LEX LOCALIS-JOURNAL OF LOCAL SELF-GOVERNMENT
ISSN:1581-5374 E-ISSN:1855-363X
VOL. 23, NO. S5(2025)

ARTIFICIAL INTELLIGENCE IN PHARMACY: REGULATORY CHALLENGES AND JURISDICTIONAL

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Abstract
Artificial Intelligence (AI) is reshaping pharmacy through its applications in drug discovery, development, clinical trials, pharmacovigilance, personalized medicine, and supply chain optimization. By enabling faster, data-driven insights, AI holds the potential to reduce costs, accelerate innovation, and improve patient outcomes. However, the regulatory landscape governing AI in pharmacy remains fragmented and inconsistent across jurisdictions. This review provides a comprehensive overview of the evolution and applications of AI in pharmacy, examining ethical and legal implications, existing regulatory frameworks, and jurisdictional disparities. It further analyzes case studies from the United States, European Union, United Kingdom, China, and India to highlight successes and shortcomings in regulatory approaches. Key barriers—including rapid technological evolution, lack of standardization, data governance issues, and limited regulatory capacity—are discussed. Finally, policy recommendations emphasize the need for adaptive, globally harmonized frameworks that balance innovation with patient safety, transparency, and equitable access. By addressing these challenges, regulators can ensure that AI fulfills its promise of transforming pharmaceutical care into a more effective, ethical, and patient-centered system.

Keywords: Artificial Intelligence; Pharmacy; Drug Discovery; Pharmacovigilance; Clinical Decision Support; Ethics; Regulation; Jurisdictional Challenges; Data Governance; Harmonization

1. Introduction

Artificial Intelligence (AI) is increasingly recognized as a transformative force in healthcare, with pharmacy being one of its most promising areas of application. The discipline of pharmacy encompasses a broad spectrum of activities—ranging from drug discovery, formulation, and clinical practice to pharmacovigilance and regulatory affairs. Each of these domains is data-intensive, involving complex decision-making processes that can benefit from advanced computational support. AI, encompassing machine learning (ML), natural language processing (NLP), and deep learning, offers novel approaches to optimize efficiency, improve patient outcomes, and accelerate pharmaceutical innovation (1,2).

Over the past decade, exponential growth in biomedical data has driven the adoption of AI tools across pharmaceutical sciences. For instance, electronic health records, genomics databases, chemical compound libraries, and adverse drug reaction reports represent vast resources that cannot be fully utilized through conventional analytical methods. AI-enabled systems are capable of processing these data sets to uncover patterns, predict drug interactions, and recommend tailored therapeutic regimens (3). This capability has profound implications for drug development, personalized medicine, and clinical pharmacy practice.

The Promise of AI in Drug Discovery and Development

Traditional drug discovery is often described as time-consuming, costly, and inefficient, with an average development timeline exceeding 10 years and costs often surpassing billions of dollars (4). AI has emerged as a catalyst in this process by identifying potential drug candidates, predicting their biological activity, and even repurposing existing drugs for new indications. Notably, AI-driven platforms have contributed to accelerating research during global health crises, including the COVID-19 pandemic, by assisting in vaccine development and drug repurposing studies (5).

AI in Pharmacy Practice and Patient Care

Within pharmacy practice, AI supports clinical decision-making through predictive models that identify potential adverse drug reactions, optimize dosing regimens, and monitor patient adherence. For example, machine learning algorithms can analyze a patient's clinical history and genetic profile to recommend personalized therapeutic plans (6). Furthermore, AI chatbots and virtual pharmacy assistants are being tested for use in community and hospital pharmacy settings, offering counseling support and medication reminders to patients (7).

The Emerging Regulatory Challenge

Despite its potential, AI adoption in pharmacy faces significant regulatory and ethical hurdles. Unlike conventional pharmaceuticals or medical devices, AI-based systems evolve dynamically as they learn from new data, raising questions about accountability and compliance. Regulatory agencies such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) are actively working to establish guidelines, yet disparities in regulatory frameworks create global inconsistencies (8). These jurisdictional differences are particularly critical in pharmacy, where AI applications often involve sensitive patient data, cross-border data transfers, and compliance with privacy laws such as the General Data Protection Regulation (GDPR) in the European Union.

Ethical and Social Considerations

Beyond regulatory concerns, ethical issues such as transparency, algorithmic bias, and data privacy remain major challenges. For example, AI models trained on incomplete or non-representative datasets may exacerbate health inequities by providing biased recommendations (9). Similarly, the reliance on patient-level data for model training requires robust safeguards to ensure compliance with ethical standards and privacy laws.

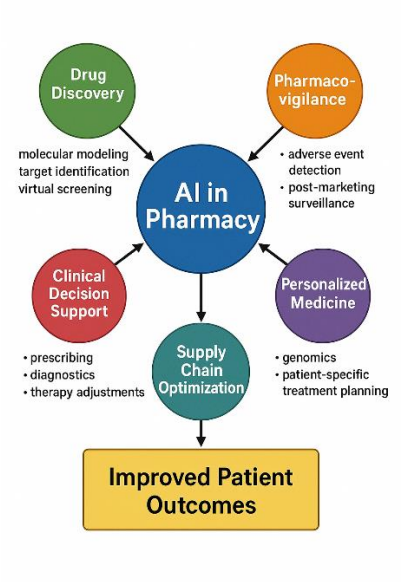
Scope of This Review

This review provides a comprehensive overview of AI in pharmacy, with a particular focus on regulatory and jurisdictional challenges. Section 2 examines the historical evolution of AI in pharmacy, while Section 3 details its major applications in drug discovery, pharmacovigilance, personalized medicine, and clinical decision-making. Sections 4 through 7 address ethical dilemmas, global regulatory frameworks, jurisdictional conflicts, and case studies. Sections 8 and 9 discuss barriers to effective regulation and propose recommendations for harmonized governance. The paper concludes with a reflection on the balance between innovation and regulation in ensuring safe, equitable, and efficient AI integration in pharmacy.

Table 1: Key Drivers of AI Adoption in Pharmacy

Driver	Description
Drug Discovery Efficiency	AI reduces time and cost of new molecule identification.
Personalized Medicine	Tailors treatment based on patient genetics and medical history.
Pharmacovigilance	Detects adverse drug reactions and improves patient safety.
Supply Chain Optimization	Streamlines inventory management and prevents drug shortages.
Clinical Decision Support	Assists pharmacists and prescribers with evidence-based recommendations.

Figure 1: Conceptual Model of AI Applications in Pharmacy



2. Evolution of AI in Pharmacy

The application of Artificial Intelligence (AI) in pharmacy has evolved over several decades, moving from early computational models to today's advanced machine learning and deep learning systems. This evolution has been shaped by advances in computing, increased data availability, and the growing complexity of pharmaceutical science. Understanding this trajectory helps clarify the current capabilities of AI as well as the challenges regulators face in integrating these technologies into healthcare systems.

2.1 Early Computational Approaches

The roots of AI in pharmacy lie in computational chemistry and the early adoption of quantitative structure–activity relationship (QSAR) models in the 1960s and 1970s. These models attempted to correlate the chemical structure of compounds with their biological activity (11). By the 1980s, molecular docking techniques allowed researchers to simulate interactions between drugs and biological targets (12). Although limited by computational power and small datasets, these tools were instrumental in reducing experimental workloads and guiding drug design (13).

In parallel, pharmacy practice began experimenting with rule-based clinical decision support systems (CDSS). These systems were designed to assist pharmacists in identifying potential drug–drug interactions and contraindications (14). While rudimentary, they marked the beginning of algorithmic reasoning in clinical pharmacy.

2.2 Machine Learning Enters Drug Discovery

The 1990s and early 2000s saw the introduction of machine learning (ML) methods into pharmaceutical research. Unlike traditional computational models, ML algorithms could learn patterns directly from large datasets. Support vector machines and artificial neural networks were applied to classify compounds, predict pharmacokinetic properties, and model toxicity (15,16).

This era coincided with the rise of high-throughput screening (HTS) technologies and genomics, which generated vast amounts of biological and chemical data. Traditional statistical approaches struggled to manage this data volume, whereas ML algorithms proved more capable of handling large, multidimensional datasets (17). This shift allowed for predictive modeling at a scale not possible in earlier decades.

2.3 Big Data and the Rise of Deep Learning

The 2010s marked a turning point as "big data" and exponential increases in computing power accelerated AI research. Deep learning (DL), a subset of ML based on artificial neural networks with multiple layers, demonstrated unprecedented accuracy in tasks such as image recognition, natural language processing, and molecular property prediction (18).

In pharmacy, DL techniques enabled automated drug discovery pipelines. Convolutional neural networks (CNNs) were used to classify compounds and analyze medical images, while generative adversarial networks (GANs) and recurrent neural networks (RNNs) allowed researchers to design novel molecules with desirable pharmacological properties (19,20). One striking example was the use of generative models to design potential COVID-19 protease inhibitors in record time (21).

Pharmacovigilance also benefited from these advances. AI algorithms began mining electronic health records, biomedical literature, and even social media to identify potential adverse drug events (ADEs) faster than conventional reporting systems (22). Regulatory authorities also adopted AI tools to assist in reviewing clinical trial submissions and post-marketing surveillance (23).

2.4 AI in Personalized Medicine and Pharmacy Practice

The convergence of genomics, electronic health records, and wearable devices created opportunities for AI-driven personalized medicine. Pharmacogenomic data, while promising, posed interpretation challenges due to its complexity. AI models bridged this gap by integrating genetic, clinical, and demographic information to recommend tailored drug regimens (24).

In clinical pharmacy practice, AI-powered CDSS expanded beyond basic interaction-checking. Modern systems now recommend individualized dosing, predict non-adherence, and assist pharmacists in optimizing polypharmacy in older patients (25). In addition, AI-driven supply chain systems were adopted by hospitals and community pharmacies to optimize inventory, reduce waste, and predict demand spikes during health crises (26).

2.5 Regulatory Recognition of AI

A critical stage in the evolution of AI in pharmacy was its recognition by regulatory authorities. The U.S. Food and Drug Administration (FDA) launched its *Digital Health Innovation Action Plan* in 2017, acknowledging the need to regulate AI-based tools, particularly adaptive algorithms that change over time (27). The European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) followed with initiatives focusing on AI in clinical trials and drug safety monitoring (28).

International organizations such as the International Coalition of Medicines Regulatory Authorities (ICMRA) have emphasized the importance of harmonized regulatory frameworks

for AI across borders (29). This regulatory engagement signaled AI's transition from a research tool to a regulated technology shaping healthcare policy.

2.6 Current Trends and Future Outlook

Current AI trends in pharmacy focus on transparency, accountability, and integration with other emerging technologies. Explainable AI (XAI) is gaining prominence, aiming to make AI decision-making interpretable for clinicians and regulators (30). Similarly, blockchain technology is being explored to secure pharmaceutical supply chains, improve traceability, and prevent counterfeiting (31).

The trajectory of AI in pharmacy reflects a shift from computational assistance to autonomous systems capable of generating hypotheses, designing molecules, and supporting complex regulatory decisions. This ongoing evolution underscores not only the vast potential of AI but also the need for adaptive, harmonized, and transparent governance frameworks (32,33).

Table 2: Evolutionary Stages of AI in Pharmacy

Period	Key Developments
1960s–1980s	QSAR models; molecular docking; early rule-based CDSS
1990s–2000s	Introduction of machine learning; compound classification; pharmacokinetic modeling
2010s	Deep learning applications; big data integration; AI in pharmacovigilance
2020s	Explainable AI; blockchain integration; regulatory harmonization efforts

3. Applications of AI in Pharmacy

Artificial Intelligence (AI) has transitioned from an emerging technology to a transformative force in pharmacy. Its applications span the entire pharmaceutical value chain, from early-stage drug discovery to clinical decision support, supply chain optimization, and personalized medicine. Each application reflects the synergy between computational power, data integration, and the ability of algorithms to identify patterns beyond human cognitive limits. This section provides a structured review of major AI applications in pharmacy.

3.1 AI in Drug Discovery and Development

Drug discovery is historically costly and time-consuming, with average timelines exceeding 10 years and costs surpassing billions of dollars. AI has introduced significant efficiencies in identifying druggable targets, screening compounds, and predicting pharmacological properties (34).

Machine learning (ML) and deep learning (DL) methods have been applied to:

- Target identification – AI models integrate omics data, biomedical literature, and protein structures to identify novel drug targets (35).
- Virtual screening – AI algorithms outperform traditional docking by predicting binding affinities with greater accuracy (36).
- De novo drug design – Generative models create novel molecules with optimized properties, accelerating lead optimization (37).
- Predicting clinical trial outcomes – AI forecasts trial success probabilities using historical datasets and biomarkers (38).

Figure 2: Evolutionary Path of AI in Pharmacy

A milestone example was Insilico Medicine's AI-designed preclinical candidate for idiopathic pulmonary fibrosis, which progressed to clinical trials in under 18 months, demonstrating accelerated drug discovery timelines (39).

3.2 AI in Pharmacovigilance

Pharmacovigilance—the monitoring of adverse drug events (ADEs)—is critical for patient safety. Traditional systems rely on voluntary reporting, often delayed and incomplete. AI addresses these limitations by analyzing real-world evidence (RWE) such as electronic health records (EHRs), clinical notes, and social media content (40).

Natural language processing (NLP) is particularly effective in detecting ADEs from unstructured clinical narratives (41). Furthermore, machine learning enhances signal detection by identifying statistically significant associations between drugs and adverse outcomes (42).

For example, the FDA's Sentinel Initiative incorporates AI for near real-time safety monitoring of marketed drugs, significantly reducing latency in pharmacovigilance activities (43)

3.3 Personalized Medicine and Pharmacogenomics

AI plays a pivotal role in tailoring therapy to individual patient characteristics, particularly genetic profiles. Pharmacogenomics generates complex datasets that require advanced analytics for interpretation. AI integrates genomic, transcriptomic, and metabolomic data with clinical records to predict optimal drug selection and dosing (44).

In oncology, AI-driven models recommend treatment regimens based on tumor genomics, maximizing efficacy while minimizing toxicity (45). Similarly, AI supports individualized dosing in anticoagulant therapy, where small variations in metabolism significantly affect outcomes (46).

The integration of wearable devices and mobile health apps with AI further enhances personalized medicine by enabling real-time therapeutic monitoring and adaptive dosing strategies (47).

3.4 Clinical Decision Support Systems (CDSS)

CDSS are vital tools in pharmacy practice, enabling pharmacists and clinicians to optimize drug therapy. Modern AI-powered CDSS extend beyond rule-based alerts to predictive modeling and contextual recommendations (48).

Key applications include:

- Drug–drug interaction prediction using ML models trained on vast drug databases (49).
- Non-adherence prediction through patient behavior modeling (50).
- Polypharmacy optimization in elderly populations with multimorbidity (51).
- Dose individualization using Bayesian AI frameworks (52).

AI-based CDSS not only reduce prescribing errors but also support pharmacists in complex therapeutic decisions, enhancing clinical outcomes.

3.5 Supply Chain and Pharmaceutical Logistics

AI enhances pharmaceutical supply chains by forecasting demand, managing inventories, and identifying counterfeit drugs (53). Machine learning algorithms analyze prescription trends, epidemiological data, and seasonal factors to optimize stock levels, reducing shortages and waste.

Blockchain integrated with AI strengthens drug traceability and combats falsified medicines, particularly in global supply chains where vulnerabilities are significant (54).

During the COVID-19 pandemic, AI-assisted forecasting models were deployed to anticipate surges in demand for critical medications, ensuring continuity of care in resource-limited settings (55).

3.6 AI in Clinical Trials

AI improves the efficiency of clinical trial design, recruitment, and monitoring. Predictive analytics identifies patients most likely to respond to therapies, while NLP extracts eligibility criteria from trial registries and EHRs (56). AI-enabled remote monitoring ensures adherence and captures patient-reported outcomes in real time (57).

These innovations reduce trial costs, enhance patient safety, and accelerate regulatory approval timelines, further demonstrating AI's value in pharmaceutical development (58).

Table 3: Applications of AI in Pharmacy

Application Domain	AI Techniques Applied	Key Benefits
Drug Discovery	ML, DL, generative models	Faster target ID, optimized molecules
Pharmacovigilance	NLP, signal detection algorithms	Early ADE detection, real-time surveillance
Personalized Medicine	Genomic AI models, adaptive dosing	Precision therapy, reduced toxicity
Clinical Decision Support	Predictive ML, Bayesian AI	Safer prescribing, polypharmacy management
Supply Chain & Logistics	ML forecasting, blockchain-AI	Reduced shortages, counterfeit detection
Clinical Trials	Predictive analytics, NLP, remote AI	Efficient recruitment, reduced costs

4. Ethical and Legal Considerations in AI-Driven Pharmacy

The rapid integration of Artificial Intelligence (AI) into pharmaceutical research, clinical practice, and regulatory processes has generated profound ethical and legal challenges. While

AI promises improved efficiency, precision, and innovation in drug development and pharmacy practice, it also raises concerns about transparency, accountability, data privacy, and fairness. Addressing these issues is essential to ensure that AI-driven pharmacy systems are not only effective but also ethically responsible and legally compliant.

4.1 Transparency and Explainability

A central ethical challenge in AI is the "black box" nature of many algorithms, particularly deep learning models. These systems often generate outputs that lack interpretability, making it difficult for pharmacists, clinicians, and regulators to understand how a decision was reached (59). In high-stakes domains such as drug safety monitoring and prescribing, opaque decision-making may undermine trust and hinder adoption (60).

Explainable AI (XAI) has emerged as a solution, offering methods to make algorithmic reasoning more interpretable for end-users (61). However, balancing explainability with predictive accuracy remains a persistent challenge.

4.2 Accountability and Liability

Determining accountability when AI systems make errors is another pressing concern. For instance, if an AI-driven clinical decision support system recommends an inappropriate drug regimen leading to patient harm, questions arise over whether responsibility lies with the pharmacist, the developer, or the institution deploying the system (62).

Current legal frameworks often struggle to assign liability in cases involving autonomous AI, especially when algorithms evolve through continuous learning. Proposals include joint liability models, software certification schemes, and mandatory AI auditing to mitigate risks (63).

4.3 Patient Privacy and Data Governance

AI systems in pharmacy rely heavily on patient data, including genetic information, electronic health records, and behavioral data from wearable devices. While such data enables personalized medicine, it also raises risks related to data breaches, unauthorized sharing, and secondary use without consent (64).

Legal instruments such as the European Union's General Data Protection Regulation (GDPR) and the U.S. Health Insurance Portability and Accountability Act (HIPAA) set standards for privacy protection, but enforcing compliance in cross-border AI collaborations remains difficult (65). Emerging frameworks advocate for patient-centric consent models and federated learning approaches, which allow algorithms to learn from decentralized data without direct sharing (66).

4.4 Bias, Equity, and Fair Access

AI algorithms may inadvertently perpetuate existing healthcare disparities if trained on biased datasets. For example, underrepresentation of minority groups in training data could lead to inaccurate drug efficacy predictions or higher rates of adverse drug events in these populations (67).

Ethical use of AI in pharmacy therefore requires diverse, representative datasets and algorithmic audits to identify and mitigate bias. From a legal perspective, discriminatory outcomes may expose healthcare institutions to liability under civil rights and health equity legislation (68).

4.5 Intellectual Property and Data Ownership

AI introduces novel challenges in intellectual property (IP). Traditional IP frameworks are designed for human inventors, yet AI systems are increasingly capable of generating new drug candidates independently (69). Legal debates continue over whether AI can be recognized as an inventor and how ownership rights should be distributed between developers, institutions, and sponsors (70).

Similarly, ownership of patient-derived data remains contested. While patients are the data source, pharmaceutical companies and research organizations often claim rights to use such data for algorithm development. Resolving these disputes requires clearer contractual frameworks and potentially new forms of "data stewardship rights" (71).

4.6 Global Legal Variability

AI-driven pharmacy operates across jurisdictions with highly variable legal environments. The European Union emphasizes strict data privacy and algorithmic transparency through the GDPR and the proposed AI Act, while the U.S. adopts a more market-driven, innovation-oriented regulatory approach (72). Low- and middle-income countries face additional challenges in balancing innovation with resource constraints and weak data protection laws (73).

This fragmentation complicates cross-border collaborations, particularly in multinational clinical trials and global pharmacovigilance efforts. Harmonization of AI governance remains a priority for international regulatory bodies.

Table 4: Ethical and Legal Challenges in AI for Pharmacy

Challenge	Ethical Concern	Legal Implication
Transparency	Black-box algorithms	Need for explainability standards
Accountability	Errors in AI-driven decisions	Unclear liability allocation
Patient Privacy	Data misuse and breaches	Compliance with GDPR, HIPAA, etc.
Bias and Equity	Healthcare disparities	Potential legal liability for discrimination
Intellectual Property	AI-generated drug designs	Debate over inventorship and data rights
Global Variability	Regulatory inconsistency	Barriers to multinational collaboration

Figure 3: Ethical-Legal Intersection in AI-Driven Pharmacy

5. Regulatory Frameworks for AI in Pharmacy

The integration of Artificial Intelligence (AI) into pharmacy has outpaced the development of comprehensive regulatory frameworks. While regulators worldwide acknowledge AI's potential to accelerate drug discovery, optimize clinical trials, and improve patient safety, they also grapple with challenges such as algorithm transparency, adaptive learning, and cross-border data governance. This section reviews regulatory approaches across major jurisdictions, highlighting convergences and divergences in policy.

5.1 United States: FDA's Risk-Based Approach

The U.S. Food and Drug Administration (FDA) has taken a risk-based approach to regulating AI in healthcare and pharmaceuticals. In 2017, the FDA released its *Digital Health Innovation Action Plan*, outlining principles for digital health technologies including AI-based software (74). This framework was expanded in the 2019 discussion paper on *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device* (75).

Key elements include:

- Software as a Medical Device (SaMD) classification under the International Medical Device Regulators Forum (IMDRF) framework.
- Pre-certification program, focusing on developer accountability rather than product-by-product approval.
- Good Machine Learning Practices (GMLP) guidance, ensuring quality in AI model development (76).

In pharmacy, the FDA applies these principles to AI-driven drug discovery tools, pharmacovigilance systems, and digital endpoints in clinical trials. However, adaptive algorithms that evolve post-deployment remain a regulatory gray area (77).

5.2 European Union: GDPR and the AI Act

The European Union (EU) combines strict data protection laws with emerging AI-specific legislation. The General Data Protection Regulation (GDPR) enforces transparency, consent, and data minimization in AI-driven pharmacy applications (78). Article 22 of the GDPR further prohibits fully automated decision-making that significantly affects individuals unless explicit consent or safeguards are in place (79).

In 2021, the European Commission proposed the *Artificial Intelligence Act (AI Act)*, the first attempt at a horizontal regulatory framework for AI (80). The AI Act categorizes systems into four risk levels—unacceptable, high-risk, limited-risk, and minimal-risk. High-risk AI, including medical and pharmaceutical applications, will require stringent conformity assessments, human oversight, and robustness checks (81).

The EU's regulatory approach emphasizes patient rights and algorithmic accountability but may impose heavy compliance burdens on pharmaceutical innovators (82).

5.3 United Kingdom: MHRA's Agile Framework

Post-Brexit, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) is developing a more flexible framework for AI. The *Software and AI as a Medical Device Change Programme* emphasizes dynamic oversight and international harmonization (83).

Distinctive elements include:

- Continuous monitoring of AI algorithms rather than static approvals.
- Collaboration with NICE (National Institute for Health and Care Excellence) to assess cost-effectiveness of AI-based interventions (84).
- Patient involvement in regulatory evaluations, ensuring transparency and trust.

This agile approach positions the UK as a testbed for AI governance models balancing safety and innovation (85).

5.4 Canada: Health Canada's Regulatory Initiatives

Health Canada has aligned with FDA and EU efforts by adopting the IMDRF framework for SaMD and developing guidance for AI/ML-based medical devices (86). In 2021, Health Canada launched a pilot project on adaptive AI regulation, focusing on real-world performance monitoring and transparency (87).

Canada's bilingual, multicultural context also raises unique challenges in ensuring that AI-driven pharmacy tools are linguistically inclusive and equitable (88).

5.5 Asia-Pacific: Diverse Approaches

Japan: PMDA and AI Integration

Japan's Pharmaceuticals and Medical Devices Agency (PMDA) actively promotes AI in drug development and clinical trials. The agency has introduced fast-track approval processes for AI-assisted technologies and encourages public–private collaborations (89).

China: State-Led AI Strategy

China's National Medical Products Administration (NMPA) integrates AI regulation into its broader national AI strategy. The country has invested heavily in AI-enabled pharmacovigilance and clinical trial platforms (90). However, limited transparency and differences in data governance norms pose challenges for global harmonization (91).

India: Emerging Regulatory Landscape

India, with its large pharmaceutical industry and growing digital health sector, has yet to establish a comprehensive AI regulation. Current frameworks focus on telemedicine and data privacy, but draft policies suggest movement toward structured AI oversight (92).

5.6 International Harmonization Efforts

The International Medical Device Regulators Forum (IMDRF) and the International Coalition of Medicines Regulatory Authorities (ICMRA) play central roles in aligning global AI standards (93). Key areas of focus include:

- Harmonized definitions of AI and SaMD.
- Common principles for Good Machine Learning Practices.
- Cross-border pharmacovigilance data sharing.

The World Health Organization (WHO) has also published guidance on the ethics and governance of AI in health, emphasizing inclusivity and equity in global adoption (94).

5.7 Challenges in Current Frameworks

Despite progress, regulatory frameworks face persistent challenges:

- Adaptive algorithms that evolve after deployment.
- Cross-border data governance and conflicts between GDPR, HIPAA, and local laws.
- Balancing innovation with compliance, particularly for smaller biotech firms.
- Regulatory capacity in low- and middle-income countries.

Future frameworks must address these challenges while ensuring patient safety and fostering innovation (95–98).

Table 5: Comparison of AI Regulatory Frameworks Across Jurisdictions

Jurisdiction	Primary Frameworks	Key Features	Challenges
USA	FDA Digital Health Plan, GMLP	Risk-based, developer pre-certification	Adaptive algorithms, evolving oversight
EU	GDPR, AI Act	Rights-based, high-risk classification	Heavy compliance burden
UK	MHRA AI Change Programme	Agile, continuous monitoring	Post-Brexit divergence, harmonization issues
Canada	IMDRF alignment, pilot projects	Real-world performance monitoring	Bilingual inclusivity, resource challenges

Japan	PMDA initiatives	Fast-track approvals, AI in trials	Balancing innovation with oversight
China	NMPA national AI strategy	State-led, large-scale integration	Transparency, global harmonization
India	Draft digital health and AI policies	Growing focus on AI regulation	Lack of comprehensive frameworks

Fragmentation of Regulatory Approaches

Different jurisdictions adopt distinct philosophies toward AI regulation. The United States follows a risk-based and innovation-oriented approach, emphasizing developer accountability and adaptive oversight through the FDA (99). In contrast, the European Union prioritizes fundamental rights and algorithmic transparency under GDPR and the AI Act (100).

These diverging frameworks complicate multinational pharmaceutical operations. For example, an AI-driven pharmacovigilance tool approved in the U.S. may face delays or denial in the EU due to stricter data privacy rules (101).

6.2 Cross-Border Data Governance

AI applications in pharmacy depend on access to large, diverse datasets, but cross-border data sharing faces significant legal hurdles. The GDPR imposes strict conditions for transferring personal health data outside the EU, while U.S. HIPAA rules offer more flexibility (102). China's Data Security Law and Personal Information Protection Law (PIPL) further restrict cross-border transfers, complicating international clinical trials and collaborative pharmacovigilance (103).

As pharmaceutical companies increasingly rely on global datasets to train AI models, conflicts between privacy laws create compliance burdens and limit algorithmic accuracy (104).

6.3 Variability in Liability Frameworks

Liability allocation for AI-driven decisions differs across legal systems. In common law jurisdictions (e.g., U.S., UK, Canada), liability is often assigned through negligence standards, leaving uncertainty for evolving algorithms (105). In civil law jurisdictions (e.g., EU countries, Japan), codified laws provide stricter standards for consumer protection, increasing regulatory burden (106).

This variability complicates the deployment of AI-based clinical decision support systems in pharmacy practice. Multinational companies may face overlapping or contradictory liability claims if adverse events occur across different regions (107).

6.4 Resource Disparities Between High- and Low-Income Countries

High-income countries (HICs) have greater regulatory capacity, technological infrastructure, and investment in AI governance. In contrast, low- and middle-income countries (LMICs) often lack robust regulatory bodies, digital infrastructure, and funding to implement AI oversight (108).

This disparity risks creating a two-tiered system, where patients in HICs benefit from advanced AI-enabled pharmacy while LMICs lag behind, relying on less-regulated, imported systems that may not align with local contexts (109).

6.5 Ethical and Cultural Divergences

Jurisdictional challenges are also shaped by ethical and cultural differences. Western countries emphasize individual privacy rights, while some Asian jurisdictions prioritize collective welfare and public health outcomes (110). These cultural divergences influence regulatory decisions on issues such as consent models, algorithmic explainability, and acceptable risk thresholds.

For example, Japan's AI strategy emphasizes trust and transparency, whereas China's approach prioritizes rapid deployment of AI for public health surveillance (111). Such variations affect global harmonization of pharmaceutical AI tools.

6.6 Lack of Harmonization in International Standards

Although international bodies like WHO, IMDRF, and ICMRA are working toward harmonized guidelines, progress remains slow. AI technologies evolve faster than regulatory consensus, leading to gaps in standard definitions, validation methods, and performance metrics (112).

Without harmonized standards, pharmaceutical companies face costly duplication of regulatory submissions across multiple jurisdictions, slowing innovation and global rollout of AI-enabled drugs and services (113).

Table 6: Jurisdictional Challenges in AI Regulation for Pharmacy

Challenge	Example Region/Case	Impact on Pharmacy AI Deployment
Regulatory Fragmentation	FDA (USA) vs AI Act (EU)	Delays in multinational approvals
Cross-Border Data Governance	GDPR (EU), HIPAA (US), PIPL (China)	Barriers to international data sharing
Liability Variability	Negligence (USA) vs Codified Laws (EU)	Uncertainty in accountability for errors
Resource Disparities	HIC vs LMIC regulatory infrastructure	Unequal global access to AI tools
Ethical Divergences	Individual vs collective approaches	Inconsistent standards for consent/privacy
Lack of Harmonization	WHO/IMDRF ongoing efforts	Regulatory duplication, slower innovation

7. Case Studies of AI Regulation in Pharmacy

Case studies provide valuable insights into how regulatory frameworks are applied to real-world AI systems in pharmacy and drug development. By examining successful and problematic implementations, lessons can be drawn to guide future regulation.

7.1 AI in Pharmacovigilance: FDA's Sentinel System

The FDA's Sentinel Initiative, launched in 2008, has increasingly incorporated AI and machine learning to monitor adverse drug events using electronic health records and insurance claims data (114). AI algorithms enable earlier detection of safety signals and reduce false positives compared to traditional statistical methods (115).

Regulatory lessons: While successful in improving post-marketing surveillance, Sentinel highlights the importance of algorithm validation and ongoing monitoring to ensure continued accuracy (116).

7.2 EU Case: AI-Driven Drug Discovery by Exscientia

Exscientia, a UK-based company, developed the first AI-designed drug candidate (DSP-1181), which entered clinical trials in collaboration with Sumitomo Dainippon Pharma in 2020 (117). Regulatory agencies, including the European Medicines Agency (EMA), worked closely with the company to establish standards for preclinical validation of AI-generated molecules.

Regulatory lessons: The case illustrates how regulators can adopt a collaborative approach with innovators to develop new frameworks for novel technologies (118).

7.3 AI for Clinical Decision Support: UK NHS Deployment

The UK National Health Service (NHS) piloted AI-driven decision support tools to optimize antibiotic prescribing and reduce antimicrobial resistance (119). Regulatory oversight by the Medicines and Healthcare products Regulatory Agency (MHRA) required risk classification and conformity assessments under medical device regulations.

Regulatory lessons: The pilot highlighted the importance of explainability and clinician oversight in building trust in AI recommendations (120).

7.4 China's Use of AI in Drug Supply Chain Monitoring

China has implemented AI for drug authenticity verification and supply chain monitoring to combat counterfeit medicines (121). The National Medical Products Administration (NMPA) mandates integration of AI-enabled track-and-trace systems within pharmaceutical supply chains.

Regulatory lessons: While effective in reducing counterfeit drugs, China's centralized model raises questions about data transparency and patient privacy protections (122).

7.5 India's Early-Stage AI Regulatory Experiences

India's pharmaceutical sector has adopted AI primarily in clinical trials and drug manufacturing optimization. Regulatory oversight remains fragmented, with guidelines emerging under the Central Drugs Standard Control Organization (CDSCO) and the Ministry of Electronics and Information Technology (MeitY) (123).

Regulatory lessons: India's case highlights the need for harmonized national frameworks to support AI in pharmacy, particularly for clinical trials involving multinational sponsors.

Table 7: Case Studies of AI in Pharmacy Regulation

Case Study	Jurisdiction	AI Application	Regulatory Lesson Learned
FDA Sentinel System	USA	Pharmacovigilance	Need for continuous algorithm monitoring
Exscientia AI drug discovery	EU/UK	AI-generated molecules	Collaborative regulation with innovators
NHS Clinical Decision Support	UK	Antibiotic prescribing	Importance of explainability & oversight
AI in Supply Chain Monitoring	China	Counterfeit drug detection	Balancing innovation with data transparency
AI in Clinical Trials	India	Trial design & manufacturing	Need for harmonized regulatory frameworks

8. Barriers to Effective Regulation of AI in Pharmacy

Despite significant progress in AI governance, several barriers hinder the effective regulation of Artificial Intelligence (AI) in pharmacy. These barriers span technological, regulatory, and socio-economic dimensions, highlighting the need for robust yet adaptable frameworks to ensure safe and equitable implementation.

8.1 Rapid Technological Evolution

AI technologies, particularly deep learning and reinforcement learning, evolve faster than regulatory frameworks. While agencies such as the FDA and EMA release periodic guidance, these documents quickly become outdated as new architectures and applications emerge (124). This creates a regulatory lag, where oversight cannot keep pace with innovation.

8.2 Lack of Standardization

There is no universally accepted definition of AI in healthcare or pharmacy. Variations in terminology, validation metrics, and performance benchmarks complicate international

harmonization (125). For instance, the IMDRF's guidelines for Software as a Medical Device (SaMD) provide a foundation, but member states interpret and implement them inconsistently.

Without standardized approaches, pharmaceutical companies face costly duplications in testing and approvals when expanding into new markets.

8.3 Data Privacy and Security Constraints

AI-driven pharmacy applications rely on sensitive patient data, yet privacy laws differ across jurisdictions. The GDPR in Europe, HIPAA in the U.S., and China's PIPL create a patchwork of rules, complicating cross-border collaborations (126).

Data localization requirements, designed to enhance sovereignty, further fragment AI development and limit the use of global datasets. This not only restricts innovation but may also lead to biased algorithms if training sets are geographically restricted.

8.4 Limited Regulatory Capacity

Many low- and middle-income countries (LMICs) lack the institutional capacity, technical expertise, and financial resources to regulate AI effectively (127). Regulators in these regions often rely on frameworks imported from high-income countries, which may not reflect local needs or constraints.

This capacity gap risks widening global inequities in access to safe and effective AI-enabled pharmacy tools.

8.5 Industry Resistance and Compliance Burden

Pharmaceutical companies often perceive AI-specific regulations as adding compliance costs and delaying innovation. The EU AI Act, for instance, has been criticized for its heavy documentation requirements, which may disproportionately burden startups and smaller biotech firms (128).

Balancing regulatory rigor with industry incentives remains a persistent challenge.

8.6 Ethical Ambiguities

While ethical frameworks exist, their practical implementation in regulation is inconsistent. Concepts such as algorithmic fairness, transparency, and accountability lack operational definitions that can be enforced in legal systems (129).

The absence of clear guidelines allows for variability in enforcement, potentially undermining public trust in AI-driven pharmacy.

8.7 Public Trust and Acceptance

Public skepticism toward AI in healthcare persists, fueled by concerns over data misuse, bias, and the "black-box" nature of algorithms (130). Without trust, even well-regulated AI systems may face resistance from both healthcare professionals and patients.

Table 8: Barriers to Effective AI Regulation in Pharmacy

Barrier	Impact on Regulation
Rapid technological evolution	Regulatory lag and outdated guidance
Lack of standardization	Duplicated testing, fragmented oversight
Data privacy constraints	Limited global collaboration, biased datasets
Limited regulatory capacity	Inequitable access in LMICs
Industry resistance	Compliance burden, slower adoption
Ethical ambiguities	Inconsistent enforcement, reduced accountability
Public trust deficit	Barriers to adoption despite regulations

Future Directions and Policy Recommendations

The regulation of Artificial Intelligence (AI) in pharmacy must evolve in parallel with technological innovation, global market integration, and societal expectations. As AI becomes increasingly central to drug discovery, pharmacovigilance, and clinical decision support, regulators face the challenge of ensuring safety, transparency, and accountability without stifling innovation. This section outlines key future directions and provides policy recommendations for shaping a sustainable and effective regulatory landscape.

9.1 Adaptive and Dynamic Regulation

Traditional static regulatory frameworks are poorly suited to rapidly evolving AI models. Future regulations should incorporate adaptive mechanisms such as "regulatory sandboxes," which allow controlled experimentation with new technologies under regulator supervision (131). Continuous post-market monitoring, similar to pharmacovigilance, should be extended to AI algorithms through lifecycle oversight models (132).

9.2 Global Harmonization of Standards

With multinational pharmaceutical operations, fragmented national regulations create inefficiencies. Harmonization efforts under organizations such as the International Council for Harmonisation (ICH) and World Health Organization (WHO) should prioritize AI in pharmacy, ensuring consistency in data validation, algorithm testing, and approval procedures (133).

A globally aligned approach could also reduce duplication of compliance costs, encouraging smaller biotech firms to innovate without regulatory barriers.

9.3 Ethical and Explainable AI

Trustworthy AI requires greater focus on explainability. Black-box models can produce highly accurate predictions but undermine transparency, particularly in regulatory submissions (134). Regulators should mandate the integration of explainable AI (XAI) techniques, ensuring that outputs can be understood and validated by clinicians and auditors.

Additionally, embedding ethical principles—fairness, accountability, and non-discrimination—into enforceable regulations can strengthen public trust.

9.4 Strengthening Data Governance

Robust AI depends on high-quality data. Future regulations should enhance data governance frameworks, focusing on interoperability, anonymization, and secure sharing of patient data across borders (135). Policymakers must balance the benefits of large-scale data access with privacy protections, ensuring compliance with GDPR, HIPAA, and similar frameworks while fostering collaborative datasets.

9.5 Capacity Building in Low- and Middle-Income Countries

Equitable global adoption of AI requires **capacity building** in LMICs. Investments in technical training for regulators, cross-border collaborations, and public-private partnerships can help bridge the expertise gap (136). Without such efforts, disparities in access to AI-enabled pharmacy will persist, deepening global health inequities.

9.6 Public Engagement and Trust-Building

Future regulation should incorporate **public consultation mechanisms** to align AI governance with societal expectations (137). Transparent communication about the benefits and risks of AI in pharmacy will be crucial in reducing skepticism and enhancing adoption by both patients and healthcare professionals.

Table 9: Key Policy Recommendations for AI Regulation in Pharmacy

Future Direction	Policy Recommendation
Adaptive regulation	Implement regulatory sandboxes and lifecycle oversight
Global harmonization	Promote ICH and WHO-aligned AI standards
Ethical & explainable AI	Mandate use of explainable AI models
Data governance	Enhance interoperability and cross-border sharing
Capacity building in LMICs	Invest in regulatory training and partnerships
Public trust and engagement	Foster transparency and public consultation

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