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VACCINE INJURY AND DEATH COMPENSATION PROGRAMME IN INDIA

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ABSTRACT

The purpose of this Article to emphasized on the need of a national level compensation programme, through launching a concerned programme "With the aim to provide monetary aid to the people who suffered either by physical injury or lost their lives while getting vaccinated." We have tried to showcase how different nations have adopted a similar kind of programme or have provided aid by means of civil litigation process. With referring to few landmark cases of India, we are able to develop a stronger viewpoint regarding the need for undertaking compensation programmes as broached above.

In addition to this, a strong urge for a No-Fault Compensation Programme is felt looking at the prevailing Covid-19 pandemic situation. Being a part of such international organisation, it creates an obligation on India's part to set up a separate statute rather than simply providing a guideline regarding the vaccine injury.

KEYWORDS:

No-Fault Compensation Program, Vaccine, AEFI, Injury, Compensation, Covid-19, negligence

METHODOLOGY

Initially, a landscape analysis and scoping review of published and unpublished literature were conducted to update the inventory of countries that have implemented vaccine injury no-fault compensation programmes and various challenges that was faced and how India can implement the same also putting emphasis upon the current COVID-19 Pandemic and current emergency approval for the covid vaccine. Published data was supplemented with official documents accessed from government websites (where available). Structured literature search was done

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using National Research Council (US) Division of Health Promotion and Disease Prevention. Washington (DC), Cumulative index to Nursing and Allied Health Literature (CINAHL) and Global Online Access to Legal Information (GOALI).

INTRODUCTION

A vaccine is a biological readiness that gives dynamic procured resistance to a specific infectious disease. A vaccine ordinarily contains a specialist that resembles a disease-causing microorganism and is regularly produced using debilitated or murdered types of the organism, its poisons, or one of its surface proteins. The vaccine stimulates the body's immunity system to perceive the specialist as a danger, obliterate it, and to additionally perceive and destroy any of the microorganisms related with that specialist that it might experience later on. Vaccines can be prophylactic or remedial.

Compensation Programmes are basically monetary aid programme for the sufferers who were primarily healthy and then suffered adverse reaction or lost their lives due to the reaction of vaccines which was supposed to be the saver of their life from a particular infectious disease but turned out to cause a serious adverse event. Thus, compensating them for the loss suffered is an ethical principle and fairness.

India being a largely populated country and one of the highest vaccine manufacturing kernel also holds a responsibility to provide its citizen a proper platform or litigation programme to redeem such compensation for the loss suffered.

Current statutes, through which Indians can seek Redressal?

In India there is no specific statute to deal with the issue of making the manufacturer liable for the vaccine. The only way through which an accused could be held liable for the suffering of the complainant is though dragging oneself to the lengthy and expensive procedure of the existing general laws.

General laws under Indian laws are **Section 304A of IPC[3], Drugs and cosmetic act[4], Torts law (medical negligence) and consumer protection act**[5]. According to the **Central Drugs Standard Control Organization:** The Drug Technical Advisory Board (DTAB), the highest

[3] *Id.* s. 304A. Causing death by negligence.—Whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both.

[4] The Drugs and Cosmetics Act, 1940 (23 of 1940)

[5] R.K. Bangia, *The Law of Torts, including Motor Vehicles Act, Consumer Protection Act and Competition Act*, (Allahabad Law Agency, Faridabad, 24th edn.)

technical body under D&C, Act, has endorsed adoption of this GCP guideline for streamlining the clinical studies in India.

According to **Good Clinical Practice Guidelines, 2.4.5.,** 6it talks about compensation for participation in the medical Research**. 2.4.7. 7**Compensation for accidental Injury, clearly states that the person who participated in the research and suffers physical injury in the clinical trial is entitled to financial or other assistance to compensate him/her equitably for any temporary or permanent impairment or disability. **2.4.7.18**Obligation of the sponsor to pay, which provide the sponsor with the obligation to compensate the person for any serious and genuine physical or mental injury, without considering the type of sponsor it is whether a government, a pharmaceutical, or an institution, before the research and trial begins. The compensation can even be provided through insurance coverage for an unforeseen damage whenever the circumstances arise.

Why India needs a proper National Regulatory (No fault Compensation programme) solely dealing with the vaccine injuries?

- **Marketing authorization**: This is a process through which evidence are collected to check a medical product, through assessing and reviewing different parameters, in relation to the product's marketing such as drugs and then to grant a license to sell the them out.
- **Licensing Activities**: It generally focuses on the step of providing licensing to the manufacturer and the distributors. It provides license after all the proper study and looking thoroughly the results of the different trial before providing it a license for the use to the general public.
- **Post-marketing surveillance including surveillance for Adverse Events Following Immunization (AEFI):** It is compulsory for giving reconnaissance of AEFI to guaranteeing the security of the vaccine.
- **Lot (Batch) Release:** Lot release is a mechanism that provides FDA with a real-time system to continuously monitor product quality, through review and testing, of many of the biological products that it regulates.

[6] 2.4.5. Compensation for Participation, *available at:* http://www.sgpgi.ac.in/sop/GCP-%20Indian.pdf (Last visited on March 19, 2021).
[7] Compensation for Accidental Injury, *available at:* http://www.sgpgi.ac.in/sop/GCP-%20Indian.pdf (Last visited on March 19, 2021).
[8] Obligation of the sponsor to pay, *available at:* http://www.sgpgi.ac.in/sop/GCP-%20Indian.pdf (Last visited on March 18, 2021).

- **Laboratory Support for vaccine testing:** To test the vaccine a laboratory support system is chosen that minimizes variability. So, this includes quantitative RTPCR (Real-Time Reverse Transcription–Polymerase Chain Reaction), antigen detection, sequencing Traditional Naturalization and multiplex immunoassays Neutralization assays Cell-mediated immunity method Viral and bacterial functional assays.
- **Regulatory inspections of Good Manufacturing Practices (GMP):** It is the test for inspecting whether the manufacturer is following good manufacturing practice or not, the test includes the building and facility check, equipment check, personnel, raw material, laboratory, labeling, etc.
- **Authorization and approval of clinical trials of vaccines:** This mechanism give approvals for the different stages of trial only proper evaluation and proper authentication. They after the completion of all the trial give the approval for use of the vaccine to the general public and many more.

What is No Fault Compensation Programmes adopted by different nations?

The No Fault Compensation Programme is a programme adopted majorly by the high-income group of nations. This programme mostly covers the injuries which are caused to child, adult, women, and for specific indications, arising from the vaccines that have been registered by the country and are being recommended by the assigned authority to be given to the citizens of their country. In no-fault liability the claimant must show that a clinical or medical blunder was a causative factor in the resultant biological damage, regardless of who is to blame (evidence of causation rather than proof of fault).All no-fault compensation programme reviewed require standard of proof showing a causal relationship between vaccination and injury caused. After the final decision the claimants (either the injured party or their family member) are compensated with the lump-sum amount after calculating the physical, mental and financial loss of the complainant. In the United States, the Vaccine Adverse Event Reporting System received reports of such vaccination adverse events at a rate of 2.45 per 100,000 doses. The China's surveillance system showed that there are 1083 adverse events out of 8067 (1.21 per 100,000 doses) that are very serious; whose remuneration costs also varies. From country to country, it differs whether they want the party can claim compensation through civil litigation or from compensation programme but the combination of both the two is not allowed.[9]

[9]Sam Halabi, Andrew Heinrich, et.al., *"No-Fault Compensation for Vaccine Injury — The Other Side of Equitable Access to Covid-19 Vaccines"* , New England Journal of Medicine, 2020, N Engl J Med 2020; Pg: 383:e125, DOI:

What is the procedure followed for No-Fault Compensation programme by different nations?

Different countries provide different way to provide compensation for No Fault Liability? The list of foreign countries and the kind of vaccines been covered under there no fault vaccine programme and who pay the compensation:

- Generally, in the major countries this kind of programme is government run or nation run programme, for instance New Zealand. Sometimes under the ambit of state ministries.
- In Denmark the source of fund to pay compensation is public revenue, which covers diseases causing permanent working inability and death. Eg: whooping cough, diphtheria, tetanus, polio, and tuberculosis etc.
- Federal Republic of Germany, Compensation programme are run through the source of fund that are collected in form of pension, paid by authorities. Here the Land Government authorities determine the local responsibilities. In the mandatory and recommended vaccines, and compensation in the injuries like adverse post vaccinal effect, defined as any impairment to health exceeding usual extent of a post vaccinal.
- France, where no specific statute is framed so as to decide the source of fund for the no fault compensation programme, but it covers all kind of damages attributable to vaccination.
- In Japan the compensation program is half funded (50%) by the National Treasury, 25% through municipalities and the rest by prefectures. The diseases which are covered under this programme has been specifically mention under Japan's Preventive Vaccination Act and TB Central Law. The name of diseases is pertussis, diphtheria, poliomyelitis, measles, rubella, tuberculosis (BCG), influenza, Japanese B encephalitis, Weil's disease, cholera, and smallpox.
- United Kingdom the source are the public funds and cover only the very severe injuries due to vaccine, diphtheria, tetanus, whooping cough, poliomyelitis, measles, rubella, tuberculosis, smallpox and any other disease that the Secretary of State specifies.[10]

10.1056/NEJMp2030600 https://www.nejm.org/doi/full/10.1056/NEJMp2030600 (Last visited on March 26, 2021)

[10]National Research Council (US) Division of Health Promotion and Disease Prevention. *Vaccine Supply and Innovation. Washington (DC)*: National Academies Press (US); 1985. Appendix E, Vaccine-Injury Compensation

Sixty five percent (65%) of the no-fault compensation programme for vaccine injuries are administered at the central government level. Germany, Italy, Republic of China and the Province of Quebec in Canada are the only jurisdictions implementing the compensation programmes at the province level (17%). Finland and Sweden are the only countries where programmes are administered by the insurance sector. Finland and Sweden are the solitary nations where projects are regulated by the protection area.

Major Global Events related to Vaccine Compensation Programme

West Africa, during the Ebola emergency, Africa was one of the most severally affected, but the government of Africa refused to accept any kind of liability related to vaccines that were considered for arrangement under the crises use authorizations.

Iraq 1990-1991 invasion and occupation of Kuwait, that leads to the start of gulf war, the United Nation's Security Council, created a subsidiary organ United Nations Compensation Commission in 1991 for the payment of damages and loss suffered to the life. The commission evaluated around 2.7 million of claims and issued 1.5 million awards with the comprehensive value of more than fifty two billion dollars, out of total, 57% was sorted for the claim. [11]

Reasons, why in majority nation, manufacturer are not made liable under No Fault Compensation Programme?

Before 1987, in USA if an injured party wants to get compensation for the damage caused due to the vaccine, then they have to file a legal suit against the manufacturer and then seek recovery. The vaccine manufacturers become quite apathetic and the manufacturer start hesitating to enter in the field of vaccine manufacturing, which does not prove to be a good sign for the development of a healthy environment. Without the compensation programme it was quite difficult for the manufacturers to predict their exposure to lawsuits.

In 1987, USA came up with the National Childhood Vaccine Injury Act which was established to form No Fault Compensation Programme through which a manufacturer was not made liable for the injury or death resulted from the side effects that were unavoidable even though the vaccine was properly prepared and was accomplished by proper guidelines

in Other Countries. Available from: https://www.ncbi.nlm.nih.gov/books/NBK216811/ (Last visited on March 22, 2021)

[11] WHO media, *No-fault compensation programme for COVID-19 vaccines is a world first*, https://www.who.int/news/item/22-02-2021-no-fault-compensation-programme-for-covid-19-vaccines-is-a-world-first (Last visited on March 29, 2021)

and warnings. This not only made the manufacturer hesitate towards this production line but also lead to an increase in the prices of the vaccine based on worst case estimates. This resulted in augmented price rises, vaccine shortages and reduction in vaccine research. This also lead to the withdrawal of many small vaccine manufacturers from the market. As litigation is an expensive and restricted avenue which is inaccessible to both the manufacturer as well as the injured party.

No Fault Compensation Programme, to a certain level has been found to be a successful scheme of removing the uncertainty of liabilities upon the manufacturers. This programme has had the potential to bring stability, fairness and efficiency to both the parties. These compensation schemes avoid polarization of the rich companies against the poor vaccine recipients through the litigation and associated negative media coverage.[12]

What are the exceptional circumstances in which a manufacturer could be made liable?

The manufacturer can be made liable only when it has been proved by the injured party that the manufacturer was incapable of adhering to the proper regulation and guidelines and the injury was caused due to that part of negligence.

If a manufacturer sells the defective or expired vaccine which does not stand up with the quality check and which surges the risk to a significant injury and to the life of the recipient of the vaccination, he/she will be held liable to any person injured by the defect under the principle stated as under Section 402A of the Restatement of Torts as under the American Jurisdiction.

In USA an individual can file a petition with the U.S. Court of Federal Claims and get compensation through the National Vaccine Injury Compensation Programme & The PREP Act established the Countermeasures Injury Compensation Programme (CICP).

Cases related to the injury caused by the vaccination and government and manufacturers are made liable for the same:

- ***Griffin v. United States*[13]:** In this case the US Supreme Court made the government liable for the Mrs. Griffin pain and suffering considering the future aspects too with the amount of $1,759,946.25. It was found that the ingestion of Sabin oral live-virus polio

[12] National Research Council (US) Division of Health Promotion and Disease Prevention. *Vaccine Supply and Innovation*. Washington (DC): National Academies Press (US); 1985. 6, Liability for the Production and Sale of Vaccines. Available from: https://www.ncbi.nlm.nih.gov/books/NBK216813/ (Last visited on March 28, 2021)

[13] 502 U. S. 46 (1991)

vaccine which was from the lot fifty six does not match up with the standard regulation but still was released due to the negligence of National Institutes of Health and results to the damage to the party which caused her a permanent quadriplegic.

- ***Grinnell v. Charles Pfizer Co.***[14]**:** In this case the number of plaintiffs is there who after receiving Type I oral polio vaccine suffered different damages like partially paralyzed and weakened left arm, illness and many more. Each plaintiff brought separate suit of action against the company as well as manufacturer. Conclusively, the manufacturer was held guilty for virulent particles in Salk killed-virus vaccine.
- ***Tinnerholm v. Parke-Davis & Co.***[15]**:** In this case the plaintiff after the induction of vaccine got permanently disabled both physically and mentally. The District court made the manufacturer liable and awarded the plaintiff the amount of $651,783.52 to be paid by the manufacturer.
- ***Stromsodt v. Parke-Davis & Co.***[16]**:** In this case a baby who was born as a normal child was given Quadrigen vaccine after which the baby starting showing some degradation. At the age when the baby was seven-year-old trial started within the court and the baby was facing a lot of disabilities such as walks unsteadily, lacks coordination, speaks but a few words, has none of the basic childhood skills normally possessed by children of his age and can neither read nor write. The court held the manufacturer liable for both breach of an implied warranty and for negligence and the damage was awarded to the plaintiff.
- ***Bruesewitz v. Wyeth LLC***[17]**:** Hannah Bruesewitz's parents filed a suit for the claim of compensation stating that Hannah after receiving DTP vaccine manufacture by Lederle Laborataries(now owned by Defendant) made their child disabled but the same was denied by the lower court in their judgement, but later the Supreme Court of United States held that the National Childhood Vaccine Injury Act of 1986, gives the parents of the sufferer to claim compensation by the manufacture in the said act.

Leading cases in India related to the vaccine injury

[14] 274 Cal.App.2d 424, 79 Cal. Rptr. 369 (Cal. Ct. App. 1969)
[15] 285 F. Supp. 432 (S.D.N.Y. 1968), aff'd, 411 F.2d 48 (2d Cir. 1969)
[16] 257 F. Supp. 991 (D.N.D. 1966), aff'd, 411 F.2d 1390 (8th Cir. 1969)
[17] 562 U.S. 223, 131 S. Ct. 1068 (2011) RULE

- ***Dr.Durga Nursing Home vs K.Dhanasekharan before the State Consumer Disputes Redressal Commission, Chennai.***[18]

  In this case the forty two days old boy due to the negligence on the part of one & two opposite parties, the baby dies. The complainant come forward with the consumer complaint alleging negligence on the part of the defendant during vaccination without following proper test before administering of the vaccinations by using expired dose and due to which, the baby died and thereby praying a sum of Rs.10,00,000/- as compensation and for costs.

The Nursing Home was in the name of 1st Respondent and the 2nd was the Dr. A. Vijaya Varma M.S., (General Surgery), the 2nd opposite party administered the OPV dose and then the DPT dose, soon after the injection the baby body turned blue and motionless, and the 2nd opposite party tried to revive the baby by pressing against the chest mouth and the mouth practice but the baby instantly died.

The district court held that the 1st Party will be held liable for not having proper equipment and the Ambulance facility and had directed to pay sum of Rs. 1,00,000/- as compensation for mental agony and hardship and sum of Rs. 5000/- as costs and dismissed the complaint as against the 2nd opposite party. Being unsatisfied with the decision of District Forum both the complainant & Party one field a separate complain in the Court.

The Court observed that the Party one & two were negligent in giving the doses of OPV & DPV as a result the baby boy turned blue and died, it was also reviled that the doses given by the Party two was expiry and was not stored as prescribed.

It was held that the opposite parties one and two are jointly and severally held liable to pay for the deficiency of service in administering the vaccination to the complainants forty two days old born child and both the defendants are directed to pay a sum of Rs.3,00,000/- as compensation for mental agony to the complainant for the hardships and mental agony undergone by his wife and himself along with the costs of Rs.5000/-.

State of Gujarat And Ors. Vs. Shahenazbanu Ashrafali [19]

The lower court have passed a degree for the damage amounting one lakh to Shannaz Banu, one and half year-old child has been negligently administered triple vaccine from the Nurse Ranjanben and suffered from poliomyelitis and permanent deformity and

[18] F.A. Nos. 1070/2011 and 683/2012
[19] 1997 ACJ 176, AIR 1996 Guj 136

disability.

Appeal was filed in the high court against the degree of trial court where the plaintiff then contented that the damage which was caused was because of the faulty way of administering injection through the way that resulted to cause poliomyelitis. But the defendant refused as he stated that the buttocks are largely muscular and sciatic nerve passes from below the muscles and it is lying 1.5" to 2" deep so there is no chance for the those particular reaction. Later it was also found that the negligent injection could only trigger and provoke poliomyelitis but could not cause it. After all the investigation it was found that poliomyelitis is caused by viral infection not by negligent injection. The court reverse the degree of lower court, and only the sum of cost of operation to be undergone by the plaintiff's child has to be executed which was around Rs. 5,000.

AEFI (Adverse events following immunization) surveillance in India

AEFI are generally the side effects of vaccines which can be mild but can also cause life-threating in rare cases. It is very important to investigate and asses each AEFI to determine whether a vaccine is casually linked to AEFI or whether reported AEFI is a mere coincidence. The key issue covers under AEFI surveillance system are as follows:

Strategies and frameworks for guaranteeing quality and security of immunizations in country

Objectives of vaccination security and AEFI surveillance

New classification of AEFI

AEFI surveillance system- reporting, investigating, examining, causality assessment and response processes

Optimum use of vaccine surveillance security data

Communication strategy on immunization safety for public and media

Cause-explicit categorization of adverse events following immunization:

	Cause-specific type of AEFI	**Definitions**
A1	Product-related vaccine's reaction	The adverse effect caused due to the multiple inherent properties of the vaccine to the person vaccinated.
A2	Quality defect related vaccine's reaction	An AEFI caused due to the major quality defect in the vaccine. Defects could be in its administration device as provided by the

		manufacturer.
A3	Immunization error related vaccine's reaction (formerly "programmatic error")	An AEFI which is caused by the inappropriate handling, prescribing or administration and thus by its nature is preventable.
A4	Immunization anxiety related vaccine's reaction	An AEFI arising from the uneasiness about the vaccine to be given.
C	Coincidental event	An AEFI caused by something other than the vaccine product, immunization error, or immunization anxiety, but a temporal related with immunization exists.
B1		Temporal relationship is consistent but there is insufficient definitive evidence that it is the vaccine that has caused the event
B2		Different factors bring about clashing patterns of consistency and irregularity with causal relationship to vaccination.
D		Unclassifiable20

Need for No-Fault Compensation Programme, Covid Vaccination Programme in India.

India being the second largest population and one of the largest vaccine manufacturing capacities in the world, India has a pivotal role in the covid-19 vaccination effort. Being the second biggest populace and one of the greatest drugs producing limits on the planet, India has a focal job in the Corona virus inoculation exertion. 21On January 3, 2021, emergency consent was given to the two made in India Covid-19 vaccine (Covishield and Covaxin) by the India's Drug controller.

[20] Ministry of Health and Family Welfare, Government of India, *AEFI (Adverse events following immunization) Surveillance and response Operational Guidelines* https://nhm.gov.in/New_Updates_2018/NHM_Components/Immunization/Guildelines_for_immunization/AEFI_Surveillance_and_Response_Operational_Guidelines_2015.pdf (Last visited on March 27, 2021)

[21] Ministry of Health and Family Welfare, Government of India, *Draft Regulatory Guidelines for Development of Vaccines with Special Consideration for Covid-19 Vaccine,* https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Regulatory_guidelines_for__development_of_Vaccine_20.9.20.pdf (Last visited on March 25, 2021)

The different range of covid vaccine trial by different producer and their emergency approval in India made it more imperative to introduce a compensating programme such as No-fault Compensation programme. Thus, the trail brings a range of patients who is under the risk of AEFI and even the death under the trail and after the vaccination. So, the question that struck to a lot of minds is, will any no-fault compensation be paid to the families of the healthcare workers and trail participants who faced AEFI &died?

WHO on No-fault compensation programme for COVID-19 vaccine

The World Health Organization (WHO) and Chubb Limited (NYSE: CB) have consented to an agreement for the COVAX Facility on February 17, 2021 for the administration of a no-fault compensation programme for the ninety two low- and middle-income countries and economies who will qualified for monetary benefits via the Gavi COVAX Advance Market Commitment (AMC) of the COVAX Facility, India is among the list of that ninety two countries.

By providing no-fault lump-sum compensation in full and final settlement of any claims, the COVAX programme aims to significantly reduce the need for recourse to the law courts, a potentially lengthy and costly process.

The No-Fault Compensation reserve is a tremendous thrust for COVAX's objective of fair worldwide admittance to Covid-19 vaccine: by giving a transparent and free system to settle genuine adverse effects, it helps those lower and medium income nations who may have such impacts, and at the same time helps manufacturers to carry out vaccines to nations in full tilt, and is a critical advantage for lower-pay governments acquiring immunizations through the Gavi COVAX AMC, said Dr Seth Berkley, CEO of Gavi.

Eligible vaccinated individual scan apply for remuneration under the programme once the portal (www.covaxclaims.com) come into effect, even if a COVAX-distributed vaccine is administered to them before March 31, 2021.

As most of us are well aware of the fact that Covid-19 vaccines have received emergency use approval with limited data, and a good range of people to receive a COVID-19 vaccine. The intensity of the above question rises as it is seen that by February 4, 2021 less than three weeks after the mass Covid-19 vaccination programme begins, there have been sixteen deaths recorded, which was in the view of state and district officials not because of the vaccine, but so far, no reports of the district, State and National AEFI Committees on the computation of these deaths and other serious AEFIs have been released. By March 13, 2021, more than eighteen million people in India have received Covishield among the twenty six million vaccinated

across the country so far. The Union health ministry has said that none of the deaths probed so far has been linked causally to the vaccines.

On March 13, 2021, National expert panel of India have decided to begin to 'take a closer look' at the death and AEFI after vaccination of Covishield the AstraZeneca vaccine made in India by the Serum Institute. As Denmark, Norway and Iceland put Astra Covid vaccine on hold, after incidence of hospitalization and death came forward after the vaccination. Thus, this not only points question on the efficiency of the vaccine but also regarding the compensation which will be provided if after the examination the cause of death and AEFI is the vaccine?

A total 8,483 adverse events had been recorded in India's vaccination programme as of February 4, 2021, the MoHFW informed parliament. However, on February 5, 2021, the ministry reported 7,580 AEFIs to parliament. There is no explanation for the discrepancy, or a break-up of what kind of adverse events people experienced, or categorization by level of health risk, or status of investigations.[22]

Thus, there are chances that vaccination might be the reason behind the death and AEFI caused. So, it automatically puts emphasis on the need of no-fault compensation programme to the person and families.[23]

SUGGESTIONS:

After observing the increasing need and demand of compensation programme such as No-fault vaccine compensation programme, it would be a dilemma for the lower- and middle-income countries, offering pharmaceutical companies' indemnity or complete immunity from lawsuit and liabilities or to offer compensation from the government funds to the large number of people injured during the vaccination which seems constitutionally and financially impossible. Ethically, a manufacturer must be held liable to pay for the injuries caused by their product. So, the government should bring a specific statute to deal with the injuries and death caused by the different vaccination programme around India. For a developing country like India, it won't be possible to provide a fully government funded compensation programme, but should adopt a partially funded one keeping in mind the nature of economy India has. Recent compensation programme adopted by Australia can be referred to in this context.

Australia compensation laws and regulations are much of a muchness to that of India, as they too do not have no-fault vaccine compensation programme neither in general nor in specifically for the Covid-19. They have Australia's National Disability Insurance Scheme, but this does not

[22] *Supra* note 8
[23] *Supra* note 9

cover temporary vaccine related injuries. Currently the Australian government has pronounced for introducing no fault compensation scheme seeing the acceleration progress rate of Covid-19 vaccine rollout plan. The Australian government has also decided to provide the vaccine's manufacturer company indemnity, likely in limited circumstances. The method of compensation distributed programme which can be adopted by India should not put liability to a particular organization rather it be government or the private organization. 24The liability should be distributed varying from circumstances and situation. That can be as follows:

1. **The Sponsor's liability:** During the clinical trial of vaccine, it is the duty upon the sponsor to perform the trial in accordance with the protocol and to get a valid consent from the participants of trials. Thus, the failure of the same and the injury and death caused due to such negligence, sponsor should be made liable to compensate.
2. **Health professionals Liability:** Publishing product information with the vaccine packaging, maintaining the appropriate storage and temperature after the supply of the vaccine and the duty to warn of contra-indications of risks, heath professional such as hospital, clinics and in some case manufactures should be held accountable to compensate.
3. **Shipment's company liability:** If the vaccine's adverse effect was caused due to the negligence of supply chain company like failing to maintain appropriate temperature and storage facility on the way of shipping, then the shipment company should be held liable.
4. **Manufacturer's liability:** It the duty of the manufacturer to follow the guideline provided by the Central Drugs Standard Control Organization**(Draft Regulatory Guidelines for Development of vaccines with Special Consideration for Covid-19 Vaccine, Draft Guidance on Approval of Clinical Trials & New Drugs, Good Clinical Practice Guidelines)**[25] and other international guidelines and they fails under the basic principles of guideline provided such as:
   - quality can't be tried into a group of item;
   - and, quality should be incorporated in every group of item during all phases of the manufacturing process.

[24] Professor Nicholas Wood, "Who pays compensation if a COVID-19 vaccine has rare side-effects?" *University of Sydney https://www.sydney.edu.au/news-opinion/news/2020/10/20/who-pays-compensation-if-a-covid19-vaccine-has-rare-side-effects.html* (Last visited on March 26, 2021)
[25] *Supra* note 19

Thus, in this case the manufacture can be made liable.

5. **Supplier's liability:** The duty to ensure that the drug is free of defects (other than stated contraindications), and in the failure of this duty the supplier should be held responsible.
6. **Government's Liability**: Potential liability of the Government if it takes any one of the above roles and if it makes the vaccine mandatory. We note that the Government has been following the medical advice and guidelines in accordance with its medical experts. Then in this case the government should be held liable.

CONCLUSION

Making an exhaustive framework for no-fault compensation programmewould be practical and would advance equity. Barring nations that can't give repayment or invulnerability to manufacturers could deny billions of individuals of the security that vaccines will bear. An important component of a successful vaccination programmeis the vaccine injury compensation programme. The developed nations have been using vaccine injury compensation programme for the past fifty years to ensure that individuals who are adversely affected in the interest of protecting the whole society are sufficiently recompensed and taken care of. A variety of schemes with different structures and approaches have been undertaken throughout the world. The countries which follow the respective compensation programme are found to be of relatively low administrative cost especially compared to Civil litigation cases. Such programme is perceived to have an acceptable approach Towards No-Fault Compensation programme in the first decade of 21st century. Considering the involvement of underdeveloped nations like Vietnam and Nepal in such compensation schemes, it is high time for India to eliminate the lengthy litigation processes regarding compensations demanded by the sufferer and their families of the deceased respectively. Keeping the three aspects –

(1) India's active participation in vaccine manufacturing

(2) To vaccination of the world's second largest population

(3) Alongside, exporting vaccines to other countries.

Introducing no fault compensation programme or any such similar schemes, would definitely be in the long-term interest of India facilitating further development of the country. Effective communication of risks and contraindications is also necessary in building trust. Further it will ensure the efficiency of the vaccine, but also help to build up confidence in the community to take the vaccine.