

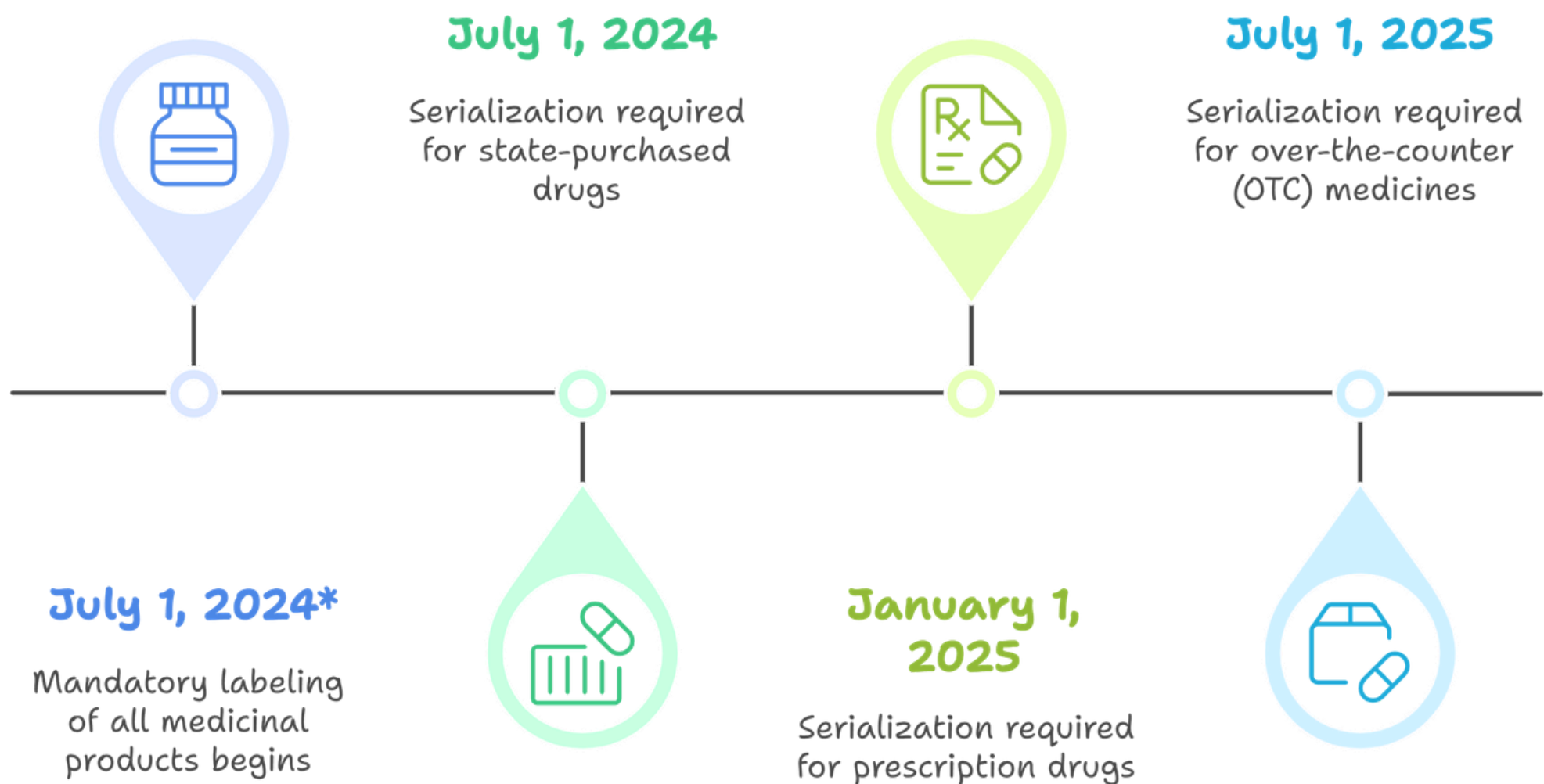


Simplifying Kazakhstan Regulatory Compliance for Pharmaceuticals



Compliance Timeline

Key dates for phased implementation of pharmaceutical traceability deadlines under the IS MPT (Information System for Marking and Traceability of Goods).



*Medicines produced and then imported/sold in Kazakhstan before 1 July 2024 will be exempt from traceability compliance requirement.

Marking Code Structure

Breakdown of Data Matrix for Pharma Industry

Serial Number

13-character
randomized
alphanumeric
Application
Identifier: 21



GTIN

14-digit numeric
code identifying
products
Application
Identifier: 01



Crypto Key

4-character
alphanumeric key
for encryption
Application
Identifier: 91



Crypto Code

44-character
alphanumeric code
for verification
Application
Identifier: 92

Key Considerations

- Crypto codes are purchased from the central system, IS MPT, by either Manufacturers or Distributors
- The maximum cost per code is 2.68 tenge (approx. \$0.0056/INR 0.45) without VAT
- One order shall contain only one GTIN, and a maximum of 150,000 marking codes
- Maximum 100 orders may be active simultaneously
- Maximum 100 requests/second from only one source

Reporting Steps

Step-by-step process to ensure complete compliance as per the guidelines

| | |
|---|---|
| 1 | Create Emission Order Initiate the process by sending an emission order to OMS |
| 2 | Fetch Marking Codes Retrieve marking codes from OMS |
| 3 | Share Utilization Report Send a report marking codes usage to OMS |
| 4 | Share Aggregation Report Send a report on marking codes aggregation to OMS |
| 5 | Share Dropout/Rejection Report Send a report on marking code exceptions (damaged/destroyed/sampling etc) to OMS |

- OMS (Order Management System) and CEDM are part of the central system, IS MPT, which is managed by Kazakhtelecom JSC.
- CEDM handles the secure exchange, storage, and processing of various electronic data generated during the traceability process.
- IS MPT (Information System for Marking and Traceability of Goods) is the overarching national traceability system in Kazakhstan.



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