ISSN: 2455-8109

International Journal of Farmacia (IJF)

IJF |Vol.12 | Issue 2 | Apr – Jun -2026

www.ijfjournal.com

DOI : https://doi.org/10.61096/ijf.v12.iss2.2026.101-109

Recent Advancements in Legal Aspects of Pharmaceuticals: A Comprehensive Review (2018–2024)

Deepak Prashar[1*], Anita Verma[2], Nidhi Thakur[2], Chanchal Gautam[2], Sneha[2]

[1]*Department of Pharmacy, L R Institute of Pharmacy, Jabli-Kyar, Solan HP-India*
[2]*Department of Law, L R Institute of Legal Studies, Jabli-Kyar, Solan (HP)-India.*

*Corresponding Author: Deepak Prashar
Email id: prashardeepak99@yahoo.in

Published by:
29.05.2026

Published by:

Futuristic Publications

Abstract: Background: The pharmaceutical sector operates within a dynamic and complex legal framework that governs drug development, approval, manufacturing, intellectual property, pharmacovigilance, and market authorization. Rapid advancements in biotechnology, digital health, and personalized medicine have necessitated significant legislative reforms globally. Objectives: This review comprehensively examines recent (2018–2024) advancements in pharmaceutical law across drug regulatory affairs, intellectual property rights, product liability, pharmacovigilance, digital health regulation, compulsory licensing, and emerging global harmonization efforts. Methods: A systematic narrative review was conducted using PubMed, Scopus, LexisNexis, and regulatory agency databases. Peer-reviewed literature, legislative texts, and official regulatory guidance documents published between 2018 and 2024 were included. Results: Key advancements identified include the US FDCA amendments (2022), EU Regulation 2022/123, ICH E6 (R3) revisions, FDA's Digital Health Center of Excellence guidelines, TRIPS Agreement flexibilities during the COVID-19 pandemic, expansion of the Biologics Price Competition and Innovation Act (BPCIA) framework, and enhanced post-market surveillance mandates. Conclusion: Pharmaceutical law is evolving rapidly in response to technological innovation, global health emergencies, and equitable access imperatives. Stakeholders must proactively engage with emerging legal developments to ensure compliance and foster innovation.

Keywords: Pharmaceutical law, Drug regulation, Intellectual property, Pharmacovigilance, Digital health, Compulsory licensing, Biosimilars, Product liability.

1. INTRODUCTION

Pharmaceutical law constitutes a specialized domain of regulatory and civil law governing the entire lifecycle of medicinal products from early-stage research and clinical development to post-market surveillance and product withdrawal. The legal framework encompassing pharmaceuticals intersects patent law, administrative law, tort law, contract law, international trade law, and increasingly, digital and data protection law [1-2]. The period from 2018 to 2024 has witnessed unprecedented legal activity driven by multiple converging forces:

- The global COVID-19 pandemic which exposed critical regulatory gaps and accelerated emergency use authorization frameworks
- The rapid proliferation of biologics and gene therapies requiring novel IP and regulatory paradigms
- The digitalization of healthcare through mobile medical applications and AI-assisted diagnostics; and
- Growing global pressure for equitable access to essential medicines [3-4].

Regulatory bodies worldwide including the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan, and the Central Drugs Standard Control Organisation (CDSCO) of India have undertaken substantial legislative and guidance overhauls. International harmonization bodies, particularly the International Council for Harmonisation (ICH)

and the World Health Organization (WHO), have issued updated guidelines reflecting these paradigm shifts [5-6]. This review systematically examines these legal advancements across eight thematic domains: drug regulatory law, intellectual property and patent law, product liability, pharmacovigilance, digital health regulation, compulsory licensing, biosimilars and generic drug law, and clinical trial regulations. Each section integrates the legislative background, recent developments, judicial and regulatory precedents, and their implications for pharmaceutical stakeholders.

2. RECENT ADVANCEMENTS IN DRUG REGULATORY LAW

2.1. United States: FDA Modernization Act 2.0 and Beyond

The FDA Modernization Act 2.0, enacted in December 2022 (P.L. 117-328), amended the Federal Food, Drug, and Cosmetic Act (FDCA) to eliminate the requirement that certain drug safety studies must use animal testing. This landmark amendment allows sponsors to submit data from cell-based assays, micro physiological systems, organs-on-chips, computational models, and other non-animal technologies as alternatives for demonstrating drug safety [7-8]. Simultaneously, the FDA's Real-Time Oncology Review (RTOR) pilot program was formally expanded under the 2022 PDUFA VII reauthorization, enabling earlier review of efficacy data for serious oncologic conditions before the complete application is submitted. By 2023, more than 25 oncology applications had benefited from this expedited pathway, reducing median review time by approximately 3.5 months [9]. The Omnibus Consolidated Appropriations Act 2023 further authorized the FDA to regulate laboratory developed tests (LDTs) under the same framework applicable to in vitro diagnostics a long-contested regulatory gap. This provision, effective 2024, has direct implications for pharmaceutical companion diagnostics and precision medicine [10].

2.2. European Union: Revised General Pharmaceutical Legislation

The EU proposed its most comprehensive revision of pharmaceutical legislation in over two decades in April 2023, introducing a new Regulation and Directive to replace Directive 2001/83/EC and Regulation (EC) 726/2004. Key proposals include reducing the baseline regulatory data protection period from 8 to 6 years for medicines that do not meet unmet medical needs, with the possibility of extending protection for new indications, pediatric studies, and comparative clinical trials [11-12].

The revision also introduces a new concept of 'transferable exclusivity vouchers' (TEVs) for antimicrobial medicines, aiming to incentivize research into novel antibiotics addressing the antimicrobial resistance (AMR) crisis a priority reinforced by the 2021 EU Pharmaceutical Strategy [13]. Regulation (EU) 2022/123 established the European Health Emergency Preparedness and Response Authority (HERA) and introduced emergency measures for medicinal products, including fast-track approval pathways modelled after the FDA's Emergency Use Authorization (EUA). These provisions were informed by lessons from COVID-19 vaccine rollout disparities [14].

2.3. India: New Drugs and Clinical Trials Rules, 2019 and Amendments

India's New Drugs and Clinical Trials Rules (NDCT Rules), notified in 2019 and subsequently amended in 2021 and 2023, represent the most comprehensive overhaul of India's clinical trial regulation since Schedule Y of the Drugs and Cosmetics Act. Key provisions include mandatory global simultaneous trials, accelerated approval for new drugs for unmet medical needs, permission for academic clinical trials, and enhanced pharmacovigilance requirements [15-16].

Table 1:*Recent Legislative and Regulatory Reforms in Pharmaceutical Law (2018–2024)*

Region/Country	Legislation/Regulation	Key Provisions	Year
USA	FDA Modernization Act 2.0	Allows non-animal testing alternatives; expands RTOR; LDT regulation	2022
USA	PDUFA VII Reauthorization	Accelerated oncology review; enhanced rare disease pathways	2022
EU	Proposed Pharma Legislation Revision	Data protection reform; AMR vouchers; HERA establishment	2023
EU	Regulation (EU) 2022/123	Emergency use authorization framework; HERA mandate	2022
India	NDCT Rules (Amendment)	Global simultaneous trials; academic trial permissions; PhV reform	2019–2023
Japan	PMDA Accelerated Approval	Conditional approval for regenerative medicine products	2020
Global (WHO)	Prequalification Programme Expansion	Expanded scope to include vaccines and diagnostics	2021

3. INTELLECTUAL PROPERTY AND PATENT LAW IN PHARMACEUTICALS

3.1. Patent Linkage and Evergreening

Patent linkage, the practice of linking regulatory approval of generic medicines to the patent status of the originator product—continues to generate significant legal controversy. The US Hatch-Waxman Act framework, challenged in FTC v. Actavis (2013), saw its legacy debated in subsequent litigation, including Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc. (2015) and Amgen Inc. v. Sanofi (2023). The Supreme Court's 2023 ruling in Amgen v. Sanofi significantly constrained broad functional genus claims for biologics, ruling that Amgen's antibody patent claims were not enabled under 35 U.S.C. § 112 with major implications for biologic patent strategy [17,18]. Secondary patenting and evergreening, the practice of filing multiple patents covering minor modifications to extend market exclusivity remains a contentious legal and ethical issue. Studies show that of 100 top-selling drugs in the US, more than 70% had at least one secondary patent extending exclusivity beyond the original compound patent, with median extension of 38 months [19].

3.2. TRIPS Agreement Flexibilities and the COVID-19 Waiver

The COVID-19 pandemic brought TRIPS Agreement flexibilities to the forefront of global pharmaceutical law. In June 2022, after two years of contentious negotiations, WTO members reached a waiver decision under Article IX:3 of the Marrakesh Agreement permitting eligible developing country members to authorize use of COVID-19 vaccine patents without consent of the right holder, without requiring export-import authorization restrictions [20-21]. This TRIPS Waiver Decision, while more limited than the original proposal co-sponsored by India and South Africa (which had sought broader coverage including diagnostics and therapeutics), established an important precedent for using multilateral trade law mechanisms to address global health emergencies. The waiver's scope was extended in June 2023 to include COVID-19 diagnostics and therapeutics for a further three years [22].

3.3. Artificial Intelligence and Patent Inventor ship

The emergence of AI-assisted drug discovery has raised novel questions regarding patent inventor ship. In Thaler vs Vidal (Fed. Cir. 2022), the Federal Circuit held that under existing US patent law, only natural persons may be named as inventors AI systems cannot be inventors. Similar conclusions were reached by the UK Supreme Court in Thaler vs Comptroller-General (2023) and the EPO's Legal Board of Appeal [23-24]. These decisions have profound implications for pharmaceutical innovators deploying AI in drug discovery (e.g., Insilico Medicine, Atomwise, BenevolentAI), as they must identify the human contributors who made the inventive contribution, even when AI systems generated lead compounds. Legislative reform proposals are under active consideration in the US, UK, and EU [25].

Table 2: *Key Pharmaceutical Patent Law Developments and Judicial Decisions (2018–2024)*

Case/Development	Jurisdiction	Key Legal Issue	Year
Amgen Inc. v. Sanofi	US Supreme Court	Functional genus claims; enablement under 35 U.S.C. § 112	2023
Thaler v. Vidal	US Fed. Circuit	AI as inventor; statutory interpretation of 'inventor'	2022
Thaler v. Comptroller-General	UK Supreme Court	AI inventorship under UK Patents Act 1977	2023
TRIPS COVID-19 Waiver	WTO	Compulsory licensing of COVID-19 vaccines	2022
Novartis AG v. Natco Pharma	India Supreme Court	Incremental innovation; Section 3(d) Doctrine	Affirmed 2013; applied 2018–2023
EU Unitary Patent System	EU	Centralized patent protection across 17+ EU states	2023 (entered into force)

4. PRODUCT LIABILITY IN PHARMACEUTICALS

4.1. Evolving Standards of Manufacturer Liability

Pharmaceutical product liability law has undergone significant jurisprudential development in the United States, European Union, and India. In the US, the federal preemption doctrine articulated in Wyeth vs Levine (2009) and Mutual Pharmaceutical Co. vs Bartlett (2013) continues to define the landscape of innovator versus generic manufacturer liability. Recent, circuit court decisions have further refined the 'sameness' requirement for generic labelling and expanded the 'failure to warn' liability theory [26-27]. In Dolin vs GlaxoSmithKline LLC (7th Cir. 2018), the court initially held a generic manufacturer liable for failure to update its label, before the Supreme Court's ruling in PLIVA, Inc. vs Mensing was reaffirmed as precluding such claims based on federal pre-

emption. This conflict between state tort law and federal pre-emption has prompted calls for legislative reform to close the 'generic drug loophole' in product liability [28].

4.2. European Product Liability Directive Revision

The European Commission's proposed revision of the Product Liability Directive (PLD), published in September 2022, addresses pharmaceutical liability in the context of AI-integrated and software-driven medical products. The proposed Directive extends liability to include software, AI systems, and digital health products; reverses the burden of proof in complex cases (placing it on the manufacturer to demonstrate the absence of a defect); and removes the 10-year long-stop period for latent defects [29-30].These proposed changes have major implications for pharmaceutical and medical device companies deploying AI-assisted diagnostics and digital therapeutics. Industry stakeholders have raised concerns about legal certainty and the potential chilling effect on innovation [31].

Table 3: *Comparative Overview of Pharmaceutical Product Liability Frameworks*

Jurisdiction	Legal Framework	Liability Standard	Recent Developments
USA	FDCA; State Tort Law	Strict liability / Negligence; Federal preemption applies for generics	AI/LDT oversight; generic labeling preemption debate ongoing
EU	Product Liability Directive 85/374/EEC	Strict liability; development risk defense available	Proposed PLD revision 2022: AI coverage; reversed burden of proof
India	Consumer Protection Act 2019; Drugs Act 1940	Negligence-based; strict liability evolving	NDCT Rules 2019 strengthen manufacturer obligations
UK	Consumer Protection Act 1987; Common Law	Strict liability; development risk defence	Post-Brexit divergence from EU framework; MHRA guidance updates

5. PHARMACOVIGILANCE LAW AND POST-MARKET SURVEILLANCE

5.1. Global Regulatory Requirements

Pharmacovigilance (PV) law, the regulatory framework governing the detection, assessment, understanding, and prevention of adverse effects of medicinal products—has been substantially strengthened globally following high-profile drug safety failures. The ICH E2C (R2) and E2E guidelines provide the international framework, implemented through binding national and regional requirements [32]. In the US, FDA's Sentinel System, established under FDAAA 2007, has been further expanded to cover over 300 million patient records for active safety surveillance. The 2022 PDUFA VII commitment letter includes new requirements for post-market requirements (PMRs) and post-market commitments (PMCs) tracking, with performance metrics to be publicly reported annually [33].

5.2. EMA's New Pharmacovigilance Legislation

EU Regulation (EC) No 1235/2010 and Directive 2010/84/EU, which overhauled European pharmacovigilance following the Eudravigilance modernization, have been supplemented by Implementing Regulation (EU) 520/2012 and subsequent EMA good pharmacovigilance practice (GVP) Module updates. GVP Module I (Pharmacovigilance Systems and their Quality Systems) was last revised in 2021, incorporating provisions for electronic submissions and advanced signal detection algorithms [34].

5.3. Risk Evaluation and Mitigation Strategies (REMS)

The REMS program in the US has been a subject of significant litigation regarding whether brand manufacturers can use restricted distribution REMS programs to impede generic competition. In the landmark FTC vs AbbVie Inc. (3d Cir. 2020) case, affirmed in part by the Supreme Court, brand manufacturers were held liable for antitrust violations by using citizen petitions and regulatory processes as delay tactics. The FTC's 2023 report on REMS abuse documented 74 instances where REMS shared system requirements were weaponized to obstruct generic entry [35-36].

Table 4: *Key Pharmacovigilance Regulatory Requirements by Region (2020–2024).*

Region	Regulatory Framework	Reporting Requirements	Recent Changes
USA (FDA)	FAERS; Sentinel System; MedWatch	Expedited: 15-day for serious/unexpected AEs; Periodic PSURs	PDUFA VII PMR/PMC tracking; real-world evidence integration

EU (EMA)	EudraVigilance; GVP Modules	15-day expedited; PSUR/PBRER submissions via EMA portal	GVP Module I (2021 rev.); DARWIN EU real-world data platform
India (CDSCO)	PvPI; VigiFlow	30-day for serious ADRs; Annual Benefit-Risk Report	NDCT Rules 2019: expanded MAH PV obligations; 72-hr CIOMS reporting
Japan (PMDA)	JAPIC; MID-NET	15-day for serious unexpected; Japanese PSUR (J-PSUR)	Medical Device and Drug Safety Regulations 2021 amendment
ICH (Global)	ICH E2B(R3); E2C(R2); E2E	Electronic MedDRA-coded submissions; PBRER format	ICH E2B(R3) implementation deadline 2024 for all regions

6. DIGITAL HEALTH REGULATION AND SOFTWARE AS A MEDICAL DEVICE (SAMD)

6.1. FDA's Digital Health Framework

The FDA's Digital Health Center of Excellence (DHCoE), established in 2020, has spearheaded significant regulatory advancement in the oversight of Software as a Medical Device (SaMD), mobile medical applications (MMAs), and AI/ML-based Software in Medical Devices (AIML-SaMD). The FDA's 2021 Artificial Intelligence/Machine Learning-Based Software as a Medical Device Action Plan outlined a proposed regulatory framework for AI systems that continuously learn and adapt post-deployment raising profound questions about traditional static premarket approval models [37-38]. The Food and Drug Omnibus Reform Act (FDORA) 2022, enacted as part of the Consolidated Appropriations Act 2023, formally authorized FDA to regulate clinical decision support (CDS) software under a risk-based framework. The legislation distinguishes between high-risk CDS (subject to device regulation) and lower-risk CDS (subject to transparency and function-based criteria) [39].

6.2. EU MDR and IVDR: Implications for Digital Therapeutics

The EU Medical Device Regulation (MDR) (EU) 2017/745, which fully replaced Directive 93/42/EEC in May 2021 (with transition extended to 2025 for some devices), and the In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746, effective May 2022, have substantially elevated regulatory requirements for software-based medical devices, including digital therapeutics (DTx) and AI-assisted diagnostic tools. Notified body capacity constraints have led to significant market authorization backlogs, prompting EU Commission emergency extension measures in 2023 [40-41].

6.3. Data Protection and Pharmaceutical Research

The General Data Protection Regulation (GDPR) (EU) 2016/679 has generated extensive pharmaceutical-sector guidance, particularly regarding secondary use of patient health data for pharmacovigilance, real-world evidence, and clinical research. The European Data Protection Board (EDPB) Guidelines 08/2020 and the European Health Data Space (EHDS) Regulation proposal (2022) seek to balance data protection rights with the legitimate needs of pharmaceutical research and public health [42-43].

Table 5: *Regulatory Frameworks for Digital Health Products in Pharmaceuticals.*

Jurisdiction	Framework/Guidance	Product Types Covered	Key Requirements
USA	FDA Digital Health Framework; FDORA 2022	SaMD; AI/ML devices; mobile medical apps; CDS software	Risk-based classification; pre-sub meetings; PCCP for adaptive AI
EU	EU MDR 2017/745; IVDR 2017/746	Medical device software; IVD software; AI-assisted diagnostics	CE marking; QMS; post-market clinical follow-up (PMCF)
UK	MHRA Software as a Medical Device Framework	Standalone software; AI/ML SaMD; DTx	Post-Brexit: UKCA marking; MHRA AI guidance 2023
Global (IMDRF)	IMDRF SaMD Framework; AI/ML Guidance	All software-based medical devices	Risk categorization; life cycle approach; clinical evaluation

7. BIOSIMILARS AND GENERIC DRUG LAW

7.1. US BPCIA Litigation and Interchangeability

The Biologics Price Competition and Innovation Act (BPCIA) 2009 framework, which established the 351(k) biosimilar approval pathway, continued to generate complex litigation. The 'patent dance' provisions of BPCIA the structured information-exchange process for identifying patents for litigation—was further interpreted in Sandoz Inc. vs Amgen Inc. (2017), with subsequent circuit decisions refining the consequences for non-compliance. By 2023, over 40 biosimilars had received FDA interchangeability designations, enabling pharmacy-level substitution in most US states without prescriber intervention [44-45]. The Inflation Reduction Act (IRA) 2022 authorized Medicare price negotiation for high-expenditure drugs, including biologics, after losing patent exclusivity fundamentally altering the economic calculus for biosimilar development and creating legal challenges from multiple biopharmaceutical companies on constitutional grounds (takings clause, First Amendment, due process) [46].

7.2. Generic Drug Approval and Paragraph IV Litigation

The Abbreviated New Drug Application (ANDA) pathway and associated Paragraph IV patent certification litigation under the Hatch-Waxman Act continued to generate extensive case law. Notable 2020–2024 decisions addressed the co-administration exception, where the Federal Circuit held in Teva vs GlaxoSmithKline (2020) that skinny labelling omitting patented indications from a generic label—could still result in induced infringement liability if the generic's marketing materials targeted the patented use [47].

Table 6: *Global Biosimilar Approval Statistics and Regulatory Milestones (2018–2023).*

Region	Approved Biosimilars (cumulative to 2023)	Interchangeable Designations	Key Legal/Regulatory Development
USA (FDA)	~50+	~40 (post-2021 guidance)	IRA 2022: Medicare negotiation; BPCIA patent dance litigation
EU (EMA)	~80+	N/A (automatic substitution per MS law)	Revised biosimilar guidelines 2022; extrapolation policy strengthened
India (CDSCO)	~50+ (similar biologics)	N/A	Biologics Guidelines 2016/amended 2022; expedited pathway for pandemic products
Japan (PMDA)	~30+	N/A	Biosimilar regulatory framework revision 2021; data exclusivity reform

8. CLINICAL TRIAL REGULATION: RECENT LEGAL DEVELOPMENTS

8.1. EU Clinical Trials Regulation No 536/2014

The EU Clinical Trials Regulation (CTR) No 536/2014, which replaced Directive 2001/20/EC, finally became operational in January 2022 following the delayed launch of the Clinical Trials Information System (CTIS). The CTR introduced a single authorization procedure for multi-member-state clinical trials, mandatory public disclosure of clinical trial data, enhanced transparency requirements, and strengthened patient informed consent provisions [48-49]. A key legal advancement under the CTR is the mandatory submission of clinical study reports (CSRs) to the EU Clinical Trials Register within 12 months of trial completion, regardless of outcome directly addressing publication bias. The CTR's provisions on emergency consent for incapacitated subjects and minors have also been refined through guidance documents issued by EMA's Ad Hoc Expert Group [50].

8.2. ICH E6 (R3) Good Clinical Practice Revision

The International Council for Harmonisation finalized the E6 (R3) Good Clinical Practice (GCP) guideline in 2023, representing the most comprehensive revision since E6 (R2) in 2016. Key changes include provisions for decentralized clinical trials (DCTs), risk-based quality management (RBQM), electronic informed consent (eConsent), remote monitoring, and the use of digital health technologies (DHTs) as trial endpoints. The addenda addressing DCTs and digital data collection were incorporated as core requirements rather than guidance supplements [51-52].

Table 7: *Comparison of Major Clinical Trial Regulatory Frameworks.*

Region	Framework	Governing Body	Key Recent Changes
USA	21 CFR Parts 50, 56, 312	FDA, OHRP	Decentralized trials guidance 2023; single IRB requirement expanded
EU	CTR No 536/2014	EMA, National CAs	CTIS operational Jan 2022; mandatory CSR disclosure; transparent data sharing

India	NDCT Rules 2019 (amended 2021)	CDSCO, IEC	Global simultaneous trials; academic CTs; expedited review for NCEs
Global	ICH E6(R3) GCP	ICH	DCT provisions; RBQM; eConsent; digital endpoint guidance (2023)
Global	Declaration of Helsinki (2013)	WMA	Reaffirmed 2022; placebo use guidance; research in LMIC considerations

9. EMERGING LEGAL ISSUES: GENE THERAPY, NANOMEDICINE, AND PANDEMIC PREPAREDNESS

Gene therapy and advanced therapy medicinal products (ATMPs) have emerged as a distinct regulatory subcategory requiring tailored legal frameworks. In the EU, ATMPs are governed by Regulation (EC) 1394/2007 and the Committee for Advanced Therapies (CAT). Recent revisions proposed in 2023 seek to streamline the hospital exemption while strengthening traceability and long-term follow-up requirements for gene therapies, reflecting the experience with CAR-T cell therapies [53]. Nanomedicine products including nanoparticle drug delivery systems and nanomaterial-based contrast agents occupy a regulatory grey area in most jurisdictions. The EMA's reflection papers on nanomedicines and the FDA's 2022 guidance on drug products containing nanomaterials have sought to clarify requirements, but critics argue that significant legal uncertainty persists regarding safety characterization, environmental risk assessment, and post-market surveillance [54-55]. The COVID-19 pandemic exposed critical gaps in pharmaceutical law related to emergency preparedness: supply chain resilience, voluntary patent pools, liability indemnification for pandemic vaccines, and international equitable distribution. The WHO's Pandemic Treaty negotiations (ongoing since 2021) and the proposed amendments to the International Health Regulations (IHR) seek to create binding legal obligations on TRIPS flexibilities, technology transfer, and pathogen access and benefit-sharing (PABS) [56].

10. CONCLUSION

The period 2018–2024 has witnessed a remarkable expansion and transformation of pharmaceutical law across all major dimensions: regulatory approvals, intellectual property, product liability, pharmacovigilance, digital health, clinical trials, and access to medicines. Legislative bodies, regulatory agencies, and international organizations have responded with varying degrees of agility to the twin imperatives of fostering innovation and ensuring equitable, safe access to medicinal products. Key trends include the increasing integration of digital technologies and AI into regulatory frameworks, the ongoing tension between patent protection and access (crystallized in the TRIPS COVID-19 waiver), the shifting landscape of biosimilar and generic competition under IRA pricing reforms, and the emergence of globally harmonized standards through ICH, IMDRF, and WHO instruments. Future research must focus on the legal challenges posed by AI-generated drug discoveries, the post-market legal accountability of adaptive AI-enabled medical devices, the implementation of TRIPS waiver mechanisms in future health emergencies, and the harmonization of regulatory requirements for ATMPs and nanomedicines across jurisdictions. Pharmaceutical law practitioners, regulators, and industry stakeholders must develop the interdisciplinary competencies needed to navigate this rapidly evolving legal landscape.

REFERENCES

[1] Brody H. The future of pharmaceutical regulation. N Engl J Med. 2019; 380(1): 6–9.
[2] Kesselheim AS, Avorn J. The role of litigation in defining drug risks. JAMA. 2020; 323(18): 1825–1836.
[3] Bambha K, Bhatt DL. COVID-19 and pharmaceutical emergency use authorization: legal and ethical dimensions. Lancet. 2021; 397(10282):1371–1383.
[4] Hassenteufel P, Genieys W. Pharmaceutical regulation in Europe: between coordination and competition. Eur J Health Law. 2019; 26(4): 295–314.
[5] International Council for Harmonisation. ICH guidelines overview. Geneva: ICH; 2022.
[6] World Health Organization. WHO prequalification of medicines programme: annual report 2022. Geneva: WHO; 2023.
[7] US Congress. FDA Modernization Act 2.0 (P.L. 117-328). Washington DC: US Government Publishing Office; 2022.
[8] FDA Center for Drug Evaluation and Research. New alternative methods for drug safety testing: implementation guidance. Silver Spring (MD): FDA; 2023.
[9] FDA Oncology Center of Excellence. Real-time oncology review outcomes report 2018–2023. Silver Spring (MD): FDA; 2023.
[10] US Congress. Consolidated Appropriations Act 2023 (P.L. 117-328), Division FF, Title III. Washington DC: US Government Publishing Office; 2023.

[11] European Commission. Proposal for a Regulation of the European Parliament and of the Council on Union procedures for the authorization and supervision of medicinal products for human use [COM (2023) 193]. Brussels: European Commission; 2023.
[12] European Commission. Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use [COM (2023) 192]. Brussels: European Commission; 2023.
[13] European Commission. EU pharmaceutical strategy for Europe. Brussels: European Commission; 2021.
[14] European Parliament and Council. Regulation (EU) 2022/123 on a reinforced role of the European Medicines Agency. Off J Eur Union. 2022; L20: 1–44.
[15] Ministry of Health and Family Welfare, India. New Drugs and Clinical Trials Rules, 2019. Gazette of India. 2019 Mar 19; Part II, Section 3, Subsection (i).
[16] Central Drugs Standard Control Organisation. Amendments to NDCT Rules 2019. New Delhi: CDSCO; 2021.
[17] Amgen Inc. vs Sanofi, 598 U.S. (2023). United States Supreme Court.
[18] Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., 574 U.S. 318 (2015). United States Supreme Court.
[19] Feldman R. May your drug price be evergreen. J Law Biosci. 2018; 5(3): 590–647.
[20] World Trade Organization. Ministerial decision on the TRIPS agreement. Twelfth Ministerial Conference, MC12/DEC/1. Geneva: WTO; 2022.
[21] Abbott FM, Reichman J. Emergency use of intellectual property pre- and post-TRIPS. J Int Econ Law. 2020; 23(3): 527–573.
[22] World Trade Organization. Extension of TRIPS waiver to therapeutics and diagnostics. General Council Decision WT/L/1159. Geneva: WTO; 2023.
[23] Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022). United States Court of Appeals for the Federal Circuit.
[24] Thaler v. Comptroller-General [2023] UKSC 49. United Kingdom Supreme Court.
[25] World Intellectual Property Organization. Revised issues paper on IP and artificial intelligence. WIPO/IP/AI/2/GE/22/1 REV. Geneva: WIPO; 2022.
[26] Wyeth v. Levine, 555 U.S. 555 (2009). United States Supreme Court.
[27] Mutual Pharmaceutical Co. v. Bartlett, 570 U.S. 472 (2013). United States Supreme Court.
[28] Dolin v. GlaxoSmithKline LLC, 901 F.3d 803 (7th Cir. 2018). United States Court of Appeals for the Seventh Circuit.
[29] European Commission. Proposal for a Directive of the European Parliament and of the Council on liability for defective products [COM (2022) 495]. Brussels: European Commission; 2022.
[30] Machnikowski P, ed. European product liability: an analysis of the state of the art in the era of new technologies. Cambridge: Intersentia; 2022.
[31] Pharmaceutical Research and Manufacturers of America (PhRMA). Comments on proposed EU Product Liability Directive revision. Washington DC: PhRMA; 2023.
[32] International Council for Harmonisation. ICH E2C (R2) periodic benefit-risk evaluation report (PBRER). Geneva: ICH; 2012 (updated 2022).
[33] FDA. Sentinel Initiative: 2022 annual report. Silver Spring (MD): FDA; 2023.
[34] European Medicines Agency. Good pharmacovigilance practices (GVP) Module I: pharmacovigilance systems and their quality systems. Amsterdam: EMA; 2021.
[35] FTC v. AbbVie Inc., 976 F.3d 327 (3d Cir. 2020), cert. denied, 142 S. Ct. 2679 (2022). United States Supreme Court.
[36] Federal Trade Commission. FTC report on REMS misuse and generic drug access. Washington DC: FTC; 2023.
[37] FDA Digital Health Center of Excellence. Artificial intelligence/machine learning (AI/ML)-based software as a medical device (SaMD) action plan. Silver Spring (MD): FDA; 2021.
[38] FDA. Marketing submission recommendations for a predetermined change control plan for artificial intelligence-enabled device software functions. Silver Spring (MD): FDA; 2023.
[39] US Congress. Food and Drug Omnibus Reform Act (FDORA). Washington DC: US Government Publishing Office; 2022.
[40] European Parliament and Council. Regulation (EU) 2017/745 on medical devices. Off J Eur Union. 2017; L117: 1–175.
[41] European Commission. Regulation amending MDR transition dates. Brussels: European Commission; 2023.
[42] European Parliament and Council. Regulation (EU) 2016/679 (General Data Protection Regulation). Off J Eur Union. 2016; L119: 1–88.

[43] European Commission. Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space [COM (2022) 197]. Brussels: European Commission; 2022.
[44] Sandoz Inc. v. Amgen Inc., 582 U.S. 1 (2017). United States Supreme Court.
[45] FDA. Biosimilar and interchangeable products: 2023 progress report. Silver Spring (MD): FDA; 2024.
[46] US Congress. Inflation Reduction Act of 2022 (P.L. 117-169). Washington DC: US Government Publishing Office; 2022.
[47] GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc., 976 F.3d 1347 (Fed. Cir. 2020). United States Court of Appeals for the Federal Circuit.
[48] European Parliament and Council. Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. Off J Eur Union. 2014; L158:1–76.
[49] European Medicines Agency. Clinical Trials Information System (CTIS): overview and guidance. Amsterdam: EMA; 2022.
[50] EMA Ad Hoc Expert Group. Guidance on emergency/deferred consent under CTR No 536/2014. Amsterdam: EMA; 2023.
[51] International Council for Harmonisation. ICH E6 (R3): guideline for good clinical practice. Geneva: ICH; 2023.
[52] ICH Expert Working Group. ICH E6 (R3) addendum on decentralized and hybrid clinical trials. Geneva: ICH; 2023.
[53] European Medicines Agency. Reflection paper on revision of ATMP Regulation 1394/2007. Amsterdam: EMA; 2023.
[54] FDA. Drug products, including biological products that contain nanomaterials: guidance for industry. Silver Spring (MD): FDA; 2022.
[55] European Medicines Agency. Reflection paper on nanotechnology-based medicinal products for human use. Amsterdam: EMA; 2019 (updated guidance expected 2024).
[56] World Health Organization. Pandemic treaty and IHR amendments: progress report. Geneva: WHO; 2023.