
- Funeral benefit and death benefit;
- Survivor's pension.

Funeral expenses are available under this NFCS.

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

Loss of earnings appear to be covered under this NFCS as occupational compensation ('Berufsschadensausgleich') is paid (see BGV, Section 30). They are quantified on an individualised basis.

The maximum quantum that can be awarded under this scheme depends on the nature of the injury and is determined by reference to tariffs/guidelines established by law.

Time limits for claims

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

There is no specific time limit to file a claim under this compensation scheme.

Evaluating claims – standard of proof required

The standard of proof required by the scheme is that on the balance of probabilities.

In case of scientific uncertainty regarding the cause of an applicant's condition, compensation can still be awarded with the consent of the highest Land authority responsible for the compensation of war victims ('Kriegsopferversorgung') – see Section 61 IfSG.

Appeals and the right to litigate

There is a restricted right to litigate - If a person has opted to apply to the NFCS, this prevents them from starting a civil liability claim against third (non-state) parties. In this case, claims against third parties are assigned by law to the federal state liable to pay compensation. However, any claims which are not covered or exceed the compensation coverage provided by the relevant legislation (BVG) can still be asserted against third parties.

There is both an internal opposition process and an external review process where the social court reviews the Social Affairs Office decision.

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:

‘Infektionsschutzgesetz’ (‘IfSG’): <https://germanlawarchive.iuscomp.org/?p=2487> [English translation]

‘Versorgung nach dem Bundesversorgungsgesetz’ (‘BVG’): <https://www.gesetze-im-internet.de/bvg/BJNR104530960.html> [in German]

Academic literature:

Looker, C. and Kelly, H. No-fault compensation following adverse events attributed to vaccination: a review of international programmes. *Bull World Health Organ* 89:371–378 (2011). doi:10.2471/BLT.10.081901. Available at: <https://apps.who.int/iris/bitstream/handle/10665/270902/PMC3089384.pdf?sequence=1&isAllowed=y>.

Other resources:

Robert Koch Institute website: https://www.rki.de/DE/Content/Kommissionen/STIKO/Impfsicherheit/sicherheit_impfungen_node.html

Iceland

Introduction

Iceland introduced a no-fault compensation scheme for COVID-19 vaccine injuries in 2020, which is regulated under the Act no. 156/2020 of December 23, 2020, Amending the Patient Insurance Act no. 111/2000 (Right to Compensation Due to Vaccination), and the Patient Insurance Act No. 111/2000 (as amended).

The administrator of this scheme is Sjúkratryggingar Íslands (Icelandic Health Insurance), which is an agency administering public health insurance in Iceland, handling negotiation and payment for health services and carrying out additional tasks. Icelandic Health Insurance is regulated by the Act on Health Insurance, no. 112/2008, and its board members are appointed by the Minister of Health.

As Icelandic Health Insurance is funded through the State Treasury (see Act no. 112/2008, Article 54) the funding for this NFCS seems to come from the Icelandic state budget.

Vaccines Covered

This NFCS covers vaccines against COVID-19 administered between 2020 and 2023 provided by the Icelandic health authorities. Liability covers damage resulting from the properties of the vaccine or its incorrect handling, including during its transport, storage, distribution or vaccination by a healthcare professional.

Although not specifically indicated in the law, it seems this scheme includes vaccines approved for emergency use and standard approvals.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS all injuries are potentially covered.

Charges for making a claim

There are no known charges for making a claim under this scheme.

Claimants

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

- An injured vaccinated person;
- Dependants who lose their supporting person upon the death of the injured person.

The claimant is allowed to nominate a legal representative to make their claim under this scheme.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient (in case of death of the injured person)	Legal heirs of a deceased vaccine recipient
Both eligible economic and eligible non-economic losses are compensated	Not specified	It is not known whether any compensation is available for legal heirs of a deceased vaccine recipient.

It is not known whether NFCS payment consists of periodic payments, lump sum payments, or a mix of periodic payments and lump sum payments.

It is not specified whether funeral costs are covered under this NFCS.

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

Loss of earnings are paid under this scheme. They are quantified on an individual basis.

Compensation under this scheme is capped, with a top value of ISK 5,000,000.

There is a minimum claim value under this NFCS of IKR 116,057 for incidents occurring in 2020; IKR 121,047 for incidents occurring in 2021.

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 four years from the moment the injured party received or could have received knowledge of the injury, but no later than ten years after the incident that resulted in the injury.

Evaluating claims – standard of proof required

The injury should be 'in all probability' caused by Covid-19 vaccination.

Appeals and the right to litigate

There is a restricted right to litigate - a claim for damages might be filed only for any outstanding amount not compensated by the NFCS.

There is an external review process where the decision of the Icelandic Health Insurance can be challenged by filing an appeal with the Welfare Appeals Committee.

Useful information and links

It is not known whether the scheme produces periodic reports including data on claims & financial performance.

Links to legislation:

Act no. 156/2020: <https://www.althingi.is/altext/151/s/0680.html>.

Act No. 111/2000: <https://www.althingi.is/lagas/nuna/2000111.html>.

Other resources:

Vaccine NFCS page on the Icelandic Health Insurance website: <https://island.is/sjuklingatrygging-baetur-vegna-tjons>.

Italy

Introduction

Italy had an existing no-fault compensation scheme for vaccines created in 1992 (through the passing of [Law no. 210/92](#)), and which incorporated COVID-19 vaccines from 2022.

This scheme was created under national legislation.

Applications for no-fault compensation are filed with Local Health Authorities (Aziende Sanitarie Locali). Since 2001, competence for the compensation procedure has been transferred from the Ministry of Health to Regions, with the sole exception of Sicily, where the state retains powers over compensation claims filed by residents.

The funding for the scheme comes from the Italian Government.

Vaccines covered

Originally, this NFCS covered nationally approved mandatory vaccines only (with the exception of particular groups of claimants, such as certain hospital workers who have undergone vaccinations, even if not mandatory), but subsequent Constitutional Court decisions have expanded the scope of the law to include other vaccines which are not compulsory but recommended by the state. COVID-19 vaccines were included in the scheme following the passing of the [Law-Decree no. 4 of 27 January 2022](#), amending Law no. 210/92.

The scheme includes vaccines approved for emergency use and standard approvals.

Injuries covered

Under this NFCS only eligible injuries are covered. Eligible injuries are injuries causing a permanent mental or physical impairment.

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:

- Injured vaccine recipient;
- Specified surviving family members in case of death of the vaccine recipient (in the following order: spouse, children, parents, siblings under the age of 18, siblings over the age of 18);
- Non-vaccinated people who have been permanently impaired as a result of contact with a vaccinated person.

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

In addition to vaccination-related injuries, note that the scheme also provides compensation for individuals who have been irreversibly damaged by hepatitis or HIV infection resulting from transfusion or administration of blood products, and to other related categories of claimants.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Estate 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 mixture of periodic payments and/or a lump sum payment (in case of death following vaccination).

The availability of funeral expenses is not specified under this NFCS.

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

Loss of earnings are not paid under this scheme.

The maximum amount of compensation that can be awarded under this scheme depends on the quantum determined by tariffs, which are set out in Table B of [Law no. 177/76](#). In case of death of the vaccine recipient, the surviving claimant is entitled to a pre-determined lump sum of € 77,468.53 (either in a single instalment or in the form of a pension over a period of 15 years).

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 from the moment the vaccine recipient becomes aware of the injury, or within 10 years from death in case of death of the vaccine recipient.

Evaluating claims – standard of proof required

The decision on causation in individual cases is made by committees of experts ('Commissioni Mediche Ospedaliere' or 'CMO'), which are made up of at least three medical officers. The specific standard of evidence adopted by the committees is not further detailed in the NFCS legislation.

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.

There is an external review process to review CMO's decisions. A request for review needs to be filed with the Ministry of Health within 30 days from notification of the CMO's decision, or from the moment the claimant has full knowledge of the decision. In addition, the Ministry of Health's decision can be reviewed by the competent Employment Tribunal (in this case, a request for review needs to be filed within one year from communication of the Ministry of Health's decision).

Useful information and links

It is not known whether annual reports including data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc) are available for this scheme.

NFCS information on the Ministry of Health website (in Italian):

<https://www.salute.gov.it/portale/indennizzo/dettaglioContenutiIndennizzo.jsp?lingua=italiano&id=921&area=indennizzo&menu=vuoto>

<https://www.salute.gov.it/portale/moduliServizi/dettaglioSchedaModuliServizi.jsp?lingua=italiano&label=servizionline&idMat=ASS&idAmb=IND&idSrv=L210&flag=P>

Links to legislation (in Italian):

<https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=13249> (Law no. 210/92)

<https://www.gazzettaufficiale.it/eli/id/2022/01/27/22G00008/sg> (Law Decree no. 4/2022)

<http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:1976-04-29;177!vig=2023-02-10> (Law no. 177/76)

Kosovo

Kosovo is a member of the COVAX NFCS.

Latvia

Introduction

Latvia had an existing no-fault compensation scheme introduced in 2013 for damage caused to patients by health care practitioners (HCPs), which can be claimed from the Latvian ‘Medical Treatment Risk Fund’. This scheme appears to also cover cases of vaccine-related injury, but only in cases when this has been caused by an HCP (for example, if the injury has been caused by an injection mistake by the HCP administering the vaccine) -see CMS Guide 2021 ([here](#)) and also the website of the Latvian Health Inspectorate administering the Fund since 2019 ([here](#)).

In 2022, Latvia introduced a new NFCS for COVID-19 vaccines through [Cabinet Regulation No. 272 Adopted on 3 May 2022](#) (‘Cabinet Regulation’), issued pursuant to Section 49.7 of the [Law on the Management of the Spread of COVID-19 Infection](#).

This scheme was created under national legislation.

It is administered by the Zāļu valsts aģentūra (ZVA) (State Medicines Agency), which is a public body.

The funding for the scheme comes from central government – see Cabinet Regulation, 1.2.

Vaccines Covered

This NFCS covers EU-approved COVID-19 vaccines administered in Latvia (namely the vaccines ‘Comirnaty’, ‘Spikevax’, ‘Vaxzevria’, ‘Jcovden’ or ‘Nuvaxovid’) – see ZVA website, [here](#).

It includes vaccines approved for emergency use and standard approvals (see Cabinet Regulation, 3.2, stating the NFCS covers ‘[any] vaccine against COVID-19 which has been registered in a centralised registration procedure in conformity with Regulation (EC) No 726/2004...’).

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS only eligible injuries are covered. Eligible injuries are those causing serious harm or moderately serious harm to a patient which are listed as adverse events in the product characteristics of the relevant COVID-19 vaccine. Additionally, the injury must have a long-lasting impact on the patient’s health, with the effects of the injury lasting for at least 26 weeks, or the injury resulting in the death of the patient. (see Cabinet Regulation, 3)

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:

- Vaccinated person who suffered an eligible injury or a legal representative of the vaccinated person;
- Legal heir of the vaccinated person in case of death due to vaccination.

(see ZVA website [here](#))

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

Funding for legal representation is not specifically offered to claimants under this scheme.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Estate 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 specifically provided 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.

Funeral expenses are not specifically provided for under this NFCS.

Compensation under this scheme calculated on an individual basis using tariffs/guidelines to assist with quantification. The tariffs are included as Annex 1 to the [Cabinet Regulation](#).

Loss of earnings are not paid under this scheme.

Compensation under this scheme has a top value of €142,290 (see Annex 1 to the [Cabinet Regulation](#), and also to Section 49.7(1) of the [Law on the Management of the Spread of COVID-19 Infection](#)).

There is a minimum claim value under this NFCS of €5000 in the event the injured claimant is undergoing medical treatment of at least 26 weeks and/or has temporary incapacity for work for at least 26 weeks (if the person is employed) and she requires medical procedures, surgical interventions, and/or rehabilitation (see Annex 1 to the [Cabinet Regulation](#)).

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 two years from the date of discovery of the damage, but no later than three years from the date of vaccination.

Evaluating claims – standard of proof required

Under this scheme, there is a double assessment of causality, looking at:

- The potential causal link between the adverse effect caused to a patient and COVID-19 vaccination (see Cabinet Regulation, 9.2); and
- The potential causal link between the adverse effect caused by COVID-19 vaccination and the serious or moderately serious harm inflicted on the health or life of a patient (see Cabinet Regulation, 9.3).

If the ZVA finds that there is a possible causal relationship between a specific side effect and COVID-19 vaccination, it prepares all the necessary information and medical documentation within five working days and submits it to a specialist in the relevant field of the clinical university hospital or to a committee of specialist doctors to assess the possible causal relationship between the side effect caused by the vaccine against COVID-19 and the severe or moderate damage to the health or life of the patient (see Cabinet Regulation, 10).

Further information on the standard used by the ZVA to determine whether there is a causal relationship between a specific side effect and COVID-19 vaccination could not be found in the relevant statute or regulation.

A decision on compensation shall be taken by the ZVA within six months after receipt of the compensation claim. If additional information needs to be requested, collected, and evaluated, the period for examining the compensation claim and taking the decision may be extended for up to one year (see Section 49.7(2) of the [Law on the Management of the Spread of COVID-19 Infection](#)).

Appeals and the right to litigate

Use of the scheme and litigation are mutually exclusive and a claimant must choose which one they take (see Section 49.7(3) of the [Law on the Management of the Spread of COVID-19 Infection](#)).

There is an external review process of the ZVA's decision. A decision of the Agency may be appealed with the Ministry of Health, whose decision may in turn be appealed in court in accordance with the the Latvian 'Administrative Procedure Law' (Cabinet Regulation, 20).

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:

Law on the Management of the Spread of COVID-19 Infection of 5 June 2020 (as amended), OP number 2020/110A.1: <https://likumi.lv/ta/en/en/id/315278-law-on-the-management-of-the-spread-of-covid-19-infection>

Cabinet Regulation No. 272 Adopted on 3 May 2022: <https://likumi.lv/ta/en/en/id/332106-regulations-regarding-compensation-for-serious-or-moderately-serious-harm-to-the-health-or-life-of-a-patient-inflicted-due-to-adverse-effects-caused-by-vaccination-against-covid-19-infection>

Link to the NFCS section on the ZVA website:

<https://www.zva.gov.lv/lv/pacientiem-un-sabiedribai/zales/vakcinas-pret-covid-19/kompensacija-par-blakusparadibu-radito-kaitejumu>

Luxembourg

Introduction

Not much information is available on vaccine injury no-fault compensation in Luxembourg, and some of the details of this scheme remain unclear. We have mapped out this scheme to the best of our knowledge.

Luxembourg passed the [Law of 4 July 2000 on the responsibility of the State on vaccinations](#) ("Loi du 4 juillet 2000 relative à la responsabilité de l'Etat en matière de vaccinations") containing provisions on compensation by the State for vaccine injuries. According to Article 1 of the Law it is provided that:

- the eligible vaccination should be a vaccination required by a legislative or regulatory provision or recommended by the State;
- the vaccination has caused the death or permanent physical disability of the vaccinated person.

The claim, however, seems to exist only insofar as the damage is not compensable under the Social Security Code ("Code de la Sécurité Sociale"). Claims under the Social Security Code are available to anyone who has suffered a medical damage, including the damage resulting from a publicly recommended protective vaccination. Successful claimants are entitled to a disability pension ("Pension d'invalidité") in accordance with Chapter II of the Social Security Code.

The main scheme administrator appears to be the National Pension Fund Authority ("Caisse Nationale d'Assurance Pension"/CNAP). The Social Security Medical Inspectorate ("Contrôle Médical

de la Sécurité Sociale"/CMSS) is the body tasked with assessing causal links between damage to health and vaccination giving right to a pension.

The funding for this NFCS seems to come from the state budget.

Vaccines Covered

This NFCS covers publicly recommended protective vaccination.

The scheme seems this scheme includes vaccines approved for emergency use and standard approvals.

Injuries Covered

Compensation under Law 4 July 2000 is limited to cases of death or permanent physical disability. It is unclear whether the compensation provided under the Social Security Code covers both temporary and permanent injuries or permanent injuries only.

Charges for making a claim

There are no known charges for making a claim under this scheme.

Claimants

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

- An injured vaccinated person with a disability claim;
- Surviving dependants of the injured vaccinated person

It is not known whether claimant is allowed to nominate a legal representative to make their claim under this scheme.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient (in case of death of the vaccine recipient)	Legal heirs of a deceased vaccine recipient
Compensation payments are for general categories and are not broken down into economic and non-economic losses.	Compensation payments are for general categories and are not broken down into economic and non-economic losses.	No compensation seems to be specifically provided for Legal heirs of a deceased vaccine recipient.

NFCS payment seem to consist mainly of periodic payments (disability pension for the injured vaccinated person and survivor's pension for surviving dependants).

Additionally, according to article 17 of Social Security Code, the following key forms of damages are covered (non-exhaustive list):

- medical care;
- dental care;
- treatment by health professionals;
- medical biology analyses;
- orthoses, prostheses, epitheses and dental implants;
- drugs, human blood and blood components;
- medical devices and medical food products;
- treatments carried out in hospitals;
- the cost of hospitalisation in the event of childbirth and in the event of hospitalisation except for simple accommodation;
- therapeutic and convalescent cures;
- rehabilitation and functional re-education;
- the cost of transporting patients;
- palliative care in accordance with the allocation procedures specified by Grand-Ducal Regulation (R. 28.4.2009);
- psychotherapies for the treatment of a mental disorder.

According to article 348 Social Security Code related to the nursing care insurance, the following damages are covered (non-exhaustive list):

- in the field of personal hygiene: aids and care aimed at keeping the body clean;
- in the field of disposal: aids and care aimed at the removal of waste from the body;
- in the field of nutrition: aids and care aimed at assisting the absorption of food, hydration and enteral nutrition;
- in the field of clothing: aid and care for dressing and undressing;
- in the field of mobility: assistance and care in changing position, moving around and entering and leaving the home.

It is not specified whether funeral costs are covered under this NFCS.

It is not clear how compensation under this scheme is quantified. There do not seem to be *de minimis* or maximum caps to compensation.

It is not known whether loss of earnings is compensated under this scheme.

Time limits for claims

It is not known whether there is a time limit between vaccination and the adverse event occurring.

It is not known whether there is a time limit within which a claim under the scheme must be brought.

Evaluating claims – standard of proof required

The 'probability of a link' seems to be sufficient to prove a causal link under this scheme.

Appeals and the right to litigate

Possible claims under general legislation seem to remain unaffected by the existence of the NFCS. The statutory claim for damages against third parties appears to pass to the state obliged to grant the benefits, see Article 1 para 2 Law 4 July 2000.

There is both an internal and an external review process. A negative decision from CNAP can be first challenged through opposition proceedings against the Executive Board of the CNAP ("Conseil d'administration de la CNAP"). If unsuccessful, the decision can then be appealed to the Social Security Arbitration Board ("Conseil arbitral de la sécurité sociale"). A final appeal that can be filed with the Higher Council of Social Security ("Conseil supérieur de la sécurité sociale"). Additionally, if there is a valid legal basis, it is possible to start litigation in court.

Useful information and links

It is not known whether the scheme produces periodic reports including data on claims & financial performance.

Links to legislation:

Law 4 July 2000: <https://legilux.public.lu/eli/etat/leg/loi/2000/07/04/n1/jo>

Social Security Code: https://legilux.public.lu/eli/etat/leg/code/secureite_sociale

Moldova

Moldova is a member of the COVAX NFCS.

Norway

Introduction

Norway had an existing no-fault compensation scheme for vaccines, which was incorporated into the Norwegian medicines compensation arrangements in 2004 by Act 430 of 10 June 2003. Covid-19 vaccines were incorporated from 21 December 2020.

This scheme was created under national legislation under the [Act Relating to Compensation for Patient Injuries, etc \(Patient Injury Act\)](#) Act 53 of 15 June 2001.

It is administered by norsk pasientskade-erstatning NPE (the patient insurer in Norway), who are a government agency under the Norwegian Ministry of Health and Care Services.

The funding for the scheme comes from Levies.

Vaccines Covered

Approved vaccines administered in Norway are covered by this NFCS. This covers EU approved vaccines, both vaccines approved for emergency use and standard approvals.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS any injury is potentially covered.

Charges for making a claim

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

There is no upfront charge for making a claim under this scheme. There is provision for a deductible added to the [Patient Injury Act](#) by Act No. 78 of 29 June 2007, but no deductible appears to have been set.

Claimants

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

- Vaccine recipient/their representative
- Estate of vaccine recipient
- Survivor of a deceased vaccine recipient

Under this scheme the claimant is allowed to nominate a legal representative to make their claim. In some circumstances funding for legal representation is provided by the scheme, but this is not automatic. There is provision for payment of legal fees for those who lack capacity, don't speak Norwegian, etc, but payment of legal representation fees is not standard. A patient ombudsman and/or a Health Care Professional can also help fill in forms.

Losses covered

This scheme pays the following

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

All payments in this scheme are secondary to other sources of compensation such as a social security payments and benefits. As set out in the [Indemnity Act](#), Act 26 of 13 June 1969 the following payments categories are available.

Live Vaccine recipients

This NFCS generally only compensates economic losses. The exception to this is the payment of permanent injury compensation.

Permanent injury compensation. This is available in cases of permanent (10+ years) and significant (over 15% disablement) injury. Permanent injury compensation is awarded for the loss of quality of life, irrespective of whether the affected individual has suffered a financial loss. The quantification of permanent injury compensation is based on the rate of medical disability, the patient's age at the time of the injury and the National Insurance Base Rate.

Loss of earnings. This covers both past lost earnings and future loss of earnings. Quantification is individual comparing pre-injury income levels with post-injury earnings; the resulting difference is the loss to be covered. This is a net loss calculation so benefits as a result of the injury will be deducted from the compensation. Travel expenses, trade union dues and pension contributions and other cost involved with employment will also be taken into consideration. Compensation for net future losses will normally be restricted to pension age. It may also be appropriate to award compensation for loss in pension amount.

Household work. If the claimant has been rendered incapable of carrying out normal household chores compensation will be provided to cover the cost of having this work done. The amount of compensation payable will depend on the extent of the injury, the residential situation, the family situation etc. There is an expectation on claimants to adjust to the new situation and, for example, redistribute household chores.

Expenses. Reasonable and necessary expenses incurred as a consequence of the injury will be covered. This can include expenses incurred in connection with medical treatment, medication, physiotherapy and transport which will not be provided by other sources. In some cases, the cost home modifications and of everyday care may also be eligible. This includes both incurred expenses and predicted future expenses.

Deceased Vaccine Recipients.

Funeral expenses. Normal funeral expenses and other reasonable expenses in connection with the death will be covered.

Loss of maintenance. Lost maintenance, covering the loss of the deceased's financial contribution to the family and domestic input in the form of work and care during a transitional period. Any benefit receivable such as funeral benefit, widow's/widower's pension and children's pension will be deducted from the compensation. Any widow or widower has a duty to make adjustments in order to gradually become able to pay for their own sustenance. This means that the compensation award is payable for a restricted period of time.

Payments consist of a lump sum payment.

Funeral expenses are available under this NFCS.

Compensation under this scheme calculated on an individual basis.

Loss of earnings are paid under this scheme. They are quantified on an individual basis.

Compensation under this scheme is not capped.

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 three years of becoming aware of the injury.

Evaluating claims – standard of proof required

NPE are responsible for both patient injury claims and pharmaceutical claims. Interestingly claims for covid vaccine injury use the patient injury claim form rather than the drug injury form. Claims are handled by a claims manager, who gathers the required medical evidence, seeks advice from an independent expert if required and then determines the claim. Successful claims are then quantified. The standard of proof required by the scheme is specified in Section 3 of the Patient Injury Act

‘In the case of compensation resulting from injury under recommended or mandatory vaccinations pursuant to Act No. 5 of [1994 August 55](#) relating to protection against communicable diseases, the right to compensation under section 2 first paragraph (d) shall apply unless the person responsible proves that one or more other causes are more likely.’

This is a reversal of the burden of proof.

Should new evidence come to light a claim can always be reopened.

Appeals and the right to litigate

There is a restricted right to litigate. Section 4 of the Patient Injury Act states

‘The Act does not prevent claims for compensation from being asserted against parties other than the Norwegian System of Patient Injury Compensation. However, claims that may be brought pursuant to this Act may not be brought against the state, regional health authorities, health trusts, county authorities and municipalities. Recourse can only be claimed against the person who has caused the damage intentionally or who has failed to pay a subsidy under section 8.’

In effect there is a requirement to use the NFCS rather than going to court.

If a claimant is unhappy with the outcome of the NFCS decision they can an appeal against the decision. This is both an internal appeals process and an external appeals process. The appeal must be sent to NPE for consideration within three weeks of the decision date. If NPE do not find grounds for reversing the decision the appeal will be sent on to the Patient Injury Compensation Board (PSN). The PSN are a separate public body. If the refusal to pay compensation is upheld by the PSN the case can then be litigated in the courts.

Useful information and links

The scheme produces an annual report including data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc)

Link of the scheme website.

[NPE - Home](#)

[LAF - Home](#)

Legislation

[Act Relating to Compensation for Patient Injuries, etc \(Patient Injury Act\)](#) Act 53 of 15 June 2001.

[Act relating to damages \(Indemnity Act\)](#) Act 26 of 13 June 1969

Poland

Introduction

Poland created a no-fault compensation scheme for COVID-19 vaccines through the passing of the Act of 17 December 2021 Amending the Act on Preventing and Combating Infections and Infectious Diseases in Humans and Other Acts ([OJ 2022 pos. 64](#)). The amendment came into effect on 27th January 2022. The amended version of the Act of 5 December 2008 on Preventing and Combating Infections and Infectious Diseases in Humans (OJ 2008 No. 234 item 1570) is available [here](#). The NFCS is regulated by Articles 17a to 17i of the Act.

It is administered by the Rzecznik Praw Pacjenta (Ombudsman for Patients' Rights), who are a public body.

The funding for the scheme comes from multiple sources – see Act of 5 December 2008 on Preventing and Combating Infections and Infectious Diseases in Humans (referred to below as 'Infectious Diseases Act'), Articles 17b, 17c and 17e. These include suppliers' payments on vaccine supply contracts (equal to 1.5% gross value of the contract), user fees, payments from the state budget, and private donations.

It should be noted, however, that the supplier contribution provision contained in Article 17c, sec. 1. does not apply to COVID-19 vaccines procured by agreement for early purchase of vaccines against COVID-19 disease caused by the SARS-CoV-2 virus stipulated by European Commission and EU Member States on 16 June 2020 (see Infectious Diseases Act, Article 17c, sec. 2).

Vaccines Covered

This NFCS covers EU-approved vaccines for specified diseases. Originally, the Compensation Fund only covered COVID-19 vaccinations. From January 2023, the scheme also covers serious adverse reactions occurring in connection to mandatory vaccinations provided for in the Preventive Vaccination Programme. It also covers anti-epidemic vaccinations (against measles, meningococcal infections, diphtheria, whooping cough, polio and hepatitis A), which are performed in persons at particular risk of infection or illness.

It is not specified in the statute whether the scheme includes vaccines approved for emergency use and standard approvals. However, as the scheme was introduced prior to covered COVID-19 vaccines receiving Standard marketing authorisation, it may be assumed this NFCS covers vaccines approved for both emergency use and standard approvals.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS only eligible injuries are covered. In order for an injury to be eligible for compensation, it has to be listed in the [Summary of Product Characteristics \(SmPC\)](#) of the relevant vaccine, and cause:

- anaphylactic shock necessitating observation in a hospital emergency department or emergency room or hospitalisation (for any period of time), or;
- hospitalisation for at least 14 days.

For more information on covered injuries, see the relevant Patients' Rights Ombudsman section on the Polish government website [here](#) (in Polish).

Charges for making a claim

There is a charge for making a claim under this scheme of PLN 200 (which corresponds to about 37 GBP). The fee is reimbursed if a claim is successful or if the proceedings cannot be initiated, and it may also be waived by the Ombudsman in certain circumstances if the claimant is experiencing financial difficulties.

Claimants

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

- Vaccine recipients and representatives of vaccine recipients (see Infectious Diseases Act, Article 17e, sec. 2).

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

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

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Estate 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 specifically provided for the dependants of a vaccine recipient.	No Compensation is specifically provided for the estate of a vaccine recipient.

Payments consist of a lump sum payment.

Funeral expenses are not available under this NFCS.

Compensation under this scheme calculated on an individual basis using tariffs/guidelines to assist with quantification. The specific amounts that can be awarded under this scheme are set out in Article 17a, and are the following:

In the event of anaphylaxis following a covered vaccination:

- PLN 3,000 in case of observation in a hospital emergency department or emergency room,
- PLN 10,000 in case of hospitalisation for up to 14 days.

In the event of hospitalisation of minimum 14 days following an adverse reaction to vaccination listed in the Summary of Product Characteristics (in proportion to the length of time spent in hospital):

Duration of hospitalisation	Benefit amount
14 - 30 days	PLN 10,000 - PLN 20,000
31 - 50 days	PLN 21,000 - PLN 35,000
51 - 70 days	PLN 36,000 - PLN 50,000
71 - 90 days	PLN 51,000 – PLN 65,000
91 - 120 days	PLN 66,000 - PLN 89,000
>120 days	PLN 100,000

In addition, a claimant may be entitled to further compensation if further treatment or hospitalisation in ICU is needed:

- surgery under general anesthesia - PLN 15,000;
- another surgical procedure or method of treatment or diagnostics posing an increased risk - PLN 5,000;
- hospitalization in an intensive care unit or intensive care unit lasting at least 7 days – PLN 10,000;
- hospitalization in an intensive care unit or intensive care unit lasting more than 30 days – PLN 20,000.

The compensation benefit may also include reimbursement of the costs of further treatment or rehabilitation after the end of the observation or hospital stay, up to PLN 10,000 (in this case, a claimant should provide copies of the treatment or rehabilitation documentation together with documentation confirming the costs incurred).

Loss of earnings are not paid under this scheme.

Compensation under this scheme is capped, with a top value of PLN 100,000 (about 18,600 GBP).

There appears to be a minimum claim value under this NFCS of PLN 3,000 in case of observation in a hospital emergency department or emergency room following an adverse reaction to a covered vaccine.

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 one year from the last day of hospital stay or observation and no later than five years after vaccination. In the event the Summary of Product Characteristics of the relevant vaccine is updated to cover the claimant's injury, the time limit will be one year from the SmPC update, but still no later than five years after vaccination.

Evaluating claims – standard of proof required

The decision on compensation is taken by the Ombudsman for Patients' Rights after obtaining an expert opinion from the Team for Benefits from the Protective Vaccination Compensation Fund. In order to be eligible for compensation an adverse event should be included in the Summary of Product Characteristics of the relevant vaccine. The standard of proof required by the scheme is not further specified.

Appeals and the right to litigate

There is a restricted right to litigate – NFCS proceedings shall not be initiated, and the initiated proceedings shall be discontinued if the applicant has been paid redress or damages on the basis of a final court decision issued in civil proceedings related to the occurrence of adverse reactions after the administered vaccine or vaccines, or if civil proceedings are pending (see Article 17f, sec. 17 and sec. 18).

If litigation is pursued after obtaining NFCS compensation, the compensation benefit granted by the NFCS is credited towards redress or damages in civil proceedings related to the occurrence of adverse reactions after the administration of a vaccine or vaccines.

There is an external review process - NFCS decisions can be appealed to the administrative court (Article 17g, sec. 3).

Useful information and links

The scheme produces a periodic report including data on claims (claim numbers, payments, etc) - The Ombudsman for Patients' Rights should submit a bi-annual report to the minister competent for health matters on vaccine compensation, in particular on the number of submitted applications and the amount of compensation benefits granted, taking into account the types of vaccines and their side effects (see Article 17i). It is not known whether this periodic report is published.

Links to Legislation:

Act of 17 December 2021 Amending the Act on Preventing and Combating Infections and Infectious Diseases in Humans and Other Acts (OJ 2022 pos. 64):

<https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20220000064>

Act of 5 December 2008 on Preventing and Combating Infections and Infectious Diseases in Humans (OJ 2008 No. 234 item 1570), as amended:

<https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20082341570/U/D20081570Lj.pdf>

Link of the scheme website:

Ombudsman for Patients' Rights website section on the Vaccine Compensation Fund:

<https://www.gov.pl/web/rpp/fundusz-kompensacyjny-szczepien-ochronnych>

Russia

Introduction

The Russian Federation had an existing no-fault compensation scheme for vaccines created in 1998 on the basis of the Federal Act 'On the Immunoprophylaxis of Infectious Disease' ([Federal Law No. 157-FZ of September 17, 1998](#)), Chapter V 'Social Support of Citizens in the Event of Post-vaccination Complications'. The NFCS is further regulated by the Decree of the Government of the Russian Federation 'On the Procedure for Paying State Lump-Sum Benefits and Monthly Monetary Compensation to Citizens When They Have Post-Vaccination Complication' of 27 December 2000, No. 1013 ([Government of the Russian Federation Decree No. 1013 of 27.12.2000](#)).

The NFCS seems to have started covering COVID-19 vaccinations since the inclusion of COVID-19 vaccines in the National Calendar of Preventive Vaccinations for Epidemic Indications in December 2020.

The scheme is administered by the Social Security Authorities of the constituent entities of the Russian Federation (органами социальной защиты населения), which are public bodies – see Decree No. 1013 of 27.12.2000, 5.

The funding for the scheme comes from the Federal government (Federal Law No. 157-FZ of September 17, 1998, Article 18 and Decree No. 1013 of 27.12.2000, 5).

Vaccines Covered

This NFCS covers nationally approved vaccines for a pre-specified list of diseases. The diseases covered are those included in the National Calendar of Preventive Vaccinations and the Calendar of Preventive Vaccinations for Epidemic Indications.

COVID-19 vaccination has been added to the Calendar of Preventive Vaccinations for Epidemic Indications by Order of the Ministry of Health entering into force on 27 December 2020 (see [here](#)).

It is not explicitly stated whether this scheme includes vaccines approved for emergency use, but as COVID-19 vaccines in the Russian Federation were introduced under [conditional approval](#) it appears that both vaccines approved for emergency use and standard approvals can be covered by this NFCS.

Injuries Covered

The kinds of injuries covered by the NFCS are not specified in the statute or government decree, however the statute provides that a list of post-vaccination complications that give citizens the right to receive state lump-sum benefits is approved by the Government of the Russian Federation on the proposal of the federal executive body in the field of healthcare (Federal Law No. 157-FZ of September 17, 1998, Article 19). According to the CMS Guide on vaccine compensation regimes 'Russian legislation provides a list of instances when a person is eligible for social compensation due to post-vaccine complications (e.g. anaphylactic accident, serious generalised allergic reactions or encephalitis)' (see [Tyupa and Shadrin 2021](#)).

This NFCS also appears to cover temporary injuries (see Federal Law No. 157-FZ of September 17, 1998, Article 21).

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 people who have been injured by a covered vaccine;
- Family members of people who have died following a covered vaccine injury.

The specific family members entitled to receive the a NFCS allowance is determined in accordance with Article 10 of the [Federal Law 'On Insurance Pensions'](#). See Decree No. 1013 of 27.12.2000, 2.

It is not known whether under this scheme the claimant is allowed to nominate a legal representative to make their claim. However, in case the person injured by a covered vaccine is a minor, the law provides that parents or *other legal representative* of the minor have the right to receive temporary disability benefits for the entire period of the minor's illness associated with a post-vaccination complication (see Federal Law No. 157-FZ of September 17, 1998, Article 21).

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 general categories and are not broken down into economic and non-economic losses.	No Compensation is specifically provided for dependants of vaccine recipients.	Compensation payments are for general categories and are not broken down into economic and non-economic losses.

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

Compensation under this scheme can be a fixed sum indicated in the statute (in cases of eligible post-vaccination complications, death or permanent disability) or individualised (in cases of temporary disability):

- In the event of an eligible post-vaccination complication, a citizen has the right to receive a state lump-sum allowance in the amount of **10,000 rubles** - Federal Law No. 157-FZ of September 17, 1998, Article 19(1).
- In the event of the death of a citizen as a result of a post-vaccination complication, members of his family have the right to receive a state lump-sum allowance in the amount of **30,000 rubles** - Federal Law No. 157-FZ of September 17, 1998, Article 19(2).
- A citizen recognized as disabled due to a post-vaccination complication has the right to receive a monthly monetary compensation in the amount of **1,000 rubles** - Federal Law No. 157-FZ of September 17, 1998, Article 20.

- A citizen whose temporary disability is associated with a post-vaccination complication is entitled to receive temporary disability benefits in the amount of **100 percent of average earnings**, regardless of continuous work experience.
- One of the parents or other legal representative of the minor has the right to receive temporary disability benefits for the entire period of the minor's illness associated with a post-vaccination complication in the amount of **100 percent of the average earnings**, regardless of continuous work experience - Federal Law No. 157-FZ of September 17, 1998, Article 21.

Funeral expenses are not specifically paid under this NFCS.

Payment for loss of earnings on an individualised basis appears to be available under this scheme only in cases of temporary disability.

Compensation under this scheme is not capped.

There is no minimum claim value under this NFCS.

Time limits for claims

The do not seem to be any specific time limits on when a claim can be brought under this scheme.

Evaluating claims – standard of proof required

The Social Security Authorities have to make a decision on the payment or refusal to pay compensation within 10 days from the date of application.

The standard of proof required adopted by the Authorities is not specified by the relevant statute or governmental decree. The claimant has to include in the application medical documents confirming the complications, disability, or death following vaccination.

Appeals and the right to litigate

The right to litigate does not seem to be affected by use of the scheme.

There appears to be an external appeal process to review the Authorities' decisions, although not much information is available on this review process – according to the Decree No. 1013 of 27.12.2000, 16, disputes over the payment of compensation 'are resolved in the manner prescribed by the legislation of the Russian Federation'.

Useful information and links

The scheme appears to produce periodic reports including data on financial performance (payments, administrative costs, etc) (Decree No. 1013 of 27.12.2000, 18). It is not known whether these reports are made available to the public.

Links to legislation:

Federal Law No. 157-FZ of September 17, 1998: <https://minzdrav.gov.ru/documents/8007-federalnyy-zakon-157-fz-ot-17-sentyabrya-1998-g>

Decree No. 1013 of 27.12.2000: <https://rulaws.ru/government/Postanovlenie-Pravitelstva-RF-ot-27.12.2000-N-1013/>

Other literature/resources:

CMS (2021). COVID-19 Vaccination and Testing in Russia - Employment Law Perspective. CMS Guide, available at: <https://cms.law/en/int/expert-guides/cms-expert-guide-to-vaccination-and-testing-for-employers/russia>

Tyupa, V. and Shadrin, A. (2021). Vaccine Compensation Regimes in Russia. CMS Guide, available at: <https://cms.law/en/int/expert-guides/cms-expert-guide-to-vaccine-compensation-regimes/russia>

Slovenia

Introduction

Slovenia introduced a no-fault compensation scheme for vaccine injuries following a 2004 decision of the Slovenian Constitutional Court which found the Communicable Diseases Act (Zakon o nalezljivih boleznih – ‘ZNB’) unconstitutional in so far as it did not regulate procedures to obtain justified waivers from compulsory vaccination and did not provide for State liability for damages suffered by individuals due to compulsory vaccination. The ZNB was amended to incorporate no-fault compensation provisions for compulsory vaccination in 2006 (see [Preložnjak and Šimović 2018](#)). No-fault compensation provision was extended to cover COVID-19 vaccination in December 2021 with the passing of the [Act on Additional Measures to Stop Spreading and Mitigate, Control, Recover and Eliminate the Consequences of COVID-19](#) (Zakon o dodatnih ukrepih za preprečevanje širjenja, omilitev, obvladovanje, okrevanje in odpravo posledic COVID-19, ZDUPŠOP), No. 206/21, which came into effect on 30 December 2021.

The administrator of this scheme is the Slovenian Ministry of Health. For Covid-19 vaccines specifically, the evaluation of damage to health or death is done by the National Institute of Public Health (NIJZ) (source: https://static.eurofound.europa.eu/covid19db/cases/SI-2021-53_2121.html).

The funding for this NFCS comes from the Slovenian state budget.

Vaccines Covered

This NFCS covers mandatory vaccines and vaccines against COVID-19 administered by a healthcare provider licensed to practice health care in the Republic of Slovenia. The NFCS also covers medicines to treat COVID-19 which have been granted a temporary marketing authorisation and have been administered by a healthcare provider licenced in Slovenia.

Although not specifically indicated in the law, it seems this scheme includes 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 those resulting in ‘grave and permanent reduction in vital body functions’.

Charges for making a claim

There are no known charges for making a claim under this scheme.

Claimants

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

- People vaccinated or cured by registered vaccinations or medicines who have suffered eligible injuries (i.e. grave and permanent reduction in vital functions);
- Spouse or partner of someone who has died following a vaccine injury
- Parents of a child below 18 years of age and above 18 if they support the child or were sharing the same household (in case of death of the child);
- Children below 18 years of age and above 18 if the injured person was supporting them (in case of death of the injured person.)

It is not known whether under this scheme the claimant is allowed to nominate a legal representative to make their claim.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Specified surviving family members of a deceased vaccine recipient
Compensation payments are for general categories and are not broken down into economic and non-economic losses.	Compensation payments are for general categories and are not broken down into economic and non-economic losses. (only in case of death of the injured vaccinated person)	Compensation payments are for general categories and are not broken down into economic and non-economic losses.

Payments consist of a lump sum payment.

Compensation under this scheme calculated on an individual basis using tariffs/guidelines to assist with quantification. Injured vaccinated people who have suffered grave and permanent reduction in vital functions are awarded compensation amounting to €60,000. The spouse or partner of someone who has died following a vaccine injury and the parents of a child below 18 years of age (and above 18 if they support the child or were sharing the same household) who has died following a vaccine injury are awarded compensation amounting to €10,000. Children below 18 years of age (and above 18 if the injured person was supporting them) are awarded compensation amounting to €20,000 – see https://static.eurofound.europa.eu/covid19db/cases/SI-2021-53_2121.html.

Loss of earnings do not seem to be paid under this scheme.

The maximum quantum that can be awarded under this scheme depends on the nature of the injury and is determined by reference to tariffs/guidelines established by law.

It is not specified whether funeral costs are covered under this NFCS.

Time limits for claims

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

Under this NFCS there is a time limit to file a claim of 6 years from date of vaccination.

Evaluating claims – standard of proof required

This NFCS decides on causation on based on an expert opinion of a specialised commission.

Appeals and the right to litigate

There is a restricted right to litigate - According to art. 53.f ZNB, '[w]ith the payment of compensation under this law, all damage for which the state is objectively responsible under this law is settled.' However, according to art. 71 of the Act on additional measures to prevent the spread, mitigation, control, recovery and elimination of the consequences of COVID-19 - ZDUPŠOP (Official Gazette of the RS, No. 206/21 of 29.12.2021), 'The provisions of this Act do not interfere with the right of persons referred to in the previous article to compensation for damages according to general regulations, and in particular, the provisions of this Act do not apply to the compensation of damages that are the result of professional irregularities in the provision of vaccination or treatment for COVID-19 or inadequate the quality of a vaccine or medicine for the treatment of COVID-19 in accordance with the regulation governing medicines.'

There is an external review process for the decision of this NFCS.

Useful information and links

It is not known whether the scheme produces periodic reports including data on claims & financial performance.

Links to legislation:

Act on Additional Measures to Stop Spreading and Mitigate, Control, Recover and Eliminate the Consequences of COVID-19 No. 206/21:

<http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO8506>.

Academic literature:

Barbara Preložnjak and Ivan Šimović. 2018. European Experiences and Croatian Perspectives of Compensation Programs in Case of Childhood Vaccine Injury. Intereulaweast, Vol. V (1). Available at: <https://hrcak.srce.hr/file/299286>.

Other resources:

Eurofund EU Policy website: https://static.eurofound.europa.eu/covid19db/cases/SI-2021-53_2121.html

Sweden

Introduction

Sweden had an existing no-fault compensation scheme for vaccines created in 1978, and which incorporated covid-19 vaccines from 21 December 2020.

This scheme is a non-statutory scheme, it consists of insurance for [members](#) of the Swedish Pharmaceutical Insurance Scheme. Membership of the scheme is voluntary, but 98% of companies that manufacture and market pharmaceutical in Sweden are members.

The scheme is administered by the Swedish Pharmaceutical Insurer (Svenska Läkemedelsförsäkringen or [LFF](#)). Companies and organizations that take out pharmaceutical insurance become a partner in the jointly owned company LFF Service AB. Each policyholder owns a share each in LFF Service AB. This company in turn owns Svenska Läkemedelsförsäkringen AB or LFF, a captive insurance company that handles the damage. The Scheme rules are set out in an [Undertaking](#).

In Sweden vaccines manufactured by Pfizer, AstraZeneca, Novavax and Moderna have been used. Pfizer, AstraZeneca, Novavax are members of Swedish Pharmaceutical Insurance scheme, so their vaccines are covered by the insurance.

Moderna has not taken out insurance from the scheme. Claims for damages from Moderna's vaccines which were reported to the LFF before 1 December 2021 are regulated by LFF. All other claims for damages from Moderna vaccines are compensated by the state via Kammarkollegiet² under the same framework as in the Pharmaceutical Insurance NFCS. Claims arising from Moderna's Covid-19 vaccine must still be made to the Pharmaceutical Insurance NFCS, who then forward the claim to Kammarkollegiet.

The funding for the scheme comes from insurance contributions levied on members of LFF. There is a statutory top up provision 2020/21:221 passed on 10-Nov-2021 whereby the Swedish Government indemnified the scheme either when the vaccine manufacturer is not part of the Swedish Pharmaceutical Insurance (as was the case with Moderna) or when the 20 million SEK cap for covid injury compensation has been reached.

Vaccines Covered

This NFCS covers nationally approved vaccines from EU approved vaccines.

It includes vaccines approved for emergency use and standard approvals.

² A Legal, Financial and Administrative Services Agency under the Ministry of Finance

Injuries Covered

This NFCS covers both temporary and permanent injuries. To be eligible for compensation the vaccine recipient must have suffered an injury for not less than 30 days.

Under this NFCS any injury is potentially covered.

Charges for making a claim

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

Claimants

The [Undertaking](#) states at Section 8 that compensation for drug damage is determined in accordance with Chapter 5 Sections 1 – 5 and Chapter 6 Section 3 of the Damages Act (Skadeståndslagen [1972:207](#))

Based on the Damages under this scheme the following categories of individuals are permitted to make a claim.

- Vaccine recipient/their representative if the vaccine recipient is a child or incapacitated
- A representative of the estate of a deceased vaccine recipient
- Survivor of a deceased vaccine recipient

Under this scheme the claimant is allowed to nominate another person to make their claim. Funding for legal representation is not provided by the scheme as per section 8.3 of the [Undertaking](#).

Losses covered

This scheme pays the following

Live vaccine recipient	Survivors 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 compensation follows Damages Act (Skadeståndslagen [1972:207](#)) and the quantification is based on the Traffic Damage Board's tables. The following categories of payment are available.

Live Vaccine Recipients

- **Incurred Costs:** medical expenses and other necessary and reasonable costs caused by the vaccine injury; The costs can be temporary or in some cases lifelong.
- **Temporary incapacity - Pain and suffering:** Compensation for transient pain and suffering, this calculated from the point the injury occurred until the vaccine recipient's condition has recovered. Based on a tables created by the [Traffic Damage Board](#).

- **Permanent Harm:** Compensation for lasting harm and inconvenience. The degree of disability is expressed as a percentage where 0% is completely undamaged and 100% is theoretically a condition when all bodily functions cease. This compensation also includes compensation for stress at work and inconvenience in general. The compensation is provided as a lump sum based on the [Traffic Damage Board's](#) tables
- **Scars or other changes in appearance:** Based on the [Traffic Damage Board's](#) tables.
- **Loss of income:** If an injury causes loss of income due to not being able to work or having a reduced capacity to work, compensation is provided for it. This is quantified as the actual loss that a person suffers taking into account sickness benefit and other benefits that have been paid. If the injury is so severe that the individual will never be able to work again compensation is provided until retirement age in the form of an annuity. Since the benefit is not pensionable, compensation for loss of pension is also provided in such cases.

Deceased Vaccine Recipients

The Damages Act (Skadeståndslagen [1972:207](#)) specifies the following compensations are available if a vaccine has caused the recipient's death.

- **Funeral expenses:** Funeral expenses, to a reasonable extent, other costs resulting from the death
- **Loss of maintenance:** Compensation for loss of maintenance shall be awarded to survivors who were legally entitled to the maintenance of the deceased or who were otherwise dependent on him, if maintenance was paid at the time of death or if it can be assumed that maintenance would have been paid in the near future thereafter. The loss is compensated to the extent that is reasonable in view of the survivor's ability and ability to contribute to his or her own livelihood through his own work or otherwise, other than through the compensation for the deceased's loss of earning. The value of the deceased's housework in the home is incorporated into a maintenance payment.
- personal injury caused by the death to someone who was particularly close to the deceased.

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

Funeral expenses are available under this NFCS.

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

Loss of earnings are paid under this scheme. They are quantified on an individual basis.

Compensation under this scheme is capped, with a top value of 10 million SEK.

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 10 years of the vaccination.

Evaluating claims – standard of proof required

Claims are reported to the LFF on a standardised claim form. LFF then request Power of Attorney authorisation from the claimant to enable them to obtain medical records. A case officer compiles the records and sends them to a relevant medical specialist and in some instances the treating doctor. An administrator then determines the case. The standard of proof required by the scheme is the damage is predominantly caused by the vaccine and could not have been foreseen.

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. However, if a claimant succeeds in their NFCS claim they sign over their rights to compensation from any other person who could be found liable for the damages to the NFCS, as specified in the [Undertaking](#) section 17.

There is an external review process where another organisation reviews the decision. [The Pharmaceutical Injury Panel](#) review the decision of the LFF. If a claimant disagrees with the decision of the Pharmaceutical Injury Panel they can take their case to court.

Useful information and links

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

Administrator

Swedish Pharmaceutical Insurer (Svenska Läkemedelsförsäkringen or [LFF](#))

[Scheme Rules – the Undertaking](#)

Appeals

[The Pharmaceutical Injury Panel](#)

Legislation and quantification

Damages Act (Skadeståndslagen [1972:207](#))

[Traffic Damage Board Tables](#)

Switzerland

Introduction

Switzerland had an existing no-fault compensation programme for mandatory or officially recommended vaccines introduced in 1970 through the [Federal Law of 18 December 1970 on Communicable Disease Control \(Epidemics Act\) 818.101](#). Originally the programme was administered at the canton level, and each canton of Switzerland used to be responsible for developing their own compensation procedures (see [Crum, Mooney and Tiwari 2021](#)).

A complete revision of the Epidemics Act was passed on 28th September 2012 and entered into force on 1st January 2016. Articles 64 to 69 of the revised Act provide for a uniform federal procedure for handling claims for compensation and moral reparation in the event of damage caused by vaccinations. There does not appear to be a specific date on which COVID-19 vaccines were explicitly incorporated into this scheme. However, the NFCS seems to have covered eligible COVID vaccination-related injuries since the introduction of COVID-19 vaccines in Switzerland in December 2020.

It is administered by the Federal Department of Home Affairs (FDHA) which is Government department (see Epidemics Act, Article 66(1)).

The funding for the scheme comes from different sources depending on the specific vaccine considered (Epidemics Act, Article 68). For recommended vaccinations, the Confederation and the canton in which the vaccination takes place each pay one half of the costs of the compensation. For compulsory vaccinations, the entire costs of the compensation shall be paid by:

- a. the Confederation if it has declared the vaccination to be mandatory;
- b. the Canton that declared the vaccination to be mandatory.

Vaccines Covered

This NFCS covers mandatory and officially recommended vaccines (Epidemics Act, Article 64).

As Switzerland [does not allow for emergency authorisation](#), it is assumed the Swiss vaccine NFCS only covers vaccines which have received standard approval.

Injuries Covered

This NFCS covers both temporary and permanent injuries.

Under this NFCS only eligible injuries are covered. In order to be eligible for compensation, an injury following a mandatory or officially recommended vaccination needs to have caused damage to health, that is an impairment lasting for a shorter or longer period of time involving financial loss (i.e. a reduction in assets).

Damage due to vaccination does not include minor side effects (e.g. redness, swelling or hardening at the injection site, headache, muscle aches, fever) which generate costs in the event of drug treatment or medical examination.

In case of severe health impairment, compensation for non-monetary damage (such as pain, suffering and emotional distress) is also awarded. The compensation awarded for non-monetary damage is proportionate to the severity of the injury (see Epidemics Act, Article 65).

Note that NFCS compensation under this scheme is granted only and to the extent that the damage suffered as a result of the vaccination is not covered by third parties, according to the principle of subsidiarity. An applicant is required to prove that she has not received payments from third parties, in particular from insurance companies, or that these payments are insufficient to cover the damages (see guidelines to applicants, available [here](#) in Italian, French and German).

Charges for making a claim

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

Claimants

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

- Vaccine recipient or legal representative of the vaccine recipient (see Article 100, [Human Communicable Diseases Ordinance 818.101.1](#))

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 this scheme.

It should be noted that, while not included as possible applicants by Article 100, [Human Communicable Diseases Ordinance 818.101.1](#), dependants and surviving relatives of deceased vaccine recipient also seem to be covered by this compensation scheme – see Epidemics Act, Article 65(1) and Code of Obligations, Article 47 (on non-economic loss compensation), which should apply by analogy to cases of vaccine compensation, and also [applicant guidelines](#) on types of damage covered. Article 47 of the Code of Obligations provides for non-economic compensation ('moral damages' or 'satisfaction') in cases of personal injury or homicide, with the surviving family of the deceased person receiving compensation. NFCS applicant guidelines also include funeral costs and damages caused by the loss of the person providing support among the categories compensated by the scheme.

Losses covered

This scheme pays the following:

Live vaccine recipient	Dependants of vaccine recipient	Surviving family 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 (compensation to dependants only appears to be available if the vaccinated person is deceased).	Both eligible economic and eligible non-economic losses are compensated.

It is not known whether payments consist of a lump sum payment, a periodic payment, or a mixture of periodic payments and a lump sum payment.

Funeral expenses are available under this NFCS.

Compensation under this scheme is individualised for economic loss, while tariffs/guidelines are used to assist with quantification of non-economic loss (the guidelines for non-economic loss are included among the documents available for download on the FDHA website [here](#)).

Loss of earnings are paid under this scheme. They are quantified on an individual basis.

Compensation under this scheme is capped for non-economic loss, with a top value of 70,000 CHF – see Epidemics Act, Article 65(3).

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 5 years of vaccination, or by the age of 21. This NFCS only covers injuries following vaccinations administered after 1 January 2016.

Evaluating claims – standard of proof required

Specific criteria to determine the existence of a causal link between vaccination and an injury are developed by the Federal Commission for Vaccination (FCV). This takes into account internationally recognized scientific criteria and the criteria used by the Swiss Agency for Therapeutic Products in order to evaluate the undesirable effects of drugs.

The FCV maintains a publicly accessible list including in particular the following elements:

- already recognized undesirable effects of a vaccination;
- criteria for establishing the causal link between vaccination and damage;
- criteria for determining the level of severity of the undesirable effects of a vaccination, in particular if the damage resulted in hospitalization, disability, death, another event or other limitation;

The FCV updates the list regularly taking into account current scientific knowledge – see [Human Communicable Diseases Ordinance 818.101.1](#), Article 86.

Appeals and the right to litigate

The right to litigate is not affected by use of the scheme. The principle of subsidiarity applies – an injured person has to make reasonable efforts to be compensated through other legal routes prior to applying to the NFCS.

There is an external review process where another organisation reviews the decision (see Epidemics Act, Article 69).

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 the scheme website:

Federal Office of Public Health website, section on vaccination NFCS (Available in German, French and Italian): <https://www.bag.admin.ch/danni-vaccinazione>

Links to legislation:

[Human Communicable Diseases Ordinance 818.101.1](#)

[Federal Law of 18 December 1970 on Communicable Disease Control \(Epidemics Act\) 818.101](#)

Academic literature:

Crum, T., Mooney, K., & Tiwari, B. R. (2021). Current situation of vaccine injury compensation program and a future perspective in light of COVID-19 and emerging viral diseases. *F1000Research*, 10, 652. <https://doi.org/10.12688/f1000research.51160.2>

Ukraine

Ukraine is a member of the COVAX NFCS.

Non-implemented National Covid Vaccine NFCS

Resolution of the Cabinet Ministers of Ukraine of 31 March 2021 No. 371, *Some questions of the State compensation of the harm connected with complications which can arise after vaccination against acute Covid-19 disease (SARS-Cov-2 caused by coronavirus)*, sets out provisions for no-fault compensation. The provisions of this Resolution that related to establishing a NFCS were repealed by Resolution of the Cabinet Ministers of Ukraine of 9 February 2022 No. 137.

United Kingdom

Introduction

The UK had an existing no-fault compensation scheme for vaccines created 22 March 1979, and which incorporated covid-19 vaccines from 31 December 2020.

This scheme was created under national legislation, the [Vaccine Damage Payments Act 1979](#) and [the Vaccine Damage Payments \(Specified Disease\) Order 2020](#).

Since 1 November 2020 it has been administered by the NHS Business Services Authority (NHSBSA), who are a public body. Prior to that it was administered by the Department for Work and Pensions, a Government Department.

The funding for the scheme comes from central Government.

Vaccines Covered

This NFCS covers vaccines for specified diseases as listed in Section 1(2) of the [Act](#) or added by a Statutory Instrument which are administered in the UK.

It potentially 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.

This NFCS will only recompense injuries which cause 60% or greater disablement.

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.

- Live vaccine recipient
- the representative of a vaccine recipient if they are a child or unable to manage their own affairs
- The estate 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 as it is not considered necessary, but legal aid is available for some appeals against the scheme decision.

Losses covered

This scheme payments are *ex gratia* and are not referred to as compensation. The scheme pays the following

Live vaccine recipient	Dependants of vaccine recipient	Estate of a deceased vaccine recipient
Payments are for general categories and are not broken down into economic and non-economic losses.	No Compensation is provided specifically for dependants	Payments are for general categories and are not broken down into economic and non-economic losses.

Payments consist of a lump sum payment. Payment under this scheme is fixed at a value of £120,000. This is a tax-free sum, but it may impact on some other social security benefits.

Funeral expenses are not available under this NFCS.

Loss of earnings are not paid under this scheme.

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 6 years of the vaccination or by the age of 21 if the vaccine recipient was a child.

Evaluating claims – standard of proof required

Applicants apply on a specified form which gives consent for NHSBSA to access the claimant's medical records. If a claim is assessed as potentially eligible it is passed to a medical assessor who determines whether:-

1. If the vaccination caused the disablement and
2. If the disablement meets the 60% or greater threshold.

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

Appeals and the right to litigate

This is an *ex gratia* scheme, 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.

There is both an internal appeals process where the NFCS itself reviews the decision and an external review process where another organisation reviews the decision. The internal review process involves claimants who are unhappy with the decision writing to NHSBSA asking for a 'mandatory reversal'. Claimants should explain why they are dissatisfied and including any additional information they want considered. NHSBSA will then review their decision and either issue a new decision or a 'Mandatory Decision Notice' which explains the reasons behind their original decision. The Mandatory Decision Notice also contains information on the external appeal option, an appeal to the Social Security & Child Support Tribunal. There is no limit on the number of times a claimant can ask for a mandatory reversal.

Useful information and links

It is unclear whether the scheme will produce data on claims & financial performance (claim numbers, payments, claim processing timeframes, administrative costs, etc) as the latest NHSBSA Annual report is for the period 2020/2021, prior to them taking on the Vaccine Damage Payment Unit.

Link of the scheme website.

[Vaccine Damage Payment: Overview - GOV.UK \(www.gov.uk\)](https://www.gov.uk/vaccine-damage-payment)

[Vaccine Damage Payment Scheme \(VDPS\) | NHSBSA](https://www.nhs.uk/vaccine-damage-payment-scheme)

Legislation

[Vaccine Damage Payments Act 1979 \(legislation.gov.uk\)](https://www.legislation.gov.uk/ukpga/1979/36)

[The Vaccine Damage Payments \(Specified Disease\) Order 2020 \(legislation.gov.uk\)](https://www.legislation.gov.uk/uksi/2020/125)

[The NHS Business Services Authority \(Awdurdod Gwasenaethau Busnes y GIG\) \(Vaccine Damage Payments Scheme\) Directions 2021 \(nhsbsa.nhs.uk\)](https://www.nhs.uk/vaccine-damage-payment-scheme)

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 [92 low- and middle-income AMC Eligible Economies](#).

COVAX Countries: Afghanistan, Algeria, Angola, Bangladesh, Benin, Bhutan, Bolivia, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroon, Central African Republic, Chad, Comoros, Congo Dem. Rep, Congo Rep., Côte d'Ivoire, Djibouti, Dominica, Egypt, El Salvador, Eritrea, Eswatini, Ethiopia, Fiji, Gambia, Ghana, Grenada, Guinea, The, Guinea-Bissau, Guyana, Haiti, Honduras, India, Indonesia, Kenya, Kiribati, Korea, Dem, People's Rep, Kosovo, Kyrgyz Republic, Lao DPR, Lesotho, Liberia, Madagascar, Malawi, Maldives Islands, Mali, Marshall Islands, Mauritania, Micronesia, Federated States of, Moldova, Mongolia, Morocco, Mozambique, Myanmar, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Rwanda, Samoa, São Tomé & Príncipe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Sudan, Sri Lanka, St Lucia, St Vincent & the Grenadines, Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Timor-Leste, Togo, Tonga, 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 [Program 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 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 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 Factor	Impairment following vaccination
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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 \(gavi.org\)](https://gavi.org/covax-ca-coip-list-covax-pr-v5.pdf)