

pulseTM
by **NABP**



DSCSA Summary

Components of Law

Part 2 of the Drug Quality and Security Act (DQSA)

- [Link to FDA Copy of DSCSA](#)

Enacted Nov 27, 2013

- Intended to supersede a growing number of differing state laws
- Phases rolling out until Nov 2023 from manufacturer to dispenser
- Facilitates the gathering of transaction data in the event of suspect and illegitimate product

Roles in DSCSA:



Manufacturers



Repackagers



Distributors



Dispensers



Third-Party Logistic
Providers

DSCSA Summary

Major Milestones



Year	2015	2018	2019	2020	2023
	Foundational		Trading Partners		Interoperability
Major Requirements	<ul style="list-style-type: none"> • T3 at the lot level (paper allowable) • Authorized TP • Suspect product handling & reporting 	<ul style="list-style-type: none"> • Affix serial number • Provide T3 lot level (electronic) • Serial number retention and verification 	<ul style="list-style-type: none"> • Transact only in serialized products • Accept return only with associated TI & TS • Initiate TH on saleable returns • Verify serial number for saleable returns (Enforcement delayed to 11-27-23) 	<ul style="list-style-type: none"> • Accept only serialized product • Suspect product reporting • Verification of serial numbers for suspect (Enforcement delayed to 11-27-23) 	<ul style="list-style-type: none"> • Implementation of an interoperable, electronic tracing of product at the S/N level (TI & TS) • Facilitate gathering of history for suspect, illegitimate, & recalls • Enhanced Verification • “Authorized” direct or indirect partners
Primary Impacted	All Trading Partners	Manufacturers/ Repackagers	Wholesalers	Dispensers/ Wholesalers	All Trading Partners



0.25 mg

0.5 mg

OZEMPIC[®] (semaglutide) injection

For Single Patient Use Only

2 mg/3 mL (0.68 mg/mL) Prefilled pen

Pen delivers doses in 0.25 mg
or 0.5 mg increments only

For subcutaneous use only

Use OZEMPIC once weekly

Contains: 1 OZEMPIC pen, 4 NovoFine[®] Plus 32G needles, Product Literature.

Dispense the enclosed Medication Guide to each patient.



ABC-015-001-13 Use only



OZEMPIC[®] 0.25 mg

solution for injection in pre-filled pen
semaglutide

subcutaneous use

once weekly

1 pen and 4 disposable needles





Authentic Ozempic® Carton



Counterfeit Carton



Authentic Ozempic® Pens

With Cap



Without Cap



Counterfeit Product

With Cap



Without Cap



Product Complaints Linked to Licensed Secondary Distributors



Patient reported consuming one tablet of an antipsychotic in bottle of BIKTARVY® and reported being unable to walk or talk.





PHARMA

Gilead says counterfeiters sold \$250M worth of fake HIV drugs, sues distributors

By Kevin Dunleavy • Jan 20, 2022 08:22am

counterfeit

counterfeit drugs

HIV

Biktarvy

Share ↗

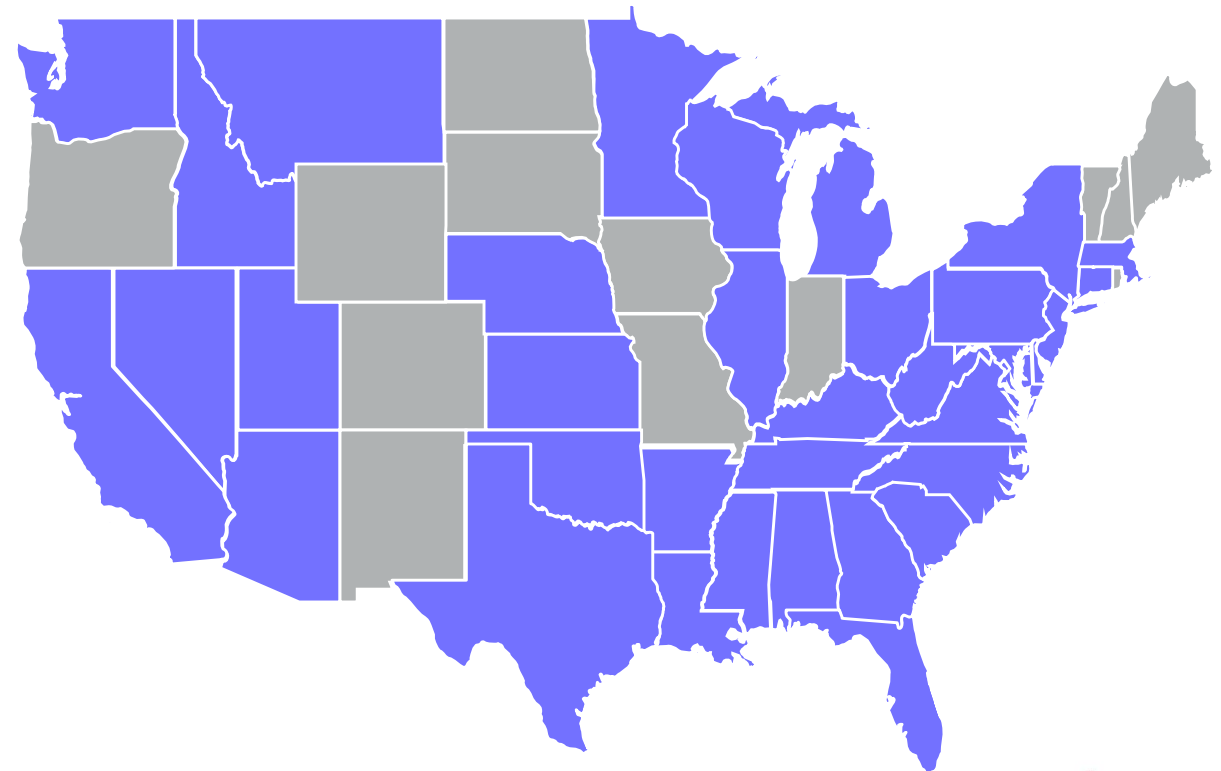


Gilead says it found counterfeit versions of its HIV drugs—mostly Biktarvy and Descovy—that were sold to pharmacies and distributed to patients. (Gilead Sciences)

Gilead [sued](#) a network of small drug distributors, claiming they endangered patients by selling more than \$250 million in counterfeit versions of the company's HIV drugs—mostly Biktarvy and Descovy—in the United States over the last two years.

Distributors of the counterfeits sold to independent pharmacies throughout the country

Over 600 unique pharmacies in 36 states



The Illicit Scheme





United States Prescription Drug Supply Chain

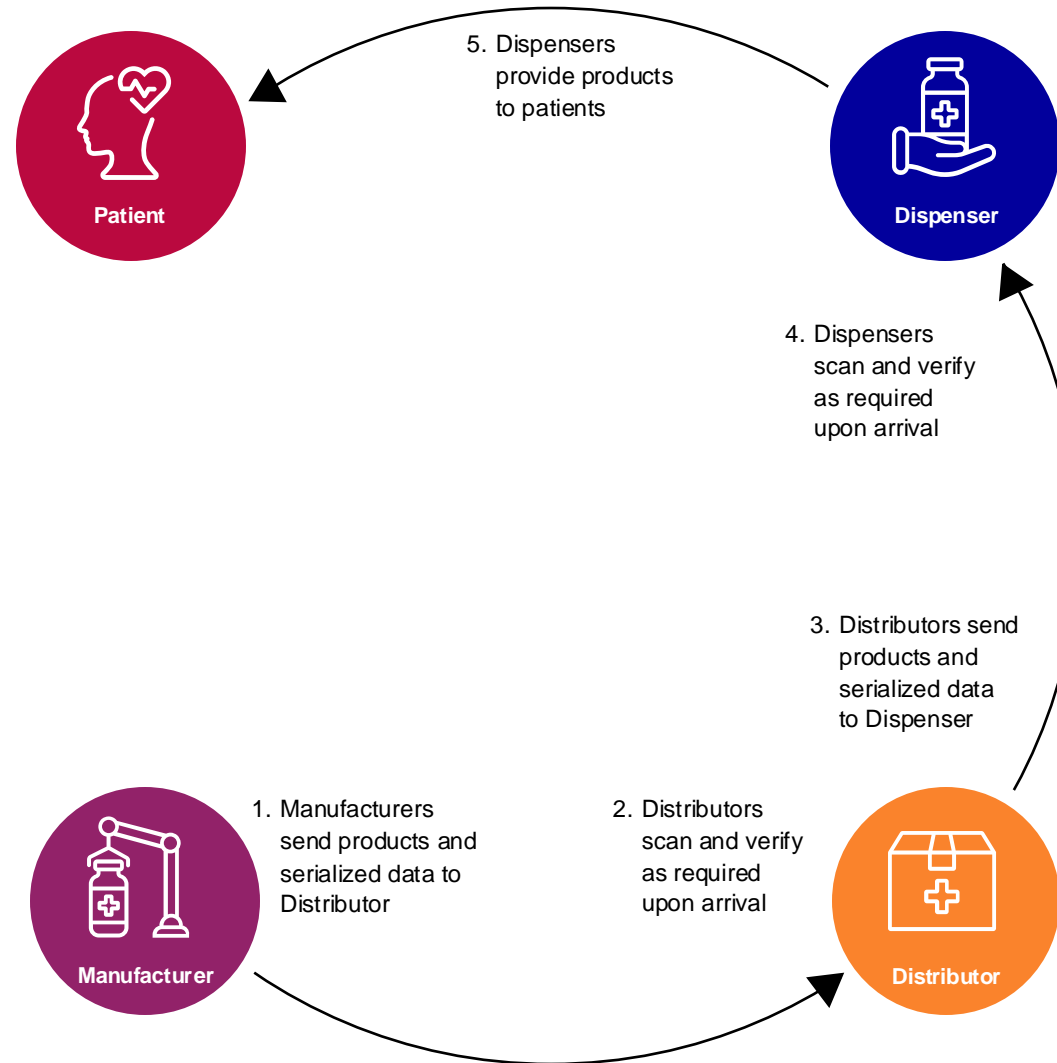
This ecosystem visualizes one way the product and product data moves throughout the supply chain from **Manufacturer** to **Patient** after November 27, 2023.*

Under DSCSA, the prescription drug supply chain is **DECENTRALIZED** – meaning there is no single source of data or truth.

Each trading partner is required to:

- 1) **store** their own serialized data;
- 2) **send and/or receive** serialized data via electronic and interoperable means; and
- 3) **respond** to requests from Federal and State Regulators and trading partners as part of investigations into suspect and illegitimate products.

DSCSA, in effect, allows and requires each trading partner to maintain sovereignty and control over their serialized data.



Today

Several hundred thousand lots
tracked by TI and TH

November 27, 2024

~4.5 Billion Units
Traced by TI



~2 Transactions per
Unit



~8-10 Billion
Transactions



~16-20 Billion
Instances of TI



6 Years of Record Retention



**~100 Billion
Instances of TI**

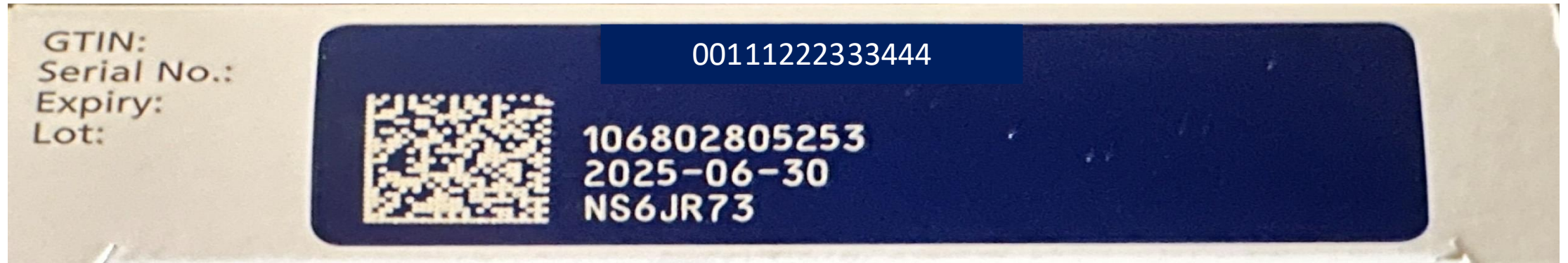


Today

Post-November

*10,000 – 20,000
times as many
DSCSA instances
recorded*

What tools does DSCSA provide to detect counterfeit medications?



Product Verification – A trading partner can verify the authenticity of the product identifiers (GTIN; S/N; Lot Number; Expiration Date) with the manufacturer.

“Manufacturer, did you affix these product identifiers to this package?”

Product Tracing – In the event of suspect, or illegitimate products, Product Tracing requests the prior ownership of the product by collecting transaction information from trading partners.

“Manufacturer, who did you sell this product to?” “Pharmacy, who did you purchase this product from?”



Good morning, Josh Bolin



Product Verification

Verify product authenticity and status

Quickly verify products using serialized identifiers and ensure compliance with DSCSA requirements.

[Open Verification →](#)



 regvrs.pulse.pharmacy



Product Verification Request

Test VRS



GTIN

Enter GTIN or scan barcode



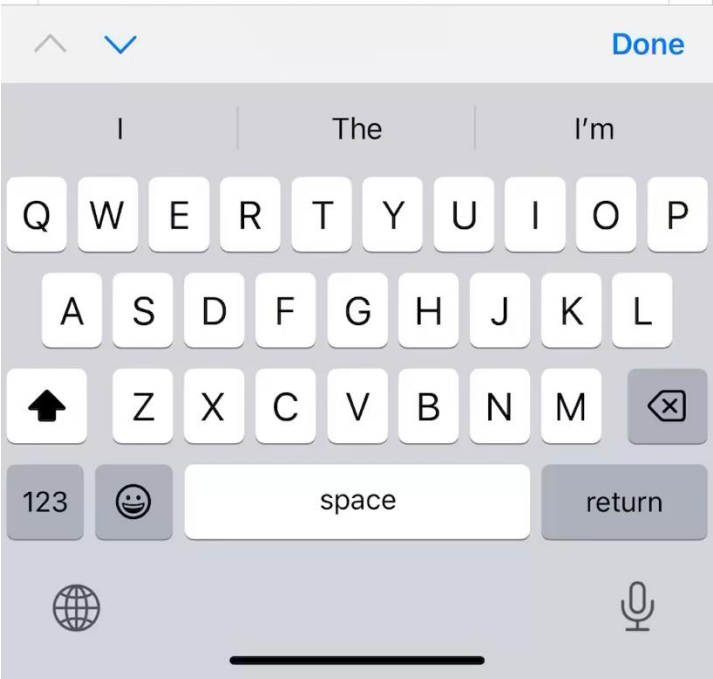
A GTIN is a number that identifies a product in the global marketplace. It's developed by the international organization GS1. It should encode for a 10-digit NDC number XXX1234567890X.

Lot Number

Enter lot number or scan barcode


Serial Number

Enter serial number or scan barcode





Product Verification

Edit Default Settings 

New Verification +

Search verification history...



Switch to desktop view for enhanced filtering and sorting capabilities.

Verified

Feb 18, 2025 16:41:42

GTIN: 00372222998800

Lot: L1

Serial: S1

Exp (YYMMDD): 250505

Context: dscsaStatusCheck

Correlation ID: f56e4928-e38f-4079-ac79-3af31108151d



regvrs.pulse.pharmacy





Dashboard

Product Verification

- Product Tracing

 Notifications

JB **Josh Bolin**
jbolin@nabp.pharmacy

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Product Verification

Edit Default Settings 

New Verification +

Search verification history...

Clear Filters

Clear Selection

Timestamp	GTIN	Lot	Serial	Exp (YYMMDD)	Status
Feb 18, 2025 16:42:07	00372222998800	L1	S2	250505	Not Verified
Feb 18, 2025 16:41:42	00372222998800	L1	S1	250505	Verified

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Product Verification for Regulators using Pulse by NABP

- Initial training in December 2024
- Initial product verification scans on Monday, January 13
- Suspect product, with a high likelihood of illegitimacy, identified with the first scans in State 1.
- Same suspect product found in State 2 the same week
- Week of January 27, different suspect product found in State 1

What is Pulse?

Digital Directory

Pulse establishes trusted and verified relationships throughout the prescription drug supply chain.

- **Enables** secure data exchange
- **Unlocks** engagement and communication
- **Maintains** sovereignty and control

Integration Platform

With trusted and verified relationships established, Pulse securely facilitates DSCSA-related communications across a decentralized supply chain:

- Product Verification
- Product Tracing
- Authorized Trading Partner Status
- Contact Information

Network Reach – 2023 Tracing Pilot Participants

State Regulators	Manufacturer or Repackagers	Distributors	Dispensers	Solution Providers	Trade, Standards, Other Orgs	Service Providers
Tracing Pilot Participants						
<ol style="list-style-type: none"> Alaska Idaho Iowa Kansas Kentucky Maryland Massachusetts North Dakota Ohio Virginia 	<ol style="list-style-type: none"> Bristol Myers Squibb EMD Serono Eli Lilly Genentech Ingenus Pharma J&J Novo Nordisk Pfizer Sanofi 	<ol style="list-style-type: none"> Amerisource Bergen Capital Wholesale Drug Cardinal Health Hercules Pharmaceuticals McKesson Mutual Drug 	<ol style="list-style-type: none"> Condo Pharmacy Intermountain Health Rite Aid Sam's Healthmart Veterans Affairs (VA) Walgreens Thrifty White Indiana University Health 	<ol style="list-style-type: none"> Trust.MED Advasur Axway Birch OS ConsortiEX Gateway Checker LedgerDomain LSPediA Movilitas.Cloud Optel RfXcel/ Antares RxScan SAP Systech Tracelink TrackTrace Rx 		
Observers & Stay Informed						
<ol style="list-style-type: none"> State BOP Executive Officers NABP District 3 NABP District 5 California CA BOP MO BOP 	<ol style="list-style-type: none"> Amgen Apotex Gilead Hikma Novartis Precision Dose Sagent Pharma 	<ol style="list-style-type: none"> ANDA, Inc Medline Industries Morris & Dickson Co Smith Drug Company Premier Rx Wholesale Value Drug Company 	<ol style="list-style-type: none"> Ro CVS Health Mart Pharmacy Mississippi Senior Care Transplant Pharmacy Uptown Pharmacy Walmart 	<ol style="list-style-type: none"> Auto-ID Solutions InfiniTrak Inmar Legisym Spherity Vantage Solutions 	<ol style="list-style-type: none"> APhA AAM GS1 US HDA IEEE NCPA OCI PDG Partnership for Safe Medicines USP 	<ol style="list-style-type: none"> ArentFox BBF Consulting C4SCS DHL Excel Excellis Insolate Murtagh Consulting OFW Law PMC PHT Storemed Vizient

Product Verification & Product Tracing Using Pulse by NABP



Because the US Supply Chain is decentralized, NABP created a mechanism to facilitate communication between regulators and trading partners.


This view visualizes how a product inquiry is made from a **Regulator** or **Dispenser**, and how trading partners can respond to the product inquiry using Pulse.

All services depicted in this map will be free for all participants.

Trading Partners are identified by GLNs

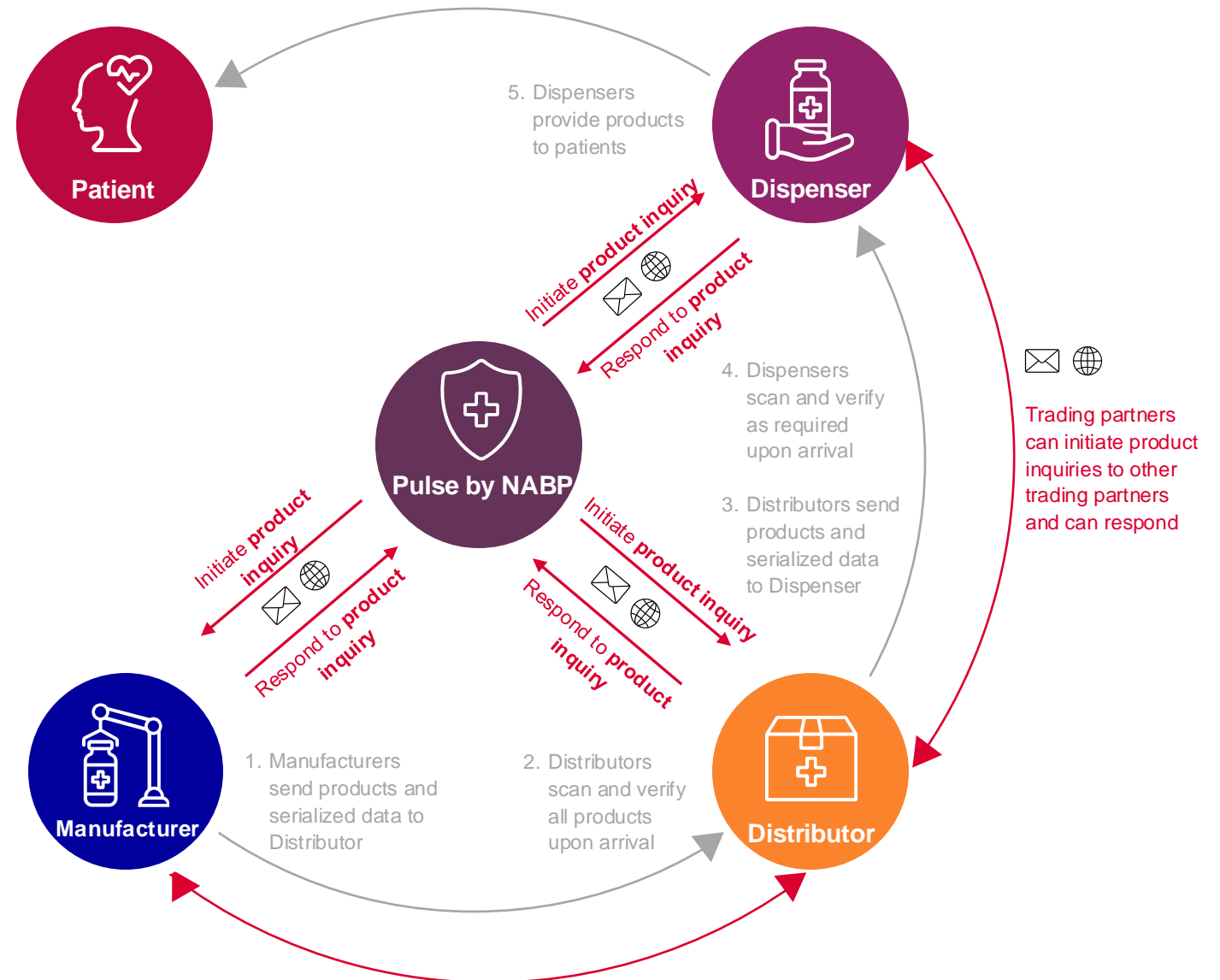
Inquiries are initiated using SGTIN

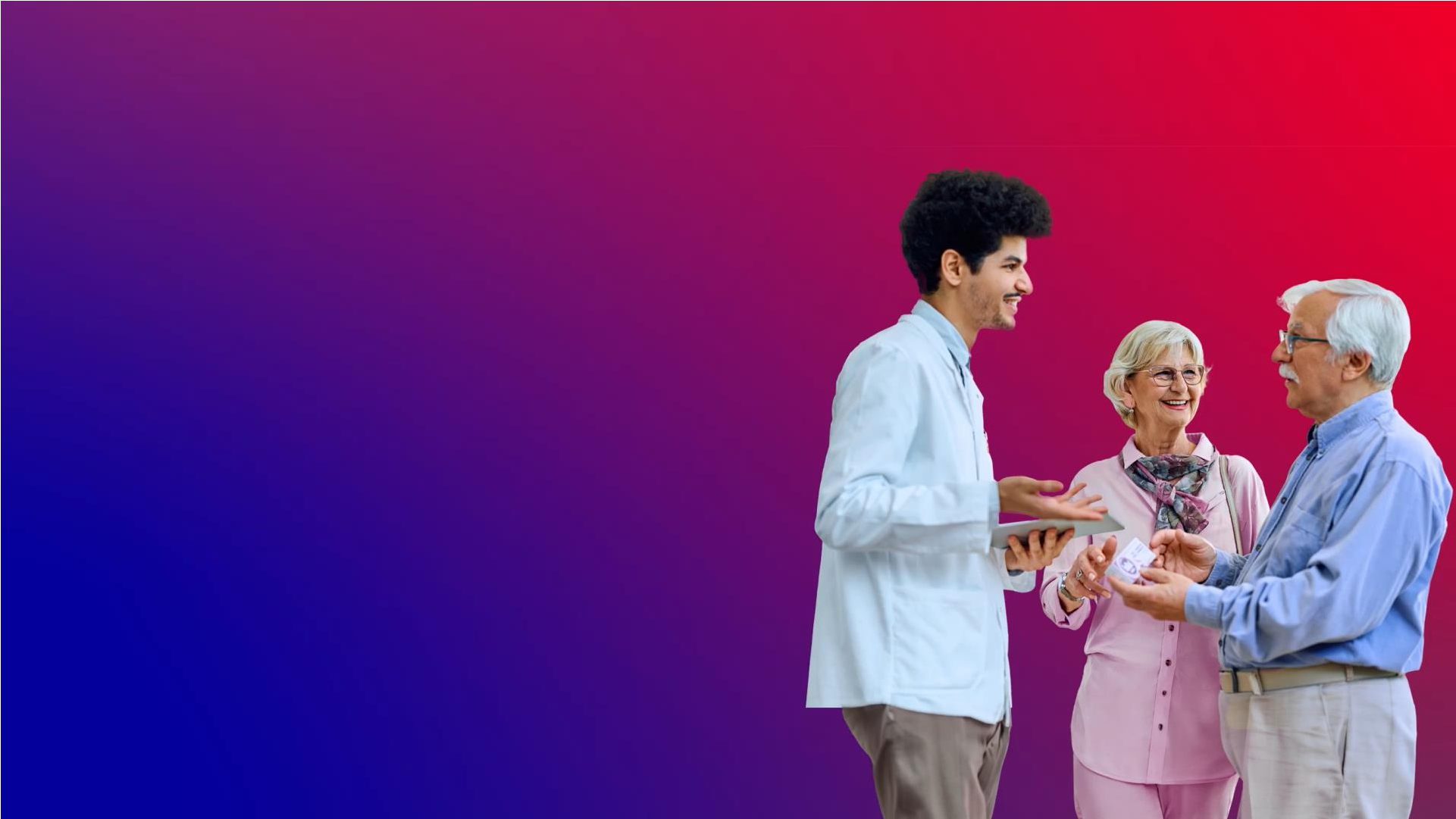
KEY

 Receive email notification from the Pulse by NABP

 Action in Pulse by NABP

Product Inquiry: product verification or product trace request





Tools and Resources

FDA Resources – <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies>

Dispenser Education Web Page – www.dscsa.pharmacy

Dispenser Education Guide – Sign up at <https://pulse.pharmacy/about/sign-up/>

Serial Number Decommissioning Pilot Report – <https://pulse.pharmacy/resources/newsroom/serial-number-decommissioning-pilot-report/>

Prosper Africa Pilot Launch – <https://pulse.pharmacy/resources/newsroom/prosper-africas-tech-for-trade-alliance-announces-a-pharmaceutical-tracing-pilot-in-south-africa/>