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# From AEFI to award: Designing the causation and adjudication standard for India's vaccine-injury compensation regime after Rachana Gangu

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**Abstract**
In Rachana Gangu v Union of India (2026), the Supreme Court directed the Union to formulate a no-fault compensation framework for serious adverse events following COVID-19 vaccination while preserving India's existing AEFI surveillance and causality-assessment architecture. The judgment resolves the question whether compensation machinery is constitutionally required but leaves the central operational question unanswered: what causal connection must an applicant prove to receive compensation? This paper argues that scientific pharmacovigilance causality and legal compensation causality serve different institutional purposes and should not be collapsed into a single test. Drawing on India's 2024 AEFI Guidelines, WHO causality methodology, the United States Vaccine Injury Table and off-table test, Australia's COVID-19 claims scheme, and Asian compensation models, the paper proposes a two-track Indian system. Presumptive 'table injuries' should qualify upon proof of vaccination, specified injury and temporal window, subject to rebuttal by a more probable alternative cause. Off-table injuries should be assessed on a claimant-friendly balance-of-probabilities standard using a structured three-part test. Indeterminate AEFI classifications should not automatically defeat claims. The paper also proposes an independent compensation authority, reasoned decisions, medical assistance for claimants, appeal, transparent publication and preservation of tort and consumer remedies with rules against double recovery.

**Keywords:** Vaccine injury, AEFI, no-fault compensation, causation, Article 21, public health law, Rachana Gangu, pharmacovigilance

## Introduction

Mass vaccination produces a distinctive problem of public law. A vaccination programme generates enormous social benefit, yet a small number of individuals may suffer serious injury even when the product is properly manufactured and administered. Ordinary negligence law is poorly fitted to that situation because compensation normally depends on identifying fault, proving individual causation through expensive expert evidence, and enduring adversarial litigation.

The Supreme Court confronted this institutional gap in Rachana Gangu v Union of India, decided on 10 March 2026 [1]. The Court accepted the continuing role of the National and State AEFI Committees, declined to create a parallel scientific inquiry, but directed the Union to formulate and publish an appropriate no-fault compensation framework for serious adverse events following COVID-19 immunisation. [1] The judgment constitutionalises the need for a remedial mechanism without prescribing its adjudicatory design.

The most difficult design issue is causation. 'No-fault' removes the requirement to prove negligence; it does not eliminate the need to establish that the vaccine sufficiently caused the injury. If the causal threshold is set at scientific certainty, the scheme may become practically inaccessible. If temporal proximity alone suffices, the scheme risks compensating coincidental illness and weakening scientific credibility. This paper develops a middle position.

## Research Question and Thesis

The research question is: what legal standard of causation should India adopt when converting an AEFI into a compensable vaccine injury? The paper argues that India should not make a WHO/AEFI scientific classification dispositive of legal entitlement. Pharmacovigilance asks whether evidence supports a causal association for safety surveillance; a compensation scheme asks whether social solidarity justifies relief to an individual claimant under a defined evidentiary standard. These functions overlap but are not identical.

The proposed solution is a two-track framework. Track One creates rebuttable presumptions for recognised vaccine-injury combinations occurring within defined time windows. Track Two governs non-table injuries through a structured balance-of-probabilities inquiry requiring a plausible medical theory, a logical sequence connecting vaccination and injury, and an appropriate temporal relationship, while permitting compensation despite scientific uncertainty where the evidence as a whole favours causation.

## Rachana Gangu and the Constitutional Basis of Compensation

Rachana Gangu arose against the background of COVID-19 vaccination and petitions concerning adverse outcomes. The Union argued that existing AEFI surveillance and ordinary consumer or civil remedies were available. The Supreme Court nevertheless concluded that a welfare State could not leave persons who suffer rare but serious adverse outcomes of a mass immunisation programme to fault-based litigation alone. It directed a dedicated no-fault framework while making clear that compensation need not imply governmental wrongdoing and that existing remedies could continue. [2]

The judgment is significant for public health law because it frames compensation as part of the State's positive constitutional responsibility rather than merely as a product-liability concession. That normative basis affects scheme design. A solidarity-based scheme should prioritise

accessibility, speed and evidentiary proportionality. Its function is not to replicate a medical-negligence trial in administrative form.

**1. Solidarity Does Not Mean Causal Indifference**

The solidarity rationale does not mean that every illness temporally following vaccination should attract compensation. A compensation programme must retain a causal boundary if it is to remain fiscally sustainable and scientifically credible. What changes in a no-fault system is the justification for relief and the kind of proof demanded: the claimant need not identify negligent conduct, and evidentiary rules can be deliberately calibrated to the fact that rare injuries are difficult to prove through conventional adversarial litigation.

This calibration is especially important where evidence is asymmetrically held. Vaccination records, AEFI investigation material, hospital files, post-mortem reports and expert committee assessments may sit across several public and private institutions. Requiring families to reconstruct that record unaided would reproduce the very access problem that a no-fault scheme is meant to solve. The State's positive obligation therefore has a procedural dimension: the scheme should organise evidence, not merely create a new form on which claimants must prove an already difficult case.

**India's Existing AEFI Causality Architecture**

India already possesses a sophisticated surveillance structure. The National AEFI Surveillance and Response Operational Guidelines 2024 [3] provide procedures for reporting, investigation, review and causality assessment of serious AEFIs. [3] The framework follows WHO methodology and is designed primarily for vaccine-safety surveillance and programme response.

WHO defines an AEFI as an untoward medical occurrence following immunisation that does not necessarily have a causal relationship with vaccination. Its revised methodology places assessed events into categories including consistent causal association, inconsistent causal association, indeterminate, and unclassifiable. [4] The system is deliberately cautious because pharmacovigilance seeks reliable safety signals, not distributive compensation.

This distinction is critical. A scientific committee may classify an event as indeterminate because population-level evidence is incomplete or because individual records are insufficient. A legal system, by contrast, routinely decides under uncertainty. Standards such as balance of probabilities exist precisely because adjudication cannot wait for scientific certainty.

**1. From a Surveillance File to a Compensation Record**

The AEFI process and a compensation process should share evidence but not collapse into one another. AEFI investigation is designed to identify safety signals, classify events and guide programme response. Compensation adjudication must additionally identify the claimant, define the legally relevant injury, apply a standard of proof, allow participation, and issue a reasoned decision capable of review. The same medical dossier can therefore serve two institutional purposes without the surveillance committee itself becoming the compensation tribunal.

Operationally, the compensation authority should receive the complete AEFI dossier where one exists, including case-investigation forms, clinical records considered, causality worksheets and the reasons for classification. The claimant should be entitled to know the material relied upon, subject to legitimate confidentiality limits concerning third parties. If the authority proposes to depart materially from an AEFI committee's scientific assessment, it should explain why and, where necessary, obtain an independent specialist opinion rather than silently substituting legal intuition for medical expertise. [10]

**Why Scientific Causation and Legal Causation Must Be Separated**

The international literature on no-fault schemes recognises causation as their central difficulty. Comparative reviews note that tort law, epidemiology and administrative compensation apply different approaches to causal inference. [5] Scientific causation may require reproducible association across populations; legal causation can legitimately ask whether, on the evidence relating to a claimant, vaccination was more likely than not a material cause.

Conflating the two standards produces two errors. First, it may deny compensation whenever epidemiological evidence is incomplete, even though the temporal course, biological mechanism and exclusion of alternatives strongly support the individual claim. Second, it may convert AEFI committees—designed for surveillance—into de facto adjudicatory bodies without procedural safeguards such as disclosure, hearing, reasons and appeal.

The compensation authority should therefore treat AEFI findings as highly relevant expert evidence but not as legally conclusive. A classification of 'consistent' should ordinarily satisfy the claimant's burden unless rebutted. 'Inconsistent' should weigh strongly against a claim but remain reviewable for procedural or evidentiary error. 'Indeterminate' should trigger legal assessment rather than automatic rejection.

**Comparative Models of Causation**

**1. United States: Table and Off-Table Claims**

The United States National Vaccine Injury Compensation Program illustrates the value of presumptive tables. The Vaccine Injury Table identifies certain vaccine-injury combinations and time windows; if the claimant satisfies the table criteria, causation is presumed unless another cause is established.6 For off-table claims, federal case law developed a structured actual-causation test. Althen v Secretary of Health and Human Services requires a medical theory causally connecting the vaccine and injury, a logical sequence of cause and effect, and a proximate temporal relationship, proved by preponderant evidence. [7]

The American model is not directly transplantable, but its architecture is useful: established injuries are handled through presumptions, while atypical claims retain a route to compensation rather than being excluded merely because science has not yet produced a table entry.

**2. Australia: Medical Opinion and Alternative Causes**

Australia's COVID-19 Vaccine Claims Scheme required medical evidence explaining why the diagnosed harm was most likely caused by vaccination and why other circumstances were less likely causes. Its policy provided for medical assessment and an independent expert process. [8] The model demonstrates the importance of structured

reasons, but a 'most likely' formulation can still become expensive if claimants must commission specialist reports without assistance.

### 3. Japan, Korea and Taiwan: Relief under Uncertainty

Comparative analysis of East Asian schemes shows greater willingness in some systems to provide relief despite residual uncertainty. Japanese practice has been described as allowing relief where a vaccine relationship cannot be conclusively denied, while Korean COVID-19 support has extended in specified circumstances to cases where causality remained unclear but alternative causes were unlikely. [9] These models demonstrate that compensation policy can legitimately tolerate more uncertainty than pharmacovigilance classification.

### 4. Comparative Lesson: Uncertainty Can Be Allocated, Not Eliminated

The comparative schemes reveal that the real policy choice is how uncertainty is allocated between the claimant and the public programme. Taiwan compensates both 'associated' and 'indeterminate' cases, while Japanese practice permits relief in categories where a vaccine relationship cannot be conclusively excluded. Korea uses differentiated categories and has, in the COVID-19 context, provided support in some uncertain cases. These approaches do not deny science; they recognise that a welfare scheme may legitimately choose a lower legal threshold than the threshold used to establish a population-level causal signal. [11]

The American experience provides a complementary warning. The Vaccine Injury Table reduces proof burdens for listed injuries, but other countermeasure programmes that require 'compelling, reliable, valid, medical and scientific evidence' illustrate how a formally no-fault regime can become difficult to access when causation is framed too strictly. India should therefore distinguish an administrative compensation standard from the higher evidentiary threshold that might be appropriate for scientific consensus, regulatory action or tort liability. [12]

## Proposed Two-Track Indian Causation Framework

India should establish a statutory or formally notified Vaccine Injury Schedule maintained by an expert committee but used by the compensation authority. The Schedule should identify vaccines, recognised serious injuries, diagnostic criteria and onset windows, and should be periodically revised in light of Indian and international evidence.

| Track | Claimant must establish | Effect |
|---|---|---|
| Track One: Presumptive/Table Injury | Proof of covered vaccination; diagnosis matching the Schedule; onset within prescribed time window; minimum seriousness threshold. | Causation presumed. Government may rebut by proving a more probable alternative cause. |
| Track Two: Off-Table Injury | Plausible medical theory; logical individual sequence of cause and effect; temporally appropriate onset; overall evidence showing vaccination more likely than not materially caused or aggravated the injury. | Claim decided on balance of probabilities. Lack of epidemiological consensus is relevant but not automatically fatal. |

For Track Two, India should adopt a claimant-friendly balance of probabilities rather than a requirement of scientific certainty. The claimant should not be required to identify a mechanism accepted beyond controversy. Instead, the authority should evaluate biological plausibility, timing, clinical course, dechallenge/rechallenge evidence where relevant, known safety signals, and credible alternative causes.

### 1. Governing and Updating the Vaccine Injury Schedule

A presumptive Schedule will remain legitimate only if its creation and revision are transparent. The expert body maintaining it should publish the evidence supporting each vaccine-injury pair, the diagnostic definition and the chosen onset window. It should review Indian AEFI data, international pharmacovigilance findings and peer-reviewed evidence at fixed intervals, with an expedited mechanism for newly detected safety signals. Schedule revision should not depend solely on the volume of litigation, because rare injuries may never generate enough claims to force doctrinal change.

The scheme should also specify the effect of later scientific developments on pending and recently rejected claims. Where a new injury is added to the Schedule because evidence has materially changed, claimants whose earlier applications were rejected only for lack of causal proof should receive a defined opportunity to seek reconsideration. This protects finality while avoiding the inequity of treating yesterday's scientific uncertainty as permanently conclusive after the State itself recognises a new causal association.

## Treatment of Indeterminate AEFI Cases

The most important rule should be that an 'indeterminate' AEFI classification is not equivalent to legal non-causation. Indeterminacy may arise from insufficient scientific evidence at population level, missing information or the novelty of an event. A compensation authority should ask a different question: after available evidence is assembled, is vaccine causation more probable than the relevant alternatives under the scheme's standard?

Where records are incomplete because of public-system failures in reporting or investigation, evidentiary uncertainty should not automatically be borne by the claimant. The authority should have an inquisitorial duty to obtain hospital records, vaccination records, autopsy material and expert opinion. Adverse inference should be available where a public authority failed to preserve information it was required to record.

### 1. Burden Shifting in Cases of Evidentiary Uncertainty

Track Two should begin with a modest claimant burden: proof of vaccination, a serious diagnosed injury, a medically plausible temporal relationship and enough material to raise a credible causal case. Once that threshold is met, the authority should investigate plausible alternative causes rather than requiring the claimant to disprove every theoretical possibility. A refusal should identify the alternative explanation that is actually supported by the

evidence and explain why it is more probable than vaccine causation.

This burden-shifting structure is particularly appropriate for indeterminate cases. 'Indeterminate' may describe the state of scientific knowledge, incomplete investigation, or unresolved competing explanations; it does not by itself answer the legal question. The authority should distinguish these reasons explicitly. Where indeterminacy arises because required records were never created or preserved by the public system, the resulting uncertainty should weigh differently from a case in which comprehensive records affirmatively demonstrate a stronger non-vaccine cause.

**Institutional Design of the Compensation Authority**

AEFI committees should remain scientific bodies. The compensation decision should be made by a separate Vaccine Injury Compensation Authority combining medical and legal competence. Separation protects both functions: surveillance experts need not convert every safety assessment into an adjudicatory proceeding, and claimants receive procedural rights before a body tasked with compensation.

Applications should be free or nominal-cost and permitted digitally and offline.

The Authority should obtain medical records directly with claimant consent instead of placing the entire documentary burden on families.

Claimants should receive access to a publicly funded independent medical opinion where causation is genuinely disputed.

Decisions should give short but reasoned findings on diagnosis, timing, alternative causes and the applicable causation track.

An internal medical-legal review panel should hear appeals, followed by judicial review under Articles 226 and 227.

Anonymised decisions and statistics should be published to create consistency without disclosing health identities.

**1. Timelines, Expertise and Quality of Reasons**

A compensation regime can fail through delay even if its legal test is sound. The implementing instrument should prescribe indicative timelines for record collection, medical assessment, first-instance decision and appeal, while allowing extensions for genuinely complex cases through recorded reasons. Interim assistance should be available in cases involving prolonged hospitalisation or severe disability where entitlement appears prima facie strong but final causation analysis will take time.

Decision panels should combine clinical and legal competence without allowing either discipline to dominate the other. Medical members should evaluate diagnosis, mechanism and alternatives; legal members should ensure that the correct burden and standard of proof are applied and that reasons address the claimant's case. Published anonymised decisions should gradually develop a body of administrative precedent, reducing unexplained variation and allowing the Schedule committee to identify recurring off-table injury patterns that may justify formal review.

**Compensation, Other Remedies and Double Recovery**

Rachana Gangu did not require immunity for manufacturers or extinguish ordinary claims. India should preserve consumer, tort and statutory remedies where negligence, manufacturing defect, failure to warn or malpractice is alleged. No-fault compensation should therefore be an additional remedial route, not an exclusive substitute.

To prevent double recovery, amounts received under the no-fault scheme can be set off against overlapping heads of damages later awarded in civil proceedings. The claimant should, however, retain compensation for heads not covered by the administrative scheme, including punitive or aggravated damages where legally available and separately proved.

**Beyond COVID-19: A Permanent Vaccine Injury Scheme**

The Court's operative direction arose from COVID-19 vaccination, but the constitutional and policy logic is broader. If social solidarity justifies compensation for rare serious harm arising from one mass vaccination programme, there is little principled basis to exclude comparable injuries arising from vaccines administered under India's Universal Immunisation Programme or future emergency campaigns. A permanent framework would also avoid the delay and inconsistency of designing an ad hoc scheme after each public-health emergency.

A permanent scheme could be funded through a combination of consolidated public expenditure and a modest vaccine-linked contribution from manufacturers or procurers, without requiring proof of manufacturer fault. Funding design should be separated from causation adjudication so that the authority deciding entitlement has no fiscal incentive to suppress valid claims.

**Recommendations**

- Create a permanent Vaccine Injury Compensation Authority distinct from AEFI surveillance committees.
- Adopt a revisable Vaccine Injury Schedule establishing rebuttable presumptions for recognised injuries and onset windows.
- Use a balance-of-probabilities test for off-table injuries through a structured three-part inquiry into medical theory, individual causal sequence and timing.
- Provide that “indeterminate” AEFI classification does not automatically defeat compensation.
- Give the authority inquisitorial powers and a duty to assist claimants in obtaining medical evidence.
- Publish anonymised reasoned decisions and aggregate outcomes to develop consistent administrative precedent.
- Preserve tort, consumer and product-liability actions while preventing double recovery through statutory set-off.
- Extend the framework beyond COVID-19 to serious injuries arising from nationally recommended or publicly administered vaccines.

**Conclusion**

Rachana Gangu has moved Indian vaccine-injury compensation from policy preference to constitutional obligation. The difficult work now begins. A no-fault system that merely replaces negligence with an impossible causal burden will satisfy the form of the judgment while defeating its remedial purpose. Conversely, a scheme based only on temporal association would undermine confidence in compensation and vaccine-safety science.

The appropriate solution is institutional differentiation. AEFI surveillance should continue to apply rigorous

scientific methods to protect population safety. Compensation law should use those findings but decide individual entitlement through legal standards calibrated to welfare, fairness and uncertainty. A presumptive table for established injuries, combined with a structured balance-of-probabilities route for atypical claims, gives India a defensible way to move from AEFI to award without confusing scientific caution with legal proof.

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