PHARMACEUTICAL
TRACK & TRACE SYSTEM

Pharmaceutical Services Programme
Ministry of Health Malaysia

More fake Avastin found in EU, thanks to FMD Scanning June, 2019

WHO warns of falsified versions of cancer drug Ponatinib February, 2019

PHOTOGRAPHS OF CONFIRMED FALSIFIED ICLUSIG PRODUCTS

1. ICLUSIG 45mg (30 tablets), Batch number PR072875

September, 2019

HSA Stops Supply of Eight Brands of Ranitidine Products in Singapore

Eight brands of ranitidine medicines have been found to contain trace amounts of a nitrosamine impurity, N-nitrosodimethylamine (NDMA), which are above the internationally acceptable level. As a precautionary measure, the Health Sciences Authority (HSA) is stopping the sale and supply of the affected ranitidine medicines at clinics, hospitals and pharmacies [see Table A for full list of medicines].

March, 2019

Kenyataan Akhbar KPK 29 Mac 2019 -Produk Losartan yang ditarik Balik di Singapura Serta Situasi di Pasaran Malaysia

BY DG OF HEALTH ON MARCH 29, 2019

Kenyataan akhbar ini dikeluarkan berikutan notis panggil balik oleh Health Sciences Authority (HSA), Singapura ke atas tiga (3) produk yang mengandungi losartan daripada sumber bahan aktif Hetero Labs Limited, India kerana kehadiran impuriti N-nitroso-N-methyl-4-aminobutyric acid (NMBA). Impuriti ini berkemungkinan boleh menyebabkan kanser kepada pengguna dalam jangka masa panjang. [...]

Pharmaceutical Serialization & Traceability

Track

Understand where an item **is** at any point in time

Trace

Understand where an item **was** at any point in time

Authenticate

Understand whether an item is **genuine** at any point in time

Global Serialization Standard for Pharmaceutical

assigning of a unique serial number to each saleable unit

product's origin

batch number

expiration date.

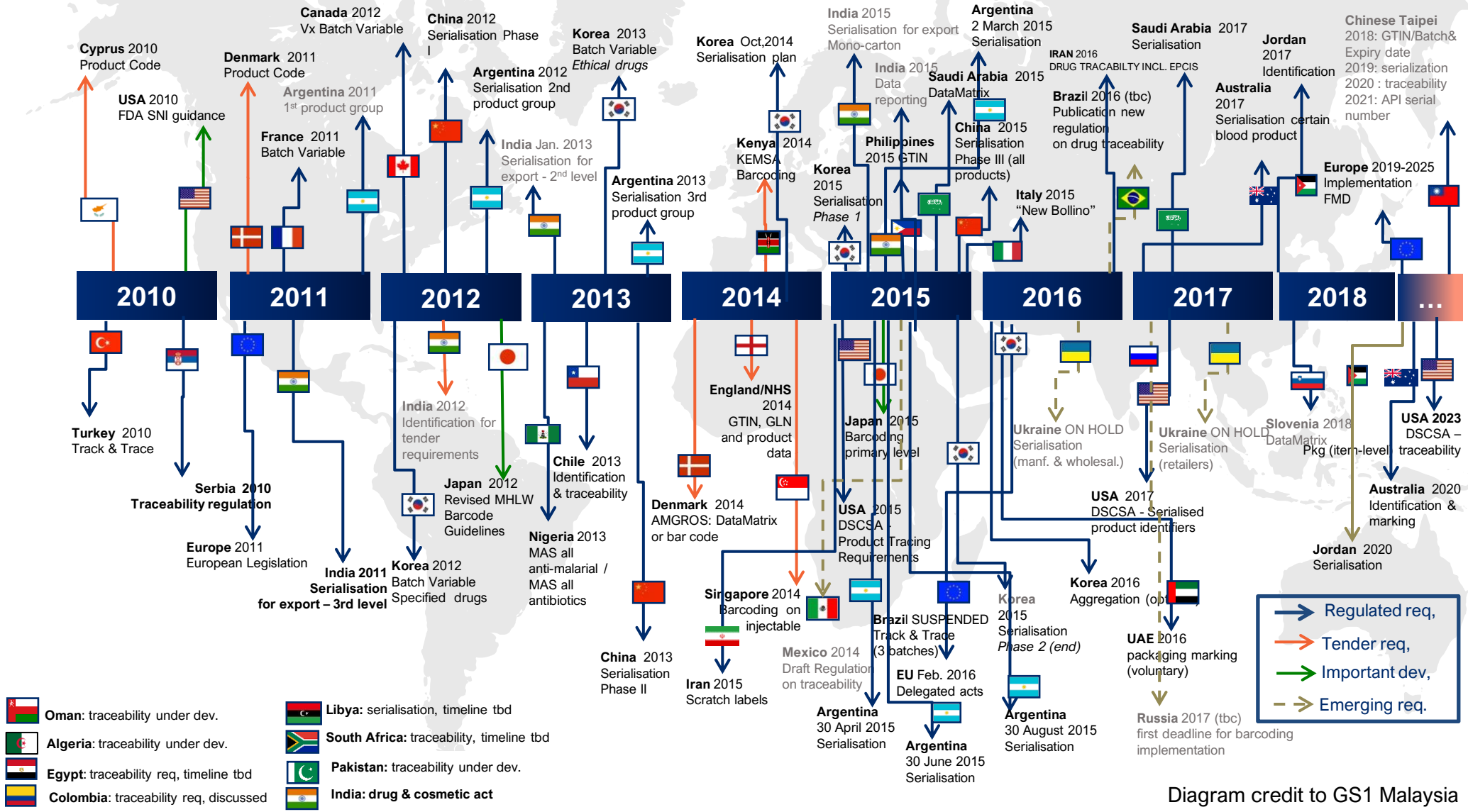
serial number

send to

Centralised Database

The units can then be tracked through its entire supply chain — from production to retail distribution to the final dispensation to the patient

Global Pharmaceutical Serialization Regulations



Oman: traceability under dev.
Algeria: traceability under dev.
Egypt: traceability req, timeline tbd
Colombia: traceability req, discussed
Libya: serialisation, timeline tbd
South Africa: traceability, timeline tbd
Pakistan: traceability under dev.
India: drug & cosmetic act

Diagram credit to GS1 Malaysia

Global Pharmaceutical Serialization Regulations

Turkey - Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use

2010

Argentina – Regulation MS 435/2011 ANMAT

2011

India – Directorate General of Foreign Trade (DGFT)

2015

EU – Falsified Medicines Directive

2019

US - Drug Supply Chain Security Act (DSCSA)

2023

?

Non-compliance with global regulations results in …

- Fines & Penalties
- Inability to sell product into global markets
- Reduction in product quality
- Inability to meet partner & customer expectations

And leads to negative business outcomes …

- Reduced competitive advantage
- Lost revenues & market shares
- Negative impact on patient safety
- Damage to brand value & declining stock price

Selected Countries Experience

Country : Argentina

Primary Objective :
Combat against SF Medicines, safety of the supply chain, improvement of recall procedures, prevention of reimbursement fraud.

Regulated:
Yes (Reg. MS 435/11 and regulations supplementary thereto)

Date of Implementation:
First stage: December 15th, 2011

Data Carrier:
Free (linear barcode, 2D DataMatrix and RFID) on secondary packaging. The last five years evolution shows that, Datamatrix is preferred and used by most companies.

Database:
Within the NRA, with centralized information

Country : EU

Primary Objective :
Prevent the entry into the legal supply chain of falsified medicinal products

Regulated:
Yes (EU – Falsified Medicines Directive 2011)

Date of Implementation:
The system will be applicable from 9 February 2019 in the majority of the EU Member State

Data Carrier:
2D barcode (Data Matrix)

Database:
Delegated Regulation (EU) 2016/161 provides that the repositories system is set-up and managed by a non-profit legal entity or nonprofit legal entities

Selected Countries Experience

Country : India

Primary Objective :
Tracking & tracing of export consignment of pharmaceuticals .

Regulated:
Yes (Directorate General of Foreign Trade (DGFT))

Date of Implementation:
July 2014

Data Carrier:
2D Data Matrix

Database:
Centralised database, maintain by the government

Country : US

Primary Objective :
Enable verification of the legitimacy of the drug product identifier down to the package level, enhance detection and notification of illegitimate products in the drug supply chain, and facilitate more efficient recalls of drug products.

Regulated:
Yes (Public Law 113-54, Title II, Drug Supply Chain Security Act) of 2013

Date of Implementation:
By November 27, 2023

Data Carrier:
The U.S. law currently specifies that the product identifier be a 2dimensional data matrix barcode for packages

Database:
Not determined yet

Selected Countries Experience

Country : Turkey

Primary Objective :

Reimbursement fraud, traceability.

Regulated:

Yes (Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use)

Date of Implementation:

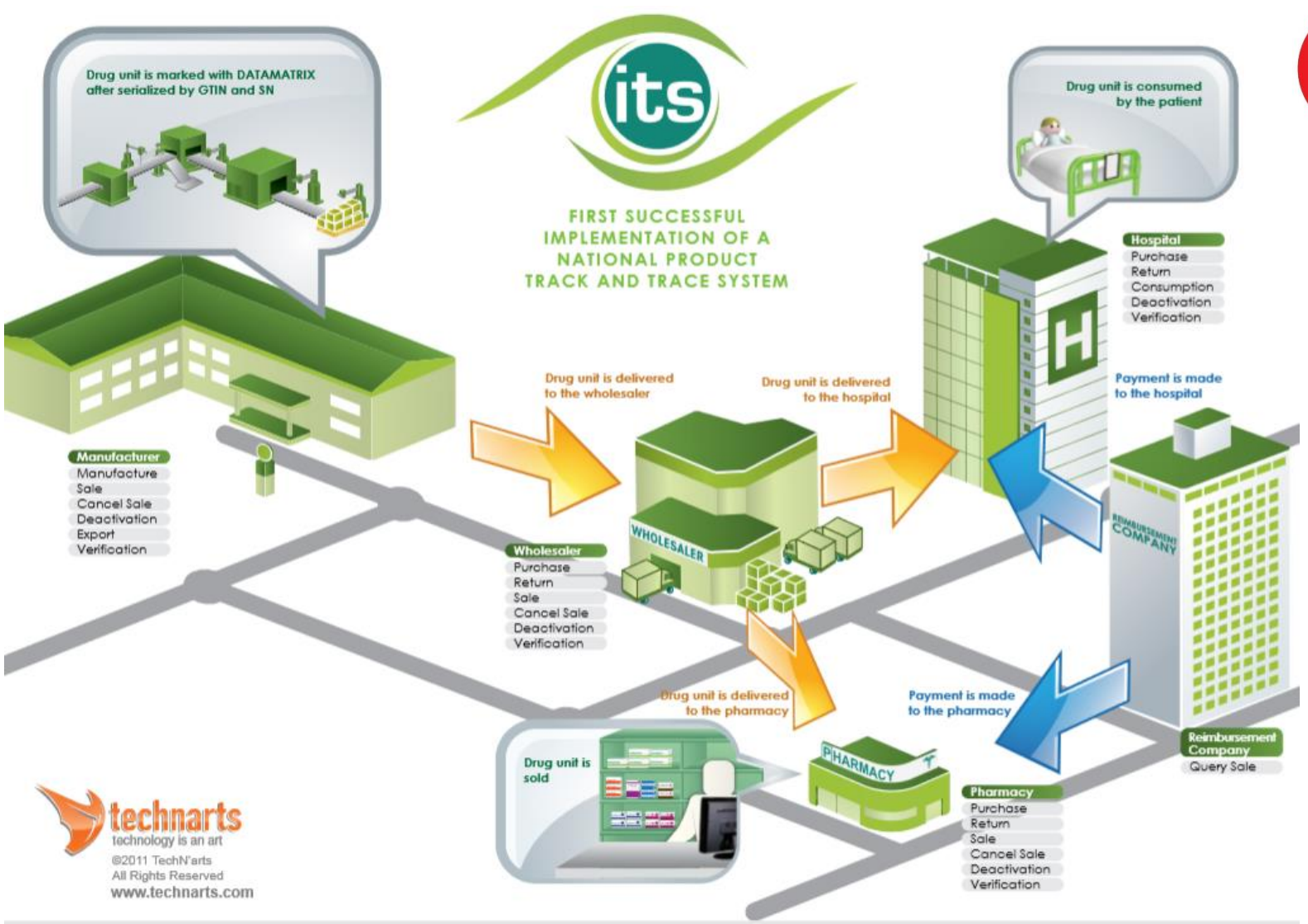
July 2012

Data Carrier:

2D Data Matrix

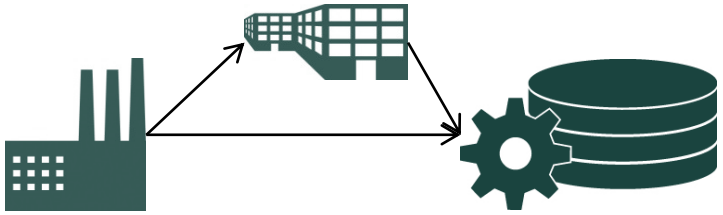
Database:

Centralised database, develop, operate & maintain by the government



Approaches to the implementation

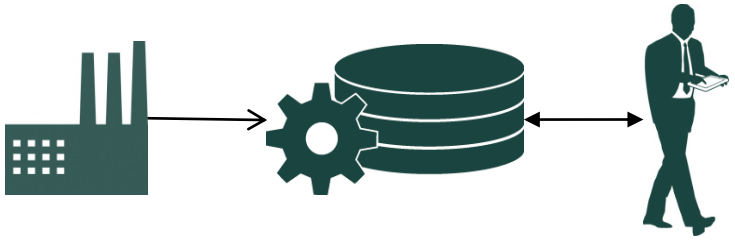
Presently there are 3 types of compliance requirements



Serialisation with **reporting to a governmental database**

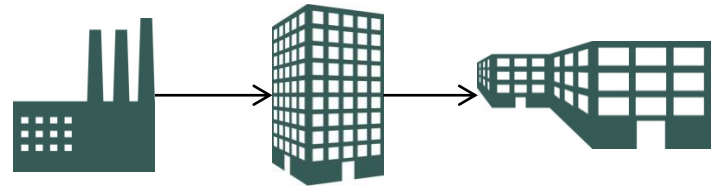
In effect

Expected



Uploading serialised trade items into an **institutional hub for verification**

Enacted



Initially **lot traceability – then full supply chain track & trace** of serialised trade items

Enacted & partially in force

- Lot traceability in force
- Serialization required by 2017
- Full serialized track & trace by 2023

Pharmaceutical Traceability

Government
Regulatory

Ministry of Health Malaysia

Patient/ Consumer
Patient Safety

Healthcare Facilities
Efficiency

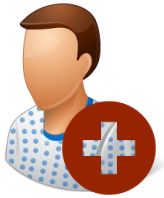
Industries
Security

Why Track & Trace ?

Strengthening Regulatory Activities through Global Standards

Cost Optimization & Operational Efficiency

Enhancing Ecosystem of Pharmaceutical Sector



Improve Patient Safety

Strengthening Regulatory Activities through Global Standards

2006

Malaysia National Medicines Policy (MNMP)

2014

Good Governance in Medicines (GGM)

2017

Pharmacy Programme Strategic Planning 2017-2021

AS$35B

Global value of counterfeit products

RM46M

Value of seized products in Malaysia in 2016

21K

Number of item of products seized in Malaysia in 2016

SF

Substandard, and Falsified, Medicines

Track & Trace system have been identified by WHO as one of the mechanism to fights SF

±20

Number of countries with track & trace regulations

AS$1B

Results of Turkey's efforts have been tremendous, the nation is seeing savings of 1 billion US dollars annually

Cost Optimization & Increase Efficiency

RM 2.32B

MOH Malaysia budget for medicines, *consumables* and vaccine in 2018

Benefits to Healthcare Facilities

- Governance of more efficient and integral medicines management
- Reduce medicines waste
- Forecasting medicines use & trends
- Improve movement of drugs in supply chain e.g. product recalls/ disaster

Potential Benefits to Industries*

Value	Impact
Reduce inventory financing and holding cost	$11 million annual savings
Reduce product waste due to obsolescence	$4 million annual

Efficient product recall management and reduce cost of recalls $3-12 million annual

* Strength In Unity, McKinsey & Company (2012)

Enhancing Ecosystem of Pharmaceutical Sector

> I am also pleased to witness initiatives under the Healthcare NKEA bearing fruit as reflected by our results in **pharmaceutical exports** and healthcare travel this year. This had allowed the expansion of the healthcare industry which in turn helped **create job opportunities**, **expand the Gross National Income** and at the same time ensure healthcare remains affordable to the public.
>
> Health Minister of Malaysia, 2016

RM 623Miliion

Malaysia's pharmaceutical export value in 2015

(+25.7%)

RM 783Million

Malaysia's pharmaceutical export value in 2017

Source: Annual Report 2016 National Transformation Plan

The pharmaceuticals-related EPPs

contributed to consistent growth in export earnings from 2011 to 2016

T&T: Enhancing Ecosystem of Pharmaceutical Sector

Bolster the pharmaceutical export growth i.e. potential market : countries which have implemented track & trace regulations and opportunity to become CMO for global brand product.

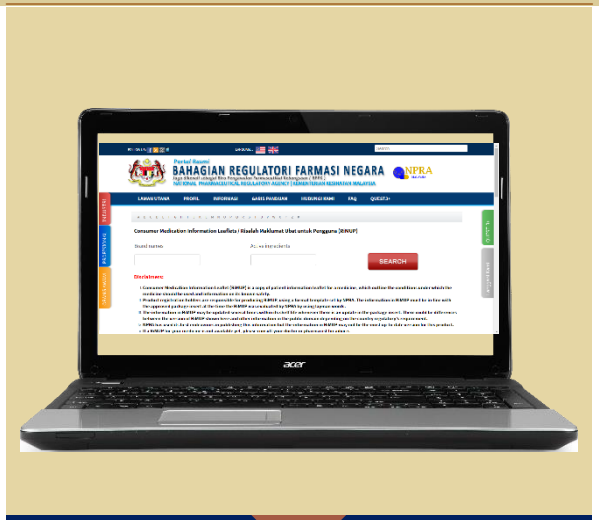
Improve Patient Safety

Minimizing Medication Error

Standard barcodes allows correct medication being serve for the correct patient

Product Authentication

More convenient for patient to identify genuine product by using mobile application



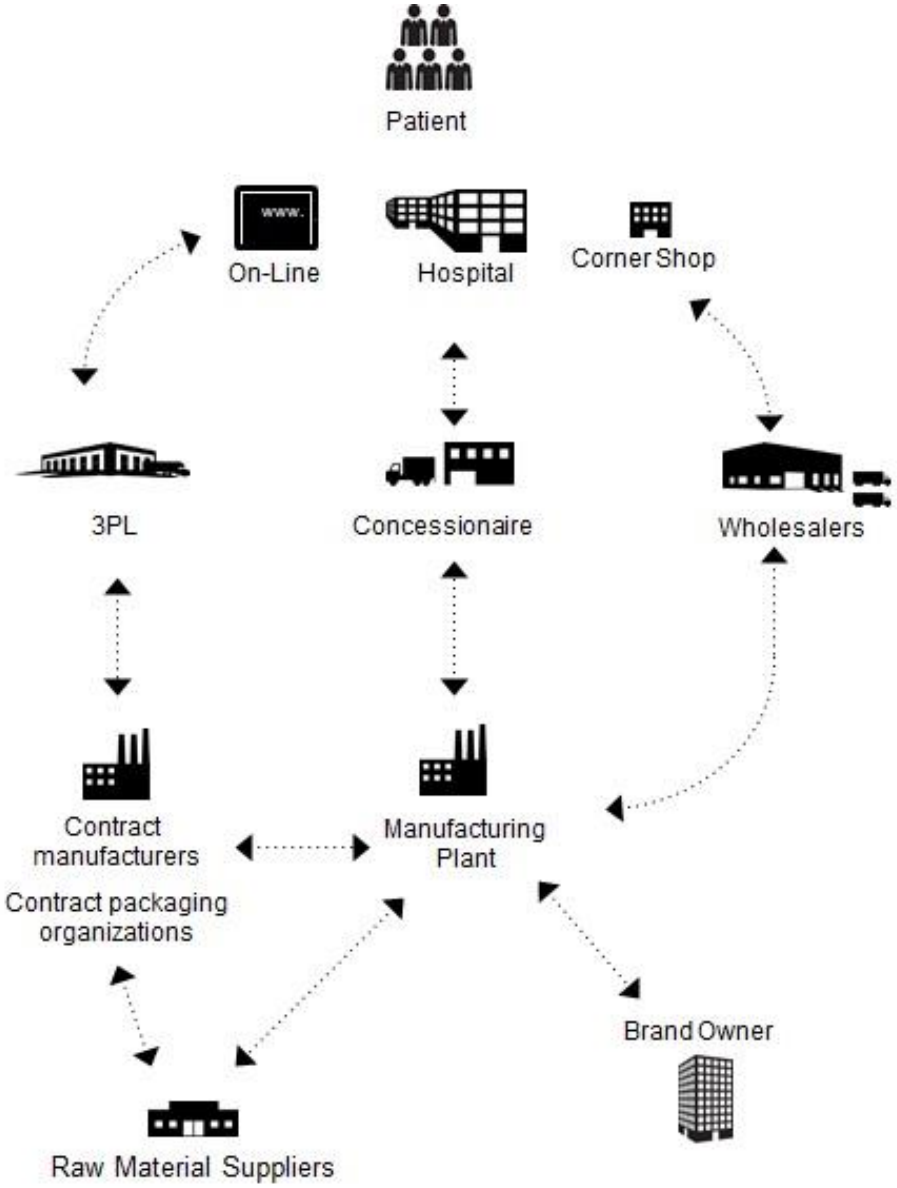
Access to Medicines Information

Improve patient adherence and knowledge on medicines

Product Traceability

Able to track the product endpoint for drug related issues (product recall etc)

Challenges In Pharmaceutical Supply Chain



Multichannel sales: growth in Over the counter and Traditional medicine through on-line web stores and corner shops

Visibility: Multiple steps in the supply chain with disrupted silo's of information

Demand-driven supply networks: Poor demand forecasting, stock outs with long lead times or over supply with drugs past expiry dates

Compliant distribution: Risk of noncompliance in warehouse and re-packing operations

Patient Outcome: challenge to have the right drug at the right time at the right quality reducing counterfeits

Track & Trace: Malaysian Perspectives

Objective: Patient Safety, Securing Supply Chain, Traceability & Visibility, Combat counterfeit & Unregistered Products

Scope

All registered product (A,X,T,N) *

*Implementation in phases

Packaging Levels

Saleable Unit
Tertiary Packaging
Aggregations

Data Carrier & Elements

GS1 2D DataMatrix

- GTIN
- Expiry date
- Lot/ batch number
- Serial Number

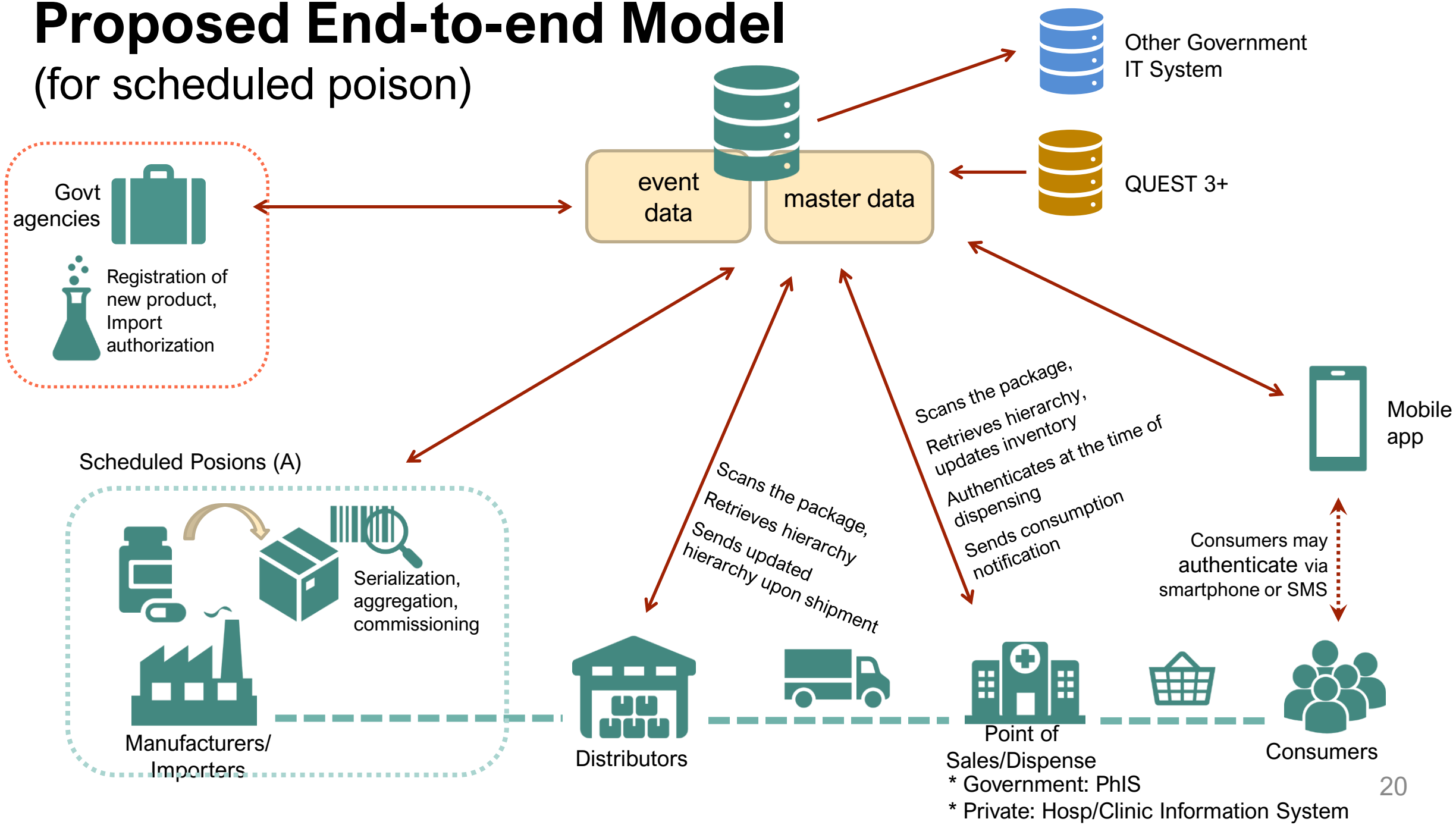
Database

Centralized Database (data own by government)

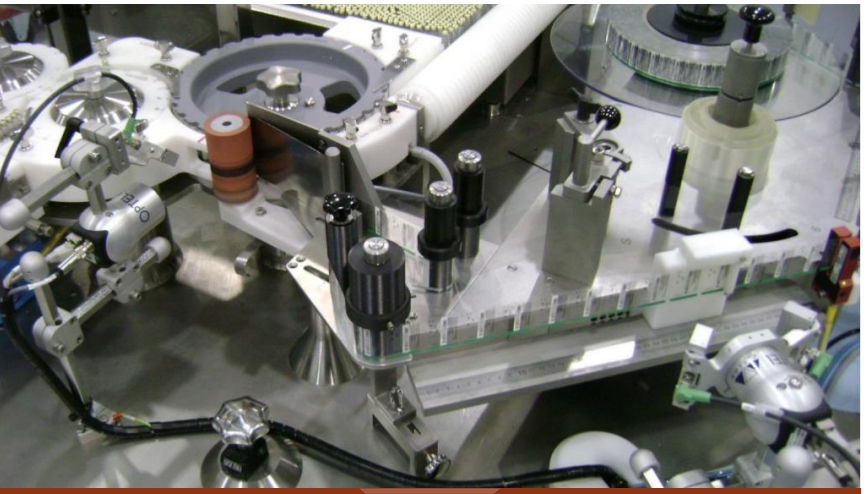
Reporting format: EPCIS

Proposed End-to-end Model

(for scheduled poison)



Serialization at Production



Either directly on the unit or on a separate label

Every unit is scanned and checked

Barcodes are again checked when in bundle

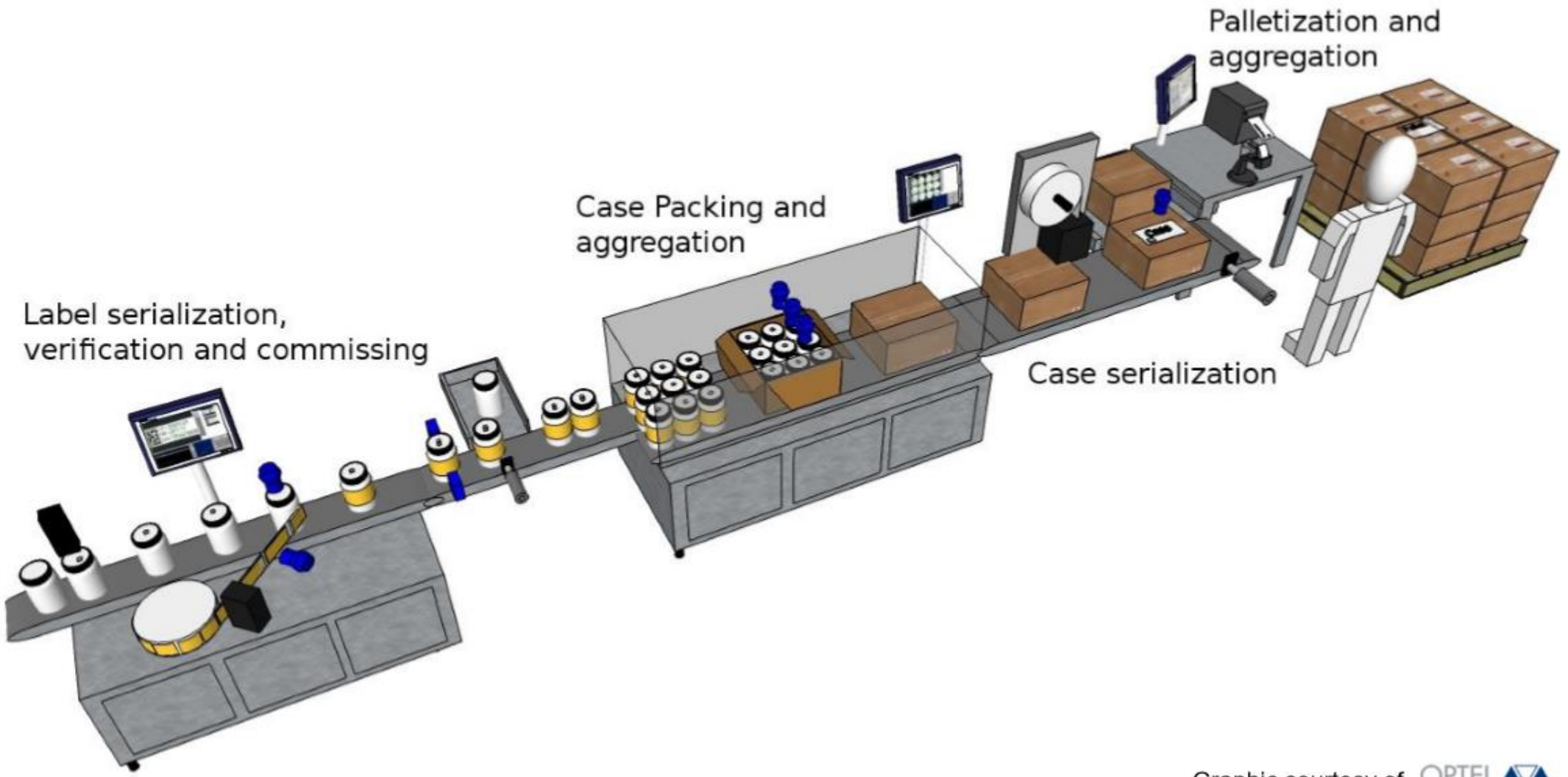
Aggregations

GTINs to identify product along the along the packaging hierarchy.

To append batch/lot and serial numbers.

Providing «unique number» for secondary and higher packaging levels.

Packaging line changes



Graphic courtesy of OPTEL VISION

Level 5: Network Level

Network EPCIS

Authentication, exchange, Govt. Reporting

Mobile Authentication

Network

Level 4: Enterprise Level

ERP

Serial No. Manager

EPCIS Event Manager

Enterprise

Level 3: Site Level Serialization Manager

Level 2: Package Line Automation

Level 1: Devices

Barcode Printer
Code Reader
RFID Reader
Applicator

Plant & DC

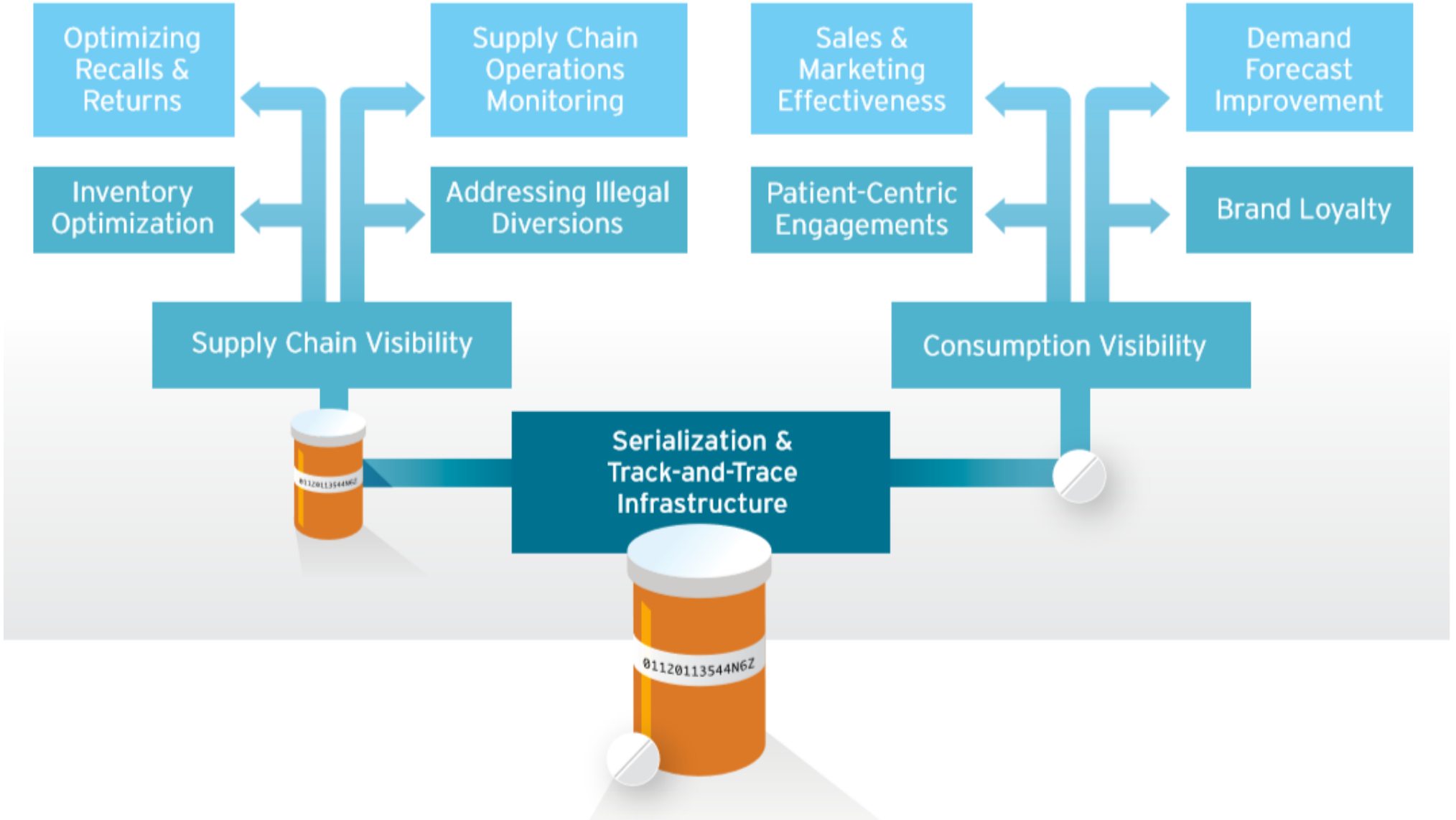
Hardware

- Repository server
- Middleware server
- External gateway router (optional)
- ERP server (optional)
- Warehouse Mobile Solution
- Packaging Serialization Line
  - Pharmaproof print and vision inspection system for serialization code
  - Manual/Automated Aggregation
  - Thermal inkjet printer
  - Printer for aggregation to case and pallet.

Software

- Any track & trace System software available in the market
- Level 1 to Level 4

Track & Trace Dimensions to Drive Value Beyond Compliance



Improve efficiency in **data management, good governance**

Reduce product **waste** due to obsolescence

Improving product **recall** efficiency and effectiveness

Improving **transaction** accuracy

Improve efficiency **inventory** assets & associated costs

Government

Minimizing diversions of product

Strengthening multiple stakeholders **collaboration**

Track & Trace Benefits

Reducing **medication errors; Patient safety**

Protecting consumer & industries from **counterfeit** product

Industries

Patient/ Consumer

Future possibilities:

Improve access for international trade
Health Transformation
Consumer Empowerment – Drug Information, compliance tools

Thank You

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