



Navigating the Drug Supply Chain Security Act (DSCSA)

Compliance, Traceability, and Best
Practices for Pharmacy Operations

I have no conflicts of interest to disclose.

Learning Objectives



Define the purpose and regulatory requirements of the DSCSA



Understand the medication supply chain from manufacturer to end user



Identify and interpret key DSCSA terminology and documentation



Recognize the operational impact of DSCSA implementation on pharmacy workflows



Apply best practice recommendations for compliance, troubleshooting, and inventory management

Key Terms

Traceability: The ability to track and verify the origin, authenticity, quality, safety, or compliance of a product

Dispenser: An entity like a retail or hospital pharmacy, authorized by law to dispense prescription drugs, excluding wholesale distributors.

Product: A prescription drug in finished form for administration to patients, without substantial further manufacturing.

Product Identifier: A graphic that includes the SN, lot number, and expiration date of a product, This can be represented as a 2D barcode or multiple linear barcodes.

Illegitimate Product: Products identified as counterfeit, stolen, adulterated, or involved in fraudulent transactions that may cause serious health consequences.

Suspect Product: Those thought to be potentially counterfeit, stolen, or adulterated.

Verification: Ensuring that product identifiers match those assigned by the manufacturer or repackager.



What is the DSCSA?

Drug Supply Chain Security Act (DSCSA)

Title II of the Drug Quality and Security Act (DQSA)

Enacted November 27, 2013



Purpose: to keep harmful or counterfeit medications from entering the prescription medication supply chain



How: through the use of electronic data exchange using the FDA recommended Electronic Code Information Services (EPCIS).

DSCSA requirements for Authorized Trading Partners

Authorized

Verification System

Product Identifiers

Transaction Records

Responsive

Return Process

Quarantine Process

Why is traceability important?

Patient
Safety

Preventing
Counterfeits

Supply Chain
Integrity

Crisis
Response

Regulatory
Compliance

How does this affect dispensers

We can only procure from licensed or registered trading partners.

All human prescription medications must be accompanied by product tracing documentation.

Provide product tracing documentation if you intend to sell a human prescription drug to an authorized trading partner.

Dispensers must store product tracing documentation for 6 years.

Dispensers must have a process in place to investigate suspect and illegitimate prescription drugs.



Product tracing

Transaction Information (TI):

A snapshot of the current transaction

Transaction Statement (TS)

States the transaction meets DSCSA requirements.

Transaction History (T3)

What happened before the current transaction

Product tracing

Transaction Information (TI):

A snapshot of the current transaction

Transaction Statement (TS)

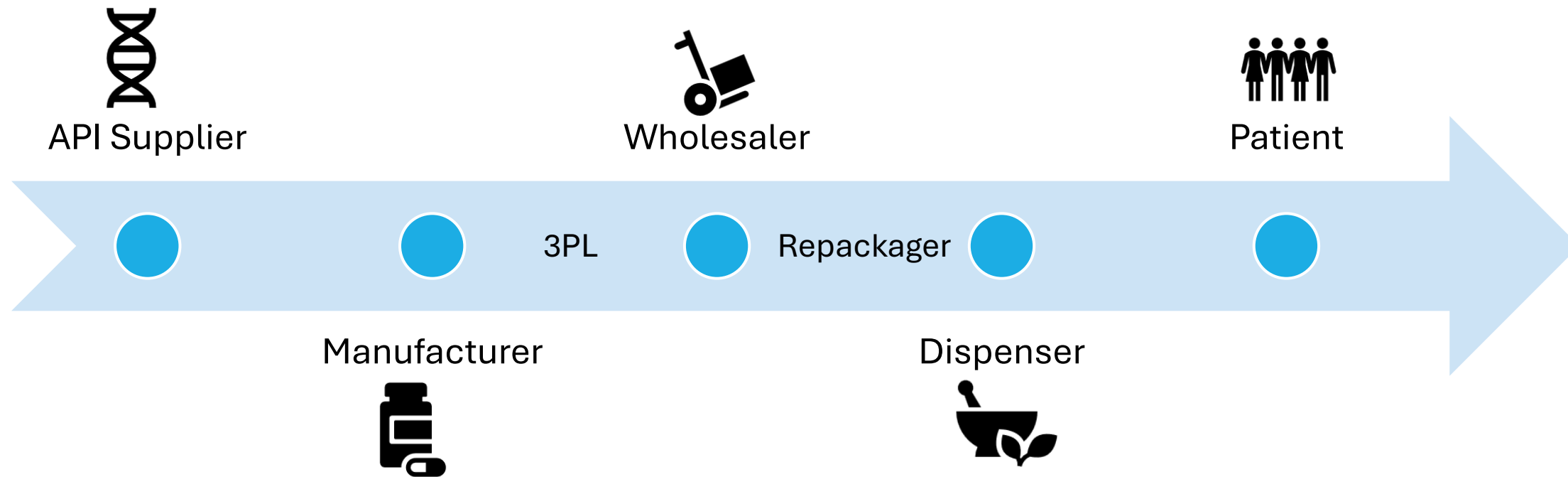
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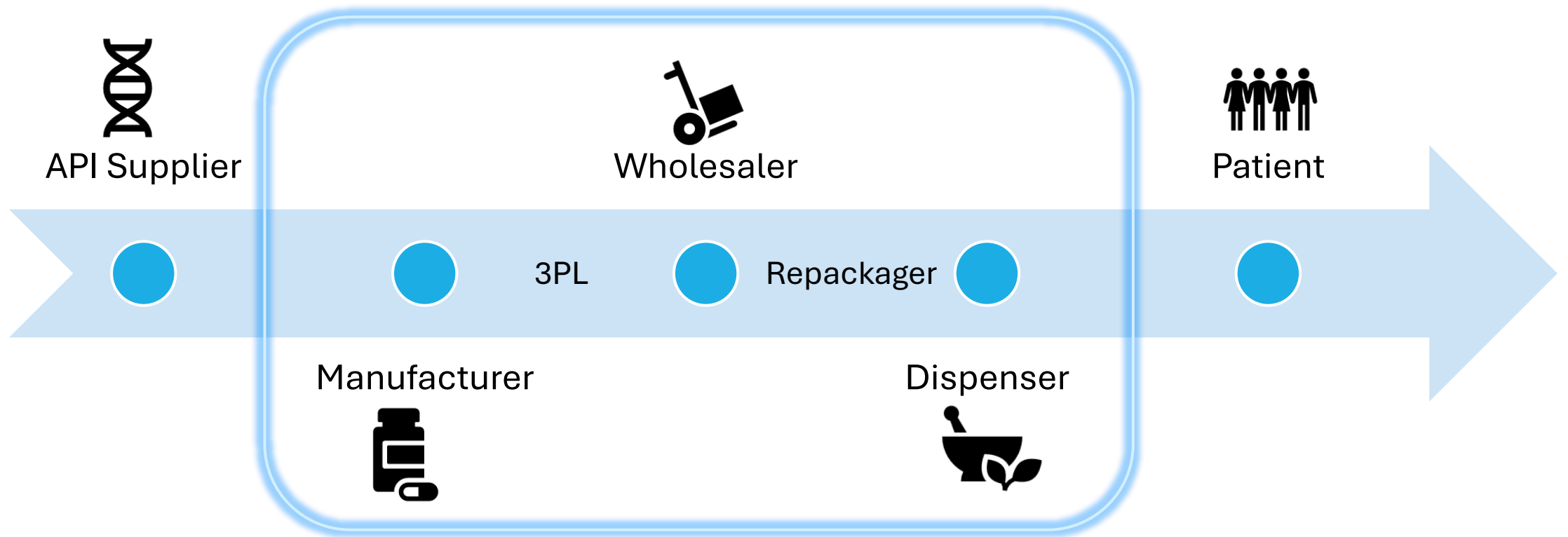
Transaction History (T3)

What happened before the current transaction

Understanding the pharmaceutical supply chain







Products & Product Identifiers



Exempt and Non-exempt Products

Non-exempt

- Human prescription medications in finished dosage form that do not require further manufacturing.

Exempt medications

- Blood or blood components for transfusion
- Radioactive drugs or biologics
- Imaging drugs
- Certain IV products
- Medical gases
- Homeopathic drugs
- Animal drugs
- Lawfully compounded drugs (503B)



Which medication is not exempt from DSCSA regulations?

a. Sevoflurane 250mL canister

b. Acetaminophen 1000mg/100mL IV

c. Aspirin 81mg chewable tablet

d. Carprofen 25mg tablet

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Non-exempt drugs will have a **2D barcode** on the package.

GTIN: A unique, globally recognized 14-digit identifier for a pharmaceutical product that is used to track and trace items through the supply chain.

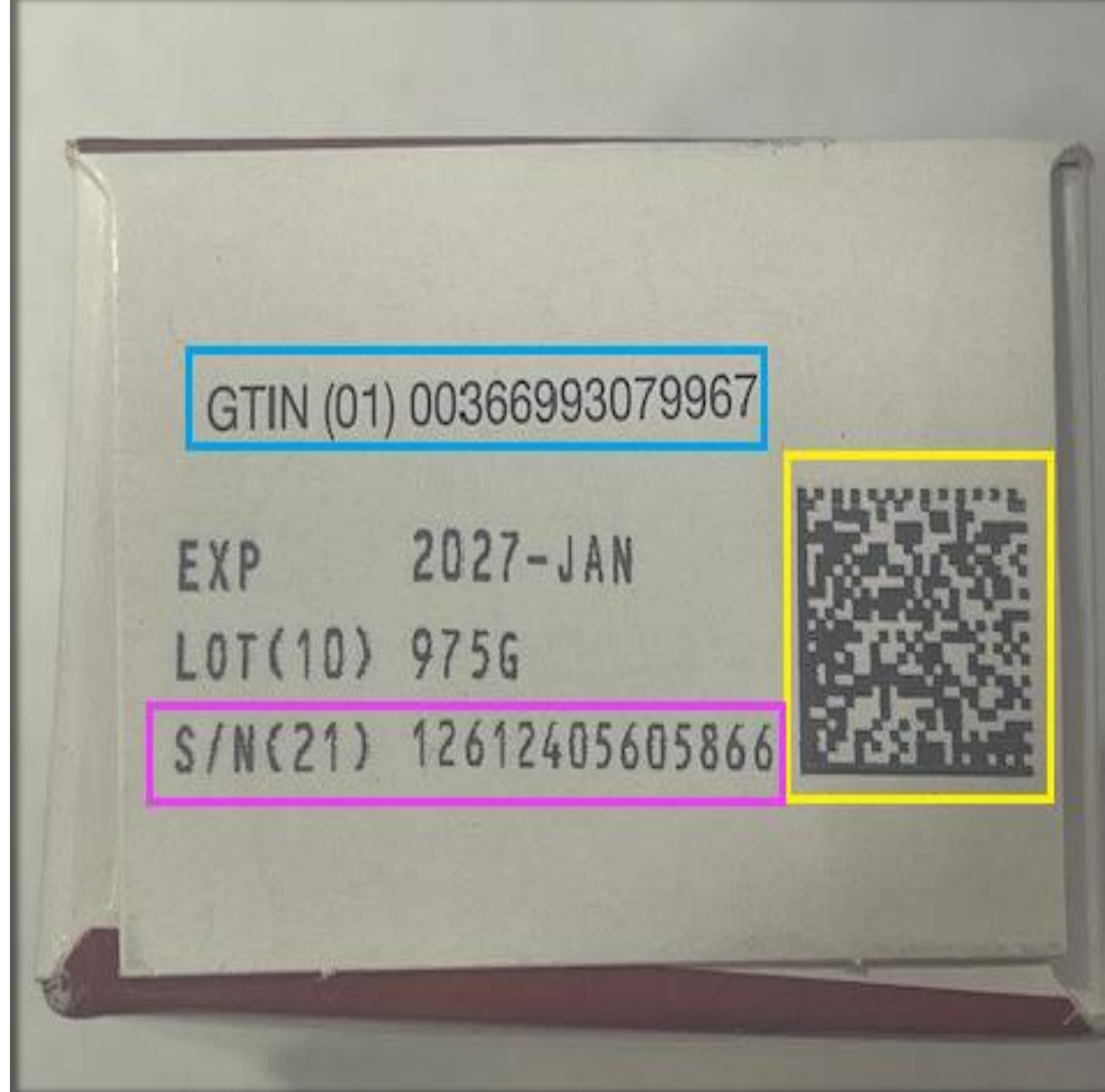
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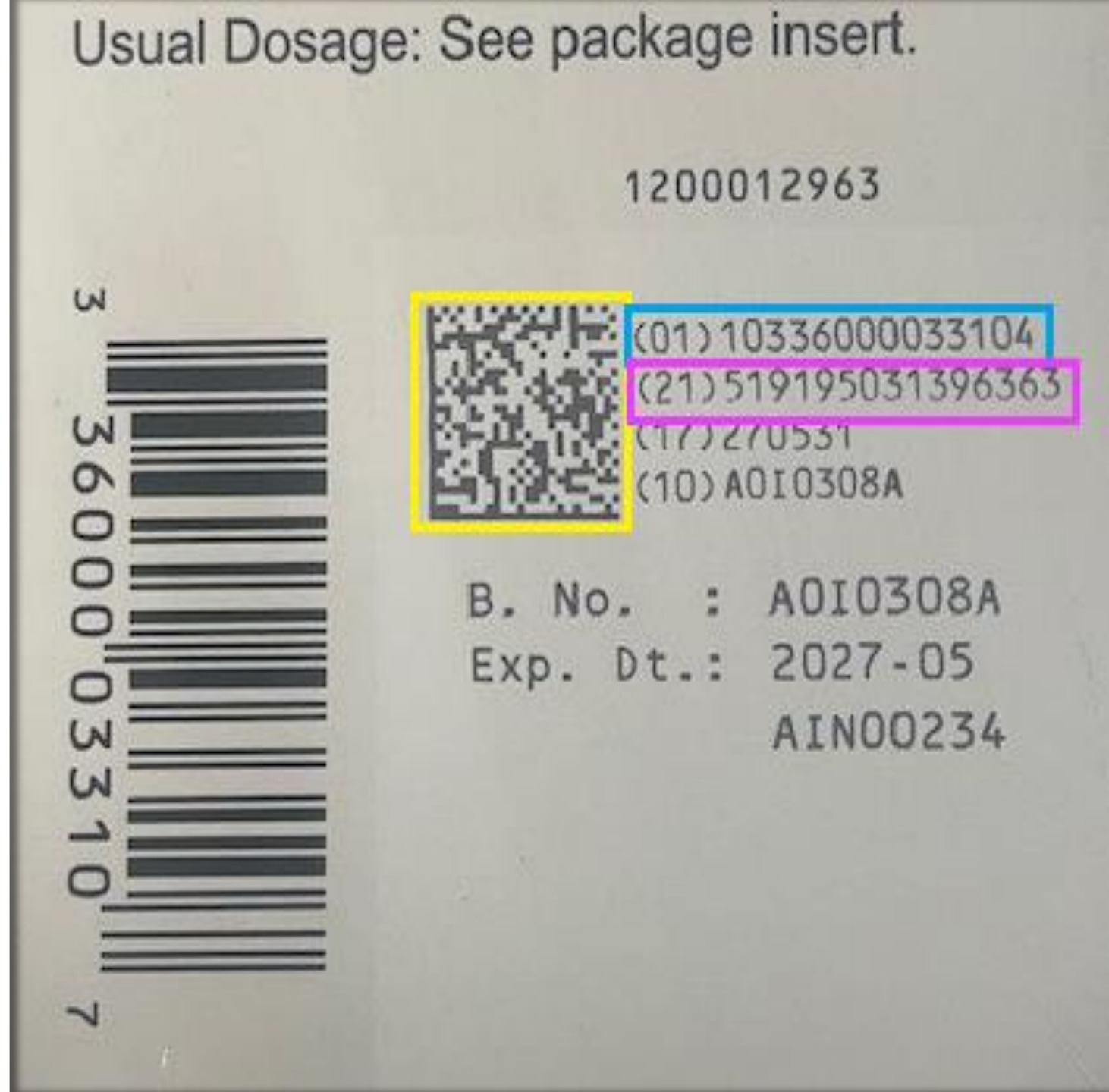
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(17)270131(10)J5P442

MAGNESIUM SULFATE IN DEX
INJECTION (10 mg/mL)



(01)50302644400549

NDC 0264-4400-54

1-0726

EXP 2027-01 LOT J5P442 D4400-54

(01) 5030264440054
(17) 270131
(10) J5P442
(21) 00005157442324

04131

ANORO ELLIPTA 62.5/25MCG 7D_INS_US

GlaxoSmithKline, Durham, NC 27701

Store 20-25C excursions 15-30C

Dry, Avoid Direct Heat and Sun

EXP: 2028-JAN LOT: 3W9R QTY: 24 EA



(17)280131(10)3W9R(30)24



(01)20301730869061(21)13678163183279

Homogeneous Case Identifiers

Which number in parenthesis indicates the serial number?

a. (17)

b. (01)

c. (10)

d. (21)

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a. (17)

b. (01)

c. (10)

d. (21)

Identifying Suspect or Illegitimate Product

Authentic Ozempic® Pens	Counterfeit Product
With Cap  Without Cap 	With Cap  Without Cap 
Authentic Ozempic® Carton	Counterfeit Carton
	

Quarantine Alerts



Quarantine



Investigate



Report

Operational Impact



Redesigning a System



DELIVERY ARRIVES



SCAN INTO COMPLIANCE
SOFTWARE



RECEIVE INTO
INVENTORY

Case Study



Case Study: General Hospital

- **Scenario:** General Hospital received an order of 10 cases of acetaminophen 1000mg/100mL IV from their wholesaler. As per General Hospital's DSCSA receiving protocol, the receiving pharmacy technician scanned the wholesaler container label, then scanned the 2D barcode on the case. They received a quarantine alert stating that the SN was unexpected. The pharmacy technician backed out of the container information screen, scanned a new case, and received the same message. 8 out of the 10 cases were flagged as unexpected. Knowing this is unusual for their wholesaler, the technician begins to try to match the cases to their container labels. The process is successful and the technician is able to complete their order.
- **Issue:** While the technician was able to complete the process, this was not the correct protocol. Container labels should match the SN of the container they are applied to.
- **Solution:** The inventory manager reached out to the wholesaler account manager with the above scenario. The account manager then connected with the distribution center to investigate.
- Please keep this case study in mind as we dive into the next segment, tips and Tricks.

Tips & Tricks



Tips

Familiarize yourself

Build Relationships

Communicate

Document

Designate a SME

Tricks

Know your inventory

Report issues immediately

Don't stress



Questions?

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Thank You!