Comprehensive Legislative and Regulatory Framework Governing the Pharmacy Profession in the Hashemite Kingdom of Jordan

Introduction

The Hashemite Kingdom of Jordan possesses one of the most structurally mature, dynamic, and heavily regulated healthcare systems in the Middle East and North Africa (MENA) region. A critical pillar of this advanced health ecosystem is the pharmaceutical sector, which is defined by a robust local manufacturing capacity that supplies approximately 25% of the country's domestic drug needs, alongside a highly developed network of community pharmacies, hospital pharmacies, specialized research organizations, and biomedical laboratories[1]. The remaining 75% of the Kingdom's pharmaceutical requirements are met through a sophisticated network of drug wholesalers and importers, necessitating rigorous border control, quality assurance, and market surveillance[1].

To sustain and protect this complex ecosystem, Jordan has established a stringent, multi-tiered legislative and regulatory framework. The governance of pharmaceutical practices, the importation and manufacturing of drugs, the pricing of medical technologies, and the execution of clinical trials are meticulously overseen by specialized statutory bodies. The tripartite regulatory architecture consists chiefly of the Jordan Pharmacists Association (JPA), the Jordan Food and Drug Administration (JFDA), and the Ministry of Health (MoH)[2]. Through continuous legislative updates—ranging from the foundational Pharmacists Association Law No. 51 of 1972 and the overarching Drug and Pharmacy Law No. 12 of 2013, to the highly modernized adoptions of Good Regulatory Practices (GRP) and Good Reliance Practices (GRelP) in 2026—the Kingdom has proactively sought to align its national frameworks with the standards of the World Health Organization (WHO) and the International Council for Harmonisation (ICH)[5].

This comprehensive report provides an exhaustive analysis of the laws, regulations, and institutional policies governing the pharmacy profession in Jordan. It examines the structural mandates of the primary regulatory authorities, the stringent operational requirements for pharmaceutical establishments, the ethical and legal boundaries of clinical research, the control of narcotic and psychotropic substances, and the evolving dynamics and challenges of daily pharmacy practice.

Institutional Governance and Professional Regulation

The regulatory architecture of Jordan's pharmaceutical sector relies on the continuous collaboration between the Ministry of Health, which sets overarching public health policies and issues establishment licenses; the JFDA, which acts as the independent executive regulatory and enforcement arm for product safety; and the JPA, which oversees the professional conduct, credentialing, and ethical adherence of the pharmacists themselves[2].

The Jordan Pharmacists Association (JPA)

Established in 1957, the Jordan Pharmacists Association (JPA) operates as the mandatory professional syndicate representing all pharmacists operating within the Kingdom[3]. The association's primary legal foundation is the Pharmacists Association Law No. 51 of 1972, which explicitly delineates its formation, objectives, internal hierarchy, electoral processes, and the rights and obligations of its members[7].

Membership Demographics and Professional Credentialing

The demographic scale of the JPA has expanded significantly in response to Jordan's growing population and the proliferation of academic pharmacy programs. The syndicate has grown from roughly 25,700 registered pharmacists in October 2020 to over 35,102 active members by 2025, solidifying pharmacy as the third-largest healthcare profession in Jordan, trailing only medicine and nursing[4]. The association represents a vast academic community, interfacing with 16 faculties and schools offering pharmacy degree programs across the nation[13].

The JPA is governed by a Managing Board elected every three years. As of the 2025 electoral cycle, the leadership includes President Dr. Zaid Ruhi Al-Kilani, Vice President Dr. Wasfi Al-Nawafleh, Secretary Dr. Abdul Hameed Alaimat, and Treasurer Dr. Yousef Malouh[10]. The association's administrative headquarters is located within the Complex of Professional Associations in Shmesani, Amman[10]. Demonstrating a commitment to digital transformation, the JPA recently launched a dedicated mobile application (available on platforms such as Google Play) that allows members to conduct financial transactions, pay syndicate dues, and verify membership statuses online, thereby streamlining administrative interactions[14].

Under Jordanian law, JPA membership is a compulsory prerequisite for practicing pharmacy; an individual cannot legally engage in pharmaceutical activities, own a pharmacy, or dispense medications without being inscribed in the JPA registry and subsequently licensed by the Ministry of Health[4]. To qualify for registration, a candidate must fulfill stringent academic and practical requirements. The applicant must possess a Bachelor of Science in Pharmacy or a Doctor of Pharmacy (Pharm.D.) degree from an accredited, recognized university[4]. Furthermore, the candidate must complete 1,440 hours of professional practical training under the direct supervision of a licensed pharmacist in an approved community pharmacy, hospital, or pharmaceutical manufacturing facility[4]. Following this practical training, the candidate must possess a clean criminal record concerning felonies or breaches of public honor, and successfully pass a national examination prescribed under the laws regulating the profession[4].

Disciplinary Oversight, Ethics, and Good Pharmacy Practice (GPP)

The Pharmacists Association Law No. 51 of 1972 equips the JPA with an internal disciplinary committee governed by a strict penal code[12]. This committee holds the statutory authority to investigate violations of professional ethics, clinical malpractice, or non-compliance with national health laws. Depending on the severity of the infraction, the disciplinary committee can impose sanctions ranging from formal warnings and financial penalties to the permanent revocation of the pharmacist's membership, effectively terminating their ability to practice in Jordan[12].

In a concerted effort to elevate the standard of clinical care, the JPA introduced the Good Pharmacy Practice (GPP) initiative in 2010, closely aligned with guidelines from the International Pharmaceutical Federation (FIP) and the WHO[1]. The GPP guidelines are designed to shift the focus of community pharmacists away from traditional product dispensing and inventory management toward patient-centered pharmaceutical care[1]. The framework emphasizes the establishment of strong, trust-based pharmacist-patient relationships, the creation of comprehensive health databases for patients, the continuous monitoring of medication adherence, and proactive engagement in public health promotion[4].

Despite the availability of these ethical guidelines, empirical research indicates that many practitioners still face systemic barriers to full implementation. Studies show that community pharmacists frequently encounter ethical dilemmas—such as requests to dispense medications for off-label indications—and often rely on informal internet searches rather than official JPA resources for ethical guidance[18]. Furthermore, a significant disparity exists between hospital and community pharmacists regarding the management of Drug-Drug Interactions (DDIs). Hospital pharmacists are statistically more likely to possess higher clinical knowledge and engage in optimal DDI screening, whereas community pharmacists cite perceived physician resistance, time constraints, and the fear of causing unnecessary patient anxiety as barriers to proactive intervention[19].

Continuing Professional Development (CPD)

To maintain clinical competency in a rapidly evolving medical and pharmacological landscape, the JPA, in alignment with national health policies, mandates Continuing Professional Development (CPD) for relicensing[20]. Pharmacists must accumulate a total of 50 CPD hours over a five-year relicensing period (averaging 10 hours annually) by participating in accredited courses, scientific conferences, and clinical seminars[20].

The shift toward online CPD—accelerated initially by the COVID-19 pandemic—has proven highly effective and is widely accepted by over 92% of Jordanian pharmacists[20]. However, systemic barriers to continuous education remain persistent challenges for the profession. Pharmacists frequently cite severe time constraints (reported by 72.2% of practitioners), transportation logistics for in-person events (69.8%), the financial costs associated with specialized training, and a shortage of highly qualified local trainers as significant obstacles[20]. The JPA continues to work alongside academic institutions to optimize these educational delivery mechanisms and ensure that the workforce remains globally competitive.

Furthermore, the JPA's integration into global pharmaceutical dialogues was highlighted when it successfully hosted the FIP Regional Congress in Amman in 2019, collaborating with the WHO and UNESCO to foster regional pharmaceutical advancement[3].

The Jordan Food and Drug Administration (JFDA)

The Jordan Food and Drug Administration (JFDA) functions as the sovereign, central regulatory authority governing the safety, efficacy, and quality of all medicinal products, medical devices, cosmetics, and foodstuffs in the Kingdom[21].

Establishment and Institutional Autonomy

The JFDA was initially conceptualized and established under Temporary Law No. 31 of 2003, subsequently achieving formalized, permanent status through the Jordan Food and Drug Administration Law No. 41 of 2008[24]. The 2008 legislative act granted the JFDA a distinct corporate identity with complete financial and administrative autonomy[23]. This structural independence is crucial for regulatory impartiality, enabling the JFDA to own movable and immovable assets, enter into legally binding international agreements, accept grants, and appoint civil attorneys to represent the administration in judicial proceedings[23]. The JFDA's financial resources are derived from a combination of public budget allocations and the regulatory fees collected for the registration, licensing, and inspection of pharmaceutical products and establishments[23]. Any financial surplus at the end of the fiscal year is transferred back to the State Treasury, and all accounts are subject to rigorous oversight by the national Audit Bureau[23].

Organizational Structure and the Board of Directors

Under Article 6 of Law No. 41 of 2008, the JFDA is governed by a Board of Directors, strategically chaired by the Minister of Health to ensure alignment with national health policies[23]. The Board's composition ensures robust, cross-sectoral collaboration and includes:

- The JFDA Director-General (serving as Vice-Chairman).
- The Secretary-General of the Ministry of Health.
- The Secretary-General of the Ministry of Agriculture.
- The Director-General of the Jordan Standards and Metrology Organization (JSMO).
- The Directors of the Food and Drug Directorates within the JFDA.
- Four highly qualified Jordanian experts in food and drug sciences, appointed by the Council of Ministers based on the Minister of Health's recommendation, serving a renewable two-year term[23].

The Board is vested with expansive executive powers. It is responsible for developing general policies for food and drug control, approving technical rules that align with international standards, authorizing the JFDA's organizational structure, drafting legislative amendments, and overseeing the annual budget and final financial statements[23]. To ensure continuous operational oversight, the Board is legally required to convene at least once every three months, with a quorum of eight members required to pass binding resolutions[23]. The Director-

General, appointed via a Royal Decree and a Council of Ministers resolution, acts as the primary executive officer, managing the day-to-day operations of the JFDA's various directorates and executing the Board's strategic decisions[23].

Regulatory Communication Policy

Recognizing the critical importance of transparent and predictable interactions with the pharmaceutical industry and the public, the JFDA instituted a comprehensive Institutional and Regulatory Communication Policy[25]. This policy establishes a unified, risk-based framework for all internal and external communications across the regulatory lifecycle. It governs routine communications (such as product registration updates), event-driven communications (such as pharmacovigilance alerts), and urgent crisis communications (such as product recalls)[25]. The policy mandates that all regulatory enforcement decisions be transmitted through approved electronic channels, documented systematically within the JFDA's Quality Management System (QMS), and audited regularly to maintain alignment with the WHO Global Benchmarking Tool requirements[25].

Core Statutory Framework: The Drug and Pharmacy Law

The cornerstone of pharmaceutical regulation and commercial practice in Jordan is the Drug and Pharmacy Law No. 12 of 2013, which superseded the older Law No. 80 of 2001[8]. This exhaustive legislation governs every aspect of the pharmaceutical supply chain, transitioning a molecule from initial laboratory research to its eventual dispensing to the patient.

Drug Registration and Market Authorization

Article 3 and subsequent provisions of Law No. 12 of 2013 strictly prohibit the transportation, distribution, or sale of any drug, serum, vaccine, or related medical supply unless the product is formally registered with the JFDA[8]. The law mandates the formation of a Higher Committee and several specialized sub-committees to meticulously evaluate applications. These sub-committees are distinctly categorized to handle specific product types, including serums and vaccines, infant formulas, herbal and natural products, cosmetics, and medical devices[8].
A medicinal product can only be registered and circulated in its final pharmaceutical form after these committees have thoroughly verified its safety, efficacy, and quality profiles[8]. The JFDA demands exhaustive documentation formatted according to the electronic Common Technical Document (eCTD) standards.

- **New Chemical Entities (NCEs):** For an NCE, pharmaceutical companies must submit all five eCTD modules, encompassing chemical structures, comprehensive pharmacological properties, active ingredients classified by the Anatomical Therapeutic Chemical (ATC) system, and exhaustive preclinical and clinical trial data[27]. The JFDA traditionally required that a new drug be actively marketed in its country of origin or a recognized reference country (such as those regulated by the US FDA or EMA) for at least one year prior to its

registration in Jordan[27].

- **Generic Medicinal Products:** For generic drugs, the Summary of Product Characteristics (SPC) and the Patient Information Leaflet (PIL) must strictly align with the approved product information of the original reference product[28]. Generic applicants must demonstrate bioequivalence and may request the inclusion of specific therapeutic indications only after the expiry of the originator's patent protection period[28].
- **Biosimilars:** Given the complexity of biological molecules, the JFDA relies on specialized guidelines for biosimilars, typically adopting EMA or US FDA standards as reference documents. Registration requires Modules 1 through 5, with exhaustive head-to-head comparability data against the reference product for quality, non-clinical, and clinical parts. Notably, Jordanian regulations explicitly prohibit the automatic substitution or interchangeability of biosimilars at the pharmacy level; such switches must be driven by clinical need and executed solely following the explicit consent of the prescribing physician[29].

Pharmacovigilance and Post-Market Surveillance

Registration is not a static endpoint but requires continuous lifecycle management. Marketing Authorization Holders (MAHs) are legally obligated to monitor the safety of their products continuously and report to the JFDA's pharmacovigilance department[27]. The JFDA evaluates Risk Management Plans (RMPs) and Periodic Safety Update Reports (PSURs/PBRERs) as part of a risk-based approach to ensure a continuous positive benefit-risk balance[28]. If new safety signals emerge, the JFDA holds the authority to mandate class labeling updates, restrict indications, or impose post-authorization safety studies[28].

The National Medicine Policy and Pricing Mechanisms

To address the escalating costs of healthcare and ensure equitable access to essential treatments across all socioeconomic demographics, Jordan has implemented a comprehensive National Medicine Policy (NMP). The NMP focuses on the rational selection of essential medicines, affordability, optimized supply systems, and sustainable drug financing[30]. A critical component of the NMP, enforced through the Drug and Pharmacy Law, is the strict governmental control over pharmaceutical pricing. All registered medications circulating in the Jordanian market have a fixed national retail price determined exclusively by the JFDA[1]. To contain expenditures, the JFDA's pricing mechanisms have increasingly incorporated formal pharmacoeconomic evaluations since 2012. These evaluations aim to balance clinical efficacy against economic value to protect the national healthcare budget and ensure that new health technologies offer genuine value for money[1]. However, the integration of pharmacoeconomics has faced hurdles due to a historical lack of deep local expertise and the difficulty of transferring global economic models directly into the Jordanian context[1].

Furthermore, the Jordan Rational Drug List (JRDL) is periodically revised by 17 national technical committees covering various medical specialties[1]. The JRDL guides public sector

procurement through the Joint Procurement Department, ensuring that state-funded health insurance programs provide necessary, cost-effective medications free of charge to eligible citizens at public health facilities[1].

Exceptional Importation of Unapproved Medicines

While the general statutory rule dictates that only JFDA-registered drugs may be circulated, the Drug and Pharmacy Law No. 12 of 2013 provides a critical, highly controlled legal pathway for the importation of unregistered, life-saving medications for personal use[27].
Patients requiring medications that are either unapproved or unavailable in the local market must obtain prior authorization from the JFDA[32]. The rigorous regulatory requirements for this exemption include:

1. **Authorized Medical Prescription:** Submission of a prescription from a licensed physician in Jordan detailing the exact medical diagnosis and confirming the absolute critical need for the proposed medication due to the absence of local therapeutic alternatives[32].
2. **Clinical Justification:** Provision of medical reports and laboratory test results proving that the requested medication is essential for treating a serious or life-threatening condition[32].
3. **Quantity Restrictions:** Adherence to strict quantity limits. The law permits only a supply sufficient for personal use, typically not exceeding a three-month duration[32].
4. **Commercial Prohibition:** An absolute prohibition against importing commercial quantities or attempting to resell these imported drugs[32].
5. **Customs Compliance:** Coordination with the Jordan Customs Department and payment of any applicable duties[32].

Importing controlled substances (narcotics or psychotropic drugs) under this personal use exemption faces the strictest possible scrutiny at the border. Patients must carry the medication in original pharmacy packaging with intact labels and possess a formal doctor's letter confirming medical necessity[33].

Licensing and Operations of Pharmaceutical Establishments

The commercial landscape of pharmacy in Jordan is heavily regulated to prevent monopolies, ensure the equitable geographical distribution of healthcare services, and maintain uncompromising standards of quality assurance. The foundational rules governing this sector are outlined in the Regulation for Licensing Pharmaceutical Establishments No. 75 of 2014, which was subsequently updated, expanded, and modernized by Regulation No. 162 of 2019[9].

Institutional Licensing Requirements

Under these regulations, the transportation, possession, distribution, and sale of pharmaceutical products are strictly limited to entities holding a valid license[9]. Establishing a

pharmaceutical entity—whether a retail community pharmacy, a wholesale distributor, a manufacturing plant, or a clinical research organization—requires explicit approval from the Minister of Health, acting upon rigorous technical examinations and recommendations from the JFDA and the JPA[9].

For community (general) pharmacies, the regulations impose strict physical and geographical parameters designed to ensure adequate service distribution and operational quality. A licensed pharmacy must have a minimum operational footprint of 32 square meters, must feature a designated reception/counseling area and a dedicated laboratory space for compounding, and, crucially, must be situated at least 200 meters away from any pre-existing general pharmacy[12].

The application dossier for a new establishment must include a copy of the pharmacist's JPA registration, national identification, a registered land deed or lease agreement for the property, and initial zoning approval from the Greater Amman Municipality (or the relevant local municipality)[9].

Anti-Monopoly and Corporate Ownership Regulations

Jordanian law enforces unique restrictions on pharmacy ownership to preserve the professional independence of healthcare practitioners, prevent overwhelming corporatization, and protect small business owners. An individual pharmacist is legally prohibited from wholly owning more than one pharmacy[35].

However, recognizing the need for capital investment and modernized retail chains, the Drug and Pharmacy Law permits corporate entities to own multiple pharmacies, but under highly specific, restrictive conditions:

1. **Pharmacist Exclusivity:** Every shareholder in the corporate entity must be a natural person who is a licensed pharmacist registered with the JPA. Non-pharmacist investors are strictly barred from owning equity in retail pharmacies[16].
2. **Parity of Scale:** The total number of pharmacies owned by the company cannot, at any point, exceed the total number of pharmacist-shareholders in that company (e.g., a company with five pharmacist-shareholders may own a maximum of five pharmacies)[12].
3. **Equity Distribution Limits:** To prevent a single individual from dominating the corporate structure, each pharmacist-shareholder must hold a minimum of 2.5% and a maximum of 30% of the company's total share capital[12].

These constraints effectively cap the scale of retail pharmacy chains, ensuring that expansion requires the continuous integration of new professional partners, thereby decentralizing market control and promoting professional equity.

Licensing Fees and Revocation Clauses

The financial and procedural obligations for licensing vary significantly depending on the scale and risk profile of the establishment. The following table summarizes the fee structures under the current regulatory regime[9]:

Type of Pharmaceutical Establishment	Associated Licensing Fees (JOD)	Approximate USD Equivalent
Private / Community Pharmacy	2,000	~$2,820
Pharmaceutical Warehouse / Wholesaler	1,000	~$1,410
Pharmaceutical Research & Development Company	1,500	~$2,115
Pharmaceutical Laboratory	1,500	~$2,115
Pharmaceutical Manufacturer (Factory)	500 (Application) 4,000 (License Grant) 1,000 (Facility Additions)	~$700 ~$5,640 ~$1,410

The Ministry of Health retains the statutory authority to nullify or revoke these licenses under specific conditions. A license may be immediately terminated if the establishment closes for a continuous period of six months without a legally justifiable cause, or if the entity fails to commence commercial operations within one year of the license being granted[9]. For large-scale pharmaceutical manufacturers, this grace period is extended to three years due to the complex, time-consuming nature of factory construction, equipment installation, and GMP validation[9].

Clinical Trials and Biomedical Research Governance

Recognizing its potential as a regional hub for medical research, advanced therapeutics, and medical tourism, Jordan became the first country in the Arab world to enact a dedicated law regulating clinical trials in 2001[37]. This foundational framework was substantially modernized and replaced by the Clinical Studies Law No. 2 of 2011, which explicitly aligns Jordanian research standards with the ethical principles of the Declaration of Helsinki and the ICH Guidelines for Good Clinical Practice (ICH-GCP)[37].

The Clinical Studies Committee and Institutional Review Boards

The Clinical Studies Law No. 2 of 2011 mandates a rigorous, dual-layered ethical and scientific approval process for any clinical trial involving human subjects.

At the local institutional level, any facility conducting research—whether a private hospital, a university, or a Contract Research Organization (CRO)—must establish an independent Institutional Review Board (IRB). By law, the IRB must consist of at least five members of both sexes, incorporating medical professionals, legal experts, and lay representatives from the local community to ensure diverse, unbiased oversight and protect the welfare of participants[39].

At the national level, the ultimate regulatory authority lies with the Clinical Studies Committee (CSC), formed under Article 12 of the 2011 Law. The CSC is a 12-member body chaired by the JFDA Director-General and includes the Drug Directorate Director and the Head of the Clinical Studies Division[41]. The CSC reviews comprehensive trial dossiers, including therapeutic protocols, Investigator Brochures, informed consent documents, and the preliminary recommendations of the local IRB, before granting final, legally binding authorization for the trial to proceed[41].

Ethical Protections, Informed Consent, and Liability

Article 5 of Law No. 2 of 2011 establishes rigid, non-negotiable criteria for patient protection. It strictly prohibits the execution of any clinical study on a human subject without their explicit, written, and dated informed consent[39]. To ensure absolute comprehension, the JFDA requires that the Informed Consent Form (ICF) and any patient-facing recruitment materials be translated accurately into Arabic, while technical scientific documents (such as the protocol) may remain in English to expedite international review timelines[39]. Furthermore, researchers are legally barred from enrolling subjects unless the participants have undergone necessary preliminary medical and laboratory tests to ensure their physiological safety and suitability for the trial[39].

A unique, robust, and highly protective feature of the Jordanian clinical trials law is the absolute requirement for domestic financial liability coverage. Sponsors or parties conducting the trial must secure an insurance contract with a domestically registered insurance company. This policy must explicitly cover any potential damages, injuries, or adverse events that a participant may suffer as a direct result of the clinical study, ensuring that victims have immediate legal recourse within Jordanian jurisdiction[37].

Ongoing Ethical Challenges and Legislative Refinement

While the 2011 Law provides a strong regulatory baseline, ongoing ethical and regulatory analyses indicate areas requiring further legislative refinement. The law has faced academic criticism for lacking exhaustive, specific statutory clauses addressing the fair, equitable selection of subjects, favorable risk-benefit assessments, and nuanced protections for highly vulnerable groups (such as minors, incapacitated individuals, and illiterate populations)[37].

In pediatric research, while the law necessitates parental consent, the concept of a child's "assent" based on developmental maturity requires tighter formalization, as school-based epidemiological studies are becoming more common in Jordan's youth-heavy demographic[43]. In acute, high-stress settings, such as Intensive Care Units (ICUs), empirical practice has seen IRBs approve proxy consent from legal representatives or close relatives on behalf of unconscious patients; however, bioethicists argue that this practice requires tighter, more explicit statutory codification to prevent exploitation[37]. Additionally, public awareness regarding clinical trials remains critically low; national surveys indicate that barely 21.8% of the Jordanian public understands the concept of a clinical trial, and general skepticism regarding health risks severely inhibits broader voluntary participation[44]. To address these evolving dynamics, the JFDA released updated draft guidelines for conducting clinical studies in 2026, seeking public and industry consultation to further enhance data reliability and participant safety[42].

Modern Regulatory Policies: GRP and Reliance Mechanisms (2026 Updates)

In early 2026, the JFDA instituted several advanced, transformative policy frameworks designed to streamline its operations, reduce bureaucratic friction, and elevate its global standing, specifically targeting an advanced maturity level under the WHO Global Benchmarking Tool (GBT)[5].

Good Regulatory Practices (GRP) Policy

Implemented in April 2026, the Good Regulatory Practices (GRP) Policy establishes a structured, principles-based framework applied across all JFDA functions, ranging from initial marketing authorization and pharmacovigilance to market surveillance and lot release[5]. The policy ensures that all JFDA regulations, guidelines, and technical standards are lawful, science-based, risk-proportionate, transparent, and consistent[5].

The GRP Policy mandates adherence to nine core principles:

Core GRP Principle	Regulatory Implication
Legality	All regulatory actions must have a clear, defined basis in national legislation.
Consistency	Requirements must be coherent, non-contradictory, and applied equally across all stakeholders.

Independence	Decisions must be free from political or commercial undue influence.
Impartiality	Stakeholders must be treated fairly; conflicts of interest must be declared and managed.
Proportionality	Regulatory burdens must be strictly proportionate to the public health risks involved.
Flexibility	The JFDA must remain agile to respond to scientific innovation, drug shortages, and emergencies.
Clarity	Documents must be easily understood, utilizing internationally aligned terminology.
Efficiency	Processes must be optimized through digital systems, reliance mechanisms, and performance KPIs.
Transparency	Regulatory information must be published openly, subject only to necessary confidentiality limits.

Table: Core Principles of the JFDA Good Regulatory Practices (GRP) Policy (2026)[5]

Good Reliance Practice (GRelP) Guideline

To further optimize the use of internal resources and drastically accelerate patient access to vital, innovative therapies, the JFDA concurrently issued the Good Reliance Practice (GRelP) Guideline[6]. Reliance is defined as the regulatory act of taking into account and giving significant weight to the scientific assessments performed by another trusted reference regulatory authority (such as the EMA, US FDA, or WHO) while maintaining sovereign independence and accountability for the final national decision[6].

To facilitate this, the JFDA utilizes two primary reliance pathways for product registration:

1. **Abridged Review Pathway:** The JFDA accepts the exhaustive clinical and non-clinical data evaluated by the reference authority but conducts a localized, focused evaluation. This national assessment focuses on Jordan-specific elements, such as pricing, local labeling/language requirements, and country-specific pharmacovigilance adaptations (e.g., verifying the local Pharmacovigilance System Master File and local QPPV structures)[6].
2. **Verification Review Pathway:** A highly streamlined, accelerated process where the JFDA relies almost entirely on the scientific assessment of the stringent reference authority. The JFDA's role is limited to verifying the authenticity of the foreign approval and confirming that the submitted product (including its exact formulation, strength, active pharmaceutical ingredient suppliers, manufacturing sites, and specifications) is completely identical to the approved reference product. To utilize this pathway, the marketing authorization holder must submit a legally binding "Sameness Letter" confirming product identicality and transparently disclosing any justified deviations[6].

The GRelP framework is comprehensive and extends far beyond initial marketing authorizations. It applies to Post-Approval Changes (PACs), allowing for rapid updates to registered products. It applies to bioequivalence evaluations, where imported generic products may be exempted from conducting local BA/BE studies if they meet international standards[6]. Furthermore, the reliance model extends to laboratory testing (utilizing an "Abridged Testing" model that relies on Certificates of Analysis from trusted foreign labs) and regulatory inspections, where the JFDA may waive time-consuming on-site GMP inspections for foreign manufacturing sites if the manufacturer provides clear, closed inspection reports from recognized reference authorities[6].

Regulation of Controlled Substances and Emerging Threats

The management, dispensing, and law enforcement concerning narcotic drugs and psychotropic substances in Jordan represent a highly sensitive intersection of public health policy and criminal law. The primary legislation governing this domain is the Narcotic Drugs and Psychotropic Substances Law No. 11 of 1988, which underwent significant, highly debated amendments in 2016 and 2021 to address escalating regional trafficking challenges and the complex socio-medical nuances of drug addiction[47].

Dispensing Restrictions and Pharmacy Compliance

Under the Drug and Pharmacy Law and the Narcotics Law, licensed pharmacists bear immense legal and ethical responsibility regarding the custody and dispensing of controlled substances. Opioids, major tranquilizers (such as benzodiazepines), and specific psychiatric medications face the strictest regulatory scrutiny. These substances can only be dispensed upon the presentation of a highly regulated, official, and verifiable medical prescription[22]. Importing such

medications for personal use by travelers requires exhaustive documentation, original pharmacy packaging, and advanced, coordinated clearance from both the JFDA and the Jordan Customs Department[33].

Enforcement Paradigms and the Decriminalization Debate

The Jordanian legislative approach to narcotics has historically been punitive. The law imposes severe penalties—including hefty financial fines, extended imprisonment, and historically, the death penalty—for the trafficking, unauthorized manufacturing, and promotion of chemical narcotics[47]. However, recent amendments (such as those in 2006 and 2016) have seen a slight paradigm shift, reducing the death penalty to life imprisonment for certain offenses and introducing provisions that protect first-time users from having a criminal record if they seek treatment, emphasizing a rehabilitative rather than purely punitive approach to addiction[48]. The National Alliance for Combating Narcotics continues to advocate for unified standards in dispensing medicines and enhancing preventive social programs[51].

The "Digital Drugs" Phenomenon

While the legal system adapts to chemical threats (such as the synthetic cannabinoid "Joker" which surged in popularity among youth), a novel challenge has emerged: "digital drugs"[47]. These are audio files utilizing binaural beats and specific psychoacoustic frequencies designed to alter cognitive states and induce effects mimicking traditional drug intoxication[47]. Legal analysts have highlighted a severe gap in the current legislative text. Because the Narcotic Drugs and Psychotropic Substances Law explicitly defines drugs as physical, chemical, or plant-based substances that cloud the mind, the promotion of digital addiction through social media platforms currently evades traditional drug enforcement[47]. Scholars argue that addressing this threat necessitates proposed amendments to the Electronic Crimes Law and enhanced coordination with psychiatric authorities to monitor the physiological impacts of these auditory phenomena, rather than awkwardly stretching the definitions within the traditional Pharmacy Law[47].

Specialized Non-Narcotic Regulations (ENDS and Sexual Enhancers)

The JFDA's regulatory net also encompasses other high-risk consumer health products. In 2019, responding to the global proliferation of e-cigarettes, the JFDA, acting under the mandate of Law No. 41 of 2008, issued specialized regulations to govern Electronic Nicotine Delivery Systems (ENDS)[52]. The JFDA established a dedicated "Tobacco and Nicotine Products Unit" to govern the registration, importation, and manufacturing of ENDS, attempting to curb the unregulated, aesthetic marketing of these devices to youth[52].

Similarly, the JFDA tightly monitors the market for sexual enhancement drugs. The Higher Population Council has noted that while supervised use of these drugs addresses legitimate clinical dysfunctions, the market is plagued by the proliferation of unlicensed, counterfeit enhancers heavily promoted via social media and unregulated television channels. These counterfeit products pose severe cardiovascular and psychological risks, necessitating

continuous market surveillance and stringent border interdiction by JFDA inspectors[55].

Pharmacy Practice Dynamics and Evolving Market Challenges

Despite the robust, modernized legislative framework designed by the JFDA and the JPA, the practical execution of daily pharmacy services in Jordan faces systemic behavioral and structural challenges, particularly at the community pharmacy level.

Antimicrobial Stewardship (AMS) and Prescription Enforcement

The Drug and Pharmacy Law strictly classifies antibiotics as prescription-only medications (POM), explicitly criminalizing the act of dispensing them without verifiable physician authorization[56]. However, extensive field studies reveal a significant, concerning disconnect between the statutory text and daily practice. A high percentage of community pharmacies continue to dispense antibiotics over the counter (OTC)[56].

Pharmacists cite extreme patient demand, competitive economic pressures (the acute fear of losing regular customers to neighboring, less compliant pharmacies), and weak, inconsistent enforcement by Ministry of Health inspectors as the primary drivers of this violation[56]. While hospital pharmacists generally exhibit high compliance with Antimicrobial Stewardship (AMS) protocols due to stricter institutional oversight, the community setting remains vulnerable. Addressing this crisis requires an integrated approach, linking the development of mandatory digital prescription verification systems with stricter, consistent penal enforcement and expansive public awareness campaigns regarding the dangers of antibiotic resistance[57].

Expanded Prescribing Roles and Clinical Knowledge Gaps

As the global pharmacy profession attempts to transition toward a comprehensive pharmaceutical care model, there is a growing, robust dialogue within Jordan regarding the expansion of pharmacists' prescribing authorities[58]. Survey data indicates that nearly 80% of Jordanian community pharmacists favor adopting a "supplementary prescribing" (SP) model, wherein they could manage and adjust specific clinical medication plans in formalized partnerships with physicians[58]. The primary motivations for this shift include a desire to better utilize the pharmacist's extensive pharmacological knowledge and advanced educational background (such as the widespread 6-year Pharm.D. degree)[58].

However, practitioners openly acknowledge significant internal barriers to this expansion. The most frequently cited obstacles include a lack of adequate formal training in physical patient assessment, the inability to independently diagnose diseases, and notable knowledge gaps in specialized fields such as pediatric pharmacotherapy[58]. This reality highlights the urgent necessity for the JPA and academic institutions to fundamentally restructure their continuing education curricula, moving beyond theoretical knowledge to practical clinical skills, to support any legislative efforts aimed at legally expanding the pharmacist's scope of practice.

Conclusion

The pharmaceutical sector in the Hashemite Kingdom of Jordan operates within an intricate, highly developed, and rapidly modernizing legal matrix. The tripartite governance system—spearheaded by the broad health policy mandate of the Ministry of Health, the rigorous regulatory and scientific enforcement of the JFDA, and the professional, ethical oversight of the JPA—ensures that the nation maintains a high standard of drug safety, manufacturing quality, and ethical clinical research.

Foundational legislation such as the Drug and Pharmacy Law No. 12 of 2013 and the Clinical Studies Law No. 2 of 2011 have established Jordan as a pioneering, transparent, and legally sound environment for pharmaceutical commerce and biomedical research in the MENA region. Furthermore, the progressive adoption of the Good Regulatory Practices (GRP) Policy and Good Reliance Practices (GRelP) in 2026 demonstrates the JFDA's proactive commitment to administrative efficiency, risk-based science, and seamless alignment with global regulatory standards.

However, the ultimate efficacy of this sophisticated legal framework relies heavily on its consistent implementation and enforcement at the grassroots level. Ongoing challenges—such as the urgent need to enforce prescription-only mandates for antibiotics, the logistical and financial barriers to mandatory continuing professional development, and the necessity to integrate novel, modern threats like digital drugs and counterfeit enhancers into the penal code—require persistent, adaptive attention. Moving forward, continuous legislative agility, coupled with stringent field inspections, enhanced digital health infrastructure, and deeper inter-professional collaboration between pharmacists and physicians, will be paramount to ensuring that Jordan's exemplary pharmaceutical laws translate effectively into optimal public health outcomes and advanced patient care.

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