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L&RS Note

Vaccine Injury Compensation Programmes: An Overview

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This L&RS Note provides an overview of the topic of vaccine injury compensation programmes (VICPs). VICPs are no-fault schemes established to compensate individuals who experience a vaccine-related injury due to the inherent, albeit very low, risks of vaccination. The Note provides information on: (1) The main arguments for and against VICPs according to published research; (2) Where VICPs have been introduced; and (3) Key features of existing VICPs.

Key points

- Globally, 25 jurisdictions have VICPs, 16 of which are in Europe.
- Ireland does not currently have a VICP, although the Government has stated its commitment to introducing one.
- Arguments made in favour of VICPs include: (1) ethical responsibility on behalf of government; (2) that VICPs protect vaccine manufacturers from costly litigation; (3) that VICPs therefore help to ensure vaccine supply; and (4) that VICPs encourage public confidence in vaccines.
- Arguments made against VICPs include: (1) VICPs damage public confidence in vaccines; (2) VICPs are costly to the exchequer; (3) that causality between a vaccine and injury is too difficult to conclusively establish; and (4) that VICPs provide manufacturers with impunity where their product does harm.
- Eligibility for VICPs varies considerably across European countries with some requiring more stringent criteria to be met than others.
- Most of the VICPs in Europe are administered and funded by central government.
- The type of compensation in Europe can vary between lump-sum payments; monetary redress based on medical care costs, loss of earnings; or monetary compensation based on non-monetary criteria such as pain and suffering, and mental distress.

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What are Vaccine Injury Compensation Programmes?

While vaccines are generally very safe and severe adverse effects from vaccines rare, they are not without the small possibility of harm. Most adverse events following vaccination are mild and resolve quickly and completely. However, even with proper design, manufacture and delivery, serious adverse events can occur following vaccination. The risk of these events is extremely low, around 1 in every 1 million doses for the measles vaccine, to provide an example[1]. At a population level, it is considered that these small risks are more than counter-balanced by the benefits of widespread immunisation, with immunisation programmes estimated to save 2 to 3 million lives globally each year[2]. However, it is clear an individual is occasionally harmed to some degree by vaccine-related adverse effects.

Vaccine injury compensation programmes are no-fault schemes established to compensate individuals who experience vaccine-related harm.

Vaccine injury compensation programmes (VICPs; also termed vaccine damage compensation schemes or vaccine damage payments) are no-fault schemes established to compensate individuals who experience serious vaccine-related harm. As indicated by the term 'no-fault' VICPs do not require injured parties or their legal representatives to prove negligence or fault by the vaccine provider, health care system or the manufacturer before compensation. They seek to waive the need for accessing compensation for vaccine-related harms through litigation, where processes are lengthy and clear negligence can be difficult to prove. Under a no-fault VICP, governments compensate individuals harmed by properly manufactured vaccines with the intention of removing the need for individuals to use legal or other processes against manufacturers[3].

Globally, 25 jurisdictions have VICPs. Most of these countries are in Europe, and a recent review study[4] identified 16 nations in Europe with VICPs (see Table 1 below). Currently, Ireland does not have a VICP, although the introduction of one has been under examination since 2001, and the current government has stated its commitment to introducing one[5]. Debates around VICPs have arguably taken on increased significance in the context of the COVID-19 pandemic as billions of COVID-19 vaccines are intended for global administration, and manufacturers of approved COVID-19 vaccines are being afforded legal indemnity through purchase agreements which means that they cannot be pursued for compensation for vaccine-related harm[6].

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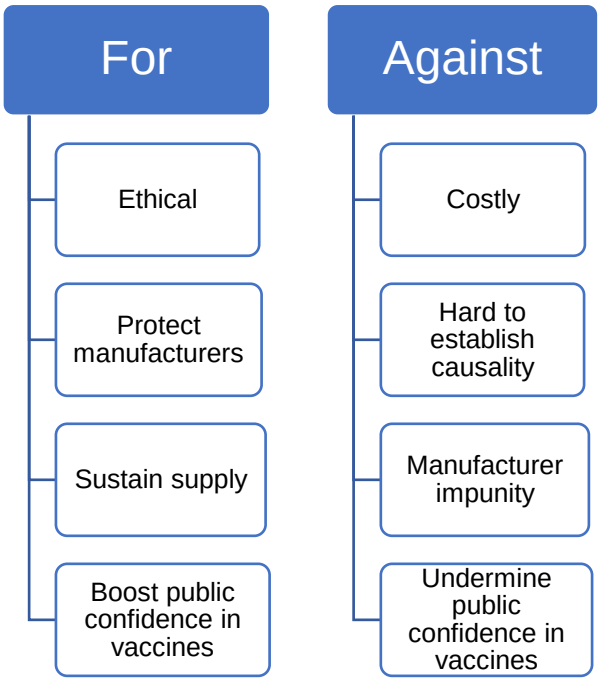
Arguments for and against VICPs

For the most part, the consensus in the peer-reviewed academic literature and among leading public health bodies (including the World Health Organization, WHO) is in favour of VICPs. However, arguments exist both in favour of and against VICPs (summarised in Figure 1).

Figure 1: Summary of arguments for and against VICPs



Source: L&RS

Perhaps the primary argument in favour of VICPs is an ethical one, which contends that because governments urge or indeed require residents to be vaccinated in order to maintain societal herd immunity against diseases, they should protect those who are damaged by these vaccines. Protecting vaccine manufacturers from costly lawsuits and consequently providing them with a degree of economic certainty is also put forward as a key argument in favour of VICPs[7]. The provision of this degree of economic certainty for manufacturers is further seen as protecting the supply of vaccines, with several scholars referencing the negative impact that lawsuits and the threat of lawsuits had on vaccine prices, vaccine research and vaccine supply in the United States prior to the establishment of the National Vaccine Injury Compensation Program in 1988[8]. A final argument commonly referenced in favour of VICPs is that they boost public confidence in vaccines, although the counterargument that VICPs undermine public confidence in vaccines by providing fuel to anti-vaccine campaigns, is simultaneously presented. Wilson and Keelan (2012) conclude that there is insufficient first-hand evidence to support the argument that VICPs either improve or decrease vaccine confidence, although they do highlight the value of reassuring the public as to the safety of vaccines where a VICP is introduced for the first time[9].

Other arguments against VICPs relate to the real or potential cost of these programmes to the exchequer, difficulties establishing a causal link between an administered vaccination and an adverse outcome, and concerns that protecting vaccine manufacturers from litigation provides them with a worrying degree of impunity in cases where their product does cause harm[10]. Governments have endeavoured to address some of these concerns within the design of VICPs,

for example by requiring standards of proof showing a causal link between vaccination and injury, although this has often led to overly strict standards of proof[11]. Empirical evidence suggests that other arguments against VICPs have been somewhat unsubstantiated; for instance a review of the jurisdictions where VICPs have been implemented shows that the costs tend to be both manageable and predictable[12]. However, in relation to this point it is important to note that most countries which have introduced VICPs are high-income countries (see Table 1) and therefore can afford to bear the costs associated with them.

A final point worth mentioning is that, while the balance of evidence tends to support VICPs, challenges with existing programmes have been raised by those involved in their administration. These challenges include: (1) lack of public awareness about the existence of VICPs; (2) overly strict standards of proof that immunisation caused injury; and (3) limitations on the ability of low-income countries to manage the costs associated with VICPs[13]. The challenge for low-income countries in maintaining national VICPs due to cost has received particular attention, with scholars advocating for the introduction of a global VICP to ensure globally equal access to compensation for vaccine injuries[14], although others have raised the legal complexities involved in administering such a system[15]. The debate around global vaccine injury mechanisms has arguably taken on more pertinence as COVID-19 vaccine programmes are rolled out worldwide[16]. Responding to this, in February 2021 an agreement was signed for the administration of a no-fault vaccine compensation programme for the 92 low- and middle-income countries and economies eligible for COVID-19 vaccine support through the Gavi COVAX Advance Market Commitment (AMC) of the COVAX Facility. The programme marks the first and only global vaccine injury compensation mechanism and is funded by a small levy on each dose supported by the Gavi COVAX AMC. It is, however, only available for serious adverse events associated with COVAX-distributed (COVID-19) vaccines until 30 June 2022[17].

Which countries have VICPs?

A 2020 global review by Mungwira and colleagues[18] published in the peer-reviewed science journal PLOS ONE reported that 25 WHO jurisdictions had no-fault VICPs, with another 126 jurisdictions reporting that they did not have VICPs, and 43 jurisdictions not providing information. Of the 25 jurisdictions with VICPs, 16 were in the European region, six in Asia, two in America, and one in Oceania. None were in Africa (see Table 1 for a list of jurisdictions). Almost all jurisdictions with VICPs, 23 of 25, were high-income; only two low and lower-middle income countries had implemented VICPs.

The Mungwira et al. (2020) global review also analysed the most common attributes of VICPs across six key areas which are administration, funding source, eligibility, claim processes and decision making, standard of proof required, and compensation. To briefly summarise, Mungwira et al. found that most VICPs (65% of VICPs evaluated) are implemented at the central or federal government level and are government funded. Eligibility criteria varied but most VICPs cover injuries arising from vaccines that are registered in the country (65%) and are recommended by authorities for routine use (57%). In most jurisdictions (78%), claim and decision-making processes are purely administrative rather than involving civil litigation.

In most jurisdictions (78%), claim and decision-making processes are purely administrative rather than involving civil litigation. All reviewed VICPs required standards of proof showing a causal association between vaccination and injury. In 52% of jurisdictions compensation was determined on a case by case basis, while 44% provided standardised compensation. Finally, in most jurisdictions (65%), vaccine injury claimants had the right to seek damages either through civil litigation or from a compensation scheme but not both simultaneously. In 26% of jurisdictions damages could be sought through a compensation scheme alone.

Table 1: Countries with no-fault VICPs

Continent	Countries with a VICP
Africa	None
American	United States, Canada
Asia	China, Japan, South Korea, Vietnam, Nepal, Thailand
Europe	Austria, Denmark, Finland, France, Germany, Hungary, Iceland, Italy, Luxembourg, Norway, Russia, Latvia, Slovenia, Sweden, Switzerland, United Kingdom
Oceania	New Zealand

Detailed overview of existing VICPs

Following on from the above, Table 2 provides an overview of key aspects of VICPs for countries in Europe with no fault VICPs. These are examined under a number of key headings which are discussed further below.

Eligibility

There can be considerable differences in terms of the vaccines covered under the various schemes as well as the level of injury required to be sustained in order to qualify for compensation. Countries such as Sweden, Finland, and Denmark compensate for injuries received from all vaccines whereas countries such as France, Germany, Norway, Switzerland, and the UK only compensate for government recommended or compulsory vaccines. Other countries determine eligibility based on occupation (e.g. health care worker), indication (e.g. travel), citizenship and time elapsed between the vaccine and a claim[19].

In terms of the level of injury sustained, some countries cite a minimum threshold for the injury to be eligible for compensation, either in financial terms or severity. Denmark requires a threshold of 3,000 Danish krone (€400) for treatment of injuries sustained, while Norway requires a threshold of 10,000 Norwegian krone (€990) for treatment (or 15% disability). Finland requires disability to last a minimum of 14 days whereas the UK defines severe injury as resulting in 60% (or greater) permanent disability[20]. Other countries that apply stringent eligibility criteria include Italy (permanent injury or death) and Switzerland (severe injury such as temporary or long-term incapacity for work).

Administration and funding

Most of the VICPs are run by central government, with only Germany and Italy currently administering the programme at a provincial level. Switzerland previously operated a system at the cantonal (state) level, though this was changed in 2016 so that the administration of the compensation programme is now done by the central government[21]. Keane et. al. cite the disparities in awards made by different states as one of the main reasons as to why Switzerland moved to a federally administered scheme[22]. Finland and Sweden are the only countries where programmes are administered by the insurance sector[23].

Most schemes are government funded although some, such as those in Finland and Sweden, are funded by industry. The schemes in Finland and Sweden are also voluntary for pharmaceutical companies to participate in with the majority of them choosing to do so[24]. The programme in Norway is funded by a special insurance organisation, the Drug Liability Association. In Latvia, its VICP (known as the Treatment Risk Fund) is funded through contributions from medical institutions[25].

Compensation[26]

With the exception of the UK which offers a lump sum payment of £120,000 (€140,000), most reviewed schemes cover medical expenses, disability pensions and death benefits[27]. These payments are usually based on the severity of the vaccine injury. Some countries also cover non-economic losses including pain and suffering and emotional distress. For example, Switzerland provides a lump-sum compensation for moral harm (mental distress) according to set rules and up to a maximum of 70,000 Swiss francs (€63,500)[28]. Other countries, such as Denmark[29] and Latvia[30], have also put a cap on individual claims.

Table 2: Overview of vaccine-injury compensation schemes for countries in Europe

Country	Eligibility	Funding source	Compensation	Number of claims awarded*	Cost *	Link
Austria	Not available.	Not available.	Not available.	Not available.	Not available.	
Denmark	All vaccines. Only citizens are eligible for compensation. A minimum threshold of treatment received for injury applies of 3,000 Danish krone (€400).	National Treasury	Pain and suffering, additional expenses and losses arising from injury less statutory benefits. Cap on a claim by an individual of €670,000.	Between 1 January 2011 and 13 April 2021, 159 claims were made of which 33 have been accepted to date.	Total cost of claims between 1 January 2021 and 13 April 2021 was 8 million Danish krone (€1.1 million). The average award was 266,706 Danish krone (€36,000).	Danish Patient Compensation Association https://pebl.dk/en/about-the-danish-patient-compensation-association

Finland	All vaccines. Requires disability to last a minimum of 14 days.	Drug manufacturer, distributer, and supplier tax.	Unreimbursed medical costs, disability pension, non-economic loss, death benefits	Recent data not available. According to a 2006 study, the average number of claims per year was 220 of which 125 was paid.	Recent data not available. From the same 2006 study, annual cost of claims was €890,000, with average claim amount of €10,000.	Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities https://www.lakevahinko.fi/en/
France	Required or compulsory vaccines. Any injury directly attributable to vaccine.	National Treasury	Medical, funeral, disability pension, death benefits, non-economic loss, losses to relatives.	Not available	Not available	The National Medical Accidents, Iatrogenic and Hospital Infections Compensation Office (ONIAM) https://www.oniam.fr/
Germany	Government recommended vaccines. Only province residents who experience a vaccine injury are eligible for compensation. Injury must exceed a normal post-vaccine reaction.	General revenues of the *Länder* (states)	Medical, funeral, disability pension, non-economic losses Supplemental payments if disability lasts for more than six months.	Recent data not available. Average of 100 claims per year paid (1961–2001)	Not available	
Hungary	Not available.	Not available.	Not available.	Not available.	Not available.	
Iceland	Not available.	Not available.	Not available.	Not available.	Not available.	
Italy	Injuries from one of five mandatory vaccines or from non-mandated vaccines required for	National Treasury	Medical, disability pension, death benefits.	Not available	Not available	

	travel or employment. Severe injury is the minimum level of injury eligible (permanent injury or death). Only province residents who experience a vaccine injury are eligible for compensation.					
Latvia	Damage to life or health (including moral damage) caused by the activities of healthcare professionals working in a medical institution.	Medical institutions	Maximum amount of compensation of €142,290 for damage to patients life or health (including moral damage).	Not available	Not available	Treatment Risk Fund https://www.vmnvd.gov.lv/en/treatment-risk-fund
Luxembourg	Not available.	Not available.	Not available.	Not available.	Not available.	
Norway	Government recommended vaccines. Damages above 10,000 Norwegian. kroner (€990) or 15% disability.	National Treasury plus drug companies' premiums.	Pain and suffering, additional expenses and losses arising from injury less statutory benefits.	Recent data not available. According to a 2006 study, the average number of claims per year was 50 of which 20 was paid.	Recent data not available. From the same 2006 study, annual cost of claims was €1.3m, with average claim amount of €50,000.	Norwegian System of Patient Injury Compensation (CPE) https://www.npe.no/en/About-NPE/
Russia	Not available.	Not available.	Not available.	Not available.	Not available.	
Slovenia	Not available.	Not available.	Not available.	Not available.	Not available.	
Sweden	All vaccines. Injuries listed in Pharmaceutical Specialities in Sweden (in Swedish only) or medical literature.	Percentage levy of drug manufacturers' annual sales.	Unreimbursed medical costs, lost wages, disability pension, death benefits.	Recent data not available. According to a 2006 study, the average number of claims per	Recent data not available. From the same 2006 study, annual cost of claims was €11.9m,	Pharmaceutical Insurance Association (LFF) https://lff.se/

				year was 600 of which 200 was paid.	with average claim amount of €18,000.	
Switzerland	Government recommended vaccines. Severe injury is the minimum level of injury eligible.	Funded by the federal Government and cantons.	Lump-sum compensation according to set rules; maximum of 70,000 Swiss francs (€63,500).	Not available	Not available	Federal Office of Public Health https://www.bag.admin.ch/dommages-vaccination
United Kingdom	Government recommended vaccines and those listed in legislation. Injury resulting in 60% (or greater) permanent disability. By vaccination, or maternal vaccination while in-utero against registered/ recommended vaccines. Vaccination must have been given in the UK or the Isle of Man, unless vaccination part of your armed forces medical treatment.	Government funded.	Standardised one-off tax-free lump sum payment of £120,000 (€140,000).	According to an FOI, between May 1978 and 30 April 2019, 6,352 claims were made of which 941. were awarded.	According to an FOI, total cost of claims between May 1978 and April 2019 was £74,690,000 (€86 million).	Vaccine Damage Payment https://www.gov.uk/vaccine-damage-payment

* Due to GDPR confidentiality issues and the merging of vaccine compensation with social security programmes and pharmaceutical, medical, or personal injury schemes in different countries, detailed information on the number of claims and overall cost of the VICP is not available for many countries. Data for Denmark was provided in a personal correspondence with the Danish Patient Compensation Association received on 19 April 2021, with the figures shown for Denmark in the table referring only to rare and serious vaccine injuries (excluding HPV and Granulom cases).

Source: Adapted from Mungwira et al. (2020), Keane et al. (2019), Looker (2011), Keelan and Wilson (2011).

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[26] The currencies in this paper have been converted as of 14 April 2021 using https://www.xe.com/currencyconverter/ and rounded to the nearest whole number.

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