Universal Library of Business and Economics Research Article

ISSN: 3064-9951 | Volume 3, Issue 3

Open Access | PP: 130-135

DOI: https://doi.org/10.70315/uloap.ulbec.2026.0303009

Maintaining Uninterrupted Supply During the Transition to Mandatory Pharmaceutical Serialization: An OTC Distribution Case from Kazakhstan

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Abstract

Mandatory pharmaceutical serialization makes product movement dependent on both physical availability and a valid digital status. This article examines how a pharmaceutical distributor in Kazakhstan maintained supply continuity while preparing for mandatory medicine marking and serialization. The source base combines recent studies on pharmaceutical traceability, serialization, supply-chain resilience, interoperability, and Kazakhstan's marking requirements with an operational case covering 30,000 packages and more than 20 SKUs. Comparative source analysis, conceptual synthesis, classification, and analytical generalization were applied. The resulting framework locates continuity risk at interfaces linking code readability, system recognition, warehouse handling, commercial release, and downstream acceptance. The case indicates that pilot verification and coordinated work across logistics, IT, and commercial operations can support go-live readiness while shipments continue. The proposed implementation logic organizes preparation around transaction mapping, pilot execution, exception ownership, cross-functional release decisions, and post-launch stabilization and can be adapted to comparable regulatory transitions in pharmaceutical distribution.

Keywords: *Pharmaceutical Serialization, Data Matrix, OTC Distribution, Supply Continuity, Track And Trace, Regulatory Transition, Pharmaceutical Logistics, Kazakhstan, Interoperability, Business Continuity.*

INTRODUCTION

Pharmaceutical serialization makes the movement of a medicine dependent on two linked states: the package must be physically available and its digital identifier must support the required transaction. This dependency extends from receipt and inventory handling to order release, shipment, downstream acceptance, and dispensing. A failure in code recognition or information exchange can hold stock that remains physically present and commercially required.

The risk becomes acute during a mandatory cutover because established product flows continue while packaging, master data, scanning procedures, information exchange, and transaction reporting are being adapted. Serialized products must meet the new identification requirements without disrupting supply to distributors, pharmacies, and other downstream participants. Regulatory compliance and ordinary product movement consequently meet at the release decision for each affected transaction.

The article aims to determine how a pharmaceutical distributor can prepare for mandatory serialization while preserving outbound supply during the transition. Three objectives guide the inquiry: to identify the points at which serialization makes physical product movement dependent on digital status, to establish how pre-launch testing and coordination among logistics, commercial operations, and IT can address these dependencies in a Kazakhstan distribution case, and to convert the resulting relationships into implementation logic applicable to comparable regulatory cutovers.

Recent literature addresses pharmaceutical traceability, protection against falsified medicines, digital supply chains, serialization costs, resilience, and interoperability, yet distributor-level continuity around mandatory go-live remains dispersed across these research streams. The proposed interpretation connects them through the transaction interface where package status, system recognition, warehouse handling, and commercial release must correspond. The hypothesis is that uninterrupted supply during a serialization cutover depends on testing this complete transaction path before the deadline and assigning cross-functional responsibility for exceptions that can stop product movement.

Citation: Nazin Vladislav, "Maintaining Uninterrupted Supply During the Transition to Mandatory Pharmaceutical Serialization: An OTC Distribution Case from Kazakhstan", Universal Library of Business and Economics, 2026; 3(3): 130-135. DOI: https://doi.org/10.70315/uloap.ulbec.2026.0303009.

MATERIALS AND METHODS

The source corpus comprised publications from 2023 to 2025 covering the operational consequences of pharmaceutical serialization [7, 8], pharmaceutical supply-chain resilience and disruption management [1, 3-5], emerging digital technologies [2], interoperability of pharmaceutical track-and-trace systems [9], pharmaceutical traceability policy [10], and Kazakhstan's national medicine-marking process [6]. Sources were screened for direct relevance to at least one continuity-critical component: operational performance, disruption preparedness, digital traceability, interorganizational information exchange, or the regulated movement of serialized medicines. The Kazakhstan regulatory source defined the national sequence against which the distributor case was interpreted.

Comparative source analysis related serialization-specific constraints to pharmaceutical supply-chain resilience, while conceptual synthesis connected physical product movement with digital transaction status. Classification separated dependencies by process interface and organizational responsibility. Analytical generalization then mapped the Kazakhstan pilot activities to these dependencies and converted the resulting relationships into distributor-level implementation logic.

RESULTS

Kazakhstan's medicine-marking system directly links product circulation to digital identification. Medicines manufactured after 1 July 2024 are subject to mandatory marking with unique Data Matrix codes, and manufacturers, importers, distributors, pharmacies, and medical organizations participate in the national traceability system [6]. Manufacturers register marked medicines before circulation. Importers and distributors receive products with assigned codes, and a medicine whose code cannot be read or is absent from the system cannot proceed to sale or use [6]. Physical inventory can become unavailable for the next transaction solely because its digital status cannot be verified.

Serialization research identifies the same dependency earlier in the pharmaceutical supply chain. A 2023 review associated serialization implementation with packaging-line availability, productivity, and additional operating costs [7]. Research conducted at 11 Irish pharmaceutical sites covering 114 packaging lines subsequently reported lower line availability and operational efficiency after serialization had been integrated into packaging operations [8]. Distribution uses different equipment and transaction sequences, but the operational mechanism is comparable: code processing, information transfer, and system recognition become conditions for completing physical product movement [7, 8].

Supply-chain resilience studies locate this problem within preparedness and disruption control. Recent research associates pharmaceutical resilience with visibility, stakeholder coordination, mitigation capability, and the ability to maintain medicine flow during disruption [1, 3-5]. The systematic review by Dienes et al. identifies risk mitigation, stakeholder collaboration, and technology investment among the recurring directions of resilience research [3]. Goswami et al. place disruptions within a supply-chain map constructed from the focal company's position and attach mitigation measures to the locations at which interruptions occur [4]. This logic is particularly applicable to serialization because the date of the regulatory change is known before the disturbance can affect ordinary distribution. Potential holds can be located and tested before the cutover.

Emerging technologies can strengthen traceability, risk management, and information visibility [2], while pharmaceutical track-and-trace systems still depend on data moving across organizations and information environments. Comparative analysis of national traceability regimes identifies legal and operational interoperability as a condition for their effective interaction [9]. Research on China likewise links track-and-trace performance to regulatory design and implementation across the pharmaceutical supply chain [10]. Kazakhstan places successive participants within one reporting sequence [6]. Readability of the identifier, recognition by the system, correspondence with the product record, and acceptance of the next transaction form one operational chain [2, 6, 9, 10].

Figure 1 represents this chain at the level required to locate the distributor's role.

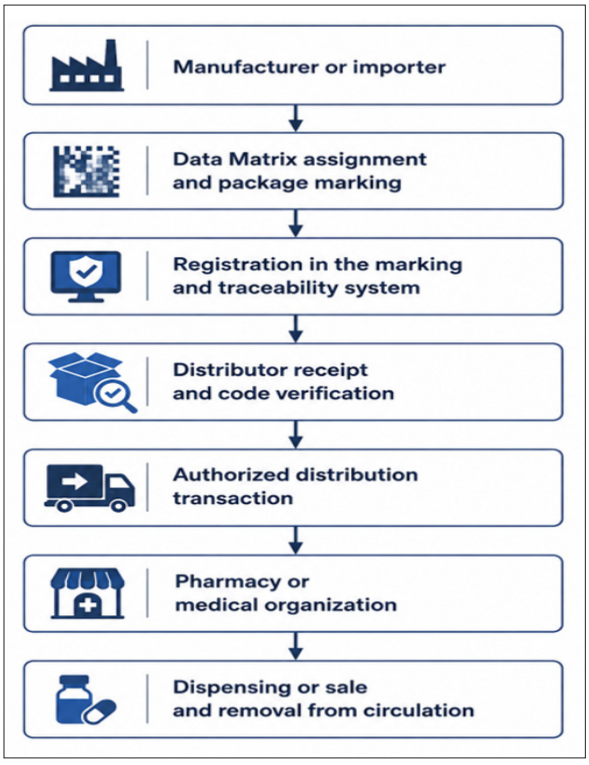

Figure 1. Simplified medicine-marking and traceability path in Kazakhstan (adapted from [6])

The distributor occupies the interface between an identifier created upstream and a downstream transaction that also requires a valid digital status. Code verification participates directly in stock release. An exception detected at receipt can prevent inventory admission, while an exception during outbound processing can hold an existing order. The operational object is the same package, but its progression depends on consistency between its physical location and serialized status.

The Kazakhstan project moved this verification into the pre-launch period. The pilot processed 30,000 pharmaceutical packages from OTC and prescription categories and tested Data Matrix reading for more than 20 SKUs. Repetition across the product range tested code processing under the conditions in which serialized products would later move through distribution. The pilot consequently exposed the forthcoming regulated process before the company became fully dependent on it. The original case records these package and SKU figures explicitly.

Logistics, commercial operations, and IT worked on the same release path. Logistics controlled receipt, handling, and preparation for dispatch. IT supported code recognition and the corresponding information transactions. Commercial operations connected serialized status with current product and shipment requirements. Their shared decision concerned whether a package could pass to the next transaction without creating an unresolved hold.

Shipments remained active during this preparation period. At official launch, the project record characterized the company as 100% ready, while distribution continued through channels serving approximately 1,000 pharmacy points in Kazakhstan. These values describe the reported project scope and go-live status. The relevant operational sequence consists of pilot processing, multi-SKU code verification, cross-functional correction, and continued shipment activity before mandatory launch.

Comparison of serialization, disruption, and interoperability research identifies the same point of failure from different positions. Serialization can reduce operational performance when equipment or information processing interferes with the normal production flow [7, 8]. Supply-chain mapping places mitigation where a disturbance enters the operating structure [4]. Interoperability research extends this requirement across organizational boundaries [9]. For pharmaceutical distribution, continuity is threatened when a required serialized event fails and consequently stops the physical transaction associated with it [4, 7-9].

This relationship changes the function of pilot testing. Scanner readability is only one condition. The identifier must remain usable through the subsequent system, warehouse, and commercial decisions. Resilience research emphasizes advance preparation and mitigation capacity [1, 3, 5], while digital supply-chain studies connect traceability with integrated information flows [2]. Testing more than 20 SKUs within a process involving logistics, IT, and commercial operations joined these requirements in the Kazakhstan case. The pilot exposed the complete operating path to the forthcoming regulatory state before formal cutover [1-3, 5].

Organizational readiness also extends beyond internal configuration. Track-and-trace systems connect multiple participants, so a distributor cannot create end-to-end traceability through its own information environment alone [6, 9, 10]. Digital technologies can improve visibility [2], but each required transaction still has to be accepted at the relevant interface. The complete transaction path is the appropriate readiness unit. Code recognition, product master data, warehouse handling, information exchange, and downstream acceptance must support one continuous movement under the new regime [2, 6, 9, 10].

The resulting readiness logic follows the points at which product movement can stop. The distributor first maps the serialized transaction path, then tests representative product flows, locates conditions that can hold movement, assigns responsibility for resolving them, and verifies the corrected transaction before mandatory cutover. Physical product availability and digital transaction readiness remain separate attributes until the process confirms both.

DISCUSSION

Serialization changes product-release control because warehouse handling, system status, and commercial shipment decisions become dependent on the serialized state of the same package. Separate preparation by logistics, IT, and commercial operations leaves gaps precisely where responsibility passes between functions. Distributor readiness requires one traceable release path with explicit authority to hold, correct, and release an affected transaction.

Implementation begins with transaction mapping. Each serialization event is linked to the corresponding physical operation, information-system action, responsible function, and downstream dependency. Equipment configuration, master data, user access, and system integration are then prepared against this defined path. This order keeps technical configuration tied to the transaction it must support.

Pilot execution should reproduce the same sequence that will later determine shipment release. Product coverage matters because code processing must remain stable across the relevant portfolio, but an isolated successful scan does not confirm that the downstream system state and warehouse transaction can be completed. Pilot completion requires successful progression through the connected operating flow.

Table 1 assigns the major preparation stages to logistics, IT, and commercial operations and identifies the continuity decision shared by the three functions.

Table 1. Functional ownership during a pharmaceutical serialization transition

Process stage	Logistics responsibility	IT responsibility	Commercial operations responsibility	Continuity control
Transaction mapping	Identify affected receipt, storage, picking, and dispatch operations	Map system events, interfaces, access, and product-data dependencies	Identify order and customer processes dependent on serialized release	Agreed end-to-end transaction path
Pilot preparation	Select product flows and organize controlled handling	Configure code recognition, system interaction, and required master data	Align testing with active product and shipment requirements	Test flow corresponds to commercial movement
Pilot execution	Process serialized stock through normal handling stages	Verify code recognition and transaction processing	Track effects of serialized status on order progression	Exceptions appear before formal cutover
Exception resolution	Control affected stock	Diagnose code, status, interface, or data failure	Assess shipment consequences and release priorities	Named owner and release condition
Go-live decision	Confirm procedures and user readiness	Confirm system operation and escalation support	Confirm readiness of active distribution flows	Joint release decision
Stabilization	Maintain controlled warehouse execution	Resolve recurring technical failures	Coordinate business effects of unresolved cases	Problems remain within managed workflows

Logistics controls the physical unit, IT controls the principal information transactions, and commercial operations connects inventory status with outbound commitments. Since no function controls every release condition, responsibility must be defined at each handoff before an exception reaches an active shipment.

Exception management follows the same principle. For every condition that prevents a serialized transaction from progressing, staff need to know which stock is affected, who controls it physically, who investigates the digital status, who evaluates the shipment consequence, and what condition authorizes release. Predefined ownership contains a local error before it spreads into unrelated inventory or orders.

Table 2 converts this principle into decision logic for recurrent serialization exceptions.

Table 2. Decision logic for serialization exceptions during distributor operations

Trigger	Immediate operational control	Coordination path	Release condition	Continuity implication
Data Matrix cannot be read	Hold the affected unit and preserve its identity	Warehouse and serialization support	Code is processed through an authorized corrective path	Unreadable unit remains separated from unaffected stock
Code is absent or unrecognized	Keep the affected unit in controlled status	IT, serialization support, and logistics	Digital status is verified for the required transaction	Digital exception remains confined to affected inventory
Product master data and serialized record do not correspond	Suspend the affected transaction	IT, master-data owner, and logistics	Records are reconciled	Repeated failure at later stages is prevented
System communication is unavailable	Preserve physical custody and record the affected transaction	IT with warehouse and commercial notification	Communication is restored and transaction status confirmed	Interruption remains limited to identified transactions
Downstream acceptance is uncertain	Hold dispatch of the affected stock	Commercial operations, logistics, and downstream counterpart	Receiving path is confirmed	Shipment is released only when the next serialized event can proceed
Legacy and serialized stock coexist	Apply the correct handling logic to each stock status	Logistics with IT and commercial oversight	Applicable rule is confirmed for the product status	Transition states remain operationally separated

Release conditions give exception handling a defined endpoint. Once the affected stock, failed transaction, corrective owner, and release criterion are known, the problem can be contained without treating the entire serialized flow as unavailable.

Early pilot execution also distributes the learning burden over the preparation period. Operators encounter code and transaction problems before mandatory dependence on the new process, IT can correct configuration while the pilot continues, and commercial operations can integrate serialized status into shipment decisions. In the Kazakhstan case, the sequence of multi-SKU testing followed by synchronized preparation is more transferable than the absolute number of packages processed.

The go-live decision should use the same shared transaction path. Logistics confirms executable warehouse procedures, IT confirms applications, interfaces, transaction states, and support routes, while commercial operations confirms that active product flows can pass through the prepared sequence and that unresolved exceptions have known escalation routes. Readiness is established when these confirmations apply to the same transactions.

Operational monitoring after cutover can focus on conditions capable of holding supply, including scan exceptions, unresolved exception age, orders held because of serialized status, release time after correction, and completion of planned SKU validation. Individual counts require process context. A small number of unresolved exceptions can remain operationally significant when they persist or affect critical product flows, while rapid technical correction is incomplete until the associated order can proceed.

Downstream readiness enters the process before dispatch because serialization continues after the product leaves the distributor. Commercial operations can incorporate counterpart readiness into existing account coordination, while logistics and IT retain responsibility for the physical and system components of the transaction. This division uses the existing commercial relationship to manage an external serialization dependency.

The resulting implementation sequence consists of transaction mapping, technical and master-data preparation, representative pilot processing, exception rehearsal, cross-functional go-live approval, and stabilization. Transfer to another pharmaceutical market requires adjustment of the regulated events, national information environment, product scope, and participant responsibilities. The decision structure remains applicable where package-level digital status determines whether pharmaceutical stock can proceed through distribution.

CONCLUSION

Mandatory serialization creates continuity risk where physical stock movement depends on successful completion of a digital transaction. Code readability, serialized and product records, information exchange, warehouse handling, commercial release, and downstream acceptance form one release path.

The Kazakhstan case addressed these dependencies before formal cutover through processing of 30,000 packages, Data Matrix testing for more than 20 SKUs, and coordinated preparation across logistics, IT, and commercial operations. Shipments continued during the transition, and the project record described full readiness at official launch for a distribution flow reaching approximately 1,000 pharmacy points.

For comparable regulatory transitions, readiness can be organized around transaction mapping, pilot exposure, explicit exception ownership, cross-functional release approval, and subsequent stabilization. These relationships support the hypothesis that supply continuity during a serialization cutover depends on integrating logistics, commercial operations, and IT around a shared serialized release process before mandatory go-live.

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