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Strengthening Regulatory Oversight of Digital Pharmaceutical Supply Chains in the United Arab Emirates

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ABSTRACT: The transformation of traditional pharmaceutical supply chain to modern digital platform creates cross-border distribution pathways challenging the conventional regulatory oversight. Although the existing frameworks provide the necessary controls over manufacturers, importers, authorized establishments, product identity and supply-chain traceability, online commerce introduces additional complexities at the point where a digital transaction becomes a physical cross-border shipment. This perspective proposes a regulatory verification layer to complement the existing pharmaceutical authentication, serialization, track-and-trace and online-seller verification mechanisms. The proposal would connect existing Emirates Drug Establishment authorization and import records, Tatmeen traceability information and customs processes.

In practice, this status could be represented by a QR code or equivalent machine-readable conformity mark accompanying the shipment, enabling rapid verification without requiring the intermediary to access the underlying regulatory record. Digital platforms and logistics providers would perform narrowly defined verification functions before fulfilment or carriage, while regulatory assessment, authorization, interpretation and enforcement would remain with the competent authority. The article distinguishes regulatory eligibility from product authentication and traceability, and examines cross-border recognition, interoperability, accountability, enforcement, cost, data governance and potential unintended consequences. The proposed model offers a risk-based and potentially scalable mechanism to connect regulatory authorization with digital fulfilment without transferring substantive regulatory authority to private intermediaries.

INTRODUCTION

The advent of industrialization and standardization has resulted in mass production of bulk drugs paving way to global access, cost efficiency and product uniformity. Consequently, pharmaceutical logistics was developed, regulated, and monitored on the assumption that a drug moves from an authorized manufacturer to a licensed wholesaler, retail pharmacy and subsequently to the end user who carries prescription from the physician to conclude the supply chain. A silent E-commerce revolution has broken this assumption. Today, a consumer can order products through internet from anywhere in the world, make the payment online and have it delivered at the doorsteps.

The rapid growth of online pharmaceutical trade has changed courier and logistics providers into critical intermediaries within the digital supply chain. These entities may receive shipments by passing the regulatory oversight of the destination country through digital transaction and physical cross-border movements.

It has been observed by the World Health Organization (WHO) that e-commerce can facilitate access to sub-standard and falsified medical products, particularly through unauthorized sources, emphasizing the importance of coordinated national and international responses [1, 2]. A scoping review of illicit online pharmacies identifies policy, regulation, enforcement, supply-chain and logistics issues as important areas requiring further research [3]. This article discusses whether a destination-country regulatory layer can be effective for digital web interfaces through which cross-border pharmaceutical transactions are executed. The proposal is not intended to create another product-authentication system but to enhance regulatory vigilance and verification by logistics intermediaries.

REGULATORY GOVERNANCE

In the United Arab Emirates (UAE), medical products and pharmaceutical establishments are governed by Federal Decree-Law No. (38) of 2024. Accordingly, the Emirates Drug Establishment (EDE) is the competent federal authority for marketing approval, without which a medical product shall not be manufactured, imported, distributed, possessed, sold, or used in the country [4]. This law is complemented by Federal Law No. (2) of 2019 on the use of information and communications technology in health fields detailing the legislative basis for centralized digital health information systems and interoperable electronic platforms [5]. The current UAE framework is particularly relevant to the proposed model. Accordingly, the recently enforced Federal Decree-Law No. (38) of 2024 requires EDE marketing approval for the circulation of medical products, subject to the exceptions provided in the law. The law also expressly addresses product traceability and establishes systems intended to support validity, safety and authenticity of medical products and the reduction and reporting of grey-market, counterfeit, expired and illegal products [4]. These provisions indicate that the proposed concept should be developed as an interface with existing regulatory infrastructure rather than as a parallel authorization regime. According to the Federal Decree by Law No. (14) of 2023 which covers broader UAE legal environment, modern technology-based trade recognizes technology-enabled commercial activity and provides a legal framework for competent authorities to prescribe conditions governing relevant activities [6]. The regulatory opportunity is therefore to define a pharmaceutical-specific verification function within the existing legal architecture, rather than to create an independent digital pharmaceutical regulator.

Distinction from Existing Pharmaceutical Verification Mechanisms

Tatmeen is a nationwide pharmaceutical traceability infrastructure [7] developed by the Ministry of Health and Prevention (MOHAP) in partnership with EVOTEQ. The platform employs pharmaceutical serialization aligned with GS1 standards to enhance visibility across the pharmaceutical supply chain, support the identification of counterfeit products, facilitate recalls and management of expired medicines, and improve traceability from the manufacturer to the end user. It represents an important existing layer of digital pharmaceutical supply-chain oversight in the UAE.

The proposed framework does not seek to replace existing authentication or traceability mechanisms such as Tatmeen. Rather, it introduces an additional decision layer that can integrate their existing outputs with jurisdiction-specific regulatory requirements to determine whether a proposed transaction is legally permissible. Regulatory eligibility can therefore serve as a complementary compliance layer, connecting evidence of product authenticity, identification, traceability, and supplier authorization with a determination of whether the specific transaction is legally permissible.

The European Union provides an important comparative example. Commission Delegated Regulation (EU) 2016/161 establishes a unique identifier and anti-tampering features and a repository system for verification of authenticity and identification of individual packs. The repository architecture also demonstrates the importance of standardized data exchange, application programming interfaces, audit trails and protection of commercially confidential information [8]. These functions are valuable but principally concern product identity and authenticity. They do not, by themselves, constitute a universal destination-country eligibility determination for every cross-border digital transaction. The EU also provides an example of seller-focused verification. Authorized online medicine retailers can be identified through a common logo linked to national registers. Again, this addresses the legitimacy of the online seller rather than necessarily determining whether a particular product and transaction are eligible for import into another jurisdiction.

It is also useful to distinguish the proposed mechanism from the two-dimensional data matrix codes already mandated under serialization regimes such as the EU Falsified Medicines Directive. Those codes confirm that an individual pack is genuine and unaltered; they do not indicate whether a specific consignment is authorized for the declared destination market or purpose. The regulatory-eligibility QR code proposed here would not replace or duplicate an existing serialization code. It could instead be issued as a companion machine-readable mark, printed on the outer shipment label, commercial invoice, or accompanying customs manifest, that resolves on scanning to a real-time regulatory-eligibility response from the EDE database rather than to static product-identity data. Where a product already carries a serialization code, the eligibility credential could instead be layered onto that existing code through an additional database field, avoiding the creation of a second parallel identifier.

A similar distinction applies domestically. A Tatmeen scan confirms that an individual pack is genuine, correctly identified, and traceable through the domestic supply chain; it does not, by itself, determine whether a specific cross-border shipment or online transaction satisfies destination-market import eligibility conditions. The two systems are therefore complementary rather than duplicative: Tatmeen could supply product-identity and traceability data as an input into a verification query, while the proposed regulatory-eligibility layer would add the destination-specific legal determination that Tatmeen does not itself provide.

The need to strengthen regulatory oversight

Emerging digital business models and marketing strategies have transformed traditional commercial practices, requiring organizations to implement more adaptive approaches. In the European Union, the Digital Services Act [9] specifies an important regulatory governance principle whereby intermediary actors are assigned proportionate due diligence and verification obligations to support regulatory objectives without assuming regulatory authority. This principle provides a useful conceptual precedent for strengthening oversight of digital pharmaceutical supply chains, where logistics providers and other intermediaries may verify the presence of required regulatory documentation while all regulatory assessment, authorization, and enforcement remain the responsibility of competent authorities.

However, the analogy of the Digital Services Act should be stated precisely. The DSA does not regulate pharmaceutical products. Its relevance is institutional: Article 30 requires certain online platforms to obtain specified trader information and a self-certification concerning compliance with applicable Union law before traders can use the platform to offer products or services to consumers [9]. This demonstrates that law can allocate defined verification and due-diligence functions to private intermediaries while retaining substantive regulatory authority elsewhere. The proposed pharmaceutical model applies this governance principle to question destination-country regulatory eligibility.

A regulatory-eligibility credential would therefore not constitute a new marketing authorization. It would be a machine-readable representation of an existing regulatory determination. The underlying decision would remain with EDE or another legally competent authority.

Proposed regulatory-eligibility verification framework

The framework should operate as a complementary layer rather than a replacement for existing controls. Product identity and serialization systems would continue to establish authenticity and traceability where applicable. Seller licensing would continue to establish the legitimacy of the supplier. The proposed layer would connect these controls with the destination-specific legal status of the transaction (Fig. 1). The authoritative regulatory database underpinning this layer could draw on existing Tatmeen traceability records alongside EDE authorization data, so that a single verification query reflects both domestic traceability status and cross-border regulatory eligibility.

The logistics provider would not be expected to determine pharmaceutical quality, interpret complex regulatory provisions or substitute for customs or EDE inspection. Its role would be limited to verifying a defined regulatory status before accepting a shipment where such verification is legally required. Where the response is negative or uncertain, the shipment would be held, declined or referred to according to predetermined rules.

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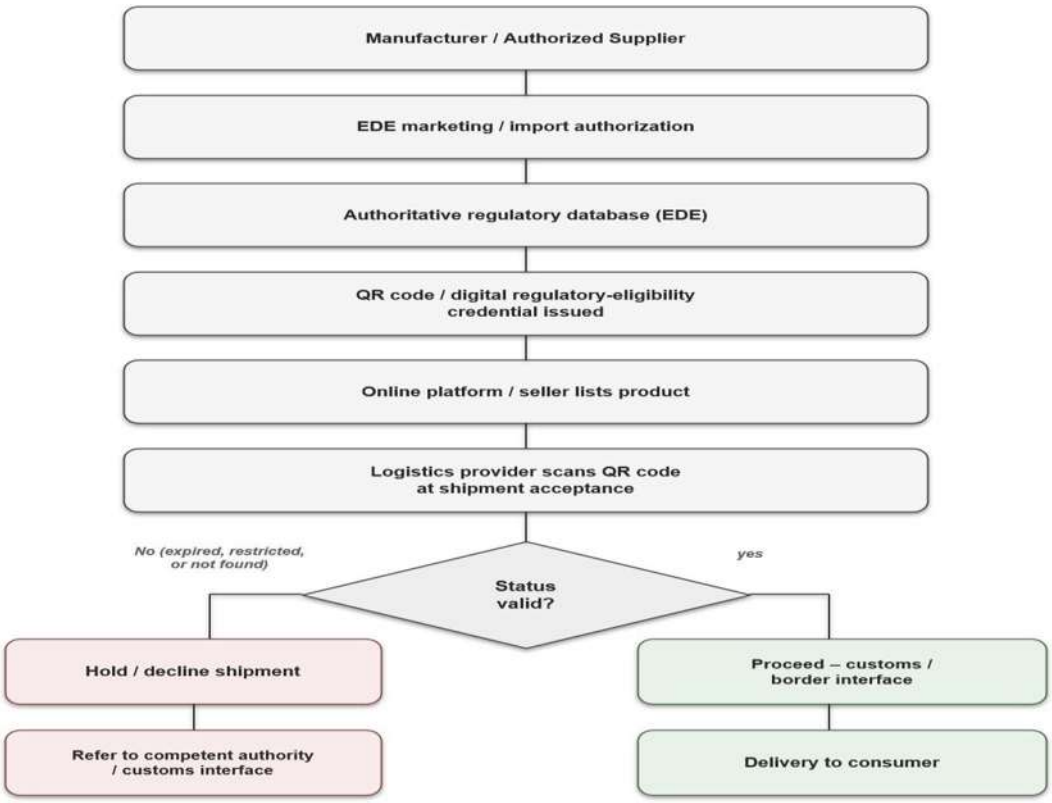

Figure 1. Proposed regulatory-eligibility verification workflow

QR code-based verification checkpoint

A practical means of operationalizing this checkpoint is a QR code or equivalent two-dimensional conformity mark issued by, or on behalf of, the EDE once a product has met the applicable marketing-authorization or import conditions. The code would be affixed to the shipment label, commercial invoice, or accompanying customs documentation and would resolve, upon scanning through a dedicated application or application programming interface, to a status of valid, expired, restricted, or not found. A logistics provider would be required to scan the code before accepting a cross-border or locally manufactured pharmaceutical consignment for carriage or last-mile delivery.

Where the response is valid, the shipment could proceed through the ordinary logistics workflow. Where the response is negative, expired, restricted or unavailable, the provider would be required to hold the shipment and refer it to the competent authority or customs interface rather than making an independent determination about the underlying regulatory question. For consignments without a printed QR code, such as older stock or certain cross-border shipments, an alphanumeric fallback code or reference to the customs declaration number could be checked against the same database, so that the absence of a QR code does not itself become a means of circumventing verification.

Legal architecture and accountability

A workable framework requires an explicit allocation of responsibility among the competent authority, manufacturer or marketing-rights holder, digital platform, logistics provider and customs authority. The competent authority should remain responsible for product classification, marketing authorization, regulatory eligibility determinations, exemptions, restrictions, interpretation, enforcement and maintenance of the authoritative regulatory database. The manufacturer or marketing-rights holder remains responsible for product quality, authenticity, regulatory submissions and applicable post-market obligations.

Digital platforms and logistics providers should have procedural rather than substantive responsibilities. A platform may be required to verify specified seller credentials or regulatory status where it facilitates a regulated transaction. A logistics provider may be required to verify the existence and validity of a regulatory credential before carriage. Neither actor should be required

to make an independent legal determination about whether a medicine is safe or authorized. Where a QR-based or equivalent conformity check is mandated, the logistics provider's procedural obligation would be limited to scanning the code at acceptance and acting on the returned status; it would not be expected to evaluate the substance of the underlying regulatory decision.

This distinction is important for liability. A supplier that falsely represents a product remains responsible for the underlying regulatory violation. A logistics provider that deliberately ignores a mandatory negative verification result may be accountable for failure to perform its defined procedural obligation. For example, a shipment flagged invalid or expired upon QR scanning that the provider nonetheless carries or delivers would fall within this category. Conversely, where a competent-authority database incorrectly identifies an authorized product as ineligible, a correction and review mechanism should be available, and responsibility should not automatically be shifted to the intermediary.

Cross-border recognition and interoperability

Cross-border recognition is one of the principal implementation challenges. A UAE regulatory credential should not automatically be treated as a foreign marketing authorization, nor should authorization in another jurisdiction automatically establish eligibility for the UAE market. The framework should therefore distinguish between domestic recognition, bilateral information-sharing arrangements, regional interoperability and broader multilateral cooperation.

Interoperability should not be confused with harmonization. Different jurisdictions can retain different substantive pharmaceutical laws while exchanging standardized regulatory-status information. A practical UAE pilot could begin with domestic verification and subsequently establish structured interfaces with selected foreign regulatory authorities where legally and technically appropriate.

To limit fragmentation, the QR code or data-matrix format used for eligibility verification should align with existing international identifier standards, such as GS1 GTIN-based serialization or ICH-IDMP product identifiers, so that a foreign regulator or a verified partner-country database could, in principle, resolve the same code rather than requiring a UAE-specific proprietary format.

The EU medicines-verification architecture demonstrates the importance of standardized identifiers, repositories, APIs, common data formats and audit trails for multi-actor verification [6]. Research on pharmaceutical regulatory systems indicates that effective implementation is influenced by the strength and execution of legislation and policies, government and political support, investment and financial resources, technical support and capacity, and engagement among relevant stakeholders [10]. These findings suggest that interoperability and governance should be designed from the outset rather than added after the technology is built.

Data governance and privacy

A digital verification system necessarily creates data flows between regulators and private intermediaries. The preferred model should therefore be verification with minimum disclosure. The logistics provider should receive only the information necessary to perform the defined verification function, rather than unrestricted access to regulatory dossiers, patient information or commercially confidential data.

The system should incorporate data minimization, purpose limitation, security, access control, retention rules and an auditable record of verification events. The EU medicines repository architecture provides a useful technical precedent by requiring interoperability, audit trails and protection of personal and commercially confidential information [6]. The UAE technology-based trade framework also provides a domestic context for secure technology-enabled commercial activity.

A verification query could return only a product identifier, regulatory status, conditions if applicable, validity period and verification timestamp. Patient identity, prescription details and confidential manufacturer information should not be exposed unless specifically required by law for a separate regulatory function.

Consistent with this principle, the QR code itself should encode only a non-sensitive reference token or unique verification identifier rather than the underlying regulatory record. The substantive data would be retrieved only when the token is resolved against the authoritative database at the time of verification, and the query would be logged for audit purposes without retaining unnecessary personal or commercial data.

COSTS AND PROPORTIONALITY

A verification obligation should be proportionate to risk. Requiring every low-risk transaction to undergo complex manual review could increase costs, delay legitimate supply and create barriers for smaller legitimate suppliers. A more feasible approach is automated verification for routine products and human review for exceptions. Implementation costs would include government database and API infrastructure, integration costs for platforms and logistics providers, cybersecurity and maintenance, staff training and compliance management. Evidence from pharmaceutical track-and-trace implementation shows that monetary investment, technical requirements, stakeholder coordination and regulatory capacity materially affect implementation [11]. These factors should therefore form part of a formal feasibility assessment before mandatory nationwide deployment.

A phased approach could begin with a limited set of high-risk categories or cross-border transactions, followed by evaluation of verification time, false-positive rates, system availability, unauthorized-shipment interceptions, compliance costs and impacts on legitimate medicine availability.

Potential unintended consequences and safeguards

The framework may produce unintended consequences if designed without adequate safeguards. False database entries could cause legitimate shipments to be rejected; excessive verification obligations could burden small suppliers and logistics operators; fragmented national systems could make cross-border commerce more difficult; cybersecurity vulnerabilities could expose regulatory or commercial data; and overly conservative automated decisions could contribute to medicine shortages. These risks support, rather than weaken, a proportionate design. The system should provide human review for ambiguous cases, an appeal or correction mechanism, defined service-level expectations, cybersecurity controls, interoperability standards and clear limits on intermediary responsibility. The objective should be to reduce regulatory blind spots without creating a new layer of indiscriminate administrative friction.

CONCLUSION

The growth of digital pharmaceutical supply chains requires regulatory oversight to evolve alongside changing modes of distribution. The appropriate response is not necessarily to construct a separate digital pharmaceutical regulatory regime, but to extend regulatory visibility to the points at which existing controls become disconnected from new modes of distribution. Existing authentication, serialization, track-and-trace and online-pharmacy verification systems remain essential, but they answer different regulatory questions.

A regulatory-eligibility verification layer could connect an existing authorization decision with the digital and physical fulfilment of a cross-border transaction. Its value would lie in providing a machine-readable, destination-specific status that can be checked by appropriately designated intermediaries without transferring substantive regulatory authority to them. For the UAE, such a model could be developed within the existing legal environment governing medical products and technology-based trade, subject to clear statutory authority, risk-based application, interoperability standards, data governance, accountability and enforcement safeguards. A phased pilot focused on defined high-risk categories would permit assessment of technical feasibility, costs, false-positive rates and public-health benefit before broader implementation.

A QR code or equivalent machine-readable conformity mark, checked by the logistics provider at the point of shipment acceptance, offers one practical and low-cost means of operationalizing this pilot without requiring intermediaries to interpret regulatory content themselves. Ultimately, the proposal is not another authentication technology. It is a regulatory bridge between authorization and fulfilment. If designed around proportionality, interoperability and clearly allocated responsibilities, such a bridge could strengthen the UAE's ability to oversee pharmaceutical commerce that increasingly occurs outside the physical boundaries of the conventional pharmaceutical supply chain.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests.

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