



DSCSA Traceability in the U.S.

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abbvie

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We're highly focused, research-oriented and patient-centric.

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In 2018, AbbVie medicines helped



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patients



In more than
175+
countries



Treating over
32+
conditions

What is the DSCSA?

Drug Supply Chain Security Act

The DSCSA was signed into law on November 27, 2013

The DSCSA includes many phases and milestones for the different entities in the supply chain:

- Manufacturer
- Repackager
- Wholesale Distributor
- Dispenser

The DSCSA has a 10 year implementation timeline with full reporting going into effect November 27, 2023

History Prior to 2013

A number of incidents related to counterfeit and/or adulterated medicine triggered concerns over the safety of the U.S. drug supply chain

Individual states, most notably Florida and California, initiated the development of e-Pedigree laws that would require the tracking of the transaction history of drug products in those states

The California e-Pedigree law had a long history:

- Signed into law in 2004, to go into effect in 2007
- In 2006, the effective date was delayed to 2009
- In early 2008 the compliance date was delayed to 2011
- In late 2008 the first phase was moved to January 1, 2015 – this date was final

History Prior to 2013

Individual state laws were a significant concern for the industry

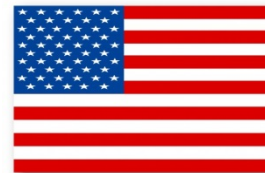
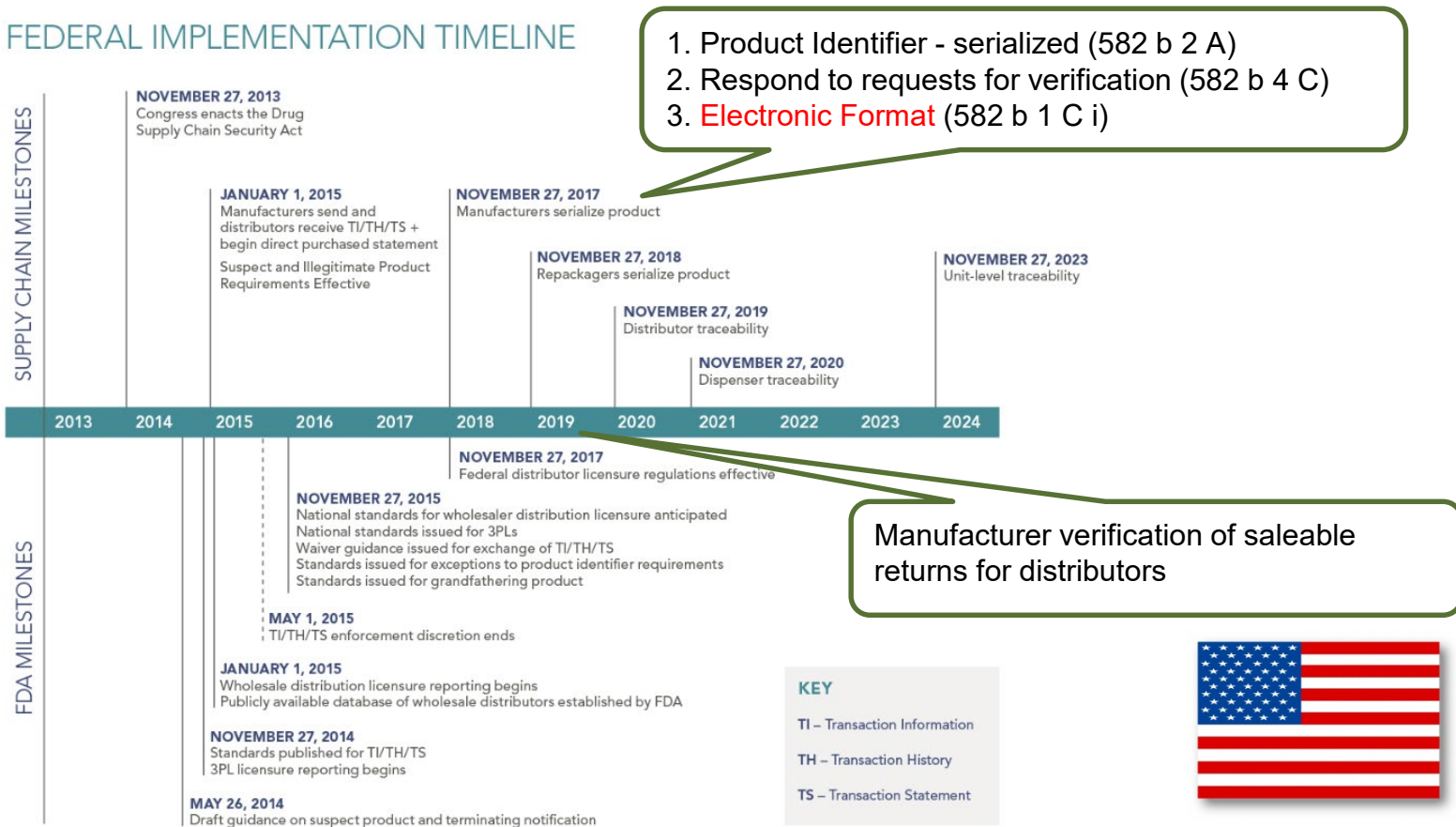
- State laws may not be compatible with each other
- Products were not packaged for individual states

A national law was needed to avoid potential conflicts – and to prevent the California law from effectively becoming a national law

The signing of the DSCSA on November 27, 2013 was a significant relief to the industry

DSCSA Timeline

FEDERAL IMPLEMENTATION TIMELINE



DSCSA Timeline

Date	Key Requirements	Requirement Description
Nov 27, 2013	<ul style="list-style-type: none">• Congress enacts the Drug Supply Chain Security Act	

DSCSA Timeline

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Jan 1, 2015	<ul style="list-style-type: none">• Provide transaction information and statement on packing slips or electronically at lot level• Implement suspect and illegitimate product process	<ul style="list-style-type: none">• Share the “T3” info: Transaction Information, Transaction History and Transaction Statement in paper or electronic format at the batch level of identification (ASN, packing slips)• Manage activities for suspect/illegitimate product assessment and reporting

Transaction Information



abbvie Packing List

Date: 01/26/2015

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581 (26) (I)

581 (26) (G)

ABBVIE US, LLC 1 N WAUKEGAN RD NORTH CHICAGO IL 60064-3500	Ship To: ...	SAP Deliv#: 502044868  EWM Deliv#: 550180 	Shipper DEA: RA0430746
For Customer Service: ABBVIE US LLC NORTH CHICAGO, IL 60064 800-255-5162	Customer No. P.O. Number	Special Ship Instructions:	
Total Pieces Shipped: _____	Route: Z00004 SCAC: CWCE		
	Bill To:		

Packing Slip
Example

581 (26) (J)

581 (26) (F)

Line #	Qty	Unit	Product No.	Batch No.	Product Description	Cust Line#
20	2,400	EA	078040448	1024437	K-TAB 10MEQ, 750MG, 100 FILMTAB TABLETS	
			Replaces Product Number: 0780413			
30	3,840	EA	078040448	1027121	K-TAB 10MEQ, 750MG, 100 FILMTAB TABLETS	
			Replaces Product Number: 0780413			
			ND: 00074780413			

581 (26) (A), (B), (D)

581 (26) (E)

581 (26) (C)

Picked: _____ Checked: _____ Packed: _____ Shipped: _____ Overpack/cases: _____

Warehouse Orders for EWM Del #: 550180

729382

729383

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Transaction Statement

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EWM Del #: 550180

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Seller has complied with each applicable subsection of FDCA 581(27)(A)-(G)

Packing Slip Example

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Nov 27, 2017	<ul style="list-style-type: none">• Product package must be serialized• Transaction info must be provided electronically• Respond to requests for verification	<ul style="list-style-type: none">• Serialization data elements include: Product identifier (GTIN), serial number, lot and expiry• Provide ability to verify product via GTIN, serial number, lot and expiry

Manufacturer Compliance Elements

November 27, 2017

“(A) In general.--Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.

Product identifier (582 b 2 A)

2D Data Matrix

- GTIN
- Serial No.
- Lot No.
- Expiry



Requests for Verification (582 b 4 C)

“(C) Requests for verification.--Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product such person believes to be manufactured by such manufacturer, a manufacturer shall, not later than 24 hours after receiving the request for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the manufacturer. If a manufacturer responding to a request for verification identifies a product identifier that does not correspond to that affixed or imprinted by the manufacturer, the manufacturer shall treat such product as suspect product and conduct an investigation as described in subparagraph (A). If the manufacturer has reason to believe the product is an illegitimate product, the manufacturer shall advise the person making the request of such belief at the time such manufacturer responds to the request for verification.

Manufacturer Compliance Elements

November 27, 2017

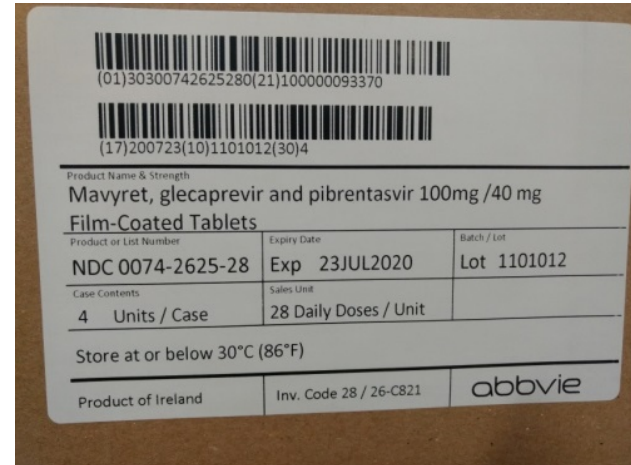
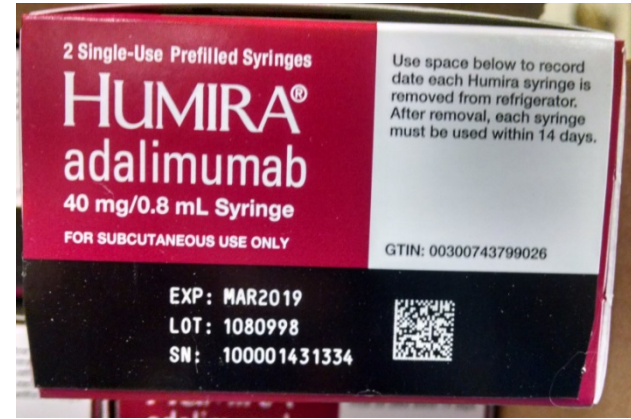
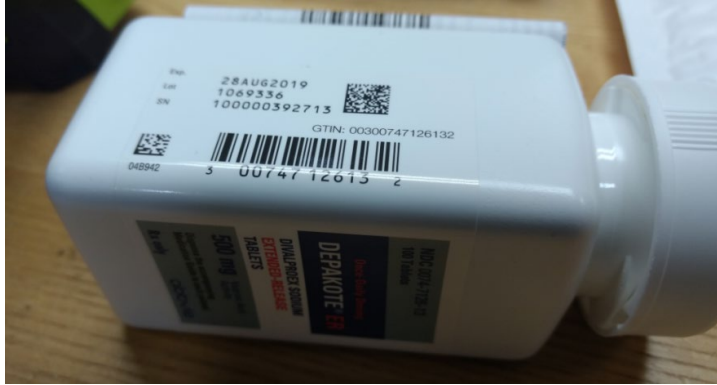
Grandfathering

- Products manufactured prior to 11-27-2017 can be shipped after 11-27-2017* and until their expiration, as “grandfathered” and not subject to 2017 DSCSA serialization regulations.

Manufacturers general requirements

- Serial number (SN) must be affixed to all packages and homogeneous shipping cases*
- All batch level transaction data (TI and TS) must be communicated electronically
- Provide for electronic verification of serial number for suspect product
- Provide electronic verification of SN for any returned product intended to be re-sold*

Serialized Product Examples



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Nov 27, 2017	<ul style="list-style-type: none"> • Product package must be serialized • Transaction info must be provided electronically • Respond to requests for verification 	<ul style="list-style-type: none"> • Serialization data elements include: Product identifier (GTIN), serial number, lot and expiry • Provide ability to verify product via GTIN, serial number, lot and expiry
Nov 27, 2018	<ul style="list-style-type: none"> • Repackagers must serialize product • FDA enforcement relief ends for serialization and verification of saleable returns 	<ul style="list-style-type: none"> • Manufacturers must verify the serial number on returned product prior to distributing the product back into the market

DSCSA Timeline - Upcoming

Date	Key Requirements	Requirement Description
Nov 27, 2019	<ul style="list-style-type: none">Distributor traceability requirementSaleable returns processing and verification	<ul style="list-style-type: none">Can only accept returned product if it can be associated with transaction information and historySerial numbers of returned product must be verified prior to redistributing product into the market
Nov 27, 2020	<ul style="list-style-type: none">A dispenser may only engage in transactions with a product if it is serialized	<ul style="list-style-type: none">Any non-serialized, grandfathered product in the supply chain prior to November 27, 2017 needs to have cleared the system
Nov 27, 2023	<ul style="list-style-type: none">Unit level traceability	<ul style="list-style-type: none">The transaction information must include the serial numbers

Returns – Impact to the Industry

In 2018, the Healthcare Distribution Alliance (HDA) estimated that between 119 and 139 million units are returned to distributors each year

- Approximately 50% of all returns may be redistributed into the market
- Each distribution site on average receives thousands of returned units per day

Distributors want the ability to verify serial numbers immediately to keep product moving



By law, manufacturers have 24 hours to respond to requests for verification

Reporting Regulations

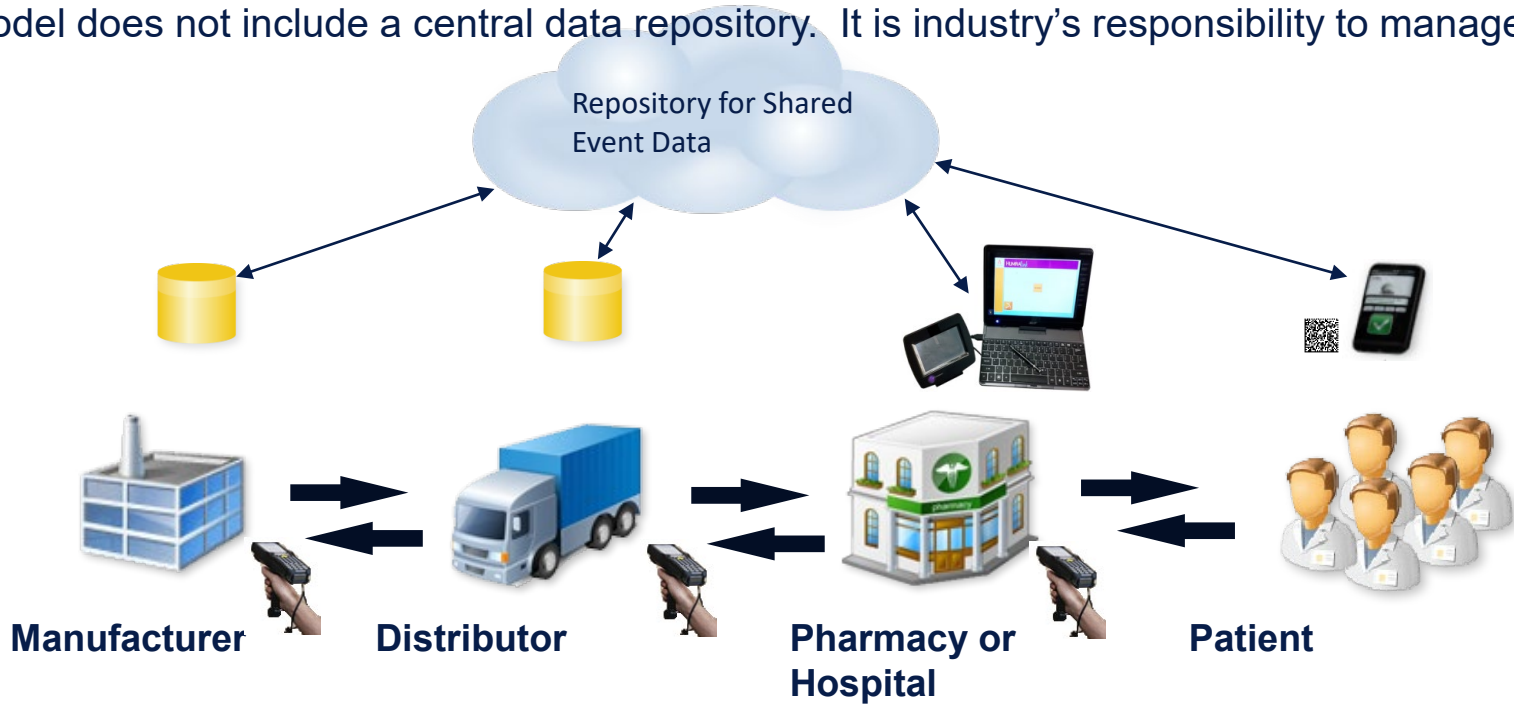
As of November 27, 2023 these are the regulations that go into effect:

- The Transaction Information shall include the product identifier at the package level
- Systems and processes must be in place to:
 - Verify product at the package level
 - Respond promptly with the Transaction Information and Transaction Statement upon request
 - Facilitate gathering of Transaction Information all the way back to the manufacturer
 - Associate saleable returns with the Transaction Information and Transaction Statement for that product
- These regulations are in close alignment with a full Track and Trace reporting model

What's Different?

A typical Track and Trace model includes a central data repository for posting data

The US model does not include a central data repository. It is industry's responsibility to manage this



Repository Governance

The FDA has offered guidance, public hearings and opportunities for pilot efforts

The FDA does not own the data or the final process

Industry groups must identify a common approach and standard

- Without a designated owner or central authority, each segment of the supply chain will represent their own best interests

What's Next?

Efforts to comply with the US DSCSA will continue

Within the next 2 years industry will need to identify a governance model so that:

- A structure can be established for managing the data
- There is time to build systems in advance of November 27, 2023

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