

# MOH MALAYSIA PLAN TO ROLL OUT Pharmaceutical **Track & Trace System**

Pharmaceutical Services Programme  
Ministry of Health Malaysia

# Presentation Outline

1. Introduction
2. Why Serialization & Traceability
3. Track & Trace: Malaysian Perspectives
4. Impact & Challenges
5. Value Beyond Compliances
6. Way forward

# Control of Pharmaceutical Products in Malaysia

## Acts & Regulations

1. Registration of Pharmacists Act 1951(revised 1989) & Regulations
2. Poisons Act 1952 (revised 1989) & Regulations
- 3. Sale of Drugs Act 1952 (revised 1989) & Control of Drugs and  
Cosmetics Regulations 1984 (revised 2006)**
4. Dangerous Drugs Act 1952 (revised 1980) & Regulations
5. Medicines (Advertisement and Sale) Act 1956 (revised 1983) &  
Regulations

# Control of Pharmaceutical Products in Malaysia

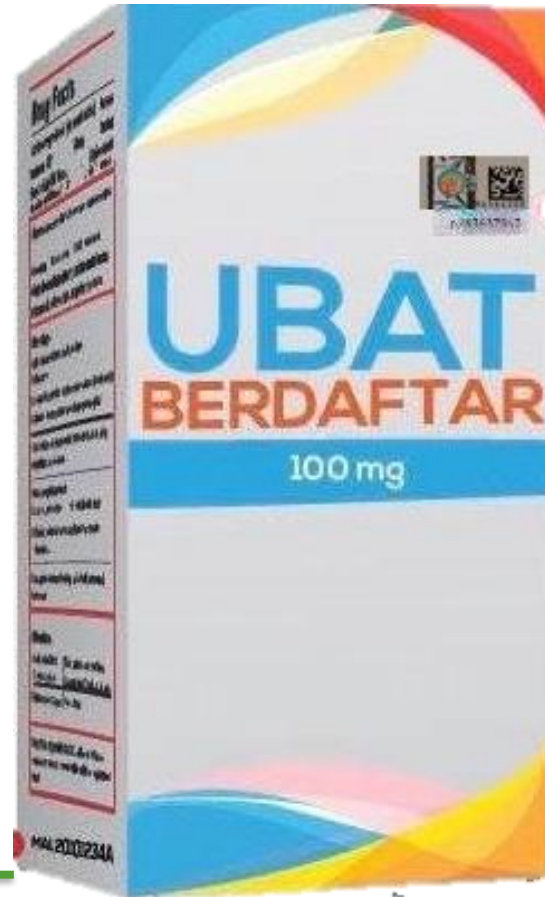
All pharmaceutical products must be registered with the Drug Control Authority (DCA) before it is marketed and sold to consumers

## Registration Number

# 1985 - 2005

Control over the sales of pharmaceutical products

Registered pharmaceutical product is given a specific registration number (eg; MAL 20001564A) to be printed on the label or its packaging



## Security Label (Hologram)

# 2005 - present

Hologram was introduced in 2005 with an extensive safety features that can be verified by both consumers and pharmacy enforcement officers

**All registered products must display product registration number and hologram security label on its packaging**

# Why Track & Trace?



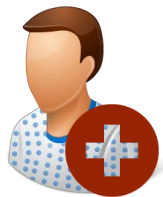
Strengthening Regulatory Activities through Global Standards



Cost Optimization & Operational Efficiency



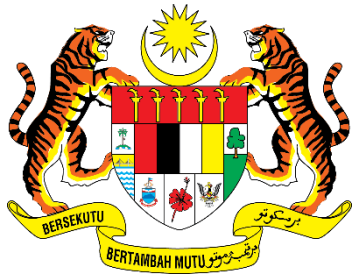
Enhancing Ecosystem of Pharmaceutical Sector



Improve Patient Safety



# Strengthening Regulatory Activities through Global Standards



**2006**

Malaysia National  
Medicines Policy  
(MNMP)

**2014**

Good Governance in  
Medicines (GGM)

**2021**

Pharmacy Programme  
Strategic Planning 2021-  
2025

**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

**±50**

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

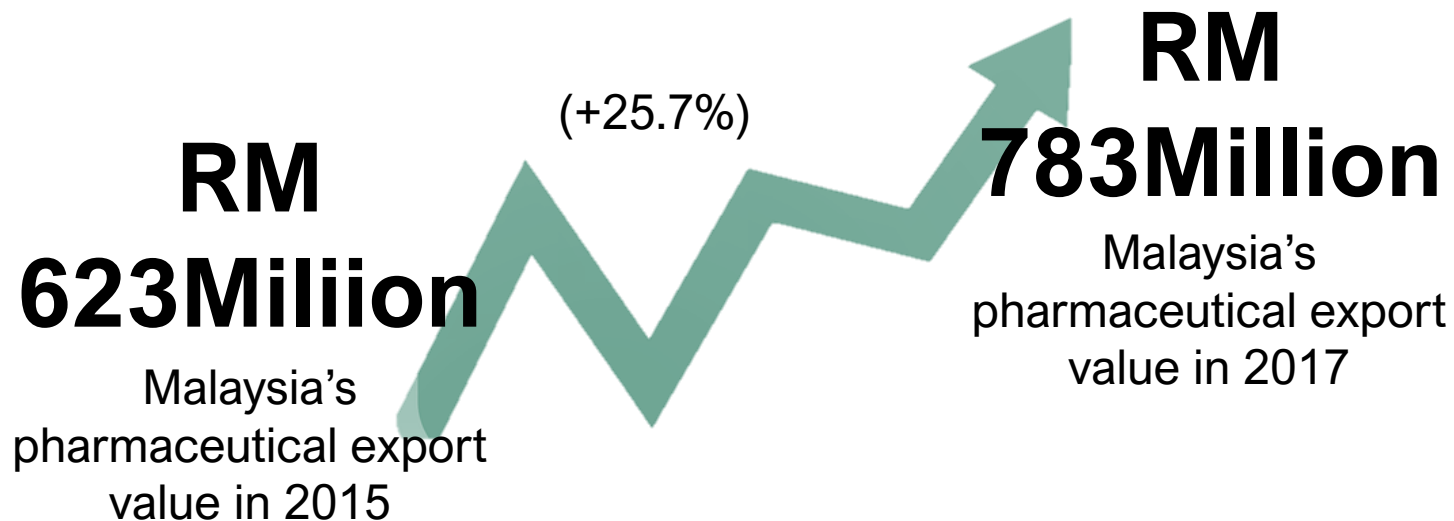
\* Strength In Unity, McKinsey & Company (2012)



## 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



### 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

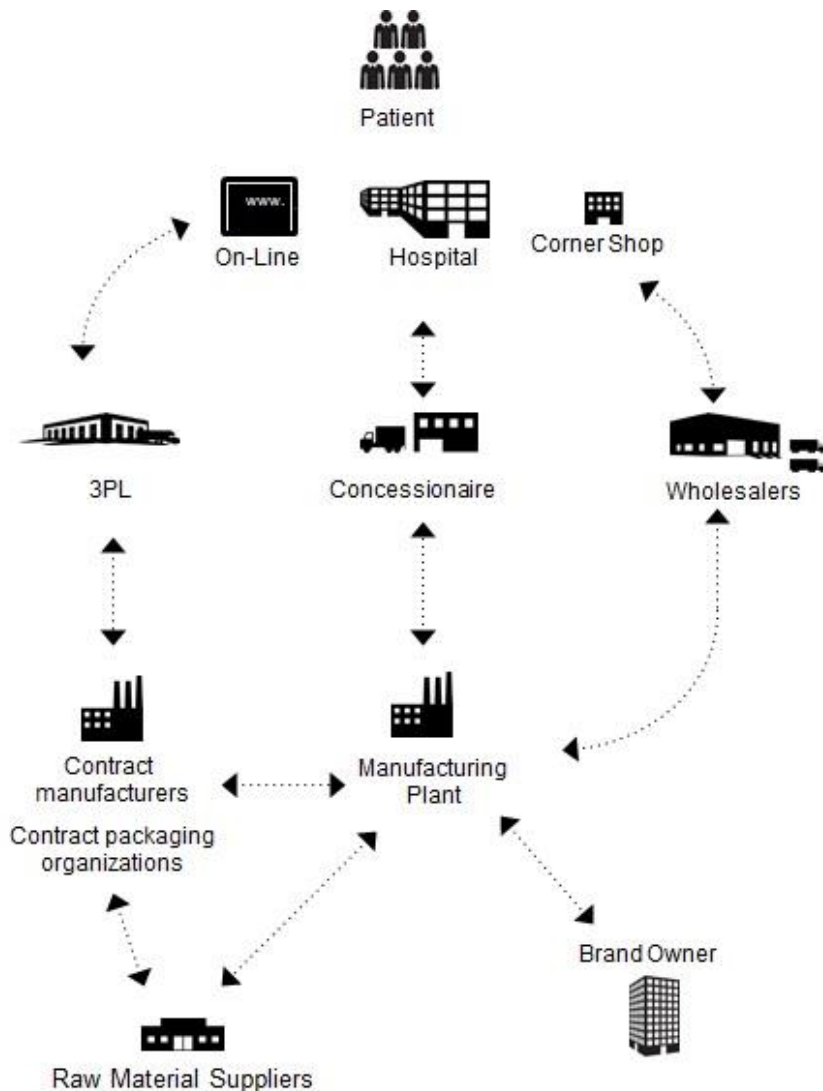
Improve patient adherence and knowledge on medicines



## 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

# Why Serialization & Traceability?



Protection against  
Substandard & Falsified  
Products



Supply Chain



Visibility

## Patient Safety

# 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

# Serialization & Traceability

assigning of a unique serial number to each saleable unit

**2D DataMatrix**



product's origin

batch number

expiration date.

serial number

send to



Centralised Database



Manufacturers/  
Importers



Distributors



Point of  
Sales/Dispense



Consumers

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

# Serialization & Traceability

## Objectives

- Market automation & efficiency
- Patient safety
- Reimbursement
- Supply chain integrity
- Combat against SF

## Deployments

- Requirement
- Solution
- Technology

## Regulatory Requirements

- Lesson learnt
- Other countries experience
- Customize to local legal requirement

## Stakeholders Engagements

### Policy Makers

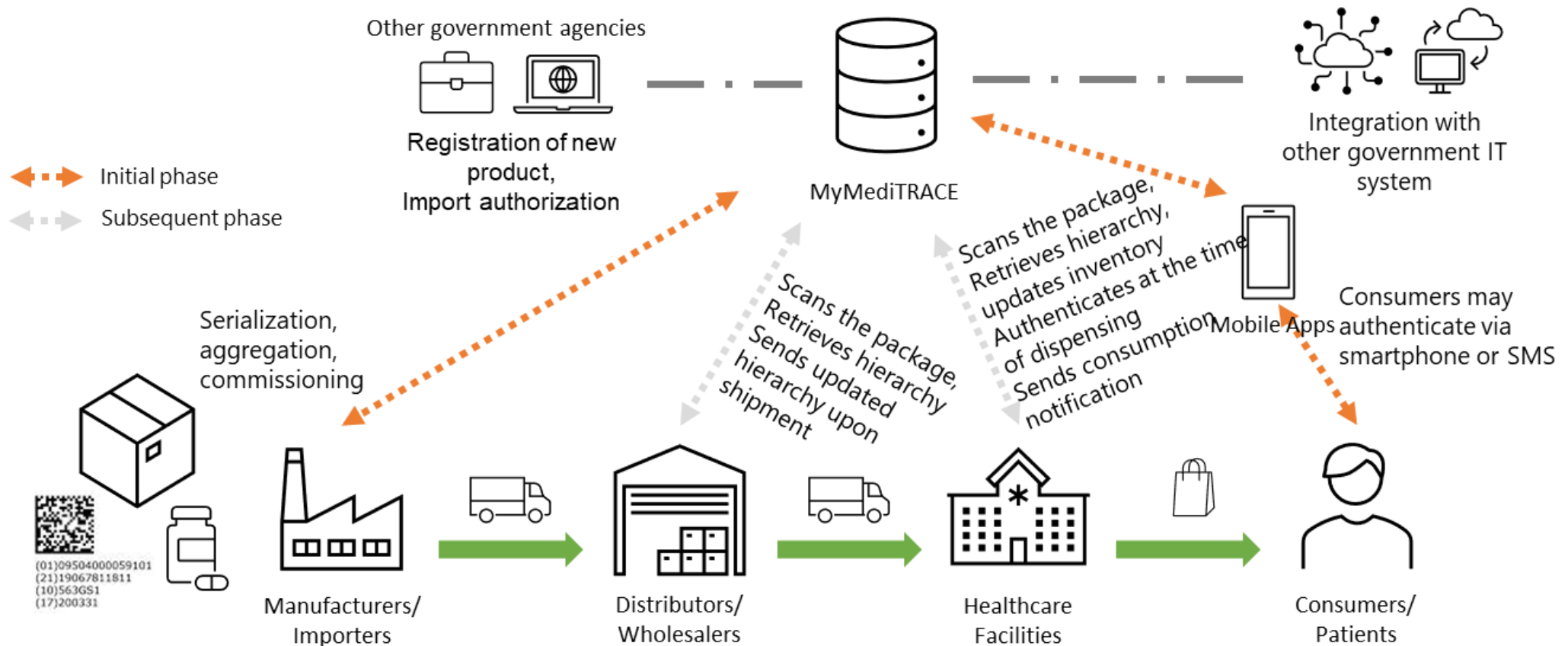
- Ministry of Health Malaysia
- Ministry of Finance
- Ministry of Science, Technology & Innovation
- Ministry of International Trade & Industry



### Other Stakeholders

# Track & Trace in Malaysia

## Proposed Track & Trace Model for Malaysia

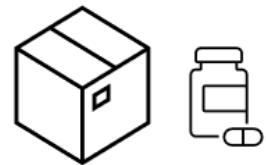


The implementation of MyMediTRACE is lead by the Pharmaceutical Services Programme MOH Malaysia. All data reported to the repository shall be own by the government. Through implementation of MyMediTRACE, MOH shall achieve following objectives:

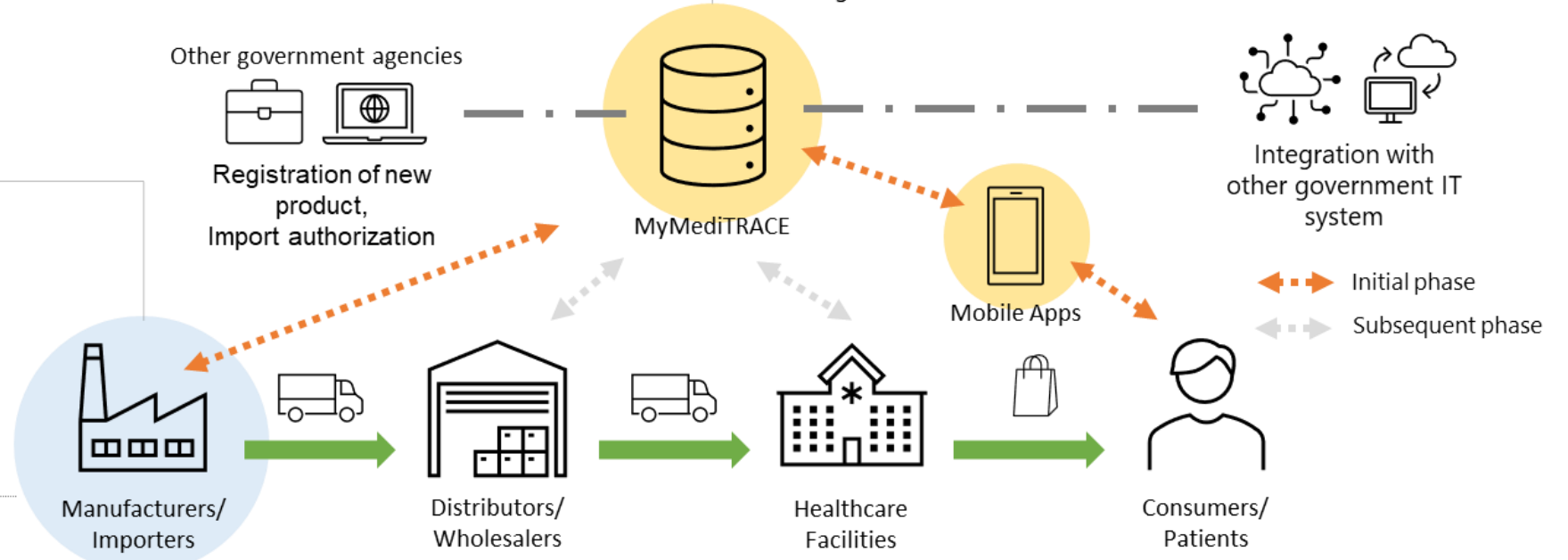
1. Strengthening Regulatory Activities through Global Standards
2. Achieving Cost Optimization & Operational Efficiency
3. Enhancing Ecosystem of the Pharmaceutical Sector
4. Improving Patient Safety

MOH Malaysia Pharmaceutical Track & Trace System (MyMediTRACE) is a national repository designed to facilitate the exchange of serialization and tracking information across different stakeholders and thus providing the means to prevent counterfeit drugs being introduced into the supply chain. All data shall be own by the government

Product Serialization



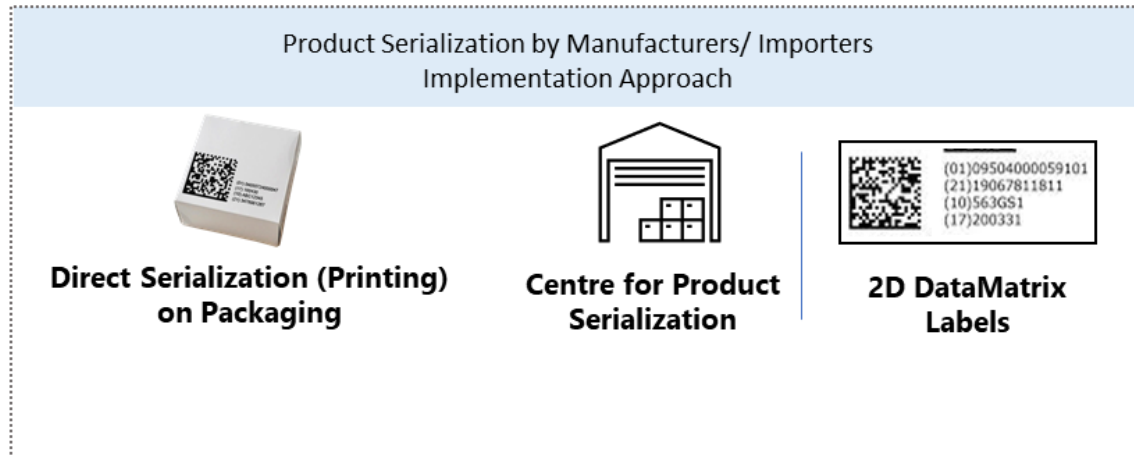
Unique serial numbers to all the involved saleable units in the country and subsequently ensuring that the saleable units' entry and exit points at all entities within the supply chain are fully captured



2D DataMatrix

(01)09504000059101  
(21)19067811811  
(10)563GS1  
(17)200331

The 2D DataMatrix will be printed/ applied on every saleable and shall be scanned and sent to the MyMediTRACE. Serialization of product can be implemented in three ways:

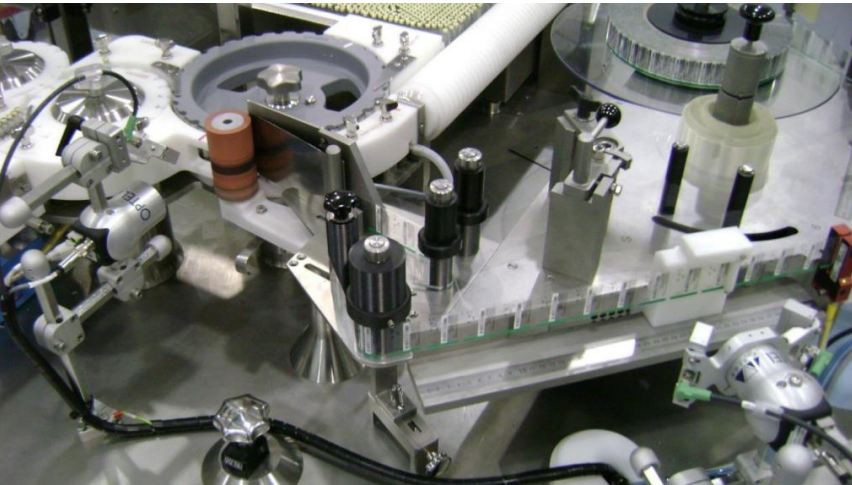


**MyMediTRACE Solution Provider**

The repository will be established through Public Private Partnership. Installation, Configuration, Customization & Integration and managed services will be implemented by an appointed solution provider.



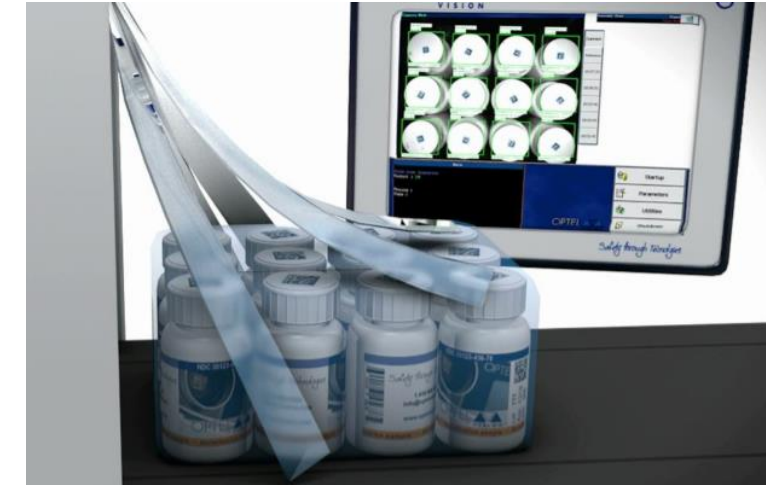
# Serialization at Production



Either directly on the unit or on a separate label

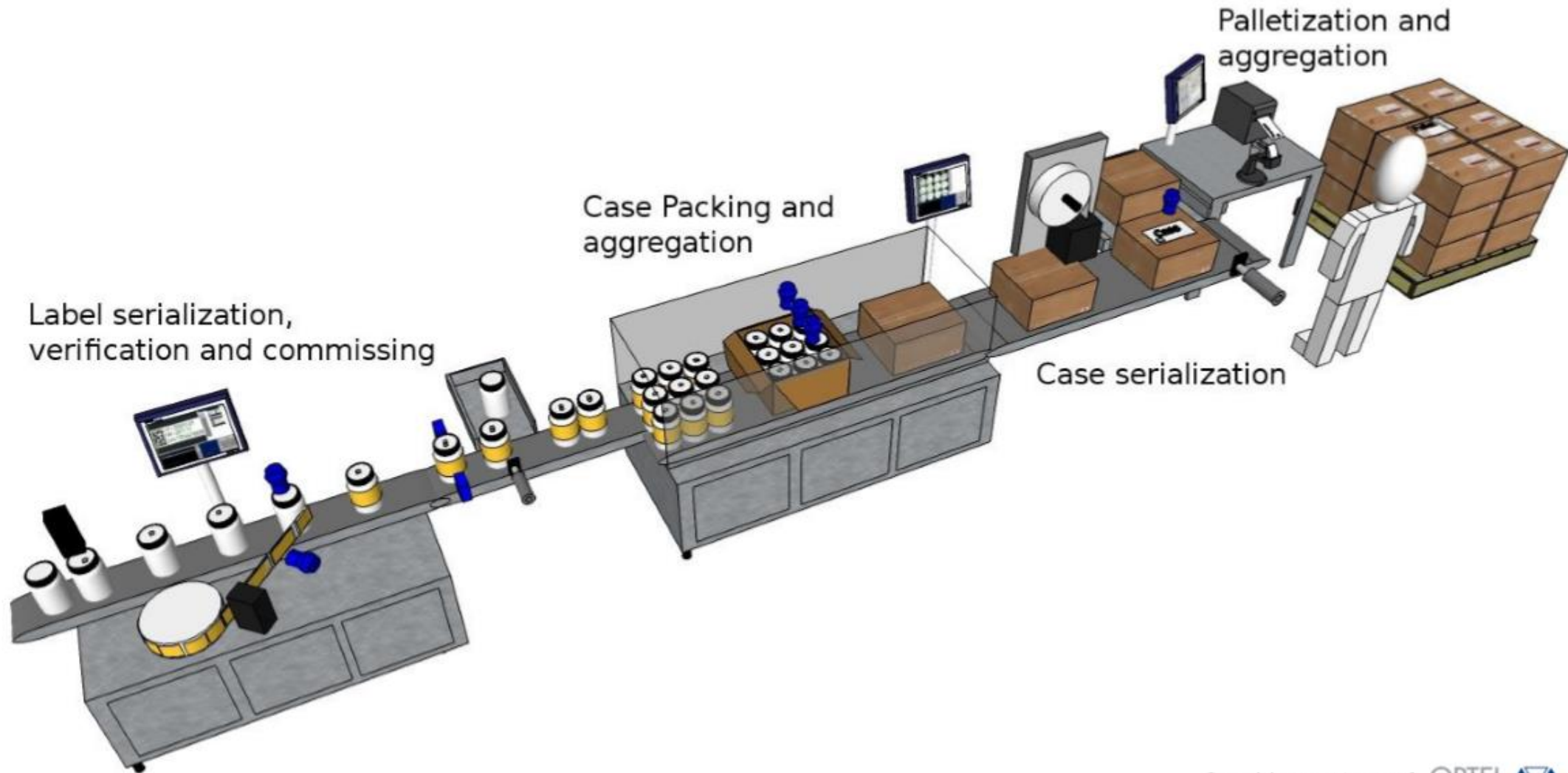


Every unit is scanned and checked



Barcodes are again checked when in bundle

# Packaging Line Changes

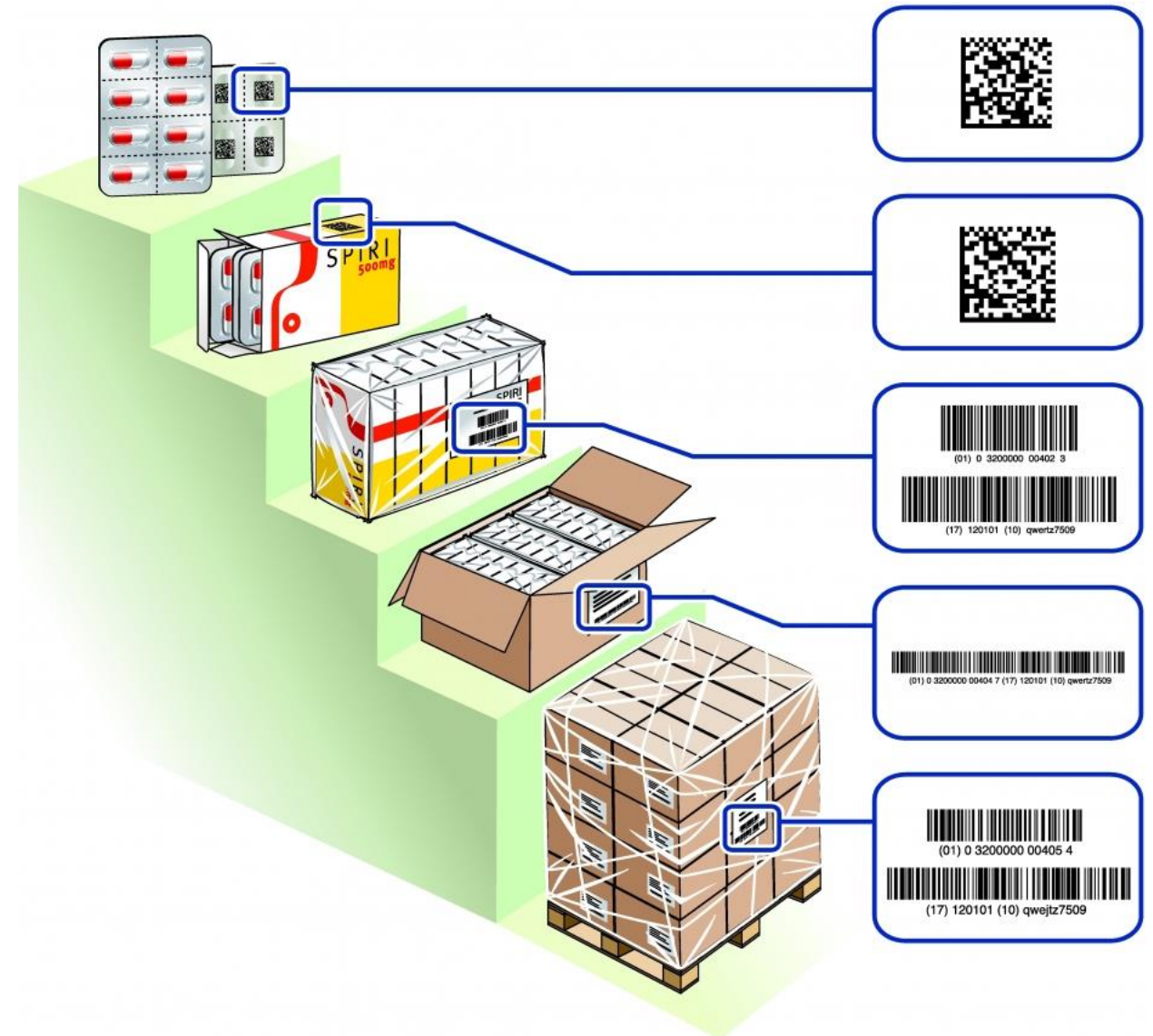


# Aggregations

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.



# System Solutions Requirement (Enterprise)

Government Reporting  
Supply Chain Integration  
End user authentication

Network Systems



**L5**

Enterprise Serial Manager  
Enterprise Serialized Repository  
ERP

Enterprise Systems



**L4**

Plant Serial Manager  
Configuration Management  
Local Serialized Repository  
Rework & Returns  
WMS/ Shipment event capture

Site Control Systems



**L3**

Batch configuration  
Serialized event capture  
Reconciliation & Reporting  
Line automation  
Camera/ Scanners  
Printers Label artwork

Device & Line Control Systems

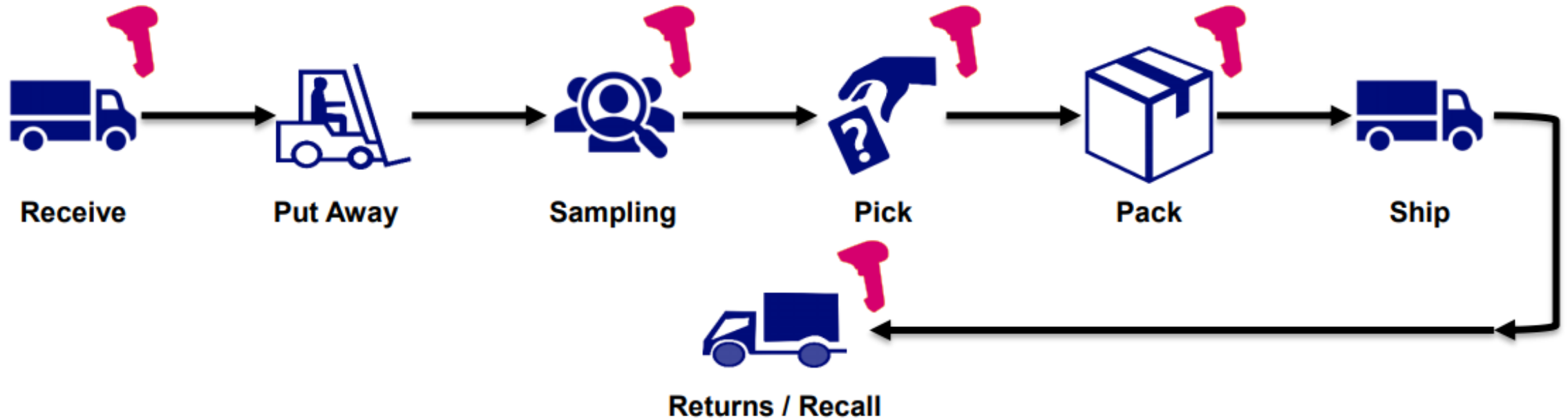


**L1-L2**

Government (L5)

Enterprise (L1 to L4)

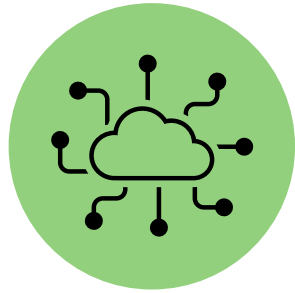
# Impact & Challenges



## Managing inventory

- Quantity vs track by individual unit.
- Scanning and validation of serial numbers in each step – ensure data accuracy and capture product movement of individual units for compliance.
- Operations has to manage both physical product and also the parallel data

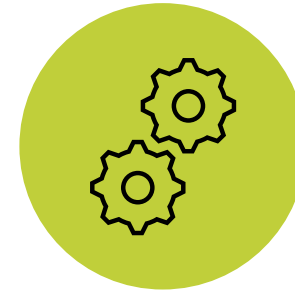
# Impact & Challenges



Technology

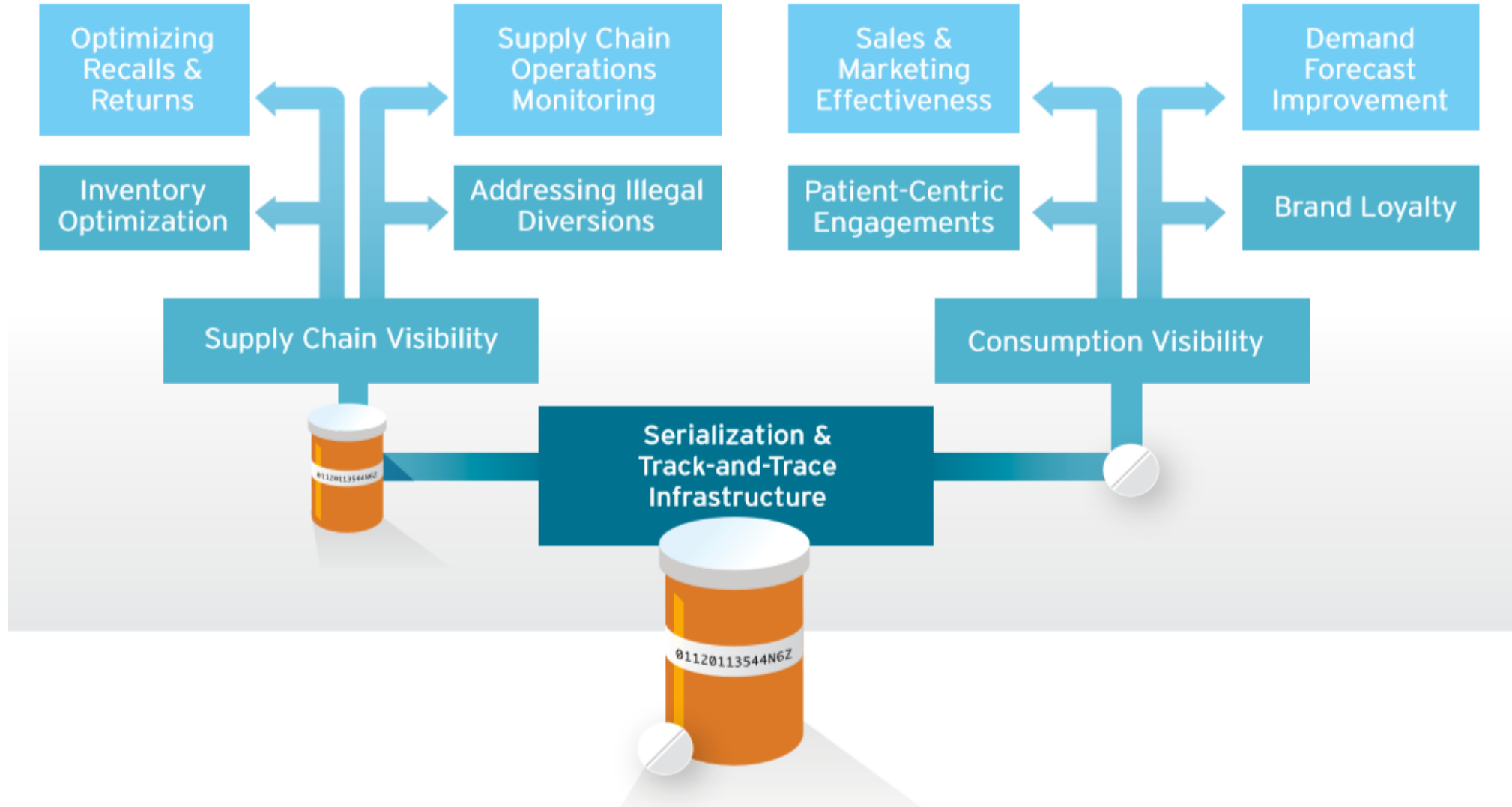


Cost

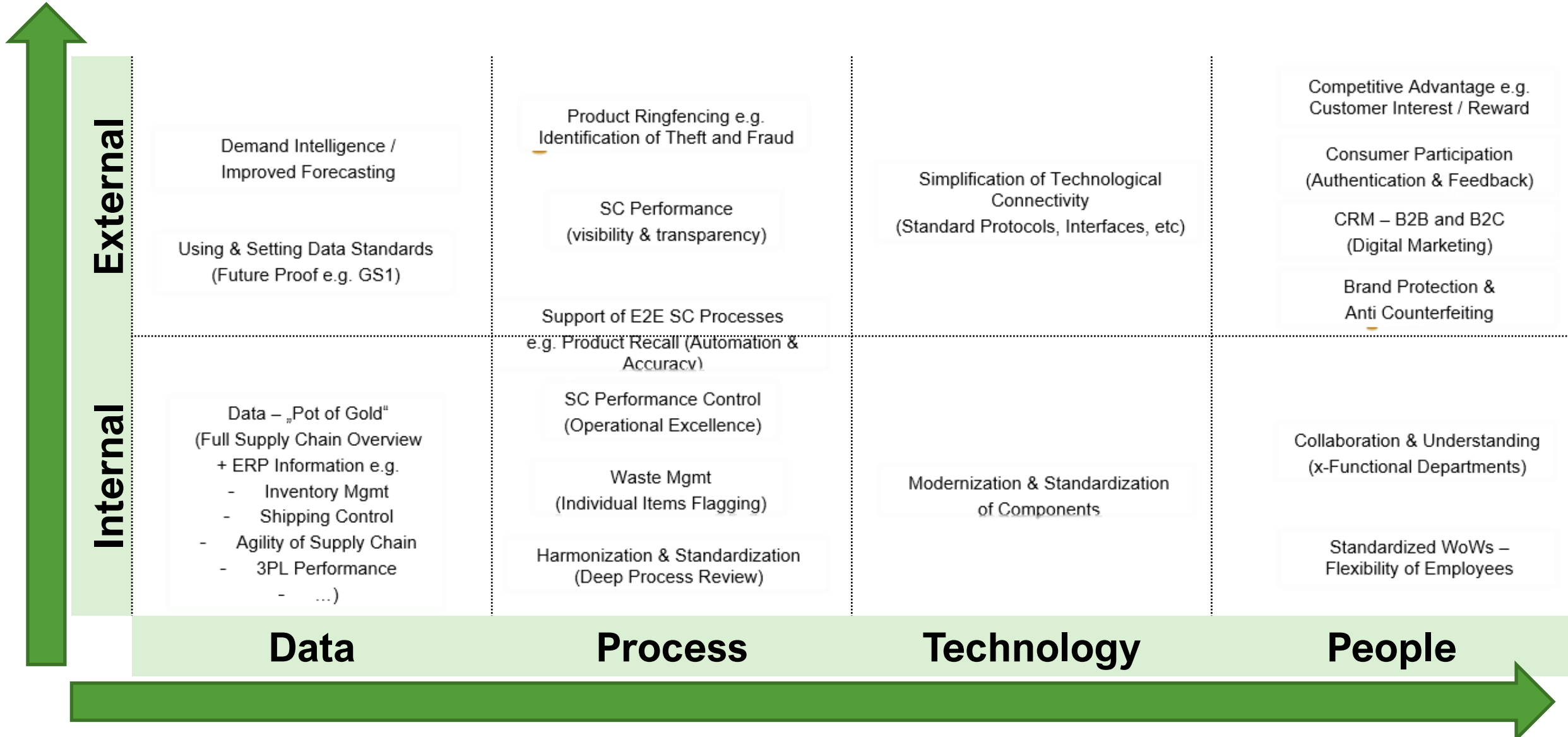


Operational  
Efficiency

# Value Beyond Compliance

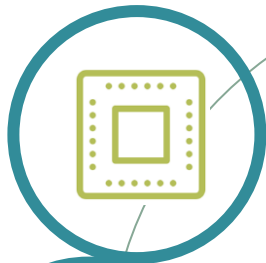


# Benefits Beyond Compliance

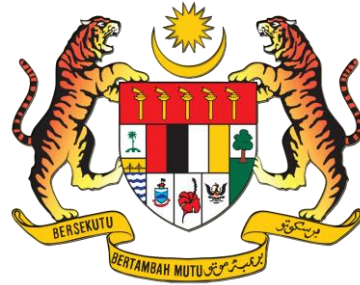




Improve efficiency in **data management, good governance**



# Government



Minimizing diversions of product

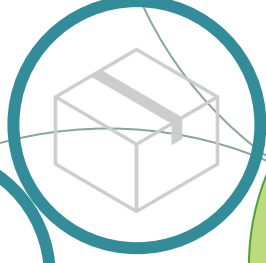
Reduce product **waste** due to obsolescence



Strengthening multiple stakeholders **collaboration**



Improving product **recall** efficiency and effectiveness



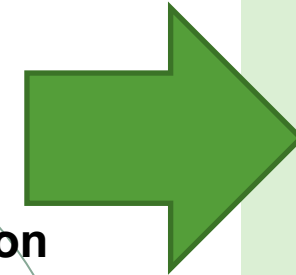
## Track & Trace Benefits



Improving **transaction** accuracy



Reducing **medication errors; Patient safety**



Improve efficiency **inventory** assets & associated costs



Protecting consumer & industries from **counterfeit** product



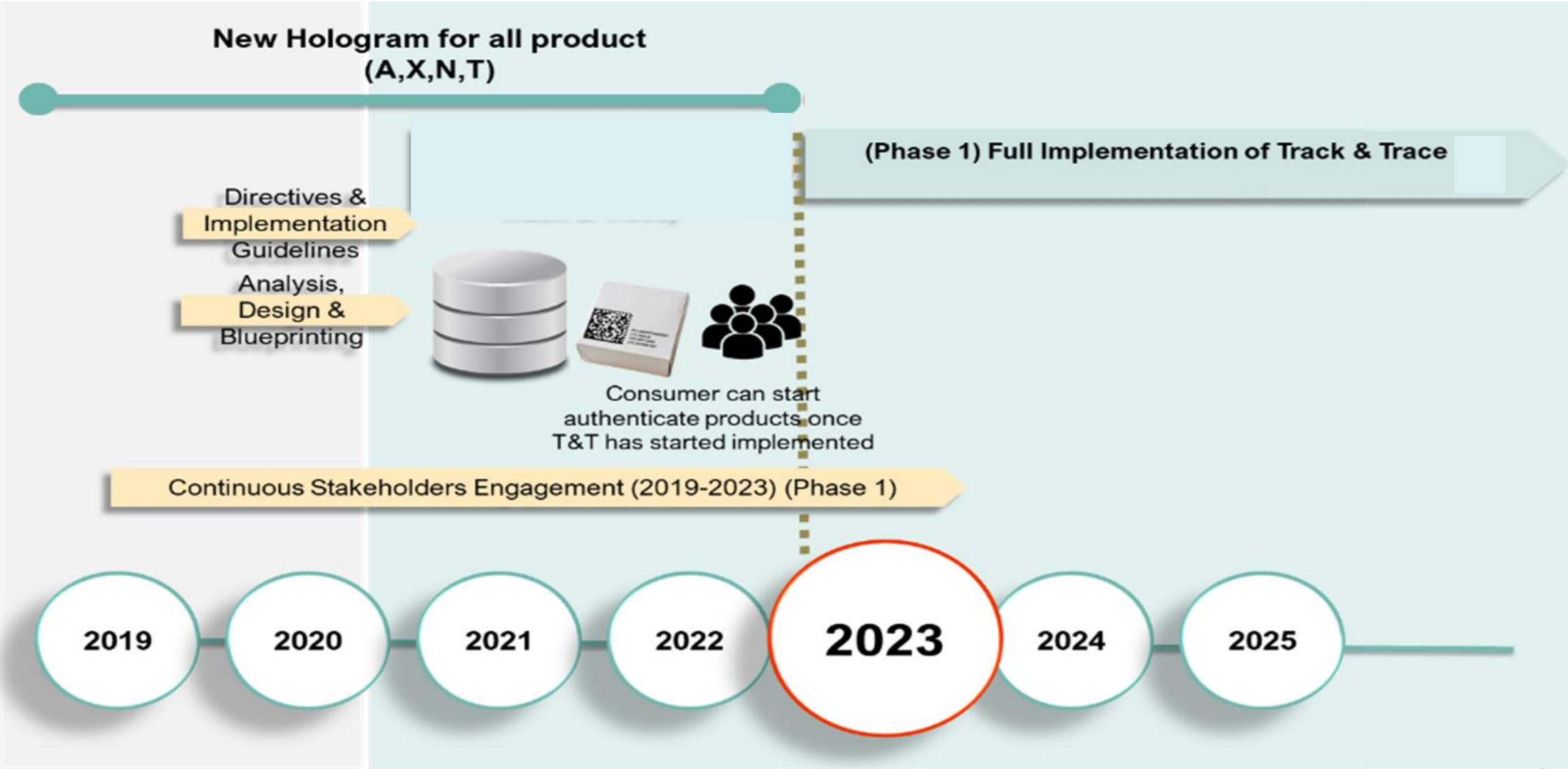
# Patient/ Consumer

# Industries

## Future possibilities:

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

# Moving forward



# Where are we now?



## ***IT Specifications & Requirements***

Level of approvals: Programme level, Ministry level, National level

- Software
- Hardware
- Implementation
- Cost
- Enterprise Architecture
- Business Value Impact Assessment (BVIA)



## ***Budget Approval***

Level of approvals: Ministry level, National level

- Governance
- Cost
- Infrastructure (includes IT)
- Business Model
- Legislation



## ***Regulatory Review & Stakeholders Engagement***

Amendment of Guidelines, Regulations, Act  
Stakeholders engagement

# Where are we now?

## Pilot Project – COVID-19 Vaccine Traceability System

### 1 Serialisation & Commissioning



1 VMS-1

BORANG DAFTAR NOMBOR SIRI  
VACCINE MONITORING SYSTEM (VMS)

Label pelikuk nombor siri:

VACCINE MONITORING SYSTEM (VMS)

GTIN>Nama Generik: COMIRNATY, Pfizer

Tarikh terima: 10 Februari 2021

No. kelompok: ABC123

Tarikh luput (awal): 1 September 2021

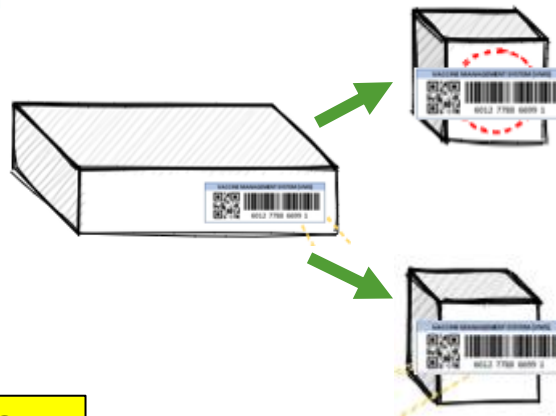
Tarikh luput (akhir): 10 Februari 2022

Kuantiti (SKU): 24 vials (24 doses)

Catatan:

PSV

### 2 Disaggregation & Issuing



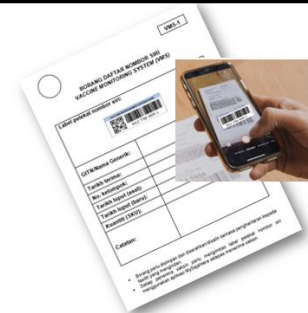
PSV

### 3 Receiving & Authenticate



PPV

### 4 Administration



Records

Vaccinee List

08-12-2020 08-12-2020 Filter

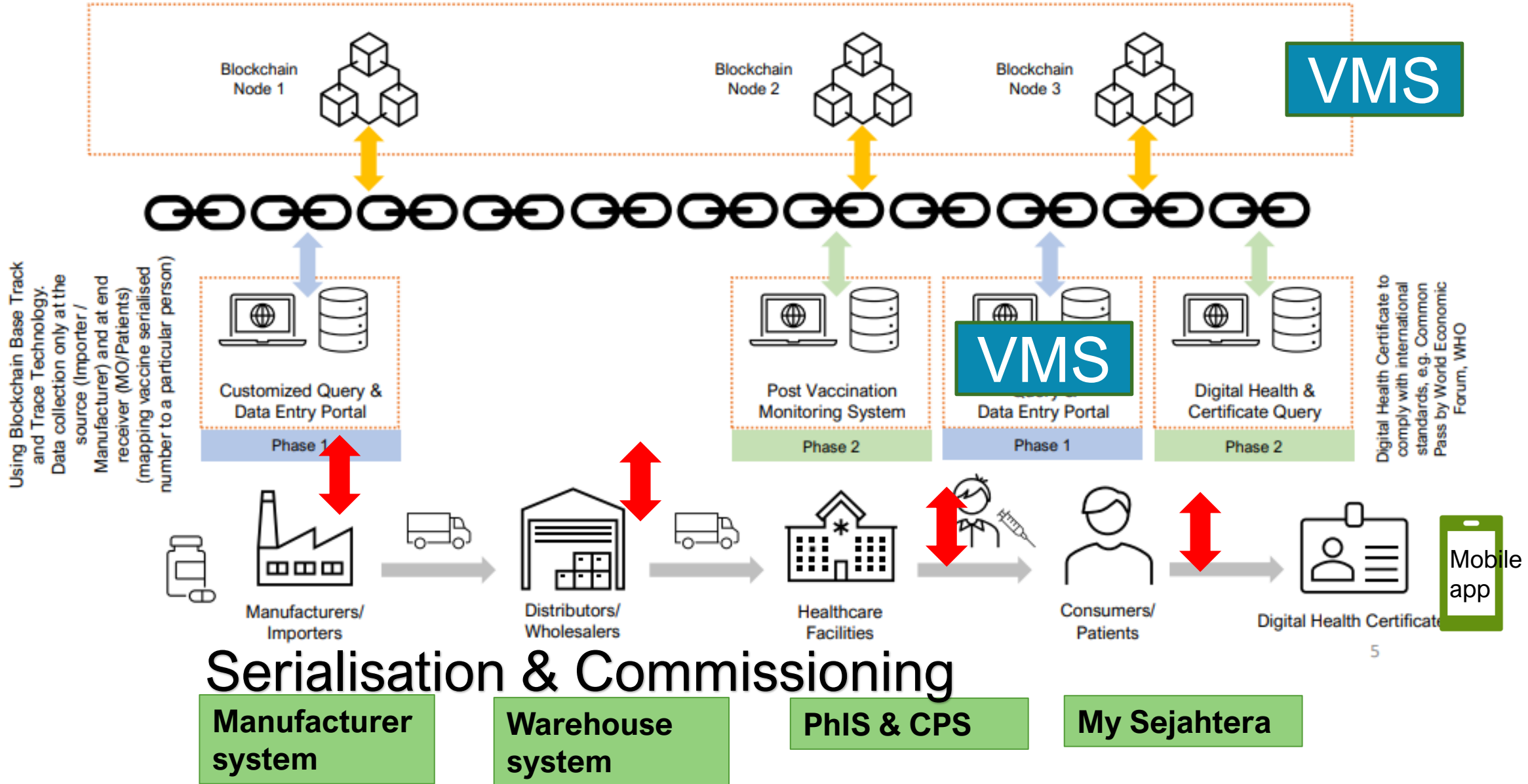
User : SN Azura  
NRIC : 781206-08-5172  
MNA No.: 123456

Location : Klinik Kesihatan Kuala Lumpur Download

Date	Name	Mobile Number / Email	IC Number	Age	Nationality	Consent	Vaccine Details	Status
08-Dec-2020 10:41	Mahesh Appanah	60123421342	831003081925	37	Malaysian	Yes	BATCH:09856	Pending
08-Dec-2020 15:42	Benny Ong Wee Tat	60176044869	831031066163	37	Malaysian	Yes		
08-Dec-2020 15:42	KumaranRamani	60172607645	890826292945	32	Malaysian	Yes		

« First 1 Last »

# Pilot Project – COVID-19 Vaccine Traceability System





“Give me six hours to chop down a tree  
and I will spend the first four sharpening the axe.”

— *Abraham Lincoln, former U.S. President*

# Thank You

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