



DSCSA

Pilot Proposal

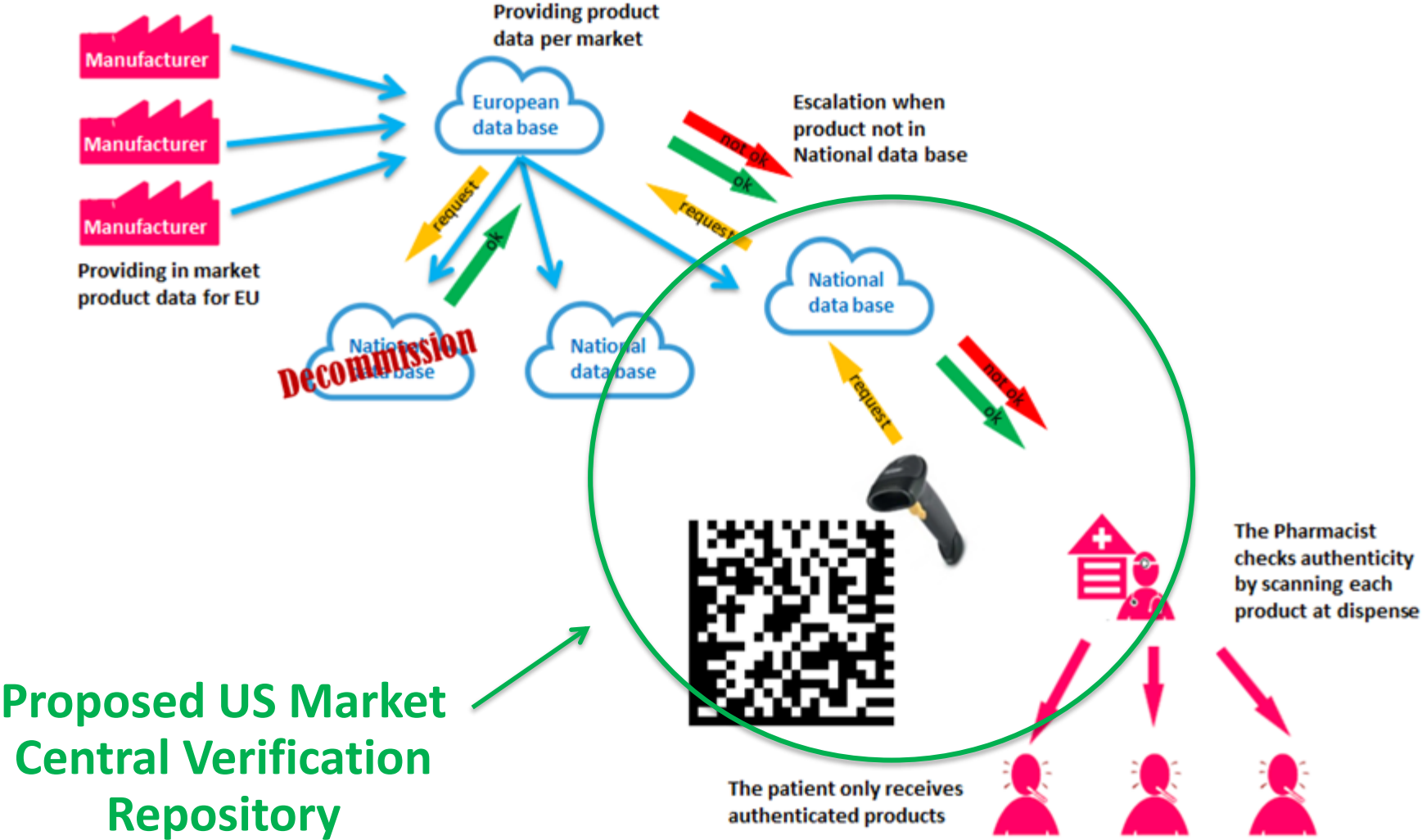
Drug Supply Chain Security Act - Verification Requirements

What is expected of manufacturers?

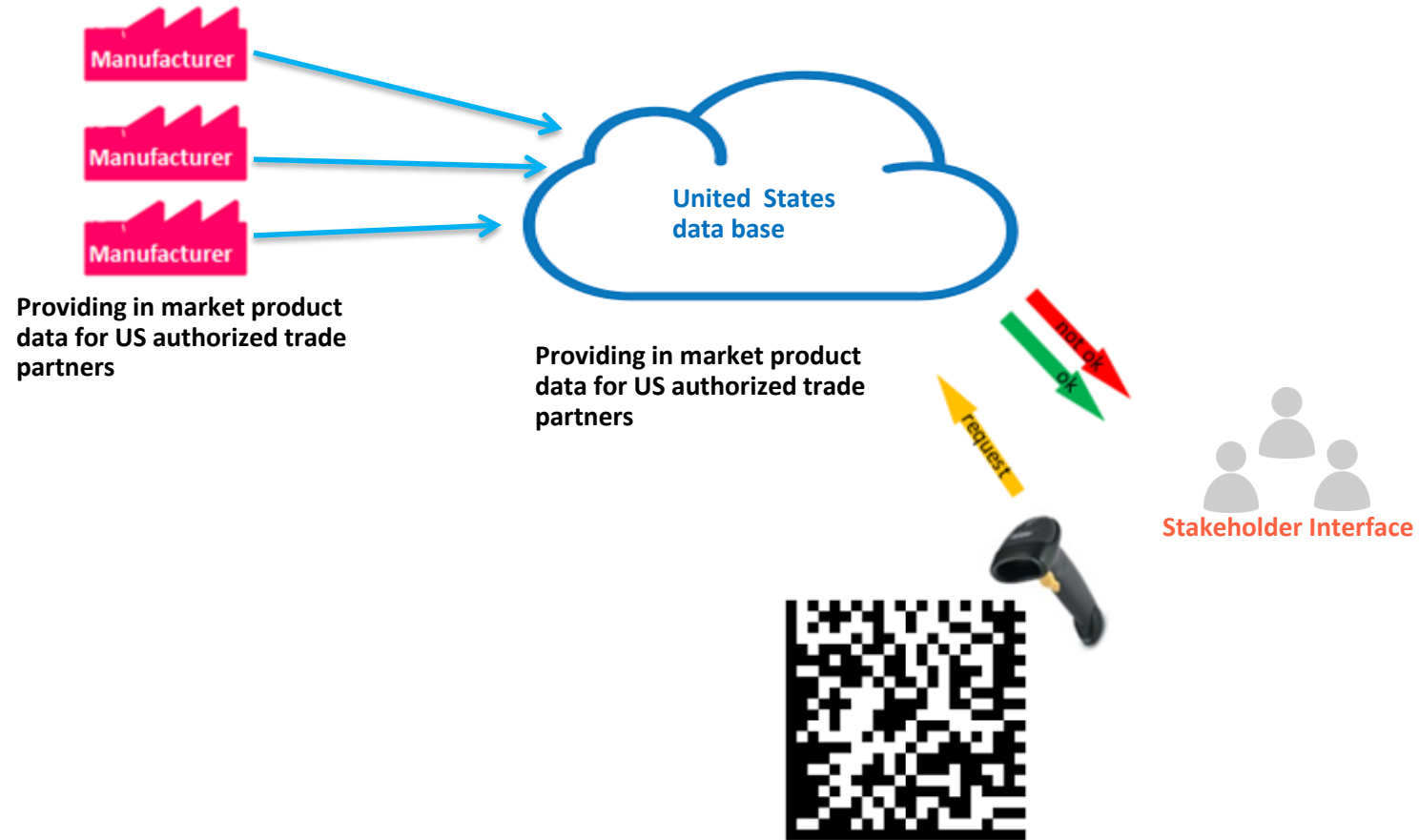
- 2015 – Verification of Suspect or Illegitimate product
- 2017 – Enhanced Verification of product utilizing the unique serialized identifier of the product
- 2019 – Verification of an authorized trade partner's saleable returns
- 2023 – Interoperable systems and processes for verification
- 2023 - Association of transaction to each saleable unit

What can we do now?

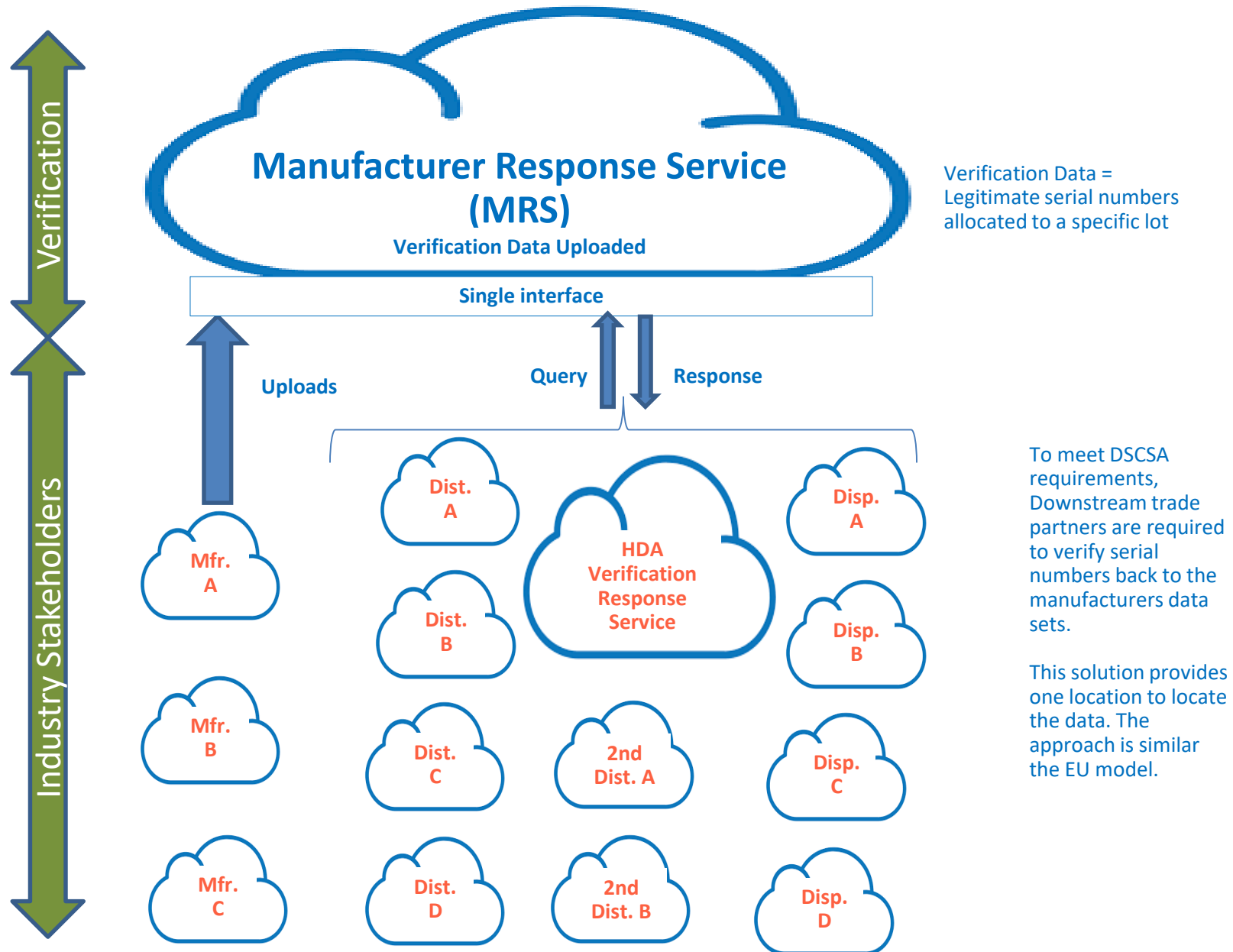
Or Something Similar to the European Database Structure



Similar to the European Database Structure.... Yet Simpler



Proposed US Market Central Repository





Log In

[Sign Up](#)

Welcome !

Log In

[Forgot Password](#)

[Help](#)

Trade Partner Log In

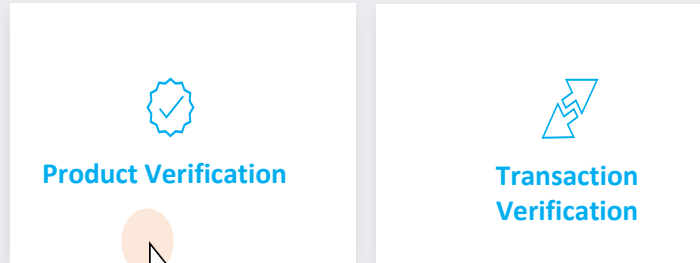
Home

Transaction
verificationProduct
Verification

Help

Distributor A

Logout



Verification Service uses the most recent event to determine if the product is valid

Product Event Disposition	Verification Response
<i>in transit</i>	VALID
active	NOT VALID (StillAtMfr)
in progress	
returned	NOT VALID (Returned)
expired	NOT VALID (Expired)
damaged	NOT VALID (Damaged)
disposed	NOT VALID (Disposed)
recalled	NOT VALID (Recalled)
destroyed	NOT VALID (Destroyed)
stolen	NOT VALID (Stolen)
Anything else	NOT VALID (UnexpectedDisp)

Verification Services

1. Bulk verification



Download Template



Upload Excel File



Download Excel Results

2. Direct connect - Begin scanning

3. User input

GTIN

Serial number

Lot number

Expiry date

Verify

Clear

Results



Download Verify Log



Verify Upload




Delete

Count: 15

	Manufacturer	GTIN	Serial number	Lot number	Expiry	Message
<input type="radio"/>	Company A	09054083013824	100000028296	1084110	06/30/2019	Verified
<input type="radio"/>	Company A	09054083013823	100000028297	1084110	06/30/2019	Not verified
<input type="radio"/>	Company A	09054083013820	100000028296	1084110	06/30/2019	Verified
<input type="radio"/>	Company A	09054083013825	200000028123	2084111	06/30/2019	Verified
<input type="radio"/>	Company A	0905083013827	20000002888	2084111	06/30/2019	Not verified



 Home

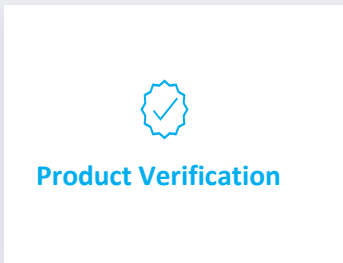
 Transaction verification


 Product Verification

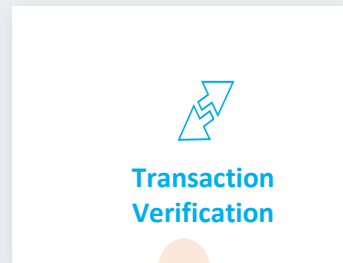
 Help >


 Distributor A

 Logout




Product Verification




Transaction Verification



Transaction Verification

Search

Search

Company, Purchase Order, Sales order, NDC, Lot, etc.

Filters

Ship date from:

MM/DD/YYYY



Ship date to:

MM/DD/YYYY



Search

Clear



Email



Download

Count: 15

	Manufacturer	Outbound delivery number	Sold to	Ship to	Customer purchase order	Ship date
<input type="radio"/>	Mfr. A	4233654789	0050700269	0050493972	2354865565	25/04/2017
<input type="radio"/>	Mfr. A	2333654789	1230700269	0055921233	4554865565	02/04/2017
<input type="radio"/>	Mfr. A	2533654789	50700269	0055803431	7854865565	02/12/2017
<input type="radio"/>	Mfr. A	8733654789	0070026900	0056637706	1234865565	02/04/2017
<input type="radio"/>	Mfr. A	2233654789	0050700269	0050699610	77854865565	12/11/2017

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View All Records

All records will be displayed,
with option to search and filter
results

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA)
TRANSACTION SUMMARY REPORT**

Transaction Verification



Search

Filters

Transaction Information

Seller Name: Mfr. A	Buyer Name: Dist. B
Seller Address: 1401 Sheridan Road, North Chicago, IL-60064, US	Buyer Address: 100 Main Street, Big City, USA
Transaction Date: 10/14/2016	Transaction ID: 0503543206
	Customer PO Number: 3060628

Product NDC: 00074455290	Transaction Line No: 10
Product Name:	
Product Dosage Form: Tablet	
Product Strength: 50 mcg	
Container Size: 1	
GTIN: 00300744552903	Lot Number: 1061101
Number of Containers: 1	Expiration Date: 2017-08-18

<input type="radio"/>	Manufacturer
<input checked="" type="radio"/>	Mfr. A
<input type="radio"/>	Mfr. A
<input type="radio"/>	Mfr. A
<input type="radio"/>	Mfr. A
<input type="radio"/>	Mfr. A

Count: 15

chase	Ship date
565	25/04/2017
565	02/04/2017
565	02/12/2017
565	02/04/2017
565	12/11/2017

Transaction History

Transaction History is Not Applicable to this Transaction

Transaction Statement

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

Next Step – Establish Pilot

Pilot Project Program under the Drug Supply Chain Security Act



Description: The FDA is required to establish one or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. Such projects shall build upon efforts, in existence as of the enactment date of the Drug Supply Chain Security Act (DSCSA) which was on November 27, 2013, to enhance the security of the pharmaceutical distribution supply chain, and consider any pilot projects conducted prior to enactment of the law. The project design will focus on utilizing the product identifier for product tracing; improving the technical capabilities of the supply chain; and identifying the system attributes that are necessary to implement the requirements established under the DSCSA. This project promotes patient safety by enhancing the security of the pharmaceutical distribution supply chain.

Milestone Description	Milestone Date	Milestone Status	Milestone Completion Date
1. Federal Register Notice announcing public workshop	February 2016	Completed	February 2016
2. Public Workshop	April 2016	Completed	April 2016
3. Establish Pilot Project Program	June 2016 <i>(October 2016)</i>	Completed	September 2017
4. Complete Pilot Project Program	September 2017 <i>(January 2018)</i>	Not Yet Started	TBD

We can execute a pilot



Thank You
