MEDICINE-RELATED ADVERSE EVENTS: GLOBAL TRENDS AND INDIAN APPROACHES IN POST MARKETING SURVEILLANCE AND COMPENSATORY JURISPRUDENCE

Liji Samuel[*]

I. INTRODUCTION

Before releasing a medicine or vaccine for commercial use, it goes through different phases to ensure its safety and efficacy on patients. It begins with the preclinical phase, goes through the clinical trial phase, post-market surveillance, and end of lifecycle. Medicines and vaccines approved by the competent authority after clinical trials are not entirely safe and free from side effects. All drugs have side effects, and some are fatal, which leads to hospitalisation of the patients or even death. The unexpected side effects are generally known as adverse events. Different usages are in vogue to address various types of adverse events, such as adverse drug events, adverse drug reactions, medication errors, etc.

Apart from independent research publications, the competent government authorities regularly publish the adverse drug reactions of many medications. Since 2016, the Indian Pharmacopoeia Commission (IPC) has been publishing drug alerts to warn the medical fraternity about the adverse reactions of medication. On August 29, 2025, the IPC published adverse drug reactions of two medicines. Similarly, in the recent past, vaccine-related deaths have also been reported in India and in other countries. As per the report of the IPC, around one lakh adverse drug events have been reported in India during 2023-24 More importantly the reporting rate of adverse events in India is less than 1%.

Countries have devised various strategies to tackle adverse events, including post-marketing surveillance systems, a no-fault compensation scheme, and the adoption of specific statutory regulations or administrative policies. In this context, this study strives to delve deeply first, to understand the nature and scope of adverse events due to drugs and vaccines; second, to identify and examine the popular strategies at the international level; third, to examine post-marketing monitoring and pharmacovigilance systems established in India; fourth, to review the legal regulations and victim compensation scheme in India; and fifth, to suggest reforms in the medico-legal regulations.

The study followed a doctrinal method. Most of the research studies discuss the reasons and causes of adverse events and address the gaps in medical reporting procedures. Though the existing literature vividly explains the impact of medicine-related adverse events on healthcare systems, the legal response has not yet been pondered on. The rights of victims of adverse events have not yet been recognised or made part of the existing regulations in India, though it amounts to serious human rights violations. Thus, it is high time to deliberate upon the rights of victims of medicine-related adverse events and to adopt appropriate legal measures to mitigate their sufferings.

To discuss the subject in detail with the above-stated objectives, the article tries to give a detailed account of the present scenario of adverse events at the global and national levels. It broadly discusses the strategic measures in two parts, such as the pharmacovigilance systems

[*] Associate Professor, Department of Law, Central University of Kerala, Kerala, India.

and legal regulations for compensating the victims in the selected jurisdictions and India. The study also puts forward suggestions that may be adopted in India for the proper reporting of adverse events and for recognising the right to compensation for victims of adverse events. The article limits its scope to post-marketing strategies and compensatory jurisprudence, and it will not examine the criminal liability of pharmaceutical corporations for adverse drug and vaccine events.

II. ADVERSE EVENTS – A GLOBAL PERSPECTIVE

Adverse drug events (ADEs) are considered one of the leading causes of death worldwide.[1] Different terms are used interchangeably in various jurisdictions to address these adverse events. The study identifies that ADEs occur either due to preventable medication errors or non-preventable Adverse Drug Reactions (ADR).[2] The term medication error (ME) is broad enough to encompass any medication error that leads to or can potentially lead to patient harm.[3] It may occur at any stage of the medication process, including logistics, prescribing, handling, administering and dispensing.[4] The National Coordinating Council for Medication Error Reporting and Prevention (no standard definition exists) defines medication errors as:

> *"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use."*[5]

The medical errors, if left unattended, lead to ADEs.[6] The adverse drug reactions are non-preventable and unintended adverse events which were not identified during the clinical trial stages. World Health Organisation (WHO) defines ADRs as, "a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function".[7] The WHO documents state that ADRs are preventable.[8] Medication-related Adverse Events (MRAE) are widely used to address all forms of undesired events in pharmacotherapy, such as ADE, ADR,

---

[1] Hervé Le Louët, Peter J Pitts, "Twenty-First Century Global ADR Management: A Need for Clarification, Redesign, and Coordinated Action" 11 *Therapeutic Innovation & Regulatory Science* 100-103 (2022).
[2] Ahmed Nouri, Nahid A. Lamfon, *et.al*., "Defining Medication Errors, Prescribing Errors, and Adverse Drug Events: A Narrative Review" 9 *Palestinian Medical and Pharmaceutical Journal* 327 (2024).
[3] O. Laatikainen, S. Sneck, *et.al.*, "Medication-related adverse events in health care—what have we learned? A narrative overview of the current knowledge" 78 *European Journal of Clinical Pharmacology* 159-170 (2021).
[4] *Ibid.*
[5] In 1995, the United States Pharmacopeial Convention (USP) spearheaded the formation of the National Coordinating Council for Medication Error Reporting and Prevention. It is an is an independent body composed of 27 national organizations. *Available at*: https://www.nccmerp.org/#:~:text=promote%20the%20safe% 20use%20of%20medications (last visited on July 29, 2025).
[6] *Supra* note 2.
[7] Public Health Nigeria, "Adverse Drug Reaction Definition By World Health Organization", WHO, *available at*: https://www.publichealth.com.ng/adverse-drug-reaction-definition-by-world-health-organization/(last visited on Aug. 02, 2025).
[8] World Health Organization, "Briefing Note: Safety of medicines – adverse drug reactions", *available at*: https://www.who.int/docs/default-source/medicines/safety-of-medicines--adverse-drug-reactions-jun18.pdf?sfvrsn=4fcaf40_2 (last visited on July 30, 2025).

and ME.[9] Additionally, Vaccine Adverse Events (VAE) or Adverse Events Following Immunisation (AEFI) are used to address health hazards caused by vaccines.[10] Nevertheless, the different definitions are in use, which leads to increased morbidity, mortality, and economic burden.[11] It equally affects patients and healthcare systems, and it is a serious threat to patients' safety and public health.[12]

Independent studies show a substantial increase in adverse drug events at the global level. The mortality rate due to ADE per 100,000 population has increased from 2.05 in 2001 to 6.86 in 2019.[13] Around ten per cent of patients are affected by at least one adverse event at the global level, and the rate of events is higher in lower-income countries.[14] As per the WHO statistics, around three million deaths occur annually due to unsafe care, and half of the harm is attributed to medications.[15] In the U.S. alone, more than 1.5 million people avail emergency services due to ADE every year, and almost 500,000 require hospitalisation.[16] Surprisingly, only 5% of the ADEs are reported even in countries where reporting is mandatory.[17] The ADE remains undetected in countries with weak reporting systems, and the patients will be exposed to unanticipated risks.[18]

Thus, the reported incidents of adverse events are less compared to actual statistics due to various reasons such as under-reporting, lack of reporting systems, reluctance of medical professionals, unawareness of patients and their families, etc. Due to the flaws in the reporting of MRAE, the adverse events of medications remain a silent killer and cause catastrophic effects on public health, economy, and health care infrastructure. Thus, proper monitoring and surveillance are imperative in the post-marketing phase of any drugs and vaccines. The cornerstone of post-marketing surveillance is the pharmacovigilance systems established in most countries to identify and report the adverse events of drugs and vaccines.

III. Patient Safety and Pharmacovigilance Systems

[9] *Supra* note 2.
[10] World Health Organization, "Adverse Events Following Immunization", *available at*: https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/aefi/aefi (last visited on July 30, 2025).
[11] *Supra* note 2.
[12] *Ibid*.
[13] Toshihiro Koyama, Shunya Iinuma, *et. al*., "Trends in Adverse Drug Event-Related Mortality from 2001 to 2019: An Analysis of the World Health Organization Mortality Database from 54 Countries" 47 *Drug Safety* 237-249 (2024).
[14] Christy L. Skelly, Manouchkathe Cassagnol, *et.al.*, "Adverse Events", *available at*: https://www.ncbi.nlm.nih.gov/sites/books/NBK558963/(last visited on Aug. 02, 2025).
[15] World Health Organization, "Patient Safety: Key Facts", *available at*: https://www.who.int/news-room/fact-sheets/detail/patientsafety#:~:text=Around%201%20in%20every%2010%20patients%20is%20harmed,in%20100%20people%20die%20from%20unsafe%20care%20%281%29 (last visited on July 30, 2025).
[16] CDC, Medication Safety Program, "FastStats: Medication Safety Data" (Apr. 17, 2024), *available at*: https://www.cdc.gov/medication-safety/data-research/factsstats/index.html#:~:text=More%20than%201.5%20million%20people%20visit%20emergency%20departments,more%20than%20twice%20as%20often%20as%20younger%20people (last visited on July 30, 2025).
[17] Chantelle Bailey and David Peddie, "Adverse drug event reporting systems: a systematic review" 82 *British Journal of Clinical Pharmacology* 17-29 (2016).
[18] *Ibid*.

In order to ensure the safety of medicines and vaccines, the International[19] and Indian regulations[20] mandate rigorous safety assessment standards in all stages of medicine development. There are generally following four phases for conducting clinical trials of new drugs.[21]

Phase I: The objective of the first phase is to estimate the safety and tolerability with the initial administration of an investigational new drug on a small group of research participants.

Phase II: In this phase, the drug is evaluated for its effectiveness in patients for particular indications and identifies the short-term side effects.

Phase III: The Phase III clinical trials demonstrate confirmatory therapeutic benefits documented during the Phase II. The results in this phase provide an adequate basis for market approval.

Phase IV: In phase IV, post-market studies are conducted after a new drug has been approved by the competent authority for a specific condition.

It has been proven that all medicines and vaccines that have gone through the different phases of clinical trials and have been finally approved by competent authorities for human use have side effects.[22]. Clinical trials can only prove the effectiveness of a particular medicine or vaccine on a limited number of research participants for a defined disease condition. However, it is unpredictable what would be the reaction of drugs on people who have different biological construction than the research participants. Hence, evaluating and monitoring drugs and vaccines are imperative even after a drug is made available in the market.

At the same time, it is important to note that the rights of research participants of clinical trials are recognised and are provided in the existing international and national regulations. The right of research participants includes the right to informed consent, freedom to withdraw from clinical trials, the right to claim compensation for harm suffered during the trial, medical care and support during the clinical trial, etc. However, the above-mentioned rights are available only to the research participants, and once it is approved for market release, the patients will not be entitled to any such rights listed under the clinical trial regulations. Hence, post-market studies are mandatory to prove the magnitude of human rights violations scientifically and to recognise the rights of victims of medicines and drugs.

Post-market surveillance is an essential phase (phase IV) of a clinical trial. Since the drugs are prescribed to a small population of less than five thousand in the phase III trial, several adverse drug reactions (ADRs) are detected when it is prescribed to the general population. Post-market surveillance is the continuing process of monitoring the safety and efficacy of drugs once the competent authority approves the medicines and vaccines for market release. The countries have adopted regulations for clinical trials, including post-market monitoring of medicines and vaccines. Post-marketing surveillance (PMS) systems are

[19] The Nuremberg Code, Helsinki Declaration, The International Ethical Guidelines for Biomedical Research Involving Human Subjects, The World Health Organization (WHO) guidelines for GCP for trials on pharmaceutical products, 1995, Guideline for Good Clinical Practice - /ICHarmonised Tripartite Guideline, 1996.
[20] The New Drugs and Clinical Trials Rules, 2019.
[21] *Id.*, sch. I.
[22] *Supra* note 8.

prevalent in most countries, including India[23], for reviewing and monitoring the performance of medications and vaccines and collecting and evaluating clinical data. Post-market monitoring helps identify previously unidentified adverse and positive effects on human beings. The positive impacts are beneficial to the patients. However, the negative consequences of all magnitudes must be measured and rectified.

Pharmacovigilance is a part of post-marketing surveillance, which is intended to identify the adverse events of medications and vaccines and to reduce their effects by following specific strategic approaches. WHO defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems".[24] The pharmacovigilance programme was introduced by the 16th WHO Assembly resolution in 1963[25] and later on by the 17th and 18th Assembly resolutions, which adopted measures for materialising it.[26] Convinced of the need for the international collection and distribution of information on adverse drug reactions, it urged the director general to study the requirements of a global programme for the collection, analysis and dissemination to member states of information on adverse drug reactions[27] and invited the member states to develop national-level monitoring systems for adverse drug reactions.[28]

To initiate international collaboration, WHO launched the Programme for International Drug Monitoring (WHO PIDM) in 1968 and the Uppsala Monitoring Centre (UMC) was established after ten years of WHO PIDM.[29] WHO PIDM is an international collaborative venture with almost 180 member states that aims to identify adverse events related to medicine and vaccines.[30] The UMC supports the member states in establishing national systems for monitoring patient safety.[31] Currently, PIDM coordinates the pharmacovigilance systems with the assistance of UMC and the Pharmacovigilance Department of the WHO.[32]

The WHO PIDM members submit reports of adverse drug events known as Individual Case Safety Reports (ICSRs) to the Vigibase, the WHO global database of drug adverse reactions. By July 2023, there were 35 million reports of adverse reactions in the VigiBase

[23] A global collaboration for patient safety*, available at*: https://who-umc.org/about-the-who-programme-for-international-drug-monitoring/about-the-who-pidm/ (last visited on July 31, 2025).
[24] World Health Organization, *A practical handbook on the pharmacovigilance of medicines used in the treatment of tuberculosis* 1 (WHO, 2012), *available at*: https://www.who.int/docs/default-source/documents/tuberculosis/a-practical-handbook-on-the-pharmacovigilance-of-medicines-used-in-the-treatment-of-tuberculosis.pdf?sfvrsn=6e5fc0cf_5 (last visited on July 31, 2025).
[25] WHO, *16th WHO Assembly Resolution*, *WHA 16.36*, *available at*: https://iris.who.int/bitstream/handle/10665/89155/WHA16.36_eng.pdf?sequence=1(last visited on July 31, 2025).
[26] WHO, *17th WHO Assembly Resolution*, *WHA 17.39*, *available at*: https://iris.who.int/bitstream/handle/10665/89267/WHA17.39_eng.pdf?sequence=1&isAllowed=y (last visited on July 31, 2025);
WHO, *18th WHO Assembly Resolution*, *WHA 18.42*, *available at:* https://iris.who.int/bitstream/handle/10665/85780/Official_record143_eng.pdf?sequence=1&isAllowed=y (last visited on July 31, 2025).
[27] 18th WHO Assembly Resolution, *Ibid.*
[28] *Ibid*.
[29] Supra note 23.
[30] *Ibid.*
[31] *Ibid.*
[32] *Ibid.*

database.[33] Similar to drugs, vaccines are also sometimes associated with adverse events. WHO also launched a vaccine pharmacovigilance programme known as Adverse Events Following Immunisation (AEFI) to collect medically important adverse events after vaccination.[34]

Apart from drugs and vaccines, herbal, traditional and complementary medicines, blood products, biologicals, and medical devices are also brought under the purview of PIDM. It encompasses a broad spectrum of activity, including medical error, substandard and spurious drugs, use of medicines for symptoms not approved for, medication-related mortality, and adverse reactions to medicines with other chemicals, food, and drinks.[35] Since the adverse events of drugs and vaccines cause overburden to the patients, families, and healthcare system, the pharmacovigilance system should be considered an essential public health mechanism rather than a luxurious developed world's medical strategy.[36]

Following the thalidomide disaster in the 1960s, most developed countries joined the WHO PIDM and established national pharmacovigilance (PV) systems. However, the approach of developing countries was not favourable, and they were reluctant to join PIDM until the 1990s.[37] Since then, the number of developing countries joining the WHO PIDM has increased. Now, most developed and developing countries have a national-level PV system for reporting of adverse events. The PV has emerged as a robust regulatory system with the collaboration of the WHO, the Council of International Organisations of Medical Sciences (CIOMS) and the International Conference on Harmonisation (ICH).[38] At the global level, the EU, WHO UMC, and ICH are internationally recognised PV systems. The regulations of the European Medicines Agency (EMA), the Food and Drug Administration (FDA) and the Pharmaceuticals and Medical Devices Agency (PMDA) are the major regulatory bodies.[39] Most developed countries are following EMA Regulations.[40]

Though the post marketing surveillance and pharmacovigilance programmes are mandated by the clinical trial regulations and the WHO, these are devoid of a human rights and victim victim-centric approach. The prime objective of these initiatives is not to recognise the rights of victims of adverse events or to provide any compensatory relief. However, countries like Sweden, Germany, Finland, etc. have established a no-fault liability compensation scheme to address the issues of victims of medicines and vaccines by adopting specific statutes or administrative policies.

IV. Recognising the Patients' Right to Compensation

[33] World Health Organization, "The WHO Programme for International Drug Monitoring", *available at*: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/networks/pidm (last visited on July 31, 2025).
[34] *Supra* note 10.
[35] World Health Organization, "The Safety of Medicines in Public Health Programmes: Pharmacovigilance an Essential Tool" 21 (2006).
[36] *Ibid.*
[37] Hamza Y. Garashi, Douglas T. Steinke, *et.al.*, "A Systematic Review of Pharmacovigilance Systems in Developing Countries Using the WHO Pharmacovigilance Indicators" 56 *Therapeutic Innovation & Regulatory Science* 717-743 (2022).
[38] Muhammad Akhtar Abbas Khan, Saima Hamid *et.al.*, "Pharmacovigilance in High-Income Countries: Current Developments and a Review of Literature" 11 *Pharmacy* 1 (2023).
[39] *Ibid.*
[40] *Ibid.*

The PV systems existing at the national and international levels are under regulatory bodies for the proper reporting of adverse events of drugs and vaccines through voluntary, non-voluntary and active reporting measures. Though repeated reports of adverse events are submitted against many medicines and vaccines, the rights of patients who have been affected by such adverse events are never considered by these PV systems or governments. PV systems are expected to identify harmful drugs or vaccines and rectify the defects or withdraw them from the market to avoid further harm to the patients. The existing legal framework on this issue is confined to three major redressal mechanisms, namely, no-faulty liability, product liability, tortious liability.

These legal frameworks of liabilities share a common purpose of protecting patient safety and compensating patients in case of medication/vaccine-related adverse events. The no-fault liability is a 'Swedish alternative' launched as an alternative to the traditional tortious liability which is based on negligence and malpractice.[41] The compensatory jurisprudence based on tort law and product liability is invoked in cases where the defect of the medicines or vaccines is proved under the rules of evidence of the respective legal systems. No-fault liability entrusts the patient with the right to report adverse events and claim compensation without proving the defects of the pharmaceuticals. By eliminating the fault from the compensatory jurisprudence, the healthcare system will become more transparent in reporting adverse events and encourage the medical professionals to collaborate with PV to find out the causes of adverse events. It will also encourage patients to report adverse events directly and process their claims more easily than traditional court proceedings, and it will significantly improve the PV in the long run.[42]

A. No-Fault Liability

Many countries like Sweden, Denmark, Finland, New Zealand, Quebec, Canada, Australia etc. are following a no-fault liability or no-fault system in compensating patients in case of adverse drug events. Among them, the Swedish no-fault system is the oldest compensatory insurance scheme. Until 1978, adverse drug events were compensated under the traditional Swedish Tort Law.[43] In 1978, Sweden launched a unique model of pharmaceutical insurance to cover the adverse health outcomes caused by drugs as an alternative to the traditional tortious liability. It was part of the government policy to introduce comprehensive social insurance to protect victims and families due to medical and work-related injuries and illnesses.[44] Three insurance schemes they introduced: firstly, security insurance in 1974 for work-related injuries, secondly, patient compensation insurance (PCI) in 1975 for medical injuries and thirdly, pharmaceutical insurance (PI) in 1978 for drug-related harms.[45]

In Sweden, the PI was introduced to supplement the weak tort law system and to support patients in processing their claims without creating the overburden of proving fault on the part

[41] Linda Persson and Lotta Westerhall, "Pharmaceutical Injury Insurance in the Nordic countries - an alternative to the traditional law of tort" 10 *International Journal of Risk and Safety in Medicine* 148 (1997).
[42] Medical Malpractice Systems around the Globe: Examples from the US- tort liability system and the Sweden-no fault system Health, Nutrition and Population (HNP), Human Development Sector Unit, Europe and Central Asia Region, Document of World Bank, 4 and 5 (2013), *available at*: https://documents.worldbank.org/en/publication/documents-reports/documentdetail/797831486996063182/medical-malpractice-systems-around-the-globe-examples-from-the-us-tort-liability-systemand-the-sweden-no-fault-system (last visited on July 31, 2025).
[43] *Ibid.*
[44] *Ibid.*
[45] *Ibid.*

of health providers or manufacturers. PI is a non-statutory system that works on a voluntary agreement among insurance providers.[46] On the other hand, patient insurance is mandatory and enforced through the Patient Injuries Act, 1996. Under the pharmaceutical insurance (PI), the manufacturers, developers of the pharmaceuticals, importers, distributors and sellers undertake an agreement to compensate the patients for personal injuries as per the terms of the agreement[47]. The Commitment Agreement defines the term drug as "substances that are intended to be used on human beings to prevent, diagnose, alleviate or cure diseases or symptoms, and it does not cover herbal or traditional medicines and homoeopathic medicines".[48] Personal injuries include psychiatric illness, and there must be a proximity with the use of one or more drugs with the personal injury to succeed in the claim process. However, the burden of proof is comparatively less in the case of the PI process.[49]

As per the Commitment agreement, the compensation is payable only in two circumstances[50]: - Proportionality: the injury stands in disproportion to the expected benefit of the treatment; and Foreseeability: the injury, by its nature or severity, is such that it could not reasonably have been foreseen.

Also, in Sweden, the health outcomes caused by the completely unintended and unexpected side effects of the drugs are compensable, and the side effects that are known are not compensable. Additionally, the patients must be made aware of all the side effects of medicines and treatments.[51] The amount of compensation will be awarded based on the Tort Liability Act, 1972. Patients who are not satisfied with the decision of the insurance company may approach the Pharmaceutical Injury Board.[52] The claimant may also invoke the jurisdiction of the court under the tortious liability laws if the grievance is redressed.[53] As per the Commitment agreement, the following are the exclusions where compensation is not payable: improper prescriptions, medical errors, medications against the rules and regulations; intentional overuse or misuse; inappropriate and incorrect use of drugs; intended side effects; injury lasts for less than a month.

The statistics of the processed claims show a steady increase in the total number of insurance claims. As per the records, the highest number of claims was settled in 2021 and 2022. In 2024, around 1029 claims were settled.[54] Following the Swedish insurance system, other countries like Finland, Denmark, etc. introduced the no-fault system for medical adverse events. In Finland, the pharmaceutical insurance system was introduced in 1984 through the Finnish Co-operative for Pharmaceutical Injury Indemnities. Any drug manufacturers, importers, or research companies can join the Co-operative. It has around 130 members as of

[46] Lotta Westerhall, "Disbursement of Indemnity for Injuries Related to Reproductive Drugs and Devices: A Swedish Perspective" 23 *Review of Law and Social Change* 443 (1997); also see, Sabina Hellborg, "Liability for medical injuries in Sweden" 23 *Journal de Droit de la Santé et de l'Assurance Maladie* 72 (2019), *available at:* https://www.diva-portal.org/smash/get/diva2:1369246/FULLTEXT01.pdf (last visited on Aug. 03, 2025).

[47] "Undertaking to pay compensation for pharmaceutical injury" (the Undertaking) is formulated as insurance terms and conditions with comments and is determined by LFF Service AB, *available at*: https://www.lakemedelsskadenamnden.se/kontakt/ (last visited on July 29, 2025).

[48] The Commitment to Compensation for Drug Injury, s. 2 and comment 2, *available at:* https://www.lakemedelsskadenamnden.se/kontakt/ (last visited on July 29, 2025).

[49] *Id.*, s. 3 and comment 3.

[50] *Id.*, s. 5.

[51] *Id.*, s. 6 and comment 6.

[52] *Ibid.* s.13 & comment 13.

[53] *Ibid.* s.15 & comment 15.

[54] Läkemedels-försäkringensstatistiktillochmed 2024, *available at*: https://lff.se/statistik/ (last visited on July 29, 2025).

now.[55] In Denmark, the Danish Act on the Right to Complain and Receive compensation protects the right of patients to raise complaints on drug-related injuries and to claim compensation. The compensation works through compulsory insurance schemes. In contrast to the Swedish PI, the Finnish compensation allows known and unknown as well as expected and unexpected drug injuries.[56] In Germany, the Medicinal Products Act imposes absolute liability on the pharmaceutical entrepreneurs.[57] Similar systems are in force in countries with some jurisdictional variations in respect of administration, extent of liability, etc.

Countries with strong pharmacovigilance systems, like the U.S., U.K. or even the EU, have not yet recognised the no-faculty compensation system for pharmaceutical adverse events. In the U.S., particularly, there is no comprehensive no-fault compensation system in place to address adverse drug events. However, a no-fault compensation known as the Vaccine Injury Compensation Program (VICP) was established under the National Childhood Vaccine Injury Act (NCVIA) in 1986.[58] The VICP was introduced to overcome the vaccine shortage due to the litigation filed against vaccine companies and healthcare providers. An aggrieved patient or his/her legal representative can file a petition before the U.S. Court of Federal Claims, and the compensation, if approved by the court, will be disbursed by the U.S. Department of Health and Human Services.[59] Similarly, the U.K. introduced a Vaccine Damage Payment Scheme (VDPS) to enforce patients' rights under the Vaccine Damage Payments Act, 1979. The payment under this scheme is fixed at a value of £120,000.[60] VDPS also works based on the no-fault theory of compensation.

B. Product Liability

The law fixing product liability for pharmaceuticals is intended to make manufacturers accountable for the adverse events caused by medicines/vaccines. The drug will be available only after vigorous clinical trial proceedings in almost all jurisdictions. However, the product liability regime makes the pharmaceutical entities responsible even after the product is made available in the market. Defective designs, manufacturing defects and inadequate warnings are the main reasons for extending product liability.[61] The most common defects of drugs/vaccines are undisclosed side effects, adverse drug/vaccine reactions, undisclosed addictive nature, contaminated drugs, improper dosage recommendations by the manufacturer, etc.[62]

Countries follow different models to litigate the claims of patients. EU directives have set out the prominent product liability system. Hence, this study confines itself to having a detailed account of the EU policies in relation to the product liability of drugs and vaccines. Most European countries have effective product liability laws to govern pharmaceutical defects. Such laws are based on the European Union Directive. The EU Product Liability Directive 85/374/EC, adopted in 1985, has been replaced by the new Directive (EU) 2024/2853

---

[55] Finnish Co-operative for Pharmaceutical Injury Indemnities, *available at*: https://www.laakevahinkovakuutus.fi/in-english/ (last visited on July 30, 2025).
[56] *Ibid.*
[57] The Medicinal Products Act, 2005, Division 16, s. 84 (Germany).
[58] National Vaccine Injury Compensation Program, *available at:* https://www.hrsa.gov/vaccine-compensation (last visited on July 31, 2025).
[59] *Ibid.*
[60] United Kingdom Covid Vaccine NFCS, *available at:* https://www.law.ox.ac.uk/nofault-compensation-schemes-for-covid-19-vaccines/united-kingdom-covid-vaccine-nfcs (last visited on July 31, 2025).
[61] Nix Patterson, "Dangerous drugs product liability", *available at*: https://nixlaw.com/practice-areas/product-liability-lawyers/drugs/ (last visited on Aug. 03, 2025).
[62] *Ibid.*

(New Directive).[63] The EC Directives are general in nature, and they can be made applicable to pharmaceutical products. The New Directive is introduced to address the challenges posed by digital technologies and online service providers. The New Directive also acknowledges the importance of psychological illness within the term personal injuries.

The New Directive aims to bring harmonisation laws, and thus it strictly directs the member states to follow the Directive, especially in the case of the burden of proof.[64] It ensures the right to compensation of the injured person in case of death, personal injury, including psychological damage.[65] To claim the compensation, they must prove the product was defective. A product is considered defective if it does not provide the safety that a person is entitled to expect or that is required under Union or national laws.[66] To reduce the burden of proof, the Directive offers situations where the adjudicating authority can presume defectiveness of a product.[67] The defendant is also permitted to rebut the presumption.[68] The complaint shall be raised within three years from the day the injured person becomes aware of the damage or defectiveness.[69] The EU directive sets out a strict liability regime for products, including medical products, where the injured person need not prove the fault or negligence of the manufacturer. The injured person is responsible for providing evidence for personal injuries and the defectiveness of the medical products, including medicines and vaccines.

The European countries, assimilating the EU Directive mandate, rolled out product liability laws for medical products, including drugs and vaccines. Germany enacted the Product Liability Act of 1989[70] to implement the EU Directive and impose strict liability. The Product Safety Act, the Drugs Act, and the Civil and Criminal Codes are the major laws regulating pharmaceutical product liability. The supply of defective products may also attract penal provisions in case it leads to personal injuries.[71] Similarly, Sweden enacted the Product Liability Act in 1992 and it is based on the underlying principle of strict liability of manufacturers of pharmaceuticals.[72] The product liability in the U.K. was dealt with under the Consumer Protection Act, 1987. Since it was before Brexit, it generally followed the EU Directive. However, in the post–Brexit era, though the Consumer Protection Act of 1987 continues to govern product liability issues, new laws may emerge in the years to come.[73] The EU members have implemented the EU directive on product liability through specific legislation, which also applies to pharmaceuticals. In the U.S., the product liability regime is still based on tort law. The principles of strict liability and negligence are applicable depending on the factual matrix of each case.

---

[63] EU Directive 2024/2853.
[64] *Id.*, art. 3.
[65] *Id.*, art. 6.
[66] *Id.*, art. 7.
[67] *Id.*, art. 10.
[68] *Id.*, art. 10(5).
[69] *Id.*, art. 16.
[70] Heinz J. Dielmann, "The New German Product Liability Act" 13 *UC Law SF International Law Review*, 425-427 (1990).
[71] Hogan Lovells, "Product Liability in Germany", *available at*: https://www.lexology.com/library/detail.aspx?g=c82a41ca-95da-4c93-b1f0cb2b1c45c189#:~:text=Germany%20has%20highly%20developed%20laws%20and%20regulations%20concerning,by%20the%20Civil%20Code%20and%20the%20Criminal%20Code (last visited on July 29, 2025).
[72] Finn Stenström and Johan Nyberg, "Sweden-Product Liability", *available at*: https://www.glimstedt.se/wp-content/uploads/2021/04/Legal-500-Sweden-Product-Liability.pdf (last visited on July 29, 2025).
[73] Adela Williams and Tom Fox, "Product Liability Laws and Regulations England & Wales 2025", *available at:* https://iclg.com/practice-areas/product-liability-laws-and-regulations/england-and-wales (last visited on July 30, 2025).

C. Tortious Liability

The tortious liability in the case of pharmaceuticals revolves around the common law principle of negligence. The tort of negligence is defined as "the breach of a legal duty of care by the plaintiff which results in the undesired damage by the defendant to the plaintiff".[74] It essentially requires a duty to take care and a breach of that duty, which causes the personal injury to patients. Negligence by itself does not attract liability, and any damage itself does not confer any legal right.[75] All countries across the globe have generally follow the traditional tort law system of adjudication to address the issues of medicine related adverse events.

As mentioned earlier, the no-fault compensation system was introduced to bypass the cumbersome court proceedings and settle the genuine claims without delay in executing compensation.[76] Along with the no-fault compensation system and product liability laws, the injured patients may approach the traditional common law courts to litigate their claims. However, the burden of proof will be on the claimant to prove that there was negligence on the part of the manufacturers of drugs and vaccines. The burden of proof is generally accepted as the sole reason for finding an alternative to the tort law system.[77] It has the limitation of addressing medication-related adverse events as it requires medical/scientific knowledge. The judicial pronouncements of adverse drug events may also negatively affect the reputation of the pharma companies. The U.S., U.K. and European Countries generally follow the tort law of compensation either by enacting specific statutes or by following the uncodified common law principles of tort law.

The global trends show a mixed approach in managing medicine-related adverse events. Though clinical trial regulations lay down stringent standards for the approval of medicines and vaccines, similar legal regulations are lacking in the post-market phase. Most countries follow a combination of administrative strategies to manage adverse events and legal regulations to compensate the victims. However, such initiatives are not universal. Thus, in the above section, the study attempted to illustrate the best legal models in some countries like Sweden, Germany, Finland, etc. Since the study aims to present a comparative perspective, it discusses the post-market surveillance and pharmacovigilance systems functioning in India, and it also tries to analyse the legal regulations existing in India to manage and mitigate the ill effects of medicine-related adverse events.

V. Adverse Events and the Need for Regulatory Reforms in India

India has a pivotal role in the pharma sector and is a global leader of generic drugs. It is one of the largest pharmaceutical industries in the world, with nearly 3000 pharma companies and 10,500 manufacturing units. It meets around 60% of global vaccine demand.[78] In 2024, Indian generic drugs accounted for 20 per cent of global exports, 40 per cent of U.S. generics

[74] Winfield and Jolowicz, *Tort*, 90 (Sweet & Maxwell, 19th edn., 2014).
[75] *Supra* note 38 at 5.
[76] *Ibid.*
[77] *Ibid.*
[78] Sumit Jha, "Indian generic drugs linked to 54 percent higher rate of severe adverse events", *available at*: https://thesouthfirst.com/health/indian-generic-drugs-linked-to-54-percent-higher-rate-of-severe-adverse-events/ (last visited on July 31, 2025).

and 25 per cent of all medicines in the U.K.[79] However, the recent news reports place the Indian pharmaceutical sector under suspicion of poor quality and side effects. The researchers studied samples of generic drugs from developed and developing economies and reported that generic drugs manufactured in India were associated with a 54% higher rate of severe adverse events.[80]

In June this year, the USFDA's division found violations in 11% of the facilities inspected in the country. Last year, the Drugs Controller General of India (DGCI)'s inspection revealed that 18 pharma companies were manufacturing spurious medicines.[81] The impact of medicine-related adverse events is common in all countries, and India is no exception. However, there is a dearth of quantitative studies. Some studies conducted in Gujarat, Maharashtra, and other northern states of India reflect the intensity of adverse drug reactions patients have experienced.[82] Some of the ADR were life-threatening and resulted in prolonged hospitalisation.[83] The performance report of the Pharmacovigilance Programme of India underscores this.

Since India is a leading industrial player in the pharma sector, the quality and safety of drugs and vaccines need to be ensured to strengthen the national and international industrial tie-ups. Hence, India introduced legal and extra-legal regulatory measures to ensure quality standards and reduce the adverse effects of drugs and vaccines. This includes specific statutory provisions, post-marketing monitoring programmes, continuing medical education programmes, etc, to manage the adverse medical events. The New Drugs and Clinical Trials Rules,[84] (NDCTR) were pathbreaking in clinical research and protecting the essential rights of patients and research participants from the adverse effects of biomedical research. These safeguards can be enforced for the injuries suffered during the clinical trial stages. However, no effective post-marketing safeguards are embedded in the existing legal regulations.

A. Pharmacovigilance Programme of India

The pharmacovigilance programme is a flagship initiative under the aegis of the Ministry of Health and Family Welfare. The Pharmacovigilance Programme of India (PvPI) was introduced as a measure for post-marketing surveillance under the Drugs and Cosmetics (II Amendment) Rules, 2005, which introduced Schedule Y to the Drugs and Cosmetics Rules, 1945.[85] The Y Schedule to the D & C Act was primarily to regulate the clinical trials of new drugs legally. In the process of approving new formulations of medicines, the Y Schedule imposed responsibility upon the researchers and manufacturers to submit Periodic Safety Update Reports (PSURs) every six months for the first two years and subsequently for every year.[86] PSURs are intended to monitor the safety and efficacy of the newly approved drugs that

[79] *Ibid.* Also see, P B Jayakumar, "India's pharmaceutical industry poised for global leadership: McKinsey report", *available at*: https://www.fortuneindia.com/business-news/indias-pharmaceutical-industry-poised-for-global-leadership-mckinsey-report/120894 (last visited on July 31, 2025).

[80] Jeff Grabmeier, "Not All Generics Are Created Equal: Study Exposes a 54% Higher Risk in Indian-Made Drugs", *available at:* https://scitechdaily.com/not-all-generics-are-created-equal-study-exposes-a-54-higher-risk-in-indian-made-drugs/ (last visited on July 31, 2025).

[81] Manu Kaushik, "India drug companies recall products from US market", *available at*: https://www.financialexpress.com/business/healthcare-india-drug-companies-recall-products-from-us-market-3693127/ (last visited on July 31, 2025).

[82] Ashwin Kamath, Sahana D. Acharya, *et.al.*, "Burden of death and disability due to adverse effects of medical treatment in India: An analysis using the global burden of disease 2019 study data" 10 *Heliyon* 6 (2024).

[83] *Ibid.*

[84] The New Drugs and Clinical Trials Rules, 2019.

[85] Drugs and Cosmetics (II Amendment) Rules, 2005.

[86] *Id.*, sch. Y.

are made available in the market. In order to implement the post-marketing surveillance, as provided in the D. & C Rules, the government launched the Pharmacovigilance Programme of India in July 2010 with All India Medical Sciences (AIIMS) as its National Coordination Centre (NCC).[87] In 2011, the Indian Pharmacopoeia Commission was designated as the NCC of the pharmacovigilance programme.

The NDCTR were adopted to revamp the clinical trial regulations. The NDCTR also has provisions for post-market surveillance of drugs and vaccines. The Rules define pharmacovigilance as "the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug-related problem".[88] As per Schedule V of the Rules, post-market assessment is necessary for all new drugs and the importers and manufacturers of new drugs shall have a pharmacovigilance system to collect, process and report the adverse drug reactions to the Central Licensing Authority. The ADR Monitoring Centres have been established to collect data from stakeholders. PvPI offers a dedicated toll-free number, mobile App and website to facilitate reporting of ADR of medicines, medical devices, and biologicals, including vaccines and herbal drugs.

As the original scheme, the health professionals were only allowed to report the adverse events, but by 2016-17, consumers and patients were allowed to report their personal injuries.[89] The Performance Report of 2023-24 reveals that 116342 Individual Complaint Reports (ICRs) have been registered across India.[90] On reviewing the scenario, the Drug Controller frequently recalls/withdraws/or bans drugs from the market.[91] So, pharmacovigilance plays a vital role by reporting adverse events at the national and international levels for the safety of patients/consumers.

B. Compensatory Jurisprudence

Indian compensatory jurisprudence is still nascent compared to other countries like Sweden, Germany and most other European countries. The issue of adverse drug events came to the forefront due to COVID-19 vaccine deaths and disabilities reported in different parts of India. Multiple litigations have been filed in the Indian courts against COVID-19 vaccines. A criminal case was filed in the High Court against AstraZeneca (Covishield) producer Bill Gates in 2021 for the post-vaccine death.[92] The Adverse Events Following Immunisation (AEFI) Committee of the Indian government has confirmed that it was caused by the adverse effects of the Covishield vaccination.[93] PILs are also pending before the Supreme Court and High Courts, urging the assessment of the COVID-19 vaccine's side effects and the implementation of a vaccine damage payment system for citizens who are severely disabled due to the COVID-

[87] Indian Pharmacopoeia Commission, "Pharmacovigilance, Guidance Document Marketing Authorization Holders of Pharmaceutical Products" 6 (2024).
[88] *Supra* note 84, s. 2(z).
[89] Indian Pharmacopoeia Commission, *Performance Report* 20 (2016-17).
[90] *Id.* at 43 (2023-24).
[91] Dr. Simi Paknikar, "Drugs Banned in India", *available at*: https://www.medindia.net/health/drugs/drugs-banned-in-india.htm (last visited on Aug. 02, 2025).
[92] A Criminal Writ Petition (St.) 18017 of 2021.
[93] Aadhya, "India's High Court Filed the World's First Vaccine Murder Case against Bill Gates, Adar Poonawalla", *available at*: https://www.inventiva.co.in/trends/high-court-filed/(last visited on July 29, 2025).

19 vaccination.[94] Indian compensatory jurisprudence is scattered over multiple laws. Those are dealt with hereunder.

C. No-Fault Liability

The Performance Reports of the PvPI reflect the need for a no-fault compensatory regime. Though it projects more than one lakh adverse events every year, the number of claims that come before the court for adjudication is nil. The surprising fact is that only 1% of the adverse events are reported in India.[95] Also, it is essential to note that as per the 2023-34 Report, out of the one lakh adverse events, around 2.4% were life-threatening, 3.6% led to death, 14% caused prolonged hospitalisation, and 12.1% were other medically important medical conditions.[96] Even though the reports do not reflect the actual statistics of adverse events, the existing data is sufficient for policymakers to properly analyse India's adverse drug events management system. The people who suffered severe and life-threatening injuries, including death, are left with no option other than approaching the courts under the tort laws or criminal laws. Moreover, many of the Indian patients and their family members are not even aware of the adverse drug events. It is the sad state of affairs that the no-fault compensation system has not yet been recognised by the Indian policy makers, either at the regulatory or administrative levels. Thus, a PIL has been filed in the Supreme Court seeking a direction to introduce a vaccine damage compensation scheme as exists in other countries.[97]

D. Product Liability

The Consumer Protection Act, 2019, is a recent addition to India's legal regulations on product liability. It replaced the old Act, the Consumer Protection Act, 1986. The new law does not provide any provisions for fixing the liability for drug-related injuries. However, the product liability provision can be equally applicable to drugs and vaccines as it is to other consumer products. It defines product liability as "the responsibility of a product manufacturer or product seller, of any product or service, to compensate for any harm caused to a consumer by such defective product manufactured or sold or by deficiency in services relating thereto".[98] The harm denotes death, illness, personal injuries, mental agony or distress under the provisions of the Act.[99]

Chapter VI of the Act deals with product liability. Product liability can be invoked when the manufacturer, service provider, or seller renders defective goods or services. The liability of manufacturers arises in the specific circumstances of manufacturing or design defect, deviation from specification, not confirming express warranty, not containing adequate instructions for correct usage.[100]

---

[94] Kanu Sarda, "Covishield vaccine row: PIL in Supreme Court seeks medical experts to study risks", *available at:* https://www.indiatoday.in/law/story/covishield-vaccine-row-pil-in-supreme-court-seeks-medical-experts-to-study-risks-involved-2533912-2024-05-01 (last visited on July 30, 2025).
[95] Akanksha Netake, Pooa Tupe, *et.al*., "Current Scenario of Adverse Drug Reactions in India: A Review on ADR Reporting, Management, Obstacles and Possible Solutions" 13 *International Journal of Creative Research Thoughts* 680 (2025).
[96] *Supra* note 91 at 45.
[97] *Supra* note 94.
[98] The Consumer Protection Act, 2019 (Act No. 35 of 2019) s. 2(34).
[99] *Id.*, s. 2(22).
[100] *Id.*, s. 84.

Negligence or fraudulent intention on the part of the manufacturer is irrelevant in fixing the liability, and it introduced strict/no-fault liability for defective goods in India for the first time.[101] The burden of proving the defect of the product lies with the claimant, and the successful claimant is eligible to get compensation and an order for recall of the product. Though the consumer protection law came into existence more than three decades ago, not many cases have been filed before the consumer fora for adjudging the defectiveness of pharmaceutical products. However, there are instances where the compensation was awarded for injury caused by defective medical devices. The Supreme Court of India approved the compensation scheme put forward by the Central Government to compensate the victims of faulty hip implants.[102] Around 4525 patients had undergone hip transplantation surgery since 2005.[103] Thus, the provisions of the Consumer Protection Act, 2019, can be effectively applied in cases of adverse drug/vaccine events arising due to the defectiveness of the drugs/vaccines.

E. Constitutional Remedies

One of the popular and easy ways to obtain compensation in India in matters relating to the life and liberty of individuals is to file a PIL and invoke the jurisdiction of the Constitutional courts under articles 32 and 226 of the Constitution. This is due to the innovative interpretation given by the apex court for article 21 of the Constitution, thereby expanding the locus standi. It was a contribution of the Indian judiciary to ensure justice to the victims of executive actions and even private actions. The ambit of article 21 is wide enough and encompasses the right to life and health. Personal injuries caused by pharmaceuticals squarely fall under the constitutional provisions. Though broad interpretations on article 21 exist, decisions on adverse drug events and the right to compensation of patients have not been considered by the constitutional courts before 2021. However, in the context of COVID-19 vaccination, multiple PILs have been filed in various High Courts of India, including in the state of Kerala. *Rachana Gangu* v. *Union of India*[104], and *Sayeeda K.A*. v. *Union of India*[105] are two prominent cases.

In *Rachana Gangu* v. *Union of India*, the petitioner's daughter succumbed to death within two days of receiving the Covishield vaccine and the representations submitted by her parents were not adequately answered either by the government authorities or the pharmacovigilance department of Serum Institute of India Pvt. Ltd. Hence, she approached the SC for issuing a writ of mandamus: for appointing an expert and independent medical board, to investigate the death of her daughter, appointing an expert medical board to prepare a protocol for the early detection and timely treatment of AEFI due to the COVID-19 vaccine, and, granting significant monetary compensation to the petitioner.

The matter is still pending before the court. By this time, the Kerala HC ordered the Government and National Disaster Management Authority (NDMA) to formulate guidelines for awarding compensation to the victims of the COVID vaccine while deciding the case *Sayeeda K.A.* v. *Union of India*.[106] The government and NDMA were directed to identify

[101] *Id.*, s. 84(2).
[102] "Supreme Court closes case against Johnson and Johnson in faulty hip implants case" *Hindustan Times*, Jan. 11, 2019, *available at*: https://www.hindustantimes.com/india-news/supreme-court-closes-case-against-johnson-and-johnson-in-faulty-hip-implants-case/story-wShCUuRxtR1ealRNMIXR5I.html (last visited on Aug. 03, 2025).
[103] *Ibid*.
[104] Writ Petition(s) (Civil) No(s). 001220/2021, dtd. Aug. 29, 2022, of the Supreme Court of India.
[105] Writ Petition (Civil) No. 17628 of 2022(C).
[106] *Ibid.*

vaccine-related deaths and to frame policy within three months to disburse the compensation. However, no such initiative has yet been taken by the Central or State Government. Instead, the Central Government challenged the decision before the Supreme Court, stating that vaccination was voluntary and condemned the interim order issued by the Kerala High Court, while a similar case (*Rachana Gangu* v. *Union of India*) is pending before the Supreme Court. So, the approach of the apex court will come out only when these cases are decided.[107]

On the other hand, the Supreme Court decision in *Jacob Puliyel* v. *Union of India* is worth mentioning here. The decision provided blanket protection for India's vaccine approval and pharmacovigilance systems[108]. The half-hearted approach of the judiciary in making a thorough scrutiny of the Indian pharmacovigilance system silenced the suffering of thousands of vaccine victims in India. The reported AEFI in India was much lower than in other countries like the U.S. and the U.K. In reality, most cases go unreported due to improper implementation of AEFI data collection and people's unawareness.[109]

Another PIL was filed by a supreme advocate, Umesh Tiwari, in May 2024, in the context of the admission made by AstraZeneca in the U.K. court that "the vaccine can, in "very rare cases", cause a blood clot-related side effect amongst those administered its vaccine".[110] The PIL seeks to constitute a medical panel to study the side effects of the COVID-19 vaccine and to introduce a vaccine damage payment system.[111] In April 2025, the SC came across another petition where a person suffered disability due to the side effects of the vaccine. The court directed him to file suit for damages.[112] Even after multiple litigations have been filed in different HCs and SCs, the state or central governments have not taken any steps to identify the actual number of COVID-19 vaccine victims or any scheme to compensate them. Similarly, it is important to note that the issue of medicine-related adverse events came to the public domain only when deaths and disabilities were reported after the COVID-19 vaccination. The issue of adverse drug reactions is not yet considered seriously by policymakers, health care providers, or drug manufacturers in India. The ignorance of patients and the lack of a supportive system to come forward and report their issues are the major drawbacks of the Indian pharmacovigilance system.

F. Tortious Liability

The liability of manufacturers in medication-related adverse events falls under the tort of negligence. The tort of negligence requires the plaintiff to provide three essential elements: at first existence of a duty to take care, secondly, breach of duty and thirdly, harm or damage. The courts' decisions are heavily based on the evidence adduced by the plaintiff, and the burden

---

[107] Aditi Suryavanshi, "SC Seeks Centre's Response on Compensation for those who Died from Adverse Effects of Covid-19 Vaccine" *The Free Press Journal*, Feb. 27, 2025, *available at*: https://www.freepressjournal.in/india/sc-seeks-centres-response-on-compensation-for-those-who-died-from-adverse-effects-of-covid-19-vaccination (last visited on July 22, 2025).

[108] Writ Petition (Civil) No. 607 of 2021.

[109] Kajal Bhardwaj and Veena Johari, "COVID-19 Vaccines in India: Judicial Blind Spots in upholding the Right to Health" 18 *Socio-Legal Review* 166 (2022).

[110] Harish V. Nair, "PIL In Supreme Court Seeking Examination of Covishield Vaccine, Compensation For Those Who Suffered" *Times of India*, May 01, 2024, *available at*: https://www.timesnownews.com/india/pil-in-supreme-court-seeking-examination-of-covishield-vaccine-compensation-for-those-who-suffered-adverse-effects-article-109752452 (last visited on July 23, 2025).

[111] *Ibid*.

[112] "SC asks man to file suit for damages after he claims disability post Covid-19 first dose" *New Indian Express*, Apr. 21, 2025, *available at*: https://www.newindianexpress.com/nation/2025/Apr/21/sc-asks-man-to-file-suit-for-damages-after-he-claims-disability-post-covid-19-first-dose-2 (last visited on July 23, 2025).

of proof always lies with the plaintiff in tort of negligence. The Indian courts have applied the principles of negligence in medical malpractice cases. The decision in *Indian Medical Association* v. *V.P. Shantha & Ors*.[113] established the liability of medical professionals to compensate their patients in case of negligence. Similarly, the negligence on the part of the pharmaceuticals is also liable to be compensated in case negligence is proved on the part of manufacturers. However, such matters have not yet come across the jurisdiction of Indian courts as in the U.S. or U.K. due to the adoption of the Consumer Protection Act and Constitutional remedies.

On analysing the Indian scenario, the study found that India lacks a transparent and effective pharmacovigilance system and proper legal regulations to ensure the accountability of the pharma sector and government authorities. The reporting of adverse events is abysmally low in India. Also, most healthcare providers are in the private sector, and there is no legal imposition on the healthcare providers to report adverse events. The Clinical Establishment Act, 2010, which governs the standards and responsibilities of clinical establishments in India, does not mandate proper reporting of adverse events to the pharmacovigilance systems. The existing pharmacovigilance system is not transparent, and people are unaware of such initiatives. In India, patients were permitted to report only after 2016. Also, the government and pharma sector corporations are least bothered about introducing compensatory schemes for Indian patients. Even after court directions, the Government of India has not yet formulated a policy, at least for COVID-19 vaccine victims. A no-fault compensatory system needs to be put in place to compensate genuine patients, and it will also help healthcare providers report adverse events fearlessly. Only by that will a proper pharmacovigilance, which is actual, reliable, and transparent, be possible.

VI. CONCLUSION

Medication-related adverse events are common in all countries, and thousands of patients have either lost their lives or gone through severe or life-threatening conditions and disabilities due to adverse drug events. On reviewing the existing literature, it is proved that MRAE is one of the major causes of the increasing mortality rate, and this is known to the world and the governments. However, the response of governments and healthcare providers is woefully disappointing. One of the basic objectives of the study was to identify the common strategic measures existing at the international level to tackle medicine-related adverse events. The study found that post-market surveillance and pharmacovigilance systems are the popular international initiatives WHO and other international agencies pushed. However, the studies reveal that only 5% of the adverse events are formally reported and the rate of reporting in India is less than 1%. Thus, the performance of existing pharmacovigilance systems is far from satisfactory. Because a pharmacovigilance system can work its best only if proper statistics of adverse events are collected, analysed, and the results are disseminated to the medical community for immediate action. The Indian pharmacovigilance system is also not working at an optimal level due to underreporting and unawareness of patients. Thus, there must be a transparent system to report all adverse events to make informed decisions about them. Above that, there shall be a robust system for active surveillance. However, such an active surveillance system is still lacking in many developed and developing countries.

The study has examined the legal response on medicine-related adverse events. The legal systems approach is different, and universal standards have yet to be evolved, as in the

[113] AIR 1996 SC 550.

case of clinical trials. There exist structured legal measures for conducting clinical trials and protecting and safeguarding the rights of research participants. However, similar legislative attempts are lacking in countries like U.S., U.K., and India, though countries like Sweden, Germany, Denmark, and Finland have established no no-fault compensation scheme by adopting specific laws and policies. The compensation models adopted by Sweden, Denmark, Finland, etc, are remarkable initiatives and are beneficial in the long run as they facilitate research initiatives without compromising the rights of patients. Similarly, the laws enacted in U.S. and U.K. are the best examples for vaccine damage payment. Such legislative or policy initiatives are still lacking in India. Though some COVID-19 vaccine-related deaths are reported in India and repeated directions issued by the Constitutional Courts, no laws or policies have yet been adopted to recognise the rights of victims of medicine-related adverse events in India. In light of the above findings, the study put forward the following suggestions:

i **Uniform nomenclature:** Different usages exist across the globe and within a nation to address adverse events. Since the data is collected and reported at the national and international levels, it is imperative to have a universally accepted nomenclature to avoid errors in reporting adverse events.

ii **Active pharmacovigilance:** The pharmacovigilance system generally works on spontaneous or voluntary reporting by healthcare professionals, paramedical providers, consumers, etc. Along with voluntary reporting, mandatory reporting must be made as the responsibility of healthcare service providers. So that all relevant adverse events can be reported.

iii **Patient participation:** Patient participation must be ensured in the pharmacovigilance programme. In India, patients are not aware of their right to report adverse events of drugs and vaccines. Thus, the government must invest in initiatives to generate awareness at all levels and equip poor patients to report the harm they suffered due to medications and vaccines.

iv **Punishment for reporting failures:** The code of conduct of medical professionals needs to be amended to impose proper reporting of adverse events as their responsibility. Since reporting is voluntary, most medical professionals do not report the events that really affect the pharmacovigilance system. No reporting or improper reporting must be limited, and Medical Commissions must play a role in shaping the code of conduct of medical and paramedical professionals.

v **Institutional Level Reporting System:** It is essential to have an institutional-level reporting system in every hospital or healthcare institution. This will avoid the delay in reporting serious adverse events, like in the case of the COVID-19 vaccine. Many victims of the COVID-19 vaccine were not aware of the reporting procedure, and the reporting authorities were not accessible to them. Thus, a mandatory provision must be included in the Clinical Establishment Act to provide a reporting facility at every single institution.

vi **No Faulty Compensation System:** A compensation scheme must be introduced for all kinds of adverse events. The court has already given directions for preparing guidelines for COVID-19 vaccine compensation. Also, a PIL is pending before the SC to introduce the vaccine damage scheme. It is necessary to compensate for all kinds of damages caused by medical error. Thus, a comprehensive system to address all types of medical errors should be formulated based on no-fault liability.

vii **Use of Technology:** Embracing new technological developments, especially AI, will help manage and predict health outcomes in the long run. Thus, the government must adopt policies to use current technical knowledge in the pharmacovigilance programme to develop an effective post-market monitoring system.