Title II – Preparing for the Future

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FDLI DQSA Conference

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LEAVITT PARTNERS

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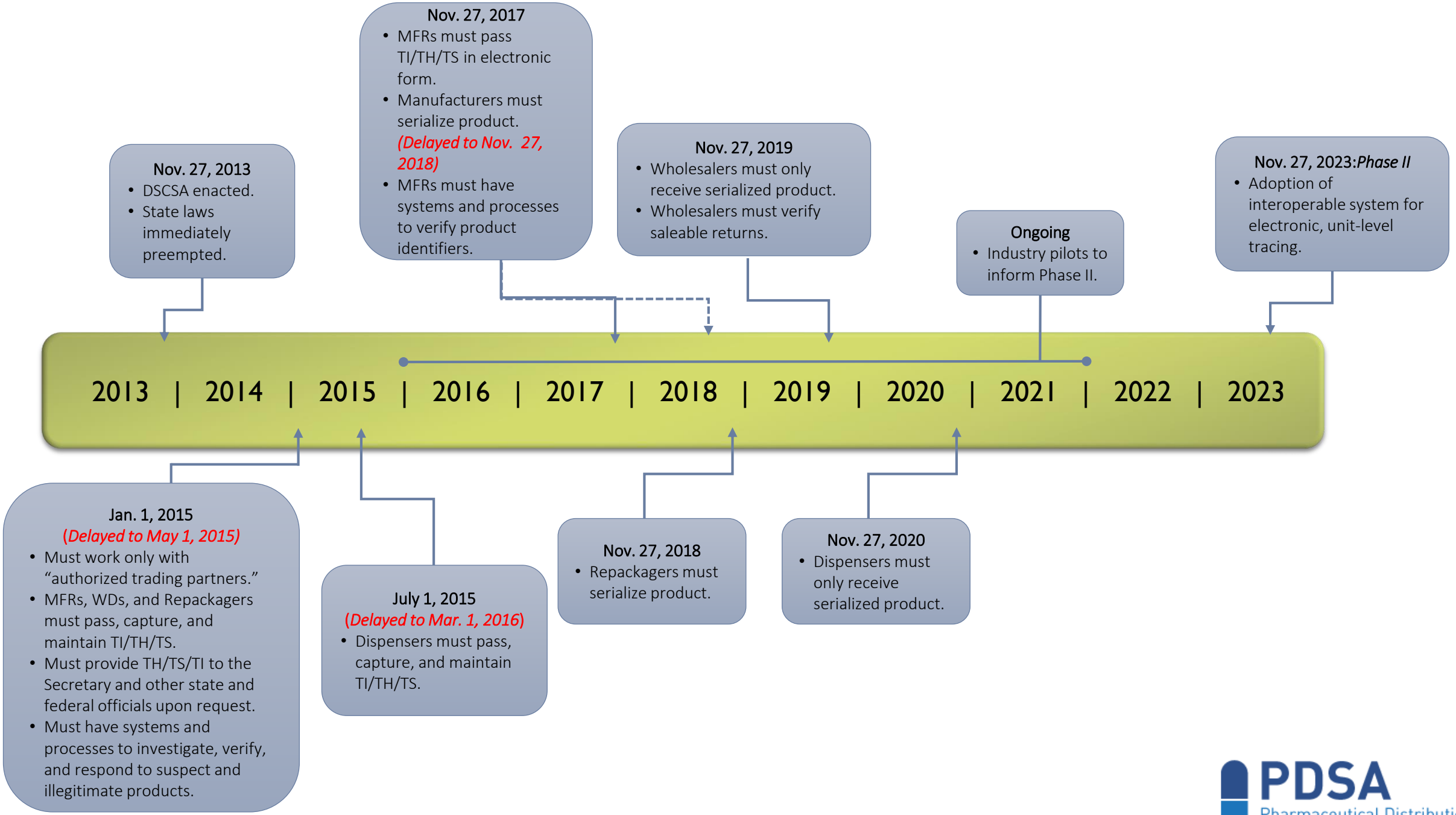


PDSA
Pharmaceutical Distribution Security Alliance

DSCSA: Phase 2 Requirements

Phase 1 . . . 18 Pages

Phase 2 . . . 6 Sentences

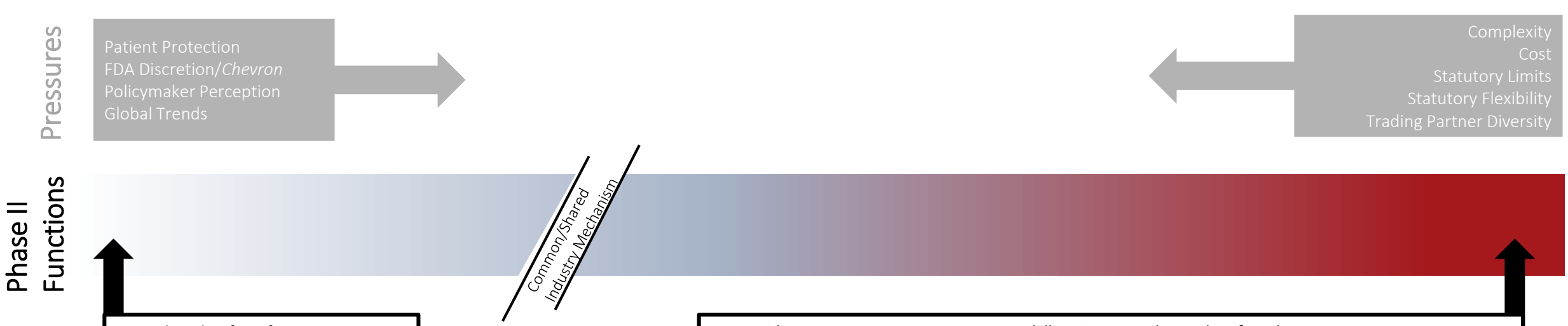
The bill also establishes a collaborative, transparent process between the FDA and stakeholders to study ways to even further secure the drug supply chain through public meetings and pilot projects.

H.R. 3204, 113th Cong., 159 Cong. Reg. 131, at 5962 (statement of Rep. Latta) (2013).

DSCSA: Phase 2 Requirements

1. Secure, electronic, interoperable exchange of TI and TS
2. Secure, electronic, interoperable verification
3. Secure, electronic, interoperable tracing

Features, Properties, and Characteristics of Phase II Systems and Processes



- Multitude of verification approaches
- Provide TI in your possession in response to inquiry
- No interconnected tracing capabilities

- Provides **prompt response** to suspect and illegitimate products when found
- Improves the **efficiency of recalls**
- Provides **transparency** and accountability in the drug supply chain
- Provides **appropriate access** to data necessary for interoperability
- **Secures data and systems** against falsification, malicious attacks, and breaches
- Enables **integration** of any size businesses
- **Fully** electronic and interoperable
- Enables trading partners and **Federal/State officials to access and use data** in the system
- Enables trading partners to capture, maintain, and exchange data **accurately and efficiently**
- Enables trading partners to verify product identifiers accurately and efficiently to **facilitate investigations** of suspect or illegitimate product, recalls, and saleable returns
- **Verifies** that a trading partner is an "authorized" trading partner
- Improves the ability of **FDA and trading partners to prevent** distribution of suspect or illegitimate product
- **Captures** the product identifier of a product for each transaction
- Provides the **status of a product** through the use of the product identifier (e.g., "dispensed" or "expired")
- Creates the **distribution history** of the product
- **Signals** that a product has been determined to be illegitimate (e.g., red flags)
- Enables authorized trading partners to **promptly respond** to a request for product tracing information

See Drug Supply Chain Security Act (DSCSA) Public Meeting Series, Enhanced Drug Distribution Security (February 28, 2018), available at https://www.fda.gov/downloads/Drugs/NewsEvents/UCM602534.pdf

DSCSA Phase 2: Looming Questions

1. Use of traceability for recalls
2. Definition of tracing
3. Alternate methods of compliance
4. Error rates and exception handling
5. Impact of data integrity
6. Response to non-direct trading partners

Questions

Backup Slides

Pharmaceutical Distribution Security Alliance (PDSA)

Membership

For more information about the PDSA, please visit http://pdsaonline.org/ or contact:

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Electronic Interoperable Unit-Level Tracing *(§ 582(g)(1)(A)–(B))*

``(g) Enhanced Drug Distribution Security.--

``(1) In general.--On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

Interoperable Exchange

``(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.

``(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

Electronic Interoperable Unit-Level Tracing *(§ 582(g)(1)(C), (F))*

Interoperable Verification

``(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.

``(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

Electronic Interoperable Unit-Level Tracing *(§ 582(g)(1)(D)–(E))*

Interoperable Tracing

``(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

``(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required--

``(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or

``(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

2019 Wholesale Distributor Requirements and Implications for 2023

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Verification requirements of the DSCSA

DSCSA Requirement:	Stakeholder:	Timing:	Impact Level:
582 (b)(4)(A) ▪ Suspect Product Investigation **582 (b)(4)(C)** ▪ Verification Requests **582 (b)(4)(E)** ▪ Manufacturer Saleable Returns	Manufacturer	▪ 27-Nov-2017 ▪ 27-Nov-2017 ▪ 27-Nov-2017	Low Low-Med Low
582 (e)(4)(A) ▪ Suspect Product Investigation **582 (e)(4)(C)** ▪ Verification Requests **582 (e)(4)(E)** ▪ Manufacturer Saleable Returns	Repackager	▪ 27-Nov-2018 ▪ 27-Nov-2018 ▪ 27-Nov-2018	Low Low Low
582(c)(4)(A) ▪ Suspect Product Investigation **582(c)(4)(D)** ▪ **Distributor Saleable Returns Requirement**	Distributor	▪ 27-Nov-2019 ▪ **27-Nov-2019**	Low **High**
582(d)(4)(A) ▪ Suspect Product Investigation	Dispenser	▪ 27-Nov-2020	Low

* Refer to the DSCSA regulation for all requirements and associated details:
https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm

582(c)(4)(D) and Verification definition

582(c)(4)
“(D) VERIFICATION OF SALEABLE RETURNED PRODUCT.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, upon receipt of a returned product that the wholesale distributor intends to further distribute, before further distributing such product, the wholesale distributor shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.”

521(28)
“(28) VERIFICATION OR VERIFY.—
The term ‘verification’ or ‘verify’ means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case **corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager**, as applicable in accordance with section 582.”

Saleable returns by the numbers

Annual Saleable Returns - Unit Volume:

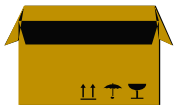
~59 Million Units

2-3% of total sales are saleable returns

Annual Saleable Returns - Return Lines:

~31 Million Lines

Weekly / Daily Breakdown



~1.1 Million Units / Week

~226K Units / Day

Peak # Saleable Returns Units/Day for DC:

4,500 Units

Peak # Saleable Returns Units/Day for Large DC:

10,000 Units

Large Distributor Annual Volume: **~19 million**
Avg. Distributor Annual Volume: **~475 thousand**
Large Generic Manuf. Annual Volume: **~2 million**
Large Branded Manuf. Annual Volume: **~1.8 million**
Average Manuf. Annual Volume: **~90 thousand**

Distributor Landscape**

Companies: 34

Facilities: 203

**Source:
HDA 2016 Factbook

*Data is based on returns processed by participating wholesale distributors November 2014 - October 2015

Saleable returns and the DSCSA

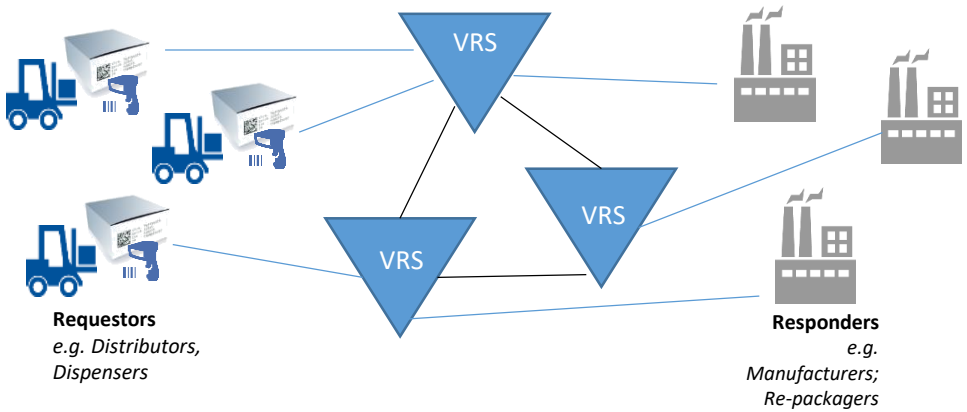
Quality / Compliance	Speed / Time	Cost
Accuracy	Data Access / IT Availability	Physical Space Considerations
Risk / Security	Governance	Solution Complexity / Scalability

Options assessed: 2016 Returns Pilot:

1. **Manufacturer scans PI at time of shipment and sends data to trading partner***
2. Manufacturer sends all PI to all direct trading partners
3. Manufacturer sends PI to central database
4. Distributor scans inbound
5. Distributor scans outbound
6. Distributor point-to-point interface with each Manufacturer
7. Distributor uses Manufacturer-provided portal
8. Distributor contacts Manufacturer (e.g. phone, e-mail)
9. **Router Service**

* most manufacturers / 3PLs are not ready to send PI data before November 2019

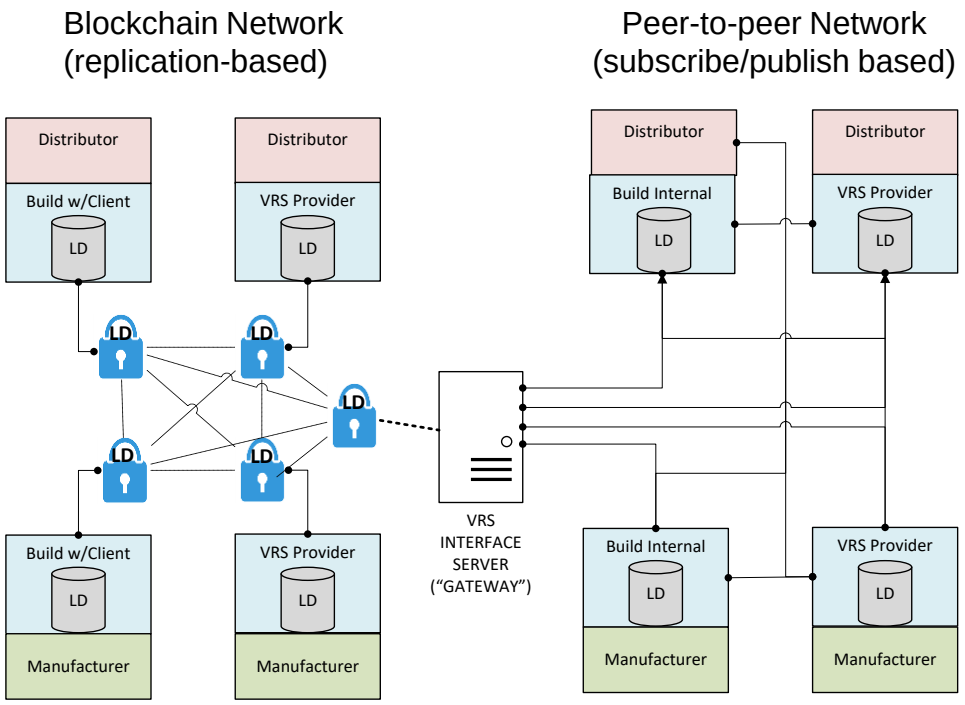
What is the VRS Network?



A network of interoperable solutions used to manage the acceptance, formatting, and delivery of requests and responses in order to support DSCSA verification requirements.

- Accept Product Identifier (PI) information from an authorized Requestor via interface or manual entry using VRS portal
- Determine routing location to where the verification request will be submitted based on the Global Trade Item Number (GTIN) provided by Requestor and master data from Responder
- Format and send the verification request to Responder's system directly or to a VRS used by the Responder
- Obtain the response and format / send or display to requestor
- Provide electronic record / audit trail capability

VRS Network and Interoperable Communication



Ecosystem Realities & Challenges:

- Blockchain and P2P co-existence
- Use of a VRS solution provider vs. DIY

Tailwinds

- Messaging standard

In-Process

- Look-up directory synchronization
- "Gateway" Development

Headwinds

- Security / Authentication Protocol

Verification Router Service Documentation

- Business Requirements Document
- Solution Architecture Reference Document
- Governance Body Charter
- VRS Registry
- VRS Request/Response Messaging Standard (under development at GS1)
- Lookup Directory Specification
- Security and Authentication Document (in progress)

<u>Other materials</u>

- Decision Log
- VRS Connectivity Status Summary
- VRS GTINs and Solution Provider Mapping
- VRS Test Cases and Scripts

Note: this list doesn't include specific solution provider documents, including blockchain synchronization protocol

All documents noted above are publicly available

Challenges to meeting 2019 (…or 2023)

With the VRS

- Bridging two technical options
- Creating guidance for industry so that there is a standard interpretation on how to use specifications and GS1 messaging standard
- Getting solution providers to collaborate and agree to specifications in a timely manner
- Relying on market players to address adherence to specifications and criteria
- Onboarding trading partner and solution providers
- Testing still needs to be done with trading partners, as well as within companies in qualified/validated environments

More broadly:

- Understanding how trading partners plan to comply
- Master data (to be able to read bar codes and receive EPCIS files)
- EPCIS implementation – moving to 1.2 and connections for those sending data

Your Generics & Biosimilars Industry

DSCSA in 2023

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FDLI

Your Generics & Biosimilars Industry

- AAM represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry.
- Our members manufacture more than 90% of all generic pharmaceuticals dispensed in the U.S., and their products are used in more than one billion prescriptions every year.
- AAM's core purpose is to improve the lives of consumers by providing timely access to affordable pharmaceuticals.
- Toward this end, AAM advances the interests of our member companies through initiatives in the scientific, regulatory, federal and state forums, international agencies, and in the public affairs arena.

aam
Association for Accessible Medicines

Your Generics & Biosimilars Industry

What does 2023 look like?

….Depends on who you ask

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Your Generics & Biosimilars Industry

Current Challenges:

- Interoperability with trading partners
- Every company is feeling the pressure
- How do you exchange Master data
- How are data errors handled
- Decommissioning
- Standards for data exchange
- Methods of exchange
- Data integrity
- Difference in Standards
- Reporting Serial Number Status

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2023 End State

- Does industry and FDA coalesce around a system and processes to fulfill 2023 requirements?
- When? Need Time to test, install and improve.

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