WHO TAKES THE SHOT – PROPOSING A FRAMEWORK FOR COMPENSATION FOR VICTIMS OF VACCINE RELATED INJURIES IN INDIA

Aryaman Keshav, Tamil Nadu National Law University

ABSTRACT

During the COVID-19 pandemic, several state governments in India implemented mandatory vaccination policies.[1] Amidst these policies, the Supreme Court issued notice to the Central government in a plea against forcing individuals to get vaccinated with COVID-19 by mandating it as a condition for access to key services.[2] The Supreme Court further held that nobody can be forced to get vaccinated, however, if individuals risk spreading the infection or burdening public health, the government can impose reasonable restrictions on individual rights to protect public health. Therefore, the vaccination can be administered if the risk is to the greater public.

Earlier this year, AstraZeneca, the company responsible for manufacturing 'Covishield' in India, admitted that the vaccine could have side effects that could lead to Thrombosis with Thrombocytopenia Syndrome (TTS).[3] This information was not widely disseminated by the general public. This raises the question of liability: who should be held responsible? The state that made it mandatory to get vaccinated; The company that manufactured the vaccine; or the individual that took the vaccine?

The author aims at analyzing the legal liability for the side effects of covidshield and highlights the reasons as to why regulations have not been framed in India regarding compensation for victims of vaccine-related injuries and finally aims to propose a framework on which the compensation scheme can be made by taking inspiration from vaccination compensation regulations around the world.

[1] Vaccination must for being in public places - The Hindu, https://www.thehindu.com/news/national/tamil-nadu/vaccination-must-for-being-in-public-places/article37588675.ece (last visited Jul 31, 2024).
[2] Jacob Puliyel v. Union of India, 2022 SCC OnLine SC 533.
[3] Investigations team & Robert Mendick, *AstraZeneca Admits Its Covid Vaccine Can Cause Rare Side Effect in Court Documents for First Time*, THE TELEGRAPH, Apr. 28, 2024, https://www.telegraph.co.uk/news/2024/04/28/astrazeneca-admits-covid-vaccine-causes-rare-side-effect/.

Introduction

During the COVID-19 pandemic, several state governments in India, including Tamil Nadu, implemented mandatory vaccination policies.[4] Amidst these policies, the Supreme Court issued notice to the Central government in a plea against forcing individuals to get vaccinated with COVID-19 by mandating it as a condition for access to key services.[5] The Supreme Court further held that nobody can be forced to get vaccinated, however, if individuals risk spreading the infection or burdening public health, the government can impose reasonable restrictions on individual rights to protect public health. Therefore, the vaccination can be administered if the risk is to the greater public.

Earlier this year, AstraZeneca, the company responsible for manufacturing 'Covishield' in India, admitted that the vaccine could have side effects that could lead to Thrombosis with Thrombocytopenia Syndrome (TTS).[6] This information was not widely disseminated by the general public. This raises the question of liability: who should be held responsible? The state that made it mandatory to get vaccinated; The company that manufactured the vaccine; or the individual that took the vaccine?

This paper critically addresses the issue of accountability in circumstances where individuals suffer adverse side effects from vaccination. It specifically explores whether the duty rests with the state, the medical practitioner, or the vaccine producer. In this way, it tackles the issues of responsibility, informed consent, and the appropriateness of current legal systems. Finally, it aims to propose a framework on which the compensation scheme can be made by taking inspiration from vaccination compensation regulations around the world.

Who can be Held Responsible?

As evidenced under article 38 of the Indian Constitution India is a welfare state.[7] Article 21 of the Indian Constitution, as interpreted by the Supreme Court in *Bandhua Mukti Morcha v.*

[4] *Vaccination must for being in public places* - THE HINDU, https://www.thehindu.com/news/national/tamil-nadu/vaccination-must-for-being-in-public-places/article37588675.ece.
[5] Jacob Puliyel v. Union of India, 2022 SCC OnLine SC 533.
[6] Investigations team & Robert Mendick, *AstraZeneca Admits Its Covid Vaccine Can Cause Rare Side Effect in Court Documents for First Time*, THE TELEGRAPH, Apr. 28, 2024, https://www.telegraph.co.uk/news/2024/04/28/astrazeneca-admits-covid-vaccine-causes-rare-side-effect/.
[7] INDIA CONST. art. 38, amended by The Constitution (One hundred sixth Amendment) Act, 2023.

Union of India (1984)[8], enshrines the right to health as an integral aspect of the broader right to life. Furthermore, in *Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996)*[9], scope of Article 21 was broadened with the court affirming that it is the government's responsibility to secure the provision of adequate medical aid to all persons and to actively promote the welfare of the public at large. Consequently, the state has an inherent obligation to protect the health and well-being of its citizens.[10]

Furthermore, in the case of *Parmanand Katara v. Union of India (1989)*[11], the Supreme Court ruled that every doctor, whether in a government hospital or elsewhere, has a professional duty to provide enough services to safeguard a patient's life.

Over 220 crore vaccines were administered in India over the period of 2019-2023.[12] Out of that approximately 174 crore vaccines were 'Covishield', developed by Oxford university and AstraZeneca. [13] Keeping that in mind, in the instances of people suffering adverse effects after taking the vaccination, who should be held responsible? The State, the doctor or the vaccine manufacturer?

1. State

In the *Jacob Puliyel v. Union of India (2021)*[14], the mandatory vaccination mandates were challenged on the grounds that such measures, if applied without informed consent, are unconstitutional. Further, it was also contested that the absence of informed consent stems from the non-transparent process of approving the vaccines for emergency use by the government.

The Supreme Court held that individuals who opt not to get vaccinated due to personal views or choices may do so without coercion. However, if their decision has the potential to spread the infection, contribute to virus mutation, or strain public health resources, thereby affecting communal health, the government may impose reasonable and proportionate restrictions on

[8] Bandhua Mukti Morcha v. Union of India AIR 1984 SC 812.
[9] Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996) 4 SCC 37.
[10] Prof. (Dr.) Gigimon V. S & Ms. Merin Mathew, *Role of State in Guaranteeing Right to Health Under Article 21 of the Constitution of India*, 5 CMRU JCLA (2023).
[11] Parmanand Katara v. Union of India AIR 1989 S.C. 2039.
[12] Ministry of Finance, Government of India, *Economic Survey 2023-24*, (2023).NATIONAL COVID-19 VACCINATION PROGRAMME MEETS ITS GOALS BY OVERCOMING R&D AND LOGISTICAL CHALLENGES, SAYS ECONOMIC SURVEY 2022-23, https://pib.gov.in/pib.gov.in/Pressreleaseshare.aspx?PRID=1894907.
[13] Ministry of Health and Family Welfare, *Co-WIN dashboard*, Aug. 1, 2024, https://dashboard.cowin.gov.in/.
[14] Jacob Puliyel v. Union of India, W.P. (C) No. 607 of 2021.

individual rights in order to protect public health, which is a legitimate and paramount state goal.

Additionally, the Supreme Court in the case found that the government had a systematic mechanism to detect and track AEFIs. No vaccine can be approved without proper and systemic review even in the instances of emergency use. Further, the Ministry of Health and Family Welfare (MoHFW) published the results of causality evaluations on its website, making relevant AEFI information available to the public.

Therefore, the Supreme Court upheld the claim of the central government that Government not liable to compensate for COVID-19 vaccine deaths as no laxity has been shown the government in dealing with Covid-19 pandemic.

2. Medical Practitioner

The liability of a doctor in India arises from the duty of care. In *Jacob Mathew v. State of Punjab and Anr., (2005)*[15], the three-judge bench observed that "The definition of negligence involves three constituents: (1) A legal duty to exercise due care on the part of the party complained of towards the party complaining the former's conduct within the scope of the duty; (2) breach of the said duty; and (3) consequential damage. Cause of action for negligence arises only when damage occurs."

In the case of Covishield, the information regarding the adverse effects of the vaccination was made publicly available. The doctor administering the vaccination owed a duty of care to the patients, including informing them of any potential side effects of the vaccine. That duty was breached when the patients were not told about the side effects by the doctor as they went ahead with the vaccination anyway. The damage resulting out of that breach of duty was the discovery of 92,114 adverse effects events being reported in India as of 19th November 2022.[16]

Despite this, the doctors cannot be held liable. In India, the doctor is regarded as a professional endowed with more prudence to defend the right interests of the patient and granted the final

[15] Jacob Mathew v. State of Punjab and Anr., Appeal (crl.) 144-145 of 2004.
[16] *Government not liable to compensate for COVID-19 vaccine deaths, injury: Centre tells Supreme Court*, THE HINDU, (2023), https://web.archive.org/web/20231027012551/https://www.thehindu.com/sci-tech/health/government-not-liable-to-compensate-for-covid-19-vaccine-deaths-injury-centre-tells-sc/article66202106.ece.

right to decide what information must be revealed to the patient considering the circumstances and how much information is to be divulged. In the landmark case of *Samira Kohli v. Dr. Prabha Manchanda & Anr. (2008)*[17], the Supreme Court of India held that "…the doctor should explain the nature, procedure and purpose of the suggested treatment, and alternatives available, and outline of substantial risks and adverse consequences of refusing treatment. In explaining risks remote or theoretical risks that may cause the patient to be frightened enough to refuse treatment being suggested need not be described."

The adverse effects related to Covishield are indeed remote if data provided by is to be considered as per which AEFI cases were observed in 0.0042% of the total vaccination cases in India.[18] Moreover, in the instance of having a pandemic, the need of the hour was to provide immunity from Covid-19 via vaccination.

3. Vaccine Manufacturers

In the United Kingdom, AstraZeneca is faced legal challenges as 75 people claimed its Covid-19 vaccination caused fatalities and serious illnesses, including thrombosis with thrombocytopenia syndrome (TTS).[19] However, Indians cannot join in on the suit as the vaccination in India was prepared by Serum Institute of India (SII).

Covishield was imported according to the mandate set up by the Central Drugs Standard Control Organisation (CDSCO). The CDSCO grants authorization to applications in cooperation with the Subject Expert Committee (SEC) which is to be supplemented with data as needed under the Second Schedule of the New Drugs Clinical Trials Rules, 2019 drafted under the Drugs and Cosmetics Act of 1940.

Moreover, The SEC recommended granting New Drug permission or regular approval based on safety, immunogenicity, and efficacy data of Covishield from Indian and overseas clinical trials.[20]

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[17]Samira Kohli v. Dr. Prabha Manchanda & Anr. Appeal (civil) 1949 of 2004.
[18] *Covishield side effects: Thrombosis chances stand at '0.000003% in India', says top government official*, MINT (2024), https://www.livemint.com/science/health/covishield-side-effects-thrombosis-india-tts-astrazeneca-vaxzevria-serum-institute-sii-11715254933285.html.
[19] Business Standard, *Why Covishield Vaccine Case Doesn't Qualify for Medical Negligence in India*, (2024), https://www.business-standard.com/finance/personal-finance/astrazeneca-s-covishield-vaccine-case-doesn-t-qualify-for-medical-negligence-in-india-explained-why-124050200590_1.html.
[20] *Supra.* Note 8.

Therefore, none of the three aforementioned parties can be held liable. In such a scenario, concerns should be raised regarding the accountability as the person suffering from the adverse effects will have nowhere to go.

Chapter 2: Assigning Accountability

In the case of *Rachana Gangu v. Union of India (2022),*[21] a 19-year-old girl died from complications 20 days after getting the Covishield vaccination from Thrombosis and Thrombocytopenia Syndrome (TTS). AEFI assessment linked her death to the vaccine. The parents had raised contention that neither them nor their daughter was informed of the adverse effects of the vaccine.

While it is true that the cases were TTS appeared were limited, months before this incidence Several European governments halted vaccination efforts to investigate the AstraZeneca vaccine after receiving complaints of blood clots and an elevated risk of thromboembolic events following immunization.[22] This risk appeared to be higher among younger people.

Even UK the country that was using AstraZeneca vaccine as widely as India, proposed an alternative for the under 30 population.[23] In this specific instance, it should be the duty of the doctor and government to provide information regarding the adverse effects of Covishield. The argument that the vaccine's benefits outweighed its effects does not hold as multiple vaccines were available at the time and the government's responsibility isn't towards one vaccine but to safeguard the health of the citizens.

In response to this case, the government, following the Supreme Court's order, asserted that the onus is on the vaccine beneficiary to seek additional information regarding the vaccine and its potential adverse effects from healthcare professionals at the vaccination site or their personal physician before making an informed decision independently. The government further stated that "once a vaccine beneficiary who has access to all relevant information, voluntarily

[21] Rachana Gangu v. Union of India, 2022 SCC OnLine SC 1125.
[22] Kajal Bhardwaj & Veena Johari, *COVID-19 Vaccines in India: Judicial Blind Spots in Upholding the Right to Health*, 18 SLR 119 (2022).
[23] Covid: Under-30s offered alternative to Oxford-AstraZeneca jab, https://www.bbc.com/news/health-56665517 (last visited Sep 1, 2024).

chooses to enter a vaccination center and receive vaccination, the question of a lack of informed consent does not arise."

Further, while the data regarding AEFI is being uploaded on the MoHFW website, it was done only after media started reporting on the cardiovascular issues that vaccine beneficiaries were developing post administration.[24] Moreover, the data is uploaded haphazardly and is incomplete. There is a lack of information on how exactly the assessment process was undertaken, what technique was used to infer causality, and if relevant documents, such as reports, or autopsy findings, were consulted prior to drawing conclusions. The government expects the beneficiary to know about the adverse effects when the information is uploaded in a non-readable form.

Furthermore, allegations of underreporting the cases of AEFI in India have consistently been raised as the English counterpart of the same vaccine in the UK has witnessed these cases in a much larger number.[25] Correct reporting of the number of AEFI is necessary for those who suffer from such severe AEFIs, as it would aid them in accessing effective treatment early. WHO maintains that "effective spontaneous reporting of AEFI is the first step to making sure that vaccine products are safe and are being safely administered."[26]

Chapter 3. Proposed Legal Framework for Compensation for Victims

3.1. Need for a Specific Law

India does not have a compensation system in place for anyone who suffers from side effects or adverse events after receiving the COVID-19 vaccination. Unlike clinical trials in India, where specific laws require compensation for participants, the Drugs and Cosmetics Act does not include a process for compensating persons who have adverse effects after receiving a vaccine licensed for limited emergency use.

The current framework for acquiring compensation for damage as a result of AEFI is tedious and requires considerable financial resources to follow through. The process for obtaining

[24] *Why the Secrecy Around Vaccine Deaths and Data Relating to Serious Adverse Events?*, THE LEAFLET, https://theleaflet.in/why-the-secrecy-around-vaccine-deaths-and-data-relating-to-serious-adverse-events.
[25] Increased under-reporting of AEFI events a worry: Experts | Pune News - Times of India, https://timesofindia.indiatimes.com/city/pune/increased-under-reporting-of-aefi-events-a-worry-experts/articleshow/87807072.cms.
[26] 'Reporting form for AEFI' (WHO, 13 April 2021).

compensation involves criminal laws or criminal provisions in the Drugs and Cosmetics Act, 1940, or civil laws like tort law and the Consumer Protection Act, 2019. In absence of specific laws, the government told people suffering from AEFI to take up the legal battle against the manufacturers. However, in instances where a vaccine manufacturer threatens the person with severe damages and defamation, those experiencing adverse effects are less likely to initiate lawsuits against the company.[27]

The argument that is often made in favor of not having a specific regulation for vaccination compensation is that the vaccines get approved after a rigorous systematic check and hence only a few rare cases see the development of AEFI. If adverse effects are infrequent and occur in a limited group, there is no reason why vaccine manufacturers cannot compensate handful of people harmed after immunization.

The government and vaccine manufacturers should be held jointly and severally liable for adverse side effects, including death, that occur as a result of immunization. In the interest of justice, they must offer adequate compensation to impacted persons or their families.

3.2. The Proposed Framework

Almost 19 States have established compensation procedures, whether through the courts or a compensation system payment, for those who have been injured by a vaccine campaign or who have died as a result of immunization.

Individuals in the UK who develop adverse reactions that result in death or a 60% or more disability are entitled for a one-off, tax-free compensation of £120,000 under the Government's Vaccine Damage Payment Scheme (VDPS).[28] Official records show that at least 144 of the 148 compensation payments issued by the VDPS went to recipients of the AstraZeneca vaccine.[29]

India, AEFI reporting was insufficient, and data for causality assessment was of poor quality. The SEC's recommendations were often imprecise. Moreover, the current system of obtaining

[27] Govt: No provision to compensate the vaccinated in case of adverse events, THE TIMES OF INDIA, Apr. 6, 2021, https://timesofindia.indiatimes.com/india/govt-no-provision-to-compensate-the-vaccinated-in-case-of-adverse-events/articleshow/81923434.cms (last visited Sep 1, 2024).
[28] Vaccine Damage Payment Scheme, 2016 (United Kingdom).
[29] Robert Mendick et al., *Oxford AstraZeneca Covid Jab Was 'Defective', Claims Landmark Legal Case*, THE TELEGRAPH, Nov. 8, 2023, https://www.telegraph.co.uk/news/2023/11/08/oxford-astrazeneca-covid-jab-defective-claims-legal-case/.

justice in form of compensation is expensive and time consuming.

Therefore, a no-fault compensation model is proposed for India. Many States have no fault compensation schemes which compensate individuals for harm without the need to prove responsibility or identify the accountable party.[30] They are based on the idea that the injured individual is entitled to compensation regardless of fault or culpability. This model not only provides compensation in a faster manner than general litigation but also makes it less expensive for people suffering from AEFI to access justice.

Austria provides full coverage for damage resulting from vaccination, expecting such a system in the contemporary India would be wishful thinking.[31] However, what can be borrowed from the Austrian Model is the provision for providing compensation for vaccinations that are mentioned under the act. This will be more palatable to the government and cause less of a financial strain on the government.

A model similar to Canada can also be established in India. The Canadian government established a nationwide vaccine damage compensation scheme for individuals who had serious adverse reactions to a licensed COVID-19 vaccine in 2021.[32] Beginning 8th December 2020, the pan-Canadian Vaccine harm Support Program (VISP) provides financial support to persons who have incurred a significant and permanent harm as a result of administering a Health Canada-authorized COVID-19 vaccine in Canada. According to the Public Health Agency of Canada (PHAC), this financial help is available to the dependents of persons who have died as a result of immunization. Financial help will be assessed on a case-by-case basis, and compensation is applied retroactively from the date of injury or death.

The proposed system should cater to people have suffered permanent harm or death. Restricting compensation to vaccinations approved by the Indian government may narrow the eligibility for reimbursement. However, this method may dissuade people from getting vaccinations from illegal providers, while also enhancing the government's accountability for the vaccines it

[30] Sam Halabi et al., *No-Fault Vaccine Injury Compensation Systems Adopted Pursuant to the COVID-19 Public Health Emergency Response,* 37 EMORY INT. LAW REV. (2022).
[31] RIS - Impfschadengesetz - Bundesrecht konsolidiert, Fassung vom 01.09.2024, https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010356.
[32] Public Health Agency of Canada, *Government of Canada Announces Pan-Canadian Vaccine Injury Support Program*, (2020), https://www.canada.ca/en/public-health/news/2020/12/government-of-canada-announces-pan-canadian-vaccine-injury-support-program.html (last visited Sep 1, 2024).

promotes.

Further, it has been observed that countries that implement compensation programs tend to incur relatively low administrative costs, particularly when compared to the expenses associated with civil litigation.[33] These programs have been regarded as an acceptable approach to no-fault compensation in the early 21st century. With underdeveloped nations such as Vietnam and Nepal participating in these schemes, it is imperative for India to consider streamlining its compensation processes by reducing the reliance on protracted litigation, which burdens both the victims and the families of the deceased.

Conclusion

The contemporary regulatory framework for adverse events following vaccination (AEFI) in India and subsequent compensation arising out of such events are exceedingly complicated, making it difficult for affected persons to get proper redress for the harm they have suffered. This intricacy creates major impediments to accessing justice, limiting the system's ability to provide meaningful remedy to persons affected by vaccine-related side effects.

The government has largely deflected responsibility by first, placing the onus on the vaccine recipients to inquire about all the potential side effects of the vaccine and, second, by stating that government is not liable to pay compensation. Instead, individuals seeking redress are directed to pursue legal action against the manufacturers.

The proposed model seeks the aid of the government in dealing with the adverse effects of the vaccine, the use of which the government itself authorized. Since, it has been held in *Jacob Puliyel v. Union of India (2021),* that the government has a proper system in place for providing authorization to the vaccines and drugs that are produced or imported, the government should have no issues in providing compensation in the rare case of a complication arising.

This specific model is also necessary as monkey pox[34] is being perceived as the next big threat for the world and if this model would be in place, the people will have a far better recourse

[33] Khushboo Agarwal & B.R. Rochan, *Vaccine Injury and Death Compensation Programme In India*, 5 IJALR (2024).
[34] WHO Director-General declares mpox outbreak a public health emergency of international concern, https://www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern (last visited Sep 1, 2024).

than they had during Covid-19 pandemic.

The need for no-fault compensation scheme is more urgent than ever. The proposed framework would provide timely and equitable redressal to the affected people without putting them through the harrowing litigation process. This approach not only aligns with the constitutional values of India but also reflects the best global practices in public health governance. As India faces the problems of large-scale vaccination campaigns, implementing a simplified compensation structure would be critical to maintaining public trust and guaranteeing the welfare of its citizens.

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