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Product Liability for Medicines and Medical Devices



Introduction: Why Medicine Breaks the Ordinary Rules of Product Liability

Ordinary product liability doctrine assumes a buyer who can inspect a product, a seller who can be sued in the same jurisdiction as the sale, and a defect that manifests close in time to use. Pharmaceuticals and medical devices satisfy almost none of these assumptions. A patient cannot “inspect” a drug’s molecular action; a device implanted inside the body reveals its defects, if at all, only years later; and the sale itself is mediated by a physician whose judgment the law has historically treated as a buffer between manufacturer and patient. These features have produced a body of law that borrows the language of ordinary product liability- defect, causation, strict liability, while applying it through doctrines found nowhere else: the learned-intermediary rule, regulatory-compliance defenses , and mass-tort litigation machinery built to handle tens of thousands of claims arising from a single product line.

2026 is an inflection year for this branch of law on every side of the Atlantic and in India. The United States is watching its largest-ever pharmaceutical mass torts move toward resolution even as new device litigation accelerates behind them. The European Union’s most significant liability reform in four decades takes effect in December, rewritten specifically with the “black box” problem of modern medicine and diagnostics in mind. The United Kingdom has opened, for the first time since 1987, a review of whether its product safety statute is fit for medical products. And India is attempting to replace a nine-decade-old drugs statute with a single law covering both drugs and devices ,a consolidation the device industry is actively resisting. This piece surveys each front, then draws out the doctrinal threads that cut across all four.

I. United States: Mass Tort as the De Facto Regulator

No federal statute governs pharmaceutical or medical device liability comprehensively. Claims are litigated state by state under a shared doctrinal core - design defect, manufacturing defect, and failure to warn, largely tracking the Restatement (Second) of Torts SECTION 402A, but the real machinery of resolution in 2026 is the multidistrict litigation (MDL) system, which consolidates pretrial proceedings for mass claims arising from a single product.

- Talc litigation nears a turning point. MDL ,the consolidated proceeding over Johnson & Johnson’s talc-based products, carried roughly 69,000 pending claims as of August 2026, making it the largest active MDL in the federal system. Years of failed Chapter 11 bankruptcy manoeuvres and inconclusive bellwether trials culminated in an approximately \$5.5 billion settlement offer disclosed in early August 2026 though, as of this update, plaintiffs’ leadership had not accepted it and the presiding judge had ordered the steering committee to explain how it intended to proceed with the bellwether process.
- Device litigation is scaling up behind it. The Bard PowerPort catheter MDL in the District of Arizona, alleging device fracture and migration, held roughly 3,500 pending actions with early test trials underway through 2026. In the parallel hernia-mesh proceedings, a federal bellwether against Covidien produced an \$88 million verdict in early August 2026 , a result plaintiffs’ counsel are already treating as leverage for the thousands of cases still in the pipeline, notwithstanding the post-trial motions and appeal that will follow.
- The learned-intermediary doctrine still does most of the doctrinal work. In most states, a manufacturer discharges its duty to warn by adequately informing the prescribing physician, not the patient directly ,the physician is treated as the intermediary best placed to weigh risk against benefit for an individual patient. The doctrine remains the single biggest structural difference between drug/device litigation and liability for an ordinary consumer product, and it is the first line of defence in nearly every failure-to-warn claim.

- Expert-evidence gatekeeping has hardened. Courts continue applying the 2023 amendment to Federal Rule of Evidence 702, which requires a judge to find causation testimony “more likely than not” reliable before admitting it , raising the evidentiary bar in cases where causation depends on contested epidemiology, as in the talc and hair-relaxer cancer litigation.
- Federal preemption remains a live defence for devices cleared through the FDA's most rigorous premarket-approval pathway, though its scope continues to be litigated device-by-device and claim-by-claim rather than settled categorically.

Watch next: *whether the talc settlement holds together through the claims-administration process, and whether the Covidien verdict pushes hernia-mesh defendants toward a global resolution before 2027.*

II. European Union: Legislating the End of the Learned-Intermediary Gap

Where the US relies on judge-made doctrine, the EU has now legislated directly. The revised Product Liability Directive, entered into force in December 2024 and must be transposed into every Member State’s national law by 9 December 2026, applying to products placed on the market after that date. It replaces the 1985 Directive that has governed EU product liability for four decades, and its drafters were explicit that digital health products, software-driven diagnostics, AI-assisted devices, connected pharmaceutical delivery systems , exposed the old framework’s gaps.

- Transposition is a genuine race. As of the second half of 2026, only Hungary & Croatia, had completed transposition, with roughly a dozen more Member States advancing draft legislation and several, notably France and Italy, expected to miss the December deadline. Because the Directive requires maximum harmonisation but leaves discrete choices to national legislators (on defences, evidentiary presumptions, and distributor liability), meaningful divergence is already emerging in the drafts, complicating compliance for pharmaceutical and device manufacturers selling across the bloc.
- The evidentiary shift matters more for medicine than for any other product category. Courts may now order disclosure of a manufacturer’s technical files, and defectiveness or causation may be presumed where a claimant faces “excessive difficulty” proving their case owing to technical or scientific complexity language drafted with pharmacological and algorithmic “black box” problems specifically in mind. For a claimant alleging that a drug’s side-effect profile was inadequately disclosed, or that a diagnostic algorithm’s error rate was concealed, this reverses decades of practical difficulty in accessing manufacturer data.
- Damages caps are gone, and psychological harm is now recoverable. The old €500 threshold for property damage and the ceiling on personal-injury compensation have been abolished, and recognised psychological harm and data loss or corruption are now compensable heads of damage, relevant to connected medical devices and digital therapeutics whose failure may cause harm beyond the purely physical.
- Regulatory compliance is not a defence. Meeting the safety obligations of the EU AI Act or the Medical Device Regulation (EU) 2017/745 will inform, but not conclusively answer, whether a product is “defective” under the new Directive , a deliberate rejection of the argument that regulatory clearance should insulate a manufacturer from civil liability.

Watch next: *whether national transpositions stay close enough to a common template to avoid fragmenting the single market for pharmaceutical and device manufacturers by the December deadline*

III. United Kingdom: A Statute Built for 1987 Confronts Digital Medicine

The UK's core product liability statute, the Consumer Protection Act 1987, has never been comprehensively reviewed since it transposed the EU's original 1985 Directive. That changed in 2025.

- The Product Regulation and Metrology Act 2025 received Royal Assent on 21 July 2025, giving government broad delegated power to update product-safety rules, including for medical products, through secondary legislation, though the Act itself makes no substantive changes on its own.
- The Law Commission's first full review of the 1987 Act is now underway, examining specifically whether the regime remains fit for digital and AI-enabled medical products; a public consultation was expected in the second half of 2026, with recommendations to government likely in late 2026 or early 2027.
- A parallel government consultation on replacing the General Product Safety Regulations 2005 ran from March to June 2026, billed as the most significant overhaul of UK product-safety law in two decades, and included a specific call for evidence on regulating AI-enabled products, squarely relevant to software-driven diagnostics and connected devices.
- The UK's post-Brexit posture remains one of deliberate, cautious divergence: it is watching how the EU's new evidentiary presumptions and abolished caps play out before deciding how far to mirror them, rather than adopting the EU model wholesale.

Watch next: *whether the Law Commission's eventual recommendations pull UK medical-product liability closer to the EU's claimant-friendly model or keep the UK's comparatively defendant-protective status quo.*

IV. India: Consolidation, Contested

India's pharmaceutical and device liability landscape sits at the intersection of two statutes that were never designed to work together: the Drugs and Cosmetics Act, 1940, which governs manufacturing, licensing, and safety standards; and Chapter VI of the Consumer Protection Act, 2019, which supplies the only general statutory cause of action for a defective product. Neither was drafted with implantable devices or software-driven diagnostics in mind, and 2026 has brought the most significant attempt yet to modernise the framework accompanied by open industry revolt.

- The Drugs, Medical Devices and Cosmetics Bill, 2026 is circulating for inter-ministerial consultation and would replace the 1940 Act with a single consolidated statute covering drugs, medical devices, and cosmetics under one regulatory and enforcement framework, administered by the Central Drugs Standard Control Organisation (CDSCO).
- The medical device industry is resisting consolidation. Manufacturers and healthcare bodies argue that folding devices into a drug-centric statute is a category error: the Bill retains drug-specific language such as “spurious” and “adulterated” for products that are properly regulated by engineering and performance standards rather than chemical composition, and it exposes device makers to the same 1–7 year imprisonment provisions that apply to drug offences, including, industry bodies argue, for purely technical or documentation lapses that carry no safety consequence.
- Regulatory reclassification is already under way independent of the Bill. CDSCO undertook a risk-based reclassification of 553 medical devices across cardiovascular and neurological categories through 2025 and 2026, and continues to digitise licensing through the SUGAM portal, changes that will feed directly into how “defect” is assessed once a case reaches a consumer commission.

- On the liability side proper, Chapter VI of the CPA 2019 remains the only general route to compensation: a claimant must show a manufacturing defect, a deviation from specifications, or an inadequate warning, and strict liability is available on that showing. But India has never developed a learned-intermediary doctrine of the kind that dominates US failure-to-warn litigation, meaning the adequacy of warnings to prescribing physicians, as opposed to patients directly, remains doctrinally underdeveloped in Indian case law. Compensation levels awarded by consumer commissions also remain modest by comparative standards, and India has no real equivalent of the punitive-damages culture that drives US mass-tort settlements.
- The result is a widening gap between India's rapidly modernising regulatory apparatus, international-standard device classification, digitised licensing, a consolidated statute in the works, and a civil liability regime that has not kept pace, leaving patients harmed by defective drugs or devices with a narrower and less certain path to compensation than their counterparts in any of the other three jurisdictions surveyed here.

Watch next: *whether the 2026 Bill survives industry pushback in something close to its current form, and whether a future amendment to the CPA 2019 or a standalone statute ever imports a learned-intermediary-style doctrine into Indian law.*

Cross-Jurisdiction Comparison at a Glance

Theme	United States	European Union	United Kingdom	India
Governing standard	State tort law (strict liability / negligence / warranty); no uniform federal statute	Near-strict liability under Directive (EU) 2024/2853, applicable from 9 Dec 2026	Consumer Protection Act 1987, under first full review since enactment	Chapter VI, Consumer Protection Act 2019; drug-specific liability fragmented across the Drugs and Cosmetics Act, 1940
Defining recent event	\$5.5 billion talc settlement offer (Aug 2026); Arizona PowerPort and Ohio hernia-mesh MDLs producing bellwether verdicts	Member-State transposition race ahead of 9 Dec 2026 deadline; evidentiary presumptions favouring claimants	Law Commission's first review of the 1987 Act since inception, examining fitness for medical products	Draft Drugs, Medical Devices and Cosmetics Bill, 2026 to replace the 1940 Act
Treatment of devices	Same doctrinal framework as drugs; FDA classification relevant to preemption defence	Intersects with the Medical Device Regulation (EU) 2017/745; safety-standard breach evidences defect	Devices regulated by MHRA; liability regime under review alongside drugs	Proposed Bill controversially regulates devices under drug-centric provisions, including criminal penalties
Burden on claimant	Plaintiff proves defect and causation (strict liability in most states); learned-intermediary doctrine shields manufacturers who warn physicians	Eased: courts may compel disclosure; defect and causation may be presumed where technical complexity makes proof excessively difficult	Claimant must show defect under s.3, 1987 Act; reform may recalibrate this for digital-health products	Claimant must prove manufacturing defect, deviation from specification, or inadequate warning; no learned-intermediary doctrine recognised
Caps /	Vary by state;	Property-damage	No general damages	Compensation

recoverable harm	punitive damages available and central to talc/mesh verdicts	threshold and personal-injury caps abolished; psychological harm now recoverable	cap; reform may adjust for digital-health harms	historically modest; CPA 2019 introduced product liability but punitive-damages culture remains limited
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V. Threads That Cut Across All Four Jurisdictions

- Regulatory approval is losing its shield everywhere except, arguably, the US preemption doctrine. The EU has legislated that AI Act or MDR compliance does not itself defeat a defect finding; the UK's ongoing review is testing the same question for the 1987 Act; and Indian consumer commissions have shown a willingness to find manufacturers and dealers jointly liable even for products that cleared regulatory approval. The US remains the outlier, where FDA premarket approval can still operate as a near-complete federal preemption defence for certain high-risk devices.
- Mass-claim infrastructure is spreading beyond the US. The MDL model - built for exactly this kind of high-volume, single-product litigation, has no direct equivalent in the EU, UK, or India, but the EU's new disclosure and presumption rules are designed to make individual and collective claims easier to bring at scale, and litigation funding for consumer claims is expanding across all three non-US jurisdictions.
- The learned-intermediary doctrine is a genuinely American peculiarity. Neither the EU's new Directive, UK law, nor Indian jurisprudence recognises an equivalent buffer between manufacturer and patient, meaning a warning that would satisfy a US court by reaching the prescribing physician may not, by itself, satisfy the adequacy-of-warning standard applied elsewhere.
- Insurance markets are already repricing this risk. Products-liability and mass-tort defence practices on both sides of the Atlantic are advising pharmaceutical and device clients to reassess coverage now, ahead of the EU's December 2026 deadline and against the backdrop of US verdicts running into nine figures, a signal that underwriters expect claim frequency and severity to rise across all four markets, not just the one generating headline verdicts.

Conclusion

The four jurisdictions surveyed here are converging on a shared premise, that a manufacturer's compliance with regulatory approval processes is necessary but not sufficient to defeat a claim that its drug or device caused harm, while diverging sharply on mechanism. The US delivers that premise through mass litigation and nine-figure jury verdicts; the EU through a rewritten statute that shifts the evidentiary burden; the UK through a cautious, still-unfinished review; and India through a regulatory consolidation that has left its civil liability framework comparatively untouched. For any practitioner advising pharmaceutical or medical device clients with a footprint across these markets, 2026 is the year in which "we met the regulatory standard" stopped being an adequate answer to a liability claim in three of the four, and the year in which the fourth, India, will decide how much further its own regime has to travel to catch up.

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