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Short communication

Pharmaceutical Advertising in Libya: Legal Foundations and the Urgent Need for Drug Scheduling Reform

Ramadan Elkalmi

Faculty of Medicine, University of Sebha, Sebha, Libya
***Email**: ram.elkalmi@sebhau.edu.ly*

Abstract
Libya's pharmaceutical sector faces a critical regulatory imbalance. While advertising is governed by a patchwork of laws and ministerial decisions, the country lacks a formal drug scheduling system to guide prescribing and dispensing practices. This commentary reviews the legal foundations of pharmaceutical promotion, identifies the consequences of unregulated prescribing, and advocates for the urgent establishment of a national drug scheduling framework. Drawing on international models and ethical imperatives, the article calls for integrated reform to protect public health, ensure responsible marketing, and promote rational pharmacotherapy in Libya's evolving healthcare landscape.
Keywords. Pharmaceutical Advertising, Drug Scheduling, Regulatory Reform, Rational Prescribing, Libyan.

Introduction

Pharmaceutical advertising in Libya has expanded rapidly across television, social media, and community pharmacies—reflecting increased public engagement with health products. Yet this growth reveals a dangerous regulatory asymmetry: promotional practices are subject to legal oversight, while drug prescribing and dispensing remain largely uncontrolled. The absence of a national drug scheduling system undermines rational use, professional accountability, and public safety.

Libya's regulatory framework for pharmaceutical and cosmeceutical advertising is rooted in legacy laws such as Law No. 106 of 1973 and Executive Regulation No. 654 of 1975 [1,2]. These texts outline foundational principles for public health protection, including ethical responsibilities for pharmacists and restrictions on drug promotion. More recent ministerial decisions—such as Resolution No. 418 of 2019 and No. 352 of 2022 [3,4]—have introduced structural reforms, including departments for pharmaceutical media and rational drug use within the Ministry of Health.

Despite these developments, Libya lacks a unified and enforceable system to govern the advertising of medicines and health-related products. Promotional content often circulates without formal approval, and public exposure to misleading claims remains a concern. The absence of a centralized Medicines Advertisement Board (MAB) or equivalent authority limits Libya's ability to monitor, evaluate, and regulate pharmaceutical advertising in alignment with international standards.

As Libya continues to develop its pharmaceutical regulatory framework, international models offer valuable guidance for ethical oversight and policy reform. Among these, the WHO's Ethical Criteria for Medicinal Drug Promotion (first released and endorsed by the World Health Assembly in 1988) provides a globally recognized foundation for promoting the rational use of medicines through transparency, scientific accuracy, and responsible advertising. These guidelines emphasize truthful, evidence-based claims, balanced presentation of risks and benefits, and clear differentiation between promotional and educational content. They also advocate for institutional accountability and professional integrity in all promotional activities [5,6]. In contrast, Libya's regulatory environment, while evolving through the efforts of the Ministry of Health and the Food and Drug Control Center, remains decentralized, with limited formal oversight and no unified national code of ethics for drug promotion. The absence of standardized enforcement mechanisms and ethical benchmarks presents challenges in curbing misleading claims and ensuring public safety. Integrating WHO's criteria into Libya's regulatory framework could offer a strategic pathway toward greater transparency, international alignment, and enhanced public trust in pharmaceutical communications

To safeguard public health and ensure ethical communication, Libya must move toward a comprehensive regulatory model—one that integrates existing laws with modern oversight mechanisms. Drawing inspiration from countries such as Malaysia, this reform must include clear advertising guidelines, licensing accountability, and a national drug scheduling system that supports rational prescribing and informed public engagement. This transformation will carry significant public health implications beyond its technical scope. By strengthening its legal and institutional framework, Libya can protect its citizens from misinformation, support professional integrity, and foster a culture of transparency and trust in pharmaceutical communication [7].

Legal Framework Governing Pharmaceutical Advertising

Libya's pharmaceutical advertising regulations are anchored in a series of legacy laws and ministerial decisions that span over five decades. The foundational text—Law No. 106 of 1973—established broad

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principles for public health protection, including provisions for medicine handling, ethical responsibilities of pharmacists, and restrictions on promotional activities. Its Executive Regulation No. 654 of 1975, particularly Chapter Twelve, Article 541, prohibited pharmaceutical advertisements in general media, permitting promotion only through scientific journals and for products registered with the Ministry of Health.

While these early laws reflected commendable ethical intent, they are now misaligned with the realities of modern media and pharmaceutical marketing. The language is rigid, enforcement mechanisms are weak, and the scope fails to address digital platforms, satellite channels, and mobile advertising. For example, Article 541 warns against unverifiable claims and unethical phrasing but lacks penalties or monitoring systems to ensure compliance. Recent ministerial reforms have attempted to modernize the regulatory landscape. Resolution No. 110 of 2016 introduced the Pharmaceutical Information and Rationalization Department. Resolution No. 418 of 2019 added a Pharmaceutical Advertising and Promotion Department to the Ministry of Health's organizational chart, and Resolution No. 352 of 2022 assigned oversight responsibilities to the Pharmacy and Medical Supplies Department under Article 16. These developments signal institutional awareness but fall short of establishing a unified, enforceable framework.

Moreover, current regulations focus primarily on registered medical products, leaving cosmeceuticals, herbal remedies, and imported promotional materials largely unregulated. Libya lacks a centralized authority akin to Malaysia's Medicines Advertisement Board (MAB), and there is no licensing system for promotional content or a formal pre-approval process for advertisements [8,9]. This fragmented oversight allows promotional practices to vary widely, exposing the public to misleading or unethical advertising. To align with international standards and protect public health, Libya must revise its legal texts and reimagine its regulatory philosophy [10]. This includes establishing a centralized advertising authority, enforcing licensing requirements, and integrating ethical oversight into all promotional activities. Only then can pharmaceutical advertising serve the public interest and uphold professional integrity.

The Regulatory Gap: Absence of Drug Scheduling

Despite Libya's evolving pharmaceutical infrastructure, the country lacks a formal drug scheduling system—a foundational tool for regulating medicine classification, prescribing authority, and public access. This regulatory void blurs the line between prescription-only and over-the-counter drugs, allowing potent substances such as antibiotics, psychotropics, and hormonal agents to circulate without adequate oversight.

Existing legislation, including Article 108 of Law No. 106 (1973), acknowledges the need to regulate prescription-only drugs but fails to establish a structured scheduling framework. In practice, this leaves healthcare providers without standardized references and regulators without enforceable tools. Pharmacists often dispense high-risk medications based on informal advice or commercial pressure, while patients engage in self-medication without informed guidance.

The consequences are far-reaching: rising antimicrobial resistance, medication misuse, and erosion of clinical integrity. Without scheduling tiers that classify drugs by therapeutic risk and supervision requirements, Libya cannot ensure rational prescribing or ethical advertising. Promotional content for high-risk drugs circulates freely, often targeting vulnerable populations with exaggerated claims and minimal safety information.

International models offer clear pathways for reform. Countries such as Malaysia and the United Kingdom employ tiered scheduling systems that link drug classification to advertising restrictions, licensing requirements, and poison control protocols. These frameworks empower regulators to distinguish between routine-use and controlled substances, determine appropriate promotional channels, and enforce accountability across the supply chain [8,9,11].

In Libya, the adoption of a national drug scheduling system represents a critical advancement in protecting public health. Such a system would enable the Ministry of Health to establish clear and enforceable boundaries for prescribing and dispensing medications, ensuring that pharmaceutical practices are both safe and consistent. It would also provide a framework for regulating promotional content, allowing oversight based on the risk profiles of various drugs and reducing the spread of misleading or harmful information. By implementing structured scheduling, consumers would be better shielded from unsafe access and misinformation, while pharmaceutical governance would begin to align more closely with international standards. Ultimately, this approach lays the foundation for a transparent, ethical, and clinically sound pharmaceutical environment—one that prioritizes patient safety and reinforces trust in the healthcare system.

Consequences of Unregulated Prescribing

The absence of a formal drug scheduling system in Libya has led to widespread clinical and ethical vulnerabilities. Without a clear classification of medicines based on therapeutic risk, prescribing authority, and supervision requirements, the distinction between prescription-only and over-the-counter drugs is dangerously blurred. This regulatory vacuum enables the uncontrolled circulation of potent substances—

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including antibiotics, psychotropics, and hormonal agents—often dispensed without proper medical oversight.

Pharmacists, operating under commercial pressure or informal guidance, may dispense high-risk medications without prescriptions. Patients, in turn, engage in self-medication practices that expose them to adverse drug reactions, drug interactions, and long-term health risks. The unchecked availability of these substances contributes to rising antimicrobial resistance, irrational polypharmacy, and erosion of clinical accountability.

Moreover, pharmaceutical advertising in this context amplifies the problem. Promotional materials often exaggerate therapeutic benefits while omitting safety information, targeting vulnerable populations with persuasive but misleading claims. Studies by Alssageer and Kowalski (2012) revealed that many Libyan physicians distrust the accuracy of information provided by pharmaceutical company representatives (PCRs), citing frequent exaggeration and omission of critical data. This undermines informed prescribing and compromises patient safety [12].

Recent findings by Atia, Gismallah, and Almogadmi (2022) identify key areas for intervention by Libyan drug policymakers. Their study advocates for the development of comprehensive guidelines to govern interactions between PCRs and healthcare professionals, supported by robust enforcement mechanisms to uphold ethical standards and promote rational prescribing. These ethical shortcomings have real-world consequences, influencing daily clinical decisions and affecting public health [13].

The Libyan Drug Formulary, officially approved under Decision No. 673 of 2018, includes approximately 779 pharmaceutical items categorized into 14 therapeutic groups [14]. This structured classification reflects a national effort to standardize prescribing practices and improve access to essential medicines. However, the absence of a formal drug scheduling system limits the ability to regulate promotional content based on risk profiles, leaving high-risk medications vulnerable to commercial exploitation and misinformation.

The lack of a structured licensing system further exacerbates the issue. Sales activities—including those involving prescription-only drugs—occur through informal channels, unauthorized vendors, and unregulated outlets. Without licenses that define the scope of practice, location, and accountability, regulators struggle to trace violations or enforce standards. As Hassali and Shakeel (2020) demonstrate in the Malaysian context, licensing tied to poison control and advertising approval creates a closed loop of accountability [8]—one that Libya urgently needs to replicate.

In sum, the consequences of unregulated prescribing are not isolated—they ripple across clinical practice, public health, and pharmaceutical ethics. Libya must adopt a national drug scheduling system and tiered licensing framework to restore integrity, protect consumers, and align with international best practices.

Recommendations

Aligned with the World Health Organisation's (WHO) principles for ethical drug promotion, Libya's pharmaceutical sector faces a defining moment. While foundational laws and ministerial decisions offer a regulatory starting point, the absence of a national drug scheduling system continues to undermine rational prescribing and weaken control over pharmaceutical advertising. Addressing this gap requires a multi-tiered reform strategy, informed by successful international models such as Malaysia's Medicines Advertisement Board and the UK's Misuse of Drugs Act 1971.

A key priority is the classification of medicines into distinct categories—prescription-only, pharmacist-supervised, and over-the-counter—based on therapeutic risk and potential for misuse. This structure would enhance prescribing practices and safeguard consumers. In parallel, a centralized Medicines Advertisement Board should be established to oversee pharmaceutical promotions, ensuring that all advertisements are reviewed by professionals from pharmacy, medicine, law, and public health before dissemination. Licensing protocols must also be revised. Separate licenses should be issued to wholesalers, retailers, and promotional agents, with mandatory inspections and penalties for non-compliance. Ethical guidelines should be enforced, requiring pharmaceutical representatives to communicate transparently and base promotional claims on scientific evidence. Public awareness campaigns would further educate citizens on drug safety and help them identify misleading advertisements.

To sustain these reforms, institutional capacity must be strengthened. Regulatory bodies should be equipped with technical expertise, digital infrastructure, and international collaboration to ensure effective oversight. Together, these measures form a coherent and ethically grounded roadmap for transforming Libya's pharmaceutical sector into one that prioritizes public health, transparency, and professional accountability.

Conclusion

Libya's pharmaceutical sector requires urgent structural reform. Despite existing laws and ministerial efforts, the absence of a national drug scheduling system continues to enable unsafe prescribing, unethical promotion, and regulatory fragmentation. To restore clinical integrity and public trust, Libya must implement a unified framework that links drug classification to advertising control, licensing

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accountability, and ethical oversight. This reform is not optional—it is essential for protecting consumers, guiding professionals, and aligning with international standards.

Conflict of interest. Nil

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