DSCSA Update:
End to End Serialization & Traceability
The Risks and Go Forward

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Industry Experience and Expertise

Pharmacy :

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Former Director of Public Policy and Government Affairs for CVS Health

Pharmaceutical/Medical Device :

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US Federal and State Government Affairs

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Supply Chain Policy and Compliance

Large retail public policy issues

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Strategic Business Development

Risk Assessment and Mitigation

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- Diane Darvey – Chris Smith – Steve Perlowski
- Supply Chain Work Group
- DSCSA Regulatory –
- FDA Messaging and Communication
- Policy and Government Affairs – Federal and State

Pharmaceutical Distribution Security Alliance (PDSA)
- DSCSA "Commercial Trade Association"
- Pharmacy Representation
- RxGPS – Global
- Migration and Operational Subcommittee
- Stakeholder Dynamics

Healthcare Distribution Alliance
- Pharmacy Representation
- FDA Messaging and Communication
- State Wholesale Legislation and Regulatory Frameworks

Florida Drug Distribution Wholesale Advisory Board

Overview of the Drug Supply Chain and Security Act:

- Current Status
- Serialization
- Risk
- Global to Local Readiness
- Downstream Readiness
- The Go Forward: Opportunities and Value

Drug Supply Chain Security Act

What is the Drug Supply Chain Security Act (DSCSA) and what is its purpose?

Federal law designed to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States.

The system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain.

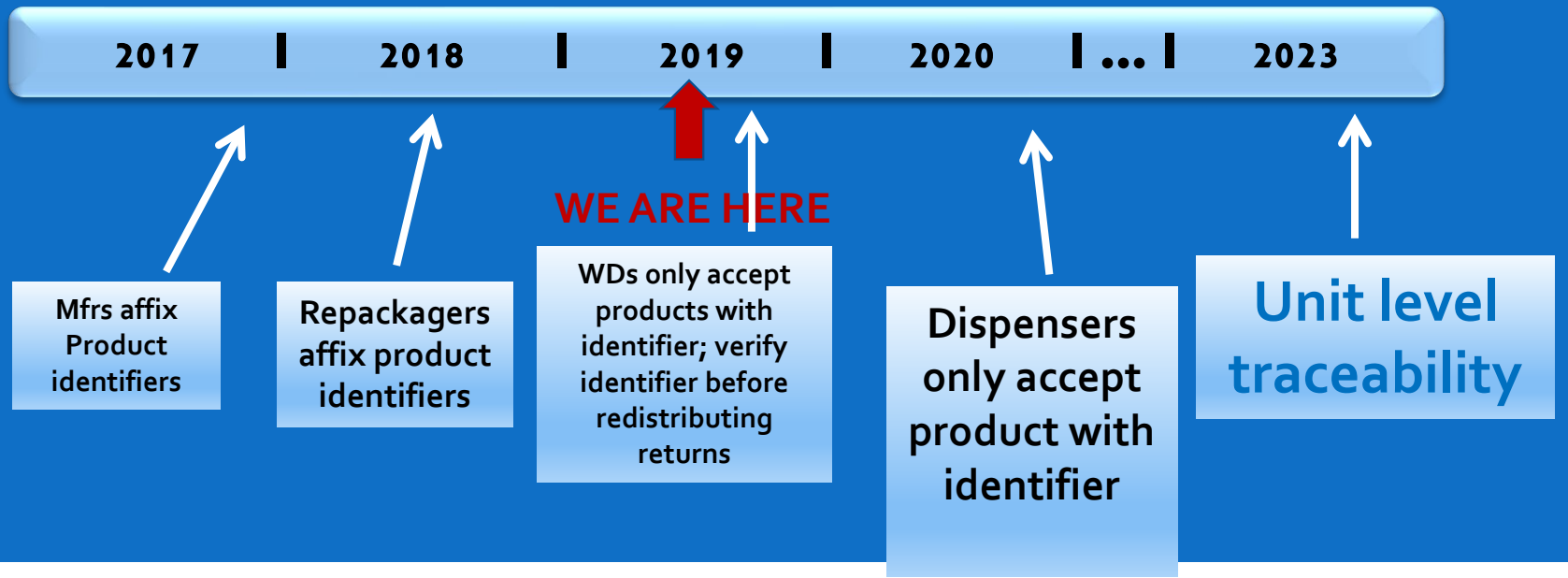
- enables verification of the legitimacy of the drug product identifier down to the package level
- enhances detection and notification of illegitimate products in the drug supply chain
- Facilitates more efficient recalls of drug products.

Requires drug manufacturers, wholesale drug distributors, repackagers, and dispensers (to work in cooperation with FDA to develop the new system over the next 10 years.

COMMERCIAL DRIVEN SOLUTION!

DSCSA Timeline – Traceability Implementation

- **11/27/2017**: Manufacturers affix product identifier to each individual package and homogenous case
- **11/27/2018**: Repackagers affix product identifier to each individual package and homogenous case
- **11/27/2019**: Wholesale distributors must only accept products that contain the required product identifier; and verify product identifier before redistributing returned products
- **11/27/2020**: Dispensers must only accept products that contain the required product identifier
- **2023**: Unit level traceability



Staggered Implementation

Regulatory Guidance and Compliance Requirements for Manufacturers, Wholesalers, and Dispensers

DCSCA: Key Provisions and Compliance Requirements

- Product identification
- Product tracing
- Product verification
- Detection and response – suspect and illegitimate
- Notification
- Wholesaler licensing
- Third-party logistics provider licensing.
- **T3**
  - Transaction Information
  - Transaction Statement
  - Transaction History

DCSCA: Key Provisions and Compliance Requirements

Track & Receive Lot Level Compliance Data

Stakeholders must be able to receive the lot-level Transaction History (TH), Transaction Information (TI), and Transaction Statement (TS) compliance documentation for every product they purchase. **"T3"**

Verify "T3" Compliance Data

Stakeholders verify the "T3" Compliance Data against the product that was shipped to them by their suppliers, and must quarantine any product they determine to be suspect or questionable.

Store "T3" Compliance Data

Stakeholders must store the compliance information associated with every shipment they receive for a period of at least 6 years from the date of shipment receipt.

Retrieve & Respond to Request for Information

If the FDA or similar regulatory body issues a Request for Information (RFI), the stakeholder in question must retrieve specific compliance data within 2 business days.

DCSCA: Key Complexities

- **60% of key components of the law is statutorily ambiguous***
- General requirements – FDA role, Congressional oversight, global influences
- Operational Impacts – "aggregation and inference", error exceptions, communication, bad actors
- Delay in key FDA guidance's
- Interoperability
- Uniformity, pre-emption laws and state regulations
- Stakeholder and partner practices and business resolutions

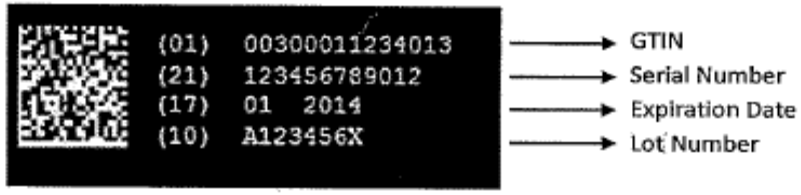
* Assessment from Pharmaceutical Distribution Alliance January 2015

What is Serialization?

- Serialization is one of the first steps toward making every capsule, vial, tablet or strip traceable through the pharmaceutical supply chain
- Manufacturers required to affix 2D Bar Codes – downstream partner prepare to receive 2D bar coded products
- Printing each saleable unit—think carton, tray and individual bottles—and homogeneous shipper (case) with a **unique identifier** (2 Dimensional Bar Code), starting Nov. 27, 2017 – delayed until June 2018.

2D Bar Code and Requirements

- **Product Identifier**: A GS-1-compliant standardized graphic that includes, in both human-readable form and on a machine-readable data carrier:
  - The standardized numerical identifier,
  - Lot number, and
  - Expiration date of the product. *(21 U.S.C. § 360eee(14))*
- **Standardized Numerical Identifier (SNI):** A set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters. *(21 U.S.C. § 360eee(20))*
- **Package:** The smallest individual saleable unit of product for distribution by a Manufacturer or Repackager that is intended by the Manufacturer for ultimate sale to the Dispenser of such product. *(21 U.S.C. § 360eee(11))*



Serialization - Challenges and Risk

Manufacturers are already applying 2D barcodes on Product

- Manufacturers are not communicating product changes
- Unexpected barcodes can stop automated processes
- Not all stakeholders have 2D technology deployed
- New barcodes are being introduced (GS1 RSS Stacked) where there is not enough room
- Linear NDC's are being left off in favor of 2D

Electronic Format - Compliance

- Some suppliers are now providing 3T information through online portals instead of packing slips. There is concern that this may increase.
- Verification by DCs and Pharmacies of 3T information via vendor portals for all incoming product is not operationally feasible
- Poor and inconsistent supplier packing slip data accuracy is also being encountered.

Supply chain organizations and 2023

- How and what structure to build

FDA Enforcement Discretion

Serialization: Granular Business Impacts

From Paper to Digits and Significant Issues:

- Packing slips
- Barcodes
- Drop Ships/340B
- Retail Level– Systems
- Downstream Stakeholders

Risks:

- Delays – Manual fixes and quarantine turnarounds.
- 1D and human readable formats still functional
- Outsourcing data storage to third parties
- Potential delays to dispensing.

What if 90, 95, or even 99% of manufactured product is serialized?

Serialization issues and risk: arithmetic vs. exponential

GS1 Paper:

Assessing Current Implementation of DSCSA Serialization Requirements

2D Bar Code Issues

Colors are a problem

- Some manufacturers are attempting to make the DSCSA Product Identifier barcode blend in with the marketing information on their packages by printing it in the same color.

Placement problems

- Found barcodes that were printed too close together, which makes it hard for workers to read whichever barcode they need to read.
- Found smudging, which I have observed can result from the ablated waste material being redeposited onto the package in the laser ablation process.
- Found some packages where the prescribing information outsert attached to the package was blocking the DSCSA 2D barcode so it was unreadable or difficult to read.

Data content problems

- McKesson found that an additional 8% of the products they analyzed did have an attempt at the DSCSA 2D barcode on them, but these barcodes either did not have all of the mandated data elements present, or the information was encoded incorrectly so it wasn't usable.
- Think of it. Only 6.6% of the products McKesson scanned contained *usable* 2D barcodes, but 8% more contained *unusable* 2D barcodes. That implies that the *majority* of attempts at compliant 2D barcodes *are not actually usable for compliance*.
- If that percentage is maintained as the number of serialized products rises—and there is little reason to believe it won't—this is an indication that we have a serious problem in the industry.

DSCA: Aggregation and Inference - Risks

Error Handling with Aggregation and Inference

- Aggregation is not required by the DSCSA, but the statute contemplates its use once serialization occurs beginning in 2023
  - Trading partners will need to know which unit-level serial numbers are contained in their shipments so they can include in their TIs and to assist with their receiving verification process.
- It is essential to making the DSCSA work
  - Pharmacies cannot scan or read each individual saleable unit to match the physical supply chain with the virtual supply chain
- **Errors will occur particularly with manual packing**
  - **PI in the physical supply chain is not in the virtual supply chain and vice versa**
    - **Operational errors, such as unreadable bar codes**
- **Estimates of 4.5 billion units per year, so even high rates of accuracy will result in a lot of errors**
- Industry is proposing that TS is not a statement of the accuracy of aggregation by manufacturers/wholesalers
  - The commissioned unit-level data from the manufacturer is the source of truth
- Industry proposes that authorized trading partners (ATPs) have controls in place to identify and resolve errors as early as possible, but leave the details up to the individual business
  - Request for FDA guidance to clarify how industry handles errors in inference/aggregation; call to permit stakeholders to resolve errors among themselves and only treat product with such errors as suspect/illegitimate where errors cannot be resolved.

DSCA: Guidance and NDC Issues

Guidance: NDC Operational Issues

- Human-readable portion of the product identifier, we understand that some stakeholders object to using the NDC instead of the GTIN.
- NDC appears somewhere on the package in a human readable format, we can be supportive of the product identifier format recommended in the Draft Guidance.
- FDA's recommendation 2D data matrix barcode be near the human-readable portion of the product identifier on the package..
- Manufacturers and repackagers may want to apply the product identifier to the package level, which corresponds with the package level at which dispensers will ultimately dispense the product.
- Manufacturers and repackagers should not be removing or transacting in drug product without linear barcodes

PDSA/FDA: Guidance and Pharmacy Risks

Draft Guidance - Verification

- FDA suggests that suspect product may be physically quarantined or electronically quarantined.
- However, FDA never defines the term "electronically quarantined."
- Wholesalers and manufacturers may already have their own understanding of what that term means and believe that they have systems to comply with "electronic quarantining," this term is unfamiliar to pharmacies.

Since pharmacies do not have any experience with electronic quarantine, they are reticent to build a system for what they believe is electronic quarantining, only to find out later that that system is not what FDA envisions.

Adding new electronic quarantining functionality will likely require significant resources and time

Global and Individual Company Risks

Global track and trace regulations incorporating the serialization, traceability, and verification of drugs will impact over 75% of the global drug supply by 2019.

Key issues risks:

- **security**
- **liability**
- **privacy**
- **technology standards and solutions**
- legal standards and SOPs
- penalties
- efficiency – "aggregation and inference"
- centralized versus distributed models
- reporting
- third party utilization
- global compliance
- inventory efficiencies

Source: Pharmaceutical Distribution Alliance, TraceLink, Contract Pharma

Global Track and Trace: Compliance and Updates

- **40 popular brand-name drugs sold in the U.S., 70% are imported.**
- **The FDA reports that 40% of finished prescription drugs sold in the U.S. are foreign-made.**

Global Serialization Readiness and Delays

- Structural Legislative and Regulatory Differences
- Hard for governments to create pharma serialization and tracing regulations that are workable
- **U.S.** Enforcement Discretion 2017-2018
- **Brazil** - withdrew their entire regulation, changed their law, and published a more reasonable timeline that would result in full serialization by the end of 2021.
- **China** - withdrew their pharma serialization regulation – delayed
- **Egypt, India and Pakistan** have each pushed back one or more of their pharma barcoding or serialization deadlines.
- **Delays in deadlines and enforcement are not uncommon. But until they are officially announced by a given government, companies should not assume they will be pushed out and should continue**

RISKS: GLOBAL AFFECTS LOCAL

Source: Pharmacychecker.com 2018

Downstream Compliance: Wholesaler

Big 3 - The Wholesaler Portal

- *Nexus of the supply chain; doing yeoman's work, yeoman's responsibility*
- Contrary to popular belief, pharmacies are **NOT** fully compliant with the DSCSA if they are only relying on their primary wholesaler's portal for DSCSA.
- Portal access may feel like a cost-effective compliance approach, but it may introduce staff inefficiencies plus business risk.

Pharmacy Issues/Risks- Portals:

- Guaranteed storage of your data for the required 6 years?
- Guarantees around portal real-time reporting?
- Confidence to access T3 quickly in the event of a suspect product investigation or government inquiry?
- If you resell, borrow or loan drug products to another dispenser, will the wholesale portal provide compliance?
- What happens to T3 if you change wholesalers?
- Drop shipments? How will manufacturers deliver T3 directly to you?

Wholesaler: Product Returns

Wholesalers Accepting Product Returns:

Until Nov. 27, 2019: wholesalers may:

- Accept saleable returns from dispensers per terms and conditions of agreement
- Redistribute such returns without providing prior TH. TH then begins with wholesaler that accepted return

Starting Nov. 27, 2019: wholesalers may accept returns: only if wholesaler can associate the returned product with the TI and TS

OIG Report: Pharmacy Readiness and Compliance Issues

The Office of the Inspector General Report on DSCSA Readiness

Key Takeaway/Risks:
OIG found that selected dispensers are moving toward full implementation of the DSCSA's requirements for the tracing of drug products. **However, some concerns exist about missing information and a lack of awareness of DSCSA requirements.**

Between December 2016 and February 2017 the Health and Human Services OIG interviewed 40 dispensers about their DSCSA readiness:

- OIG requested that dispensers submit examples of drug product tracing information provided by their trading partners
- Only 26 of the dispensers received all required elements of the DSCSA
- Remaining 14 dispensers were missing a few of the required elements
- Two of these dispensers were unaware of the DSCSA and requirements for drug product tracing
- 40 dispensers in this study received drug product tracing information in a variety of transmission modes and formats

Source: OIG Report March 2018 https://oig.hhs.gov/oei/reports/oei-05-16-00550.asp2017 | Confidential & Proprietary

Interoperability and Risk: What is the go forward to 2023?

Interoperability and Unit Level Electronic Traceability Mandate

- Real-Time Trust Information Build
- No one structured and standardized approach
- Multiple stakeholders applications and serialization architecture

Governance – Distributed and/or Centralized Model:

- Cybersecurity
- Liability/reliability
- Data privacy

Can current technology manage the goal of DSCSA 2023?

Governance & PDSA

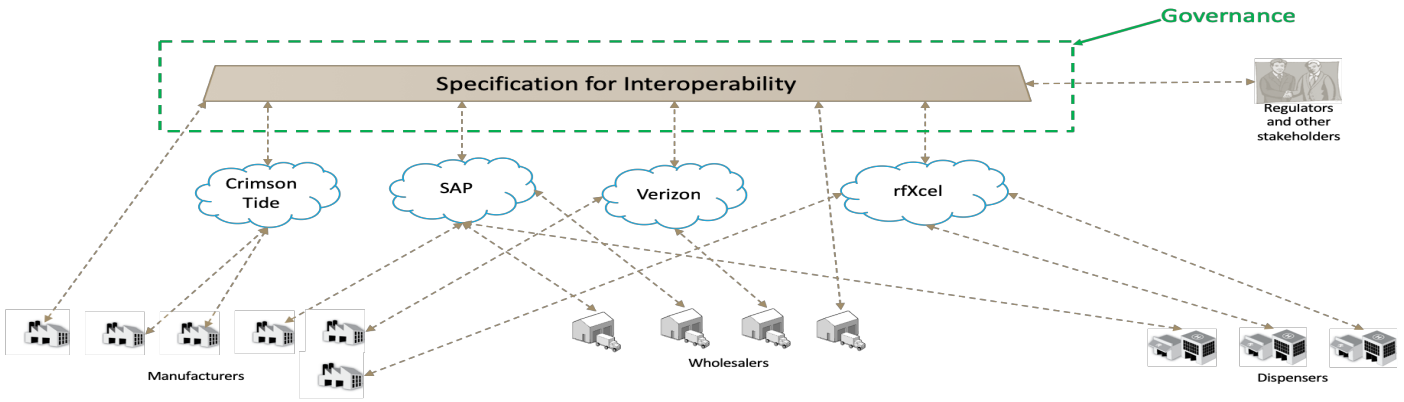
Urgent Need for DSCSA Governance

DSCSA implementation in 2023 may occur in one of three ways:

a. The implementation vision and building blocks may develop unsystematically over the next few years. This is the current process, and it is largely set by the single supply chain sector that happens to be best-organized.

b. A representative group of stakeholders from multiple sectors may organize to define a comprehensive blueprint for the end-state, and this will provide direction for development of the building blocks.

c. The government, suspecting a lack of private-sector will, or desiring to exert its influence, organizes a public-private-sector initiative under its control and direction.



**Not an exclusive illustration of vendors.

PDSA Governance Board

PDSA

- Public Private Partnership
- Dynamics
- Committees – Visioning, Governance
- White Paper

Steps to Governance:

1. Commitment among sector representatives to develop and establish a governance body to undertake the objectives on slide 3, including clear definition of the role of trade associations.
2. Consensus among sector representatives to a governance body structure (*e.g.*, Board structure and membership, rights and responsibilities, voting structure), including a transition plan that allows maximum input from all companies members under a flexible structure until a more formal (*i.e.*, 501(c) with definitive voting rights, etc.) is necessary.
3. Addition of technical advisory expertise (LP commitment to add technical expertise, such as a subcontractor).
4. Execution of objectives, beginning with blueprint development.

Pharmacy Need to Engage in Scope and Scale

DSCA 2023: Is Blockchain a Solution?

"The reason blockchain technology could be a DSCSA game changer is that each validated transaction creates a block that attaches to the chain of blocks before it, thereby creating an easy-to-follow trail."

Blockchain is not a central repository and works with any format of information

- it would not allow drugs into the system that did not come from the originating manufacturer.
- it is this data integrity that generates trust—an important element in the chain of custody."

There are many issues slowing blockchain momentum:

- **Stakeholder ecosystem**
- **Individual versus collective compliance**
- **Government role**
- **Investment requirements**
- **Time to transition**
- **Learnings from start-ups, think tanks, consulting groups, and studies**
- **Multiple groups (at least 9 identified) trying to create standards**
- **SAP has launched a supply chain tracking service based on blockchain**

Digitized World: IT and Reality

Supply Chain Expectations

- Need the ability to respond more quickly than ever while maintaining accuracy and integrity.
- Expected to be data driven and demand aware
- Must have access to and the ability to analyze disparate data sources in the time frames required
- Profound implications for business-to-business (B2B) processes and their underpinning technology
- Resilient in the face of external forces such as weather, war, workers, and regulation.

Digitized World: IT and Reality

"The reality is that leading companies are moving quickly and laggards may soon find themselves uncompetitive"

Compliance vs. ROI and Value:

How do you ensure DSCSA compliance AND maximize the value of your serialization investment?

Digitized World: Use Case for Inventory Management

What are We trying to Solve?

Create DSCSA Compliance Value

Potential value-based and revenue-generating benefits of track and trace:

- Enable target recall to reduce cost, lost sales, and time
- Eliminate duplicate return reimbursement
- Prevent counterfeit and fraudulent product returns
- Eliminate duplicate chargebacks
- Reduce cost related to investigating discrepancies in chargeback requests
- Improve inventory accuracy
- Improve inventory visibility, thus positioning and control of channel inventory
- More accurate order fulfillment and shipping
- Improve expiry management
- Prevent waste to revert to supply chain
- Improve warehouse performance analysis
- Improve production failure analysis
- Improve procurement and invoicing automation
- Enable patient-centric engagements (e.g. e-leaflets and target information)
- Improve demand forecast
- Enable track-and-trace as value-added service for customers
- Ability to conduct inventory at the bottle level for internal shrink issues

Q&A

Thank you!

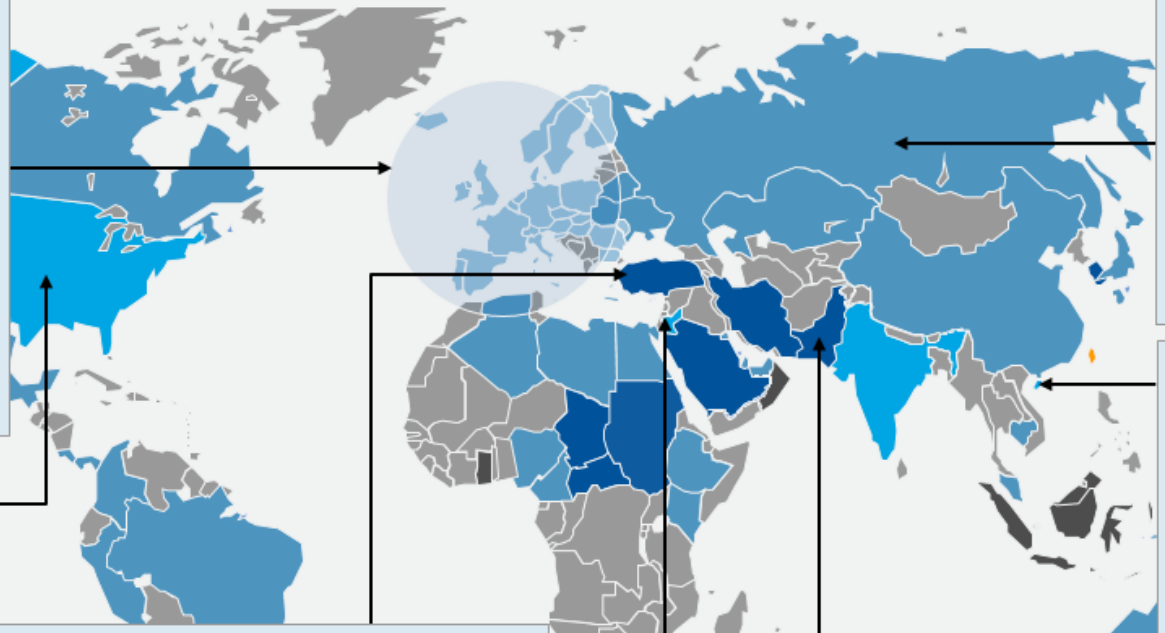
Addendum

Transaction Information

Transaction Information (TI):

- the proprietary or established name or names of the product;
- the strength and dosage form of the product;
- the National Drug Code number of the product;
- the container size;
- the number of containers;
- the lot number of the product;
- the date of the transaction;
- the date of the shipment, if more than 24 hours after the date of the transaction;
- the business name and address of the person from whom ownership is being transferred; and
- the business name and address of the person to whom ownership is being transferred.

Global Planner: Track-and-Trace, Serialization and Product Authentication Compliance Requirements



European Union, including U.K., Iceland, Norway and Switzerland

Unique identification through the use of the 2D data-matrix bar code is a mandatory requirement Feb. 2019

Product authentication required at point of dispensation (pharmacy/pharmacist/retail pharmacist); tmper evidence requirements at secondary pack level mandatory Feb. 2019

Primary stakeholders are manufacturing licence holders, contract manufacturers (CMOs) and pharmacists

Wholesalers have partial risk-based verification responsibility

European Medicines Verification Organization (EMVO) negotiation, agreement and preselection of partners and providers for governance and IT systems of national medicine verification systems; tiers of certification and qualification

U.S (FDA DSCSA) 2013

Manufacturer product identifier enforcement postponed from 27 Nov. 2017 to 26 Nov. 2018.

Aggregation

Interoperable track-and-trace system model + aggregation

Repackager mandates serialization deadline Nov. 2018

Reporting mandates for wholesalers and 3PLSs —serialization deadline Nov 2019

Dispensers serialization deadline 2020

Draft guidance document — 2017 identification of trading partners

Drug-tracing pilots and systems of interoperability consultation period late 2017 to 2018 — Deployment deadline 2023

Egypt

Ministry of Health & Population Decree No. 29/2016

GS1 standards GTIN and GLN

Comprehensive requirements

Two planned phases across 2017, 2018 and 2019:

Phase 1: Printing the 2D bar code and serialization

Phase 2: Aggregate data phase (third level of packaging)

Full track-and-trace model — manufacturers, wholesalers, DCs, importers and pharmacies

Specific June 2018 (updated from 2016) compliance dates set for manufacturers , distributors, wholesalers and pharmacies

Jordan

JFDA and Jordan Ministry of Health, in conjunction with GS1

Unit-level 2D Data, 2D data matrix serialization by 2017

Joint collaboration and possible convergence with Saudi (SFDA) regulations and GCC states

Migration period in force now prior to July 2018

July 1, 2018: GS1 data matrix with GTIN, lot and expiry-date-printed secondary package

January 1, 2020: GS1 Data Matrix with GTIN, lot, expiry date and serial-number-printed secondary package

Russia, Russian Ministry of Healthcare & Association of International Pharmaceutical Manufacturers (AIPM)

Draft law signed 28 Dec.2017

2D data matrix code on secondary packaging

Phased track-and-trace system to 2020

High priority medicines — seven therapy areas Jan. 2018: essential drug list medicines

Jan. 2019: remaining medicines registration

T&T system and barcoding pilots in 2017 — reporting in 2018

Taiwan

Taiwan Food and Drug Administration

GGTIN batch/lot number and expiration date

QR codes mandatory on packaging for patient adherence June 2016

2D data matrix secondary and tertiary packaging

2018 batch code requirement

2019 secondary and tertiary packaging

2020/2021: serialization and traceability platform

Pakistan

Drug Regulatory Authority of Pakistan (DRAP)

All registered drugs manufactured after 15 December 2017 emboss 2D barcode data matrix on the packaging

GS1 (GTIN) expiry date, batch number and price on the secondary packaging

MAH maintain database and report to Drug Regulatory Information System (DRIS)

Further requirements planned

KEY

- Operational legislation and mandates before 2017
- Legislation being planned or drafted
- Phased mandates: Product authentication model
- Pilots: Product authentication
- No legislation/data points
- Developing and phased (ongoing) mandates

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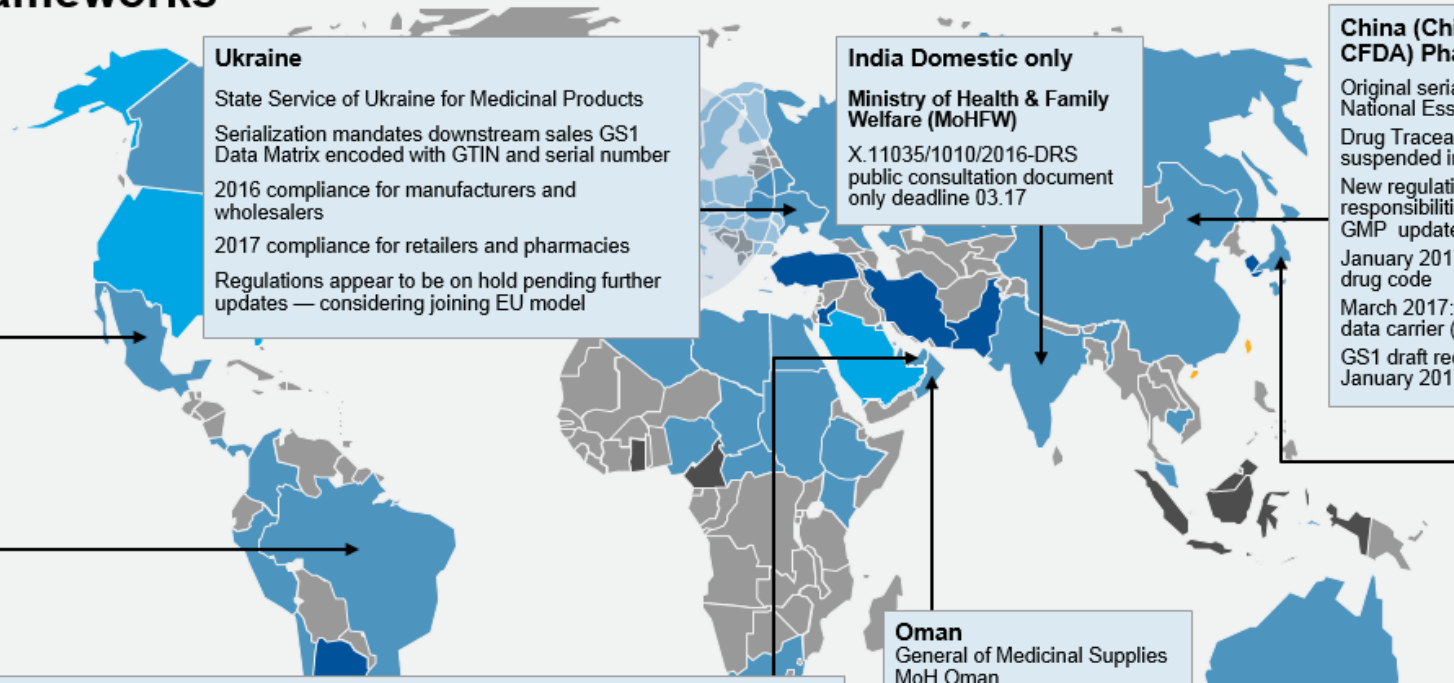
Global Planner: Planned or Draft Legislation — Serialization, Track-and-Trace and Product Authentication Frameworks



Mexico

General law of health

Draft regulations 2018

Centralized database proposed

Secondary packaging serialization

2D Data matrix SGTIN, expiry, lot, serial number

Brazil (ANVISA RDC54/2013)

Unique tracking code for primary and secondary packaging

New 2016 draft proposes simplification of previous operating model — retains three batch pilot for manufacturers

Across 2017 Final Publication of revised and updated law and new pilots (three lots) Dec 2017

Expected compliance dates due in April 2018 and 2021

New Cross industry pilots + database underway in May 2018

Ukraine

State Service of Ukraine for Medicinal Products

Serialization mandates downstream sales GS1 Data Matrix encoded with GTIN and serial number

2016 compliance for manufacturers and wholesalers

2017 compliance for retailers and pharmacies

Regulations appear to be on hold pending further updates — considering joining EU model

India Domestic only

Ministry of Health & Family Welfare (MoHFW)

X.11035/1010/2016-DRS public consultation document only deadline 03.17

China (China Food and Drug Administration CFDA) Pharmaceuticals

Original serialization and reporting of all products on National Essential Drugs List Dec. 2015

Drug Traceability Platform operations partially suspended in 2016

New regulations expected based on more distributed responsibilities –migration from monitoring platforms — GMP updates Jul 2016 from CFDA

January 2017 CFDA notice advises a standard 14-digit drug code

March 2017: CFDA notice advises linear, 2D, or RFID data carrier (non-GS1 standard)

GS1 draft recommendations and proposals January 2017

Japan

Ministry of Health, Labour and Welfare guidelines for bar codes in 2021

GS1 Data bar data carrier GTIN, expiry and lot

Special considerations for biologics products

United Arab Emirates (UAE)

UAE Ministry of Health /Dubai Health Authority (DHA)

GS1 2D Data Matrix encoded with GTIN, expiry date, batch/lot

Point-of-sale, human-readable output on 2D data matrix (GTIN, expiry date, batch/lot)

Traceability network scoping and possible regional collaboration; Cooperation Council for the Arab States of the Gulf (GCC)

Technology pilots being considered — GS1 UEA portal for master data

Oman

General of Medicinal Supplies MoH Oman

GS1 data matrix

Coding and serialization proposals

Possible collaborative regulatory frameworks with Jordan and GCC states

GTIN, batch, lot, expiry

Possible 2018 deadlines

Australia

Existing blood product traceability requirements. New requirements published in 2016 Standard for labels of prescription and related medicines

Possible serialization mandates

KEY

- Operational legislation and mandates before 2017
- Phased mandates — track-and-trace model
- Phased mandates: Product authentication model
- Pilots: Product authentication
- No legislation/data points
- Legislation being planned or drafted

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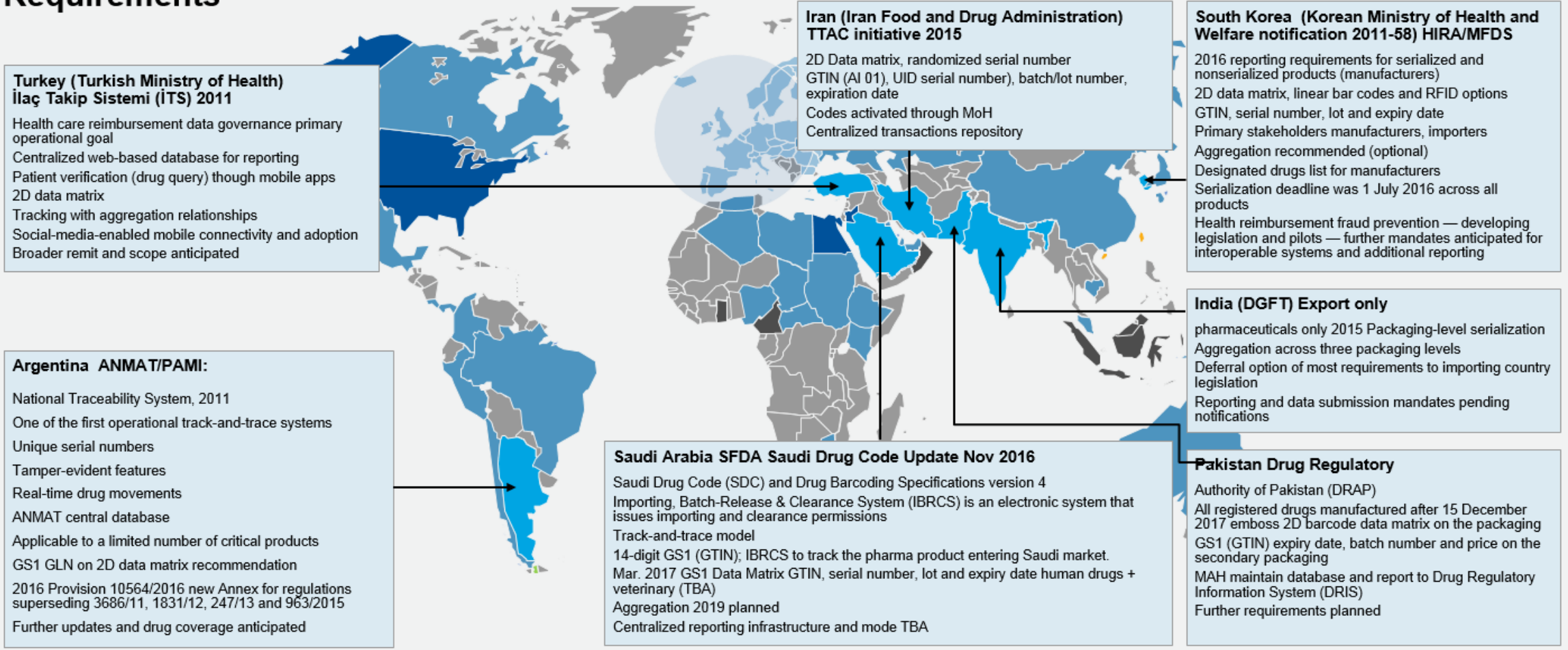
Global Planner: Operational Legislation — Serialization and Track-and-Trace Compliance Requirements



Turkey (Turkish Ministry of Health) İlaç Takip Sistemi (İTS) 2011

Health care reimbursement data governance primary operational goal
Centralized web-based database for reporting
Patient verification (drug query) though mobile apps
2D data matrix
Tracking with aggregation relationships
Social-media-enabled mobile connectivity and adoption
Broader remit and scope anticipated

Iran (Iran Food and Drug Administration) TTAC initiative 2015

2D Data matrix, randomized serial number
GTIN (AI 01), UID serial number), batch/lot number, expiration date
Codes activated through MoH
Centralized transactions repository

South Korea (Korean Ministry of Health and Welfare notification 2011-58) HIRA/MFDS

2016 reporting requirements for serialized and nonserialized products (manufacturers)
2D data matrix, linear bar codes and RFID options
GTIN, serial number, lot and expiry date
Primary stakeholders manufacturers, importers
Aggregation recommended (optional)
Designated drugs list for manufacturers
Serialization deadline was 1 July 2016 across all products
Health reimbursement fraud prevention — developing legislation and pilots — further mandates anticipated for interoperable systems and additional reporting

India (DGFT) Export only

pharmaceuticals only 2015 Packaging-level serialization
Aggregation across three packaging levels
Deferral option of most requirements to importing country legislation
Reporting and data submission mandates pending notifications

Argentina ANMAT/PAMI:

National Traceability System, 2011
One of the first operational track-and-trace systems
Unique serial numbers
Tamper-evident features
Real-time drug movements
ANMAT central database
Applicable to a limited number of critical products
GS1 GLN on 2D data matrix recommendation
2016 Provision 10564/2016 new Annex for regulations superseding 3686/11, 1831/12, 247/13 and 963/2015
Further updates and drug coverage anticipated

Saudi Arabia SFDA Saudi Drug Code Update Nov 2016

Saudi Drug Code (SDC) and Drug Barcoding Specifications version 4
Importing, Batch-Release & Clearance System (IBRCS) is an electronic system that issues importing and clearance permissions
Track-and-trace model
14-digit GS1 (GTIN); IBRCS to track the pharma product entering Saudi market.
Mar. 2017 GS1 Data Matrix GTIN, serial number, lot and expiry date human drugs + veterinary (TBA)
Aggregation 2019 planned
Centralized reporting infrastructure and mode TBA

Pakistan Drug Regulatory

Authority of Pakistan (DRAP)
All registered drugs manufactured after 15 December 2017 emboss 2D barcode data matrix on the packaging
GS1 (GTIN) expiry date, batch number and price on the secondary packaging
MAH maintain database and report to Drug Regulatory Information System (DRIS)
Further requirements planned

KEY

- Phased mandates — track-and-trace model
- Legislation being planned or drafted
- Phased mandates: Product authentication model
- Pilots: Product authentication
- No legislation or no planning
- Operational legislation and mandates before 2018

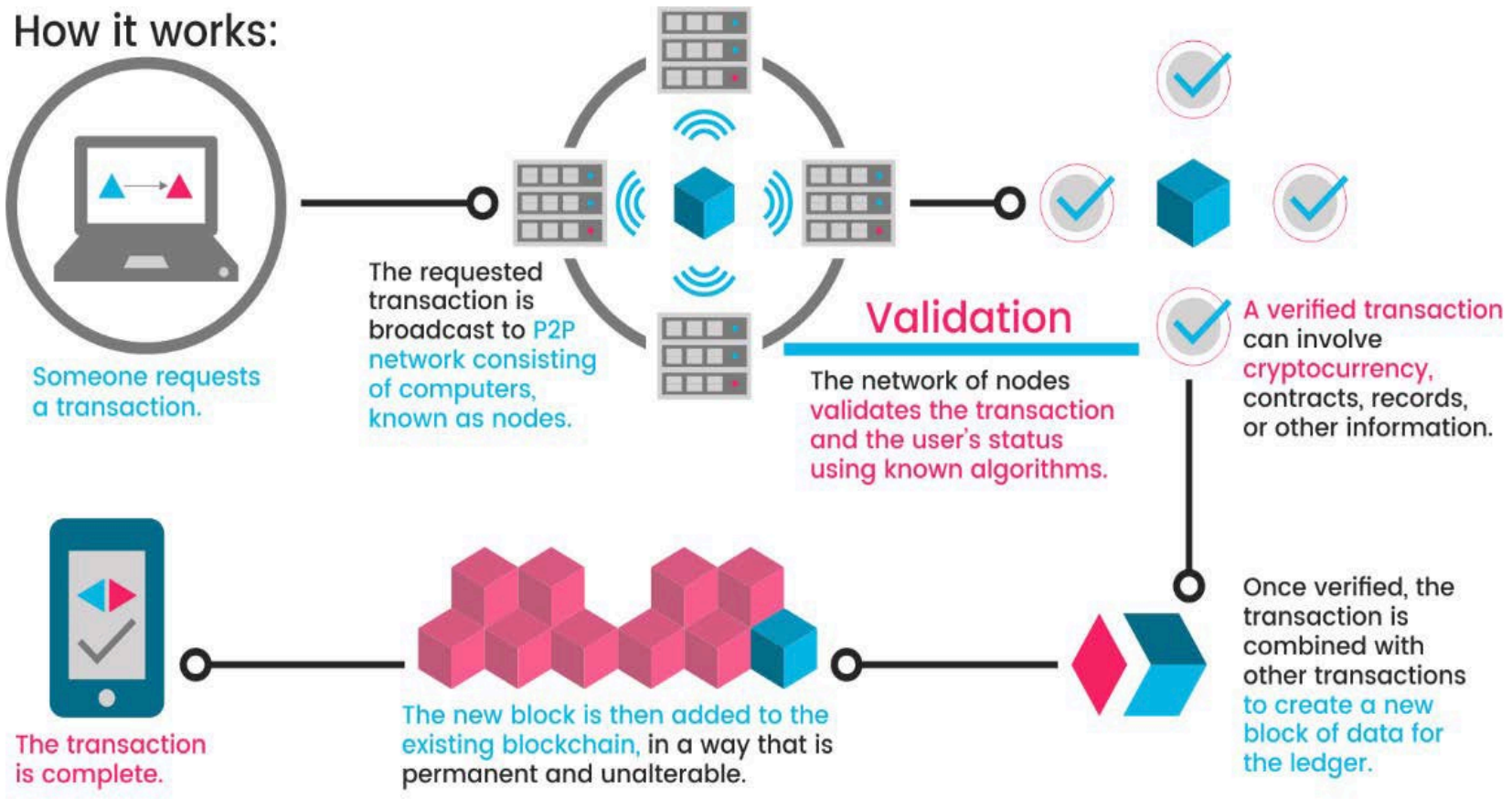
ID: 328922

Is Blockchain a Solution?

A blockchain is a distributed ledger that does the following:

- Records any transaction or information chronologically, permanently and unalterably
- Uses cryptography that is computationally impractical to break Is visible to all permissioned users
- Uses Peer-to-Peer transmission, with each node forwarding new transactional information to all others
- Can trigger transactions automatically, based on business logic and custom algorithms
- Verifies transactions through node consensus with no reliance on third-party intermediaries (e.g., clearinghouses)

Is Blockchain a Solution?: The Ecosystem



Digitized World: IT and Reality

Data: Driver of Change:

- Supply chains have over 50 times more data available to them than just five years
- Less than a quarter of that data being analyzed in near real time for value
- Within the next three years, half of all applications will have embedded cognitive capabilities —
- We will be able to do things better and faster - but also to do things that simply couldn't have been done

Rose Colored Glasses – CEO's

- 55% of supply chain organizations believe themselves to be past the midpoint of digital maturity
- Almost 8% say they are at the most advanced stage
- 57% of survey respondents felt that their business would be disrupted by either an existing competitor or a new market entry within the next year.

Source: IDC Research 2018