



The Global Language of Business

# Implementation and Dissemination of Medical Device Traceability in Turkey

Turkish Medicines and Medical Devices Agency and  
The Scientific and Technological Research Council of Turkey

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# Presentation Topics

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- Overview
  - ÜTS Purpose
  - Achievements
  - Scope
- Dissemination Activities

# Introductory Video of ÜTS



## Introductory Video



# ÜTS Purpose

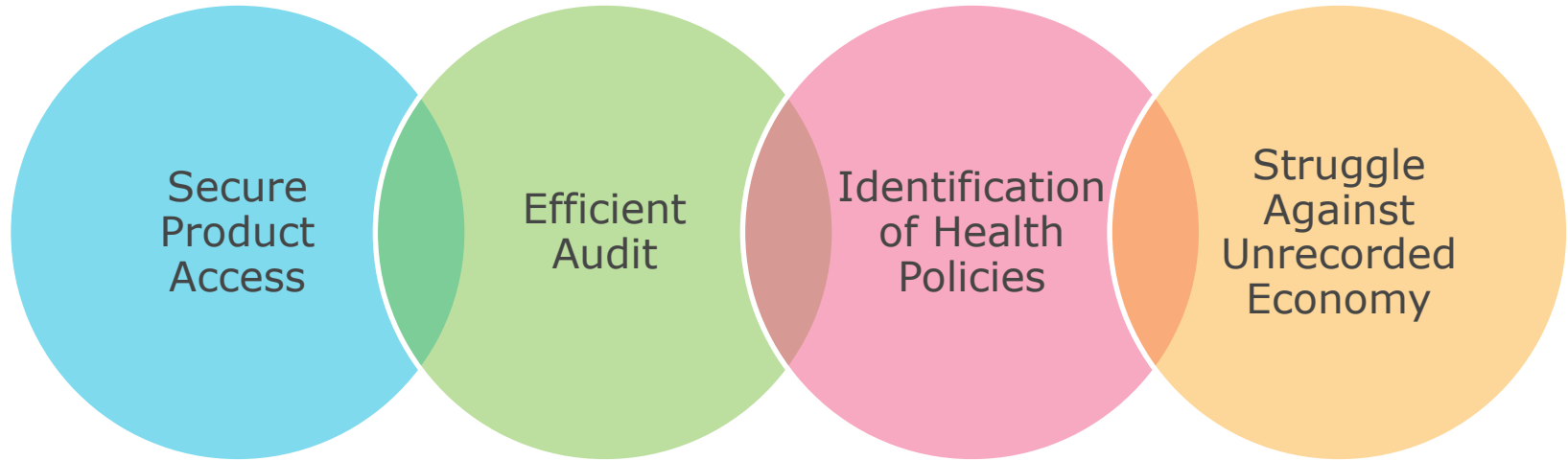


- To keep record of medical devices and cosmetic products
- To establish a **National and Original infrastructure** that can keep track of products
- **Patient safety** and protection of **public health**
- Efficient execution of **inspection services**
- Taking rapid measures for possible risks occurring during use of the products

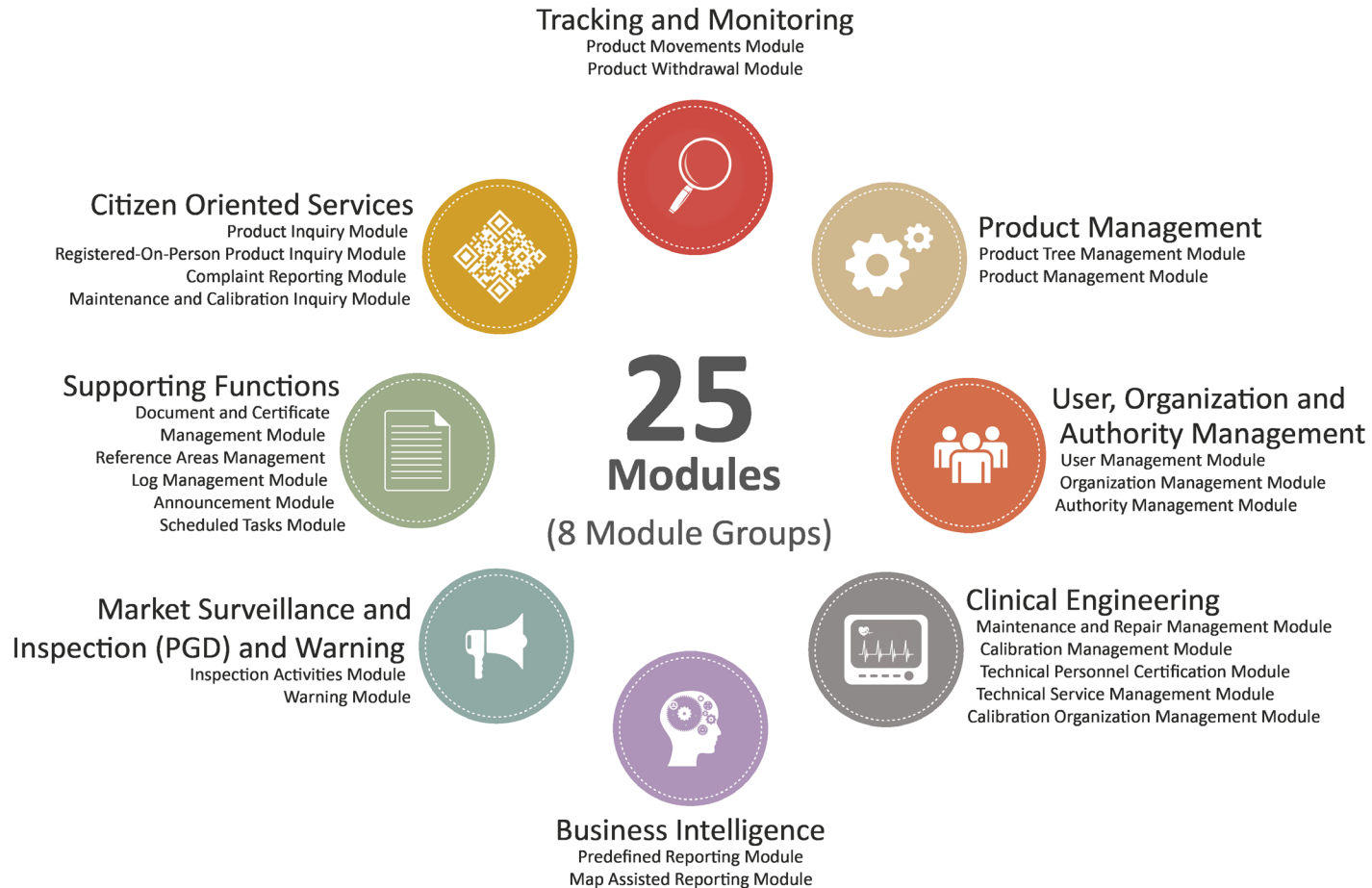


provides an infrastructure to track medical devices manufactured or imported to the place where they are sold and used.

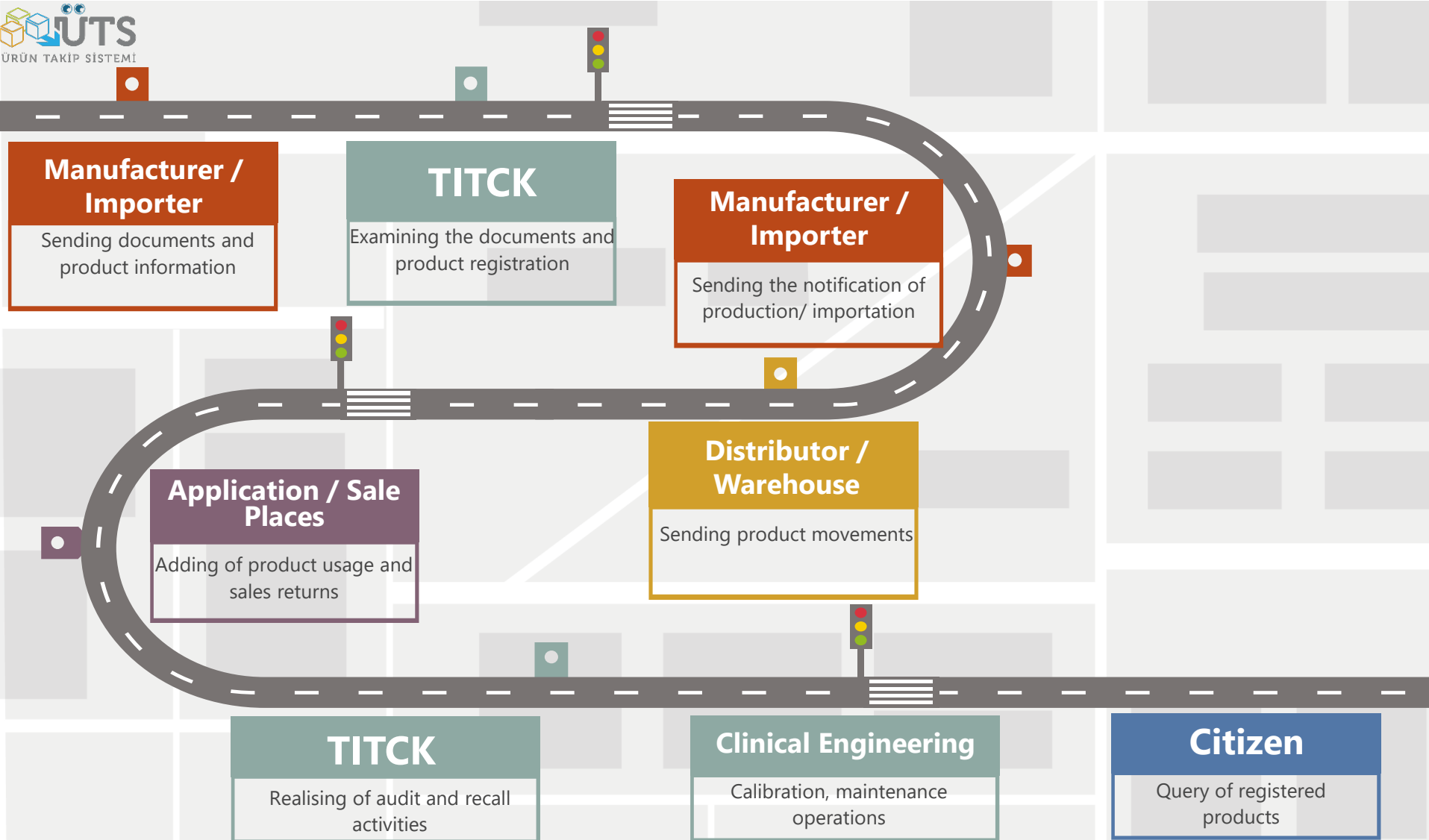
# Achievements



# Scope



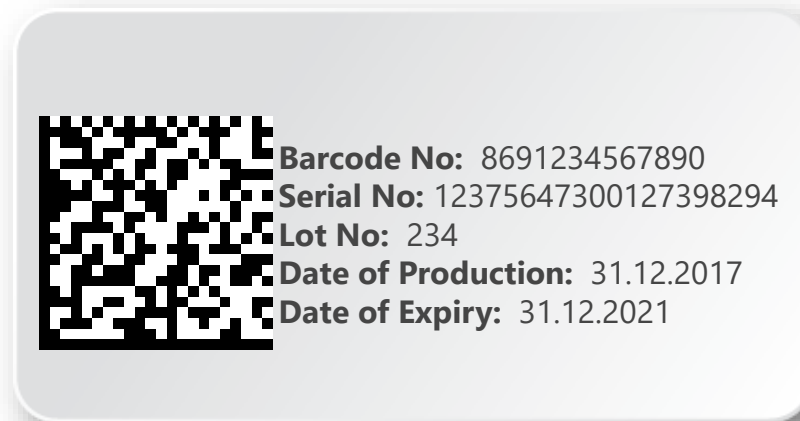
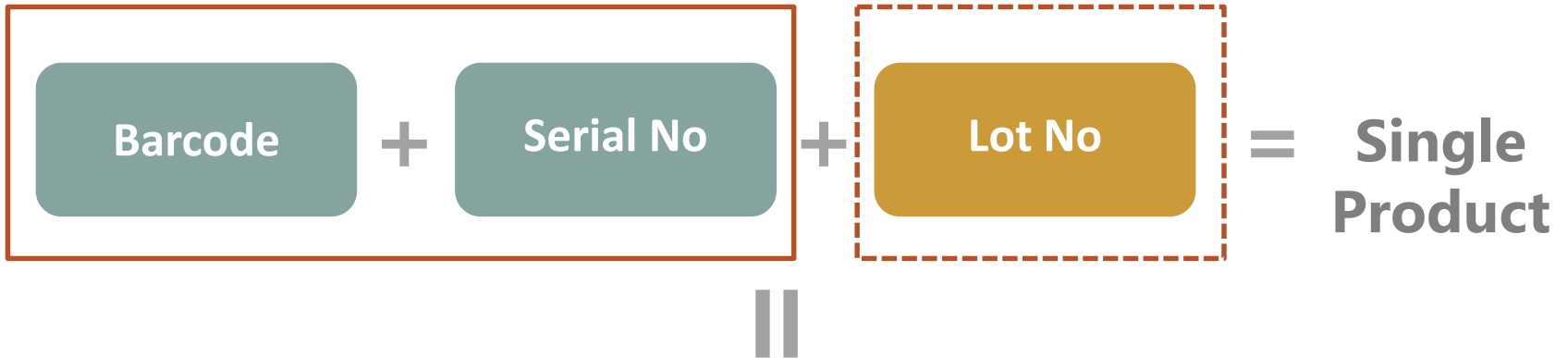
# Product Tracking System (ÜTS) Overview



# Single Product Identifier

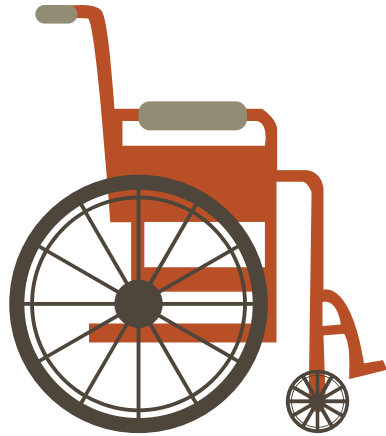


## Single Product Identifier



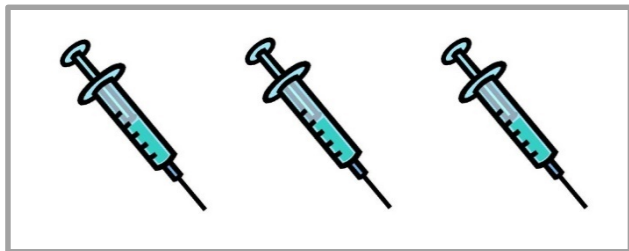


# Serial and Lot Based Tracking



Single Product

## Serial Based Tracking



Single Product Group

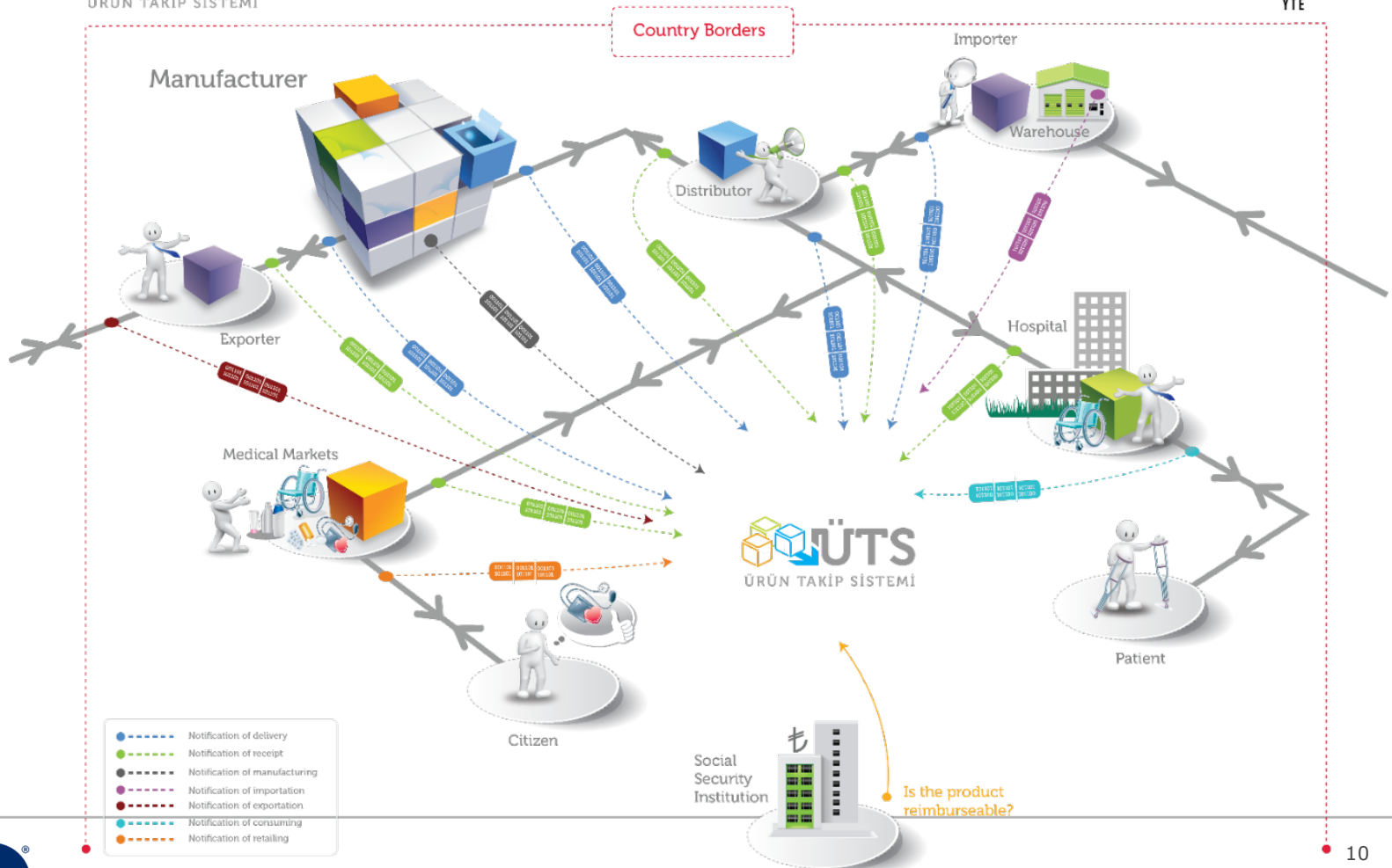
## Lot Based Tracking



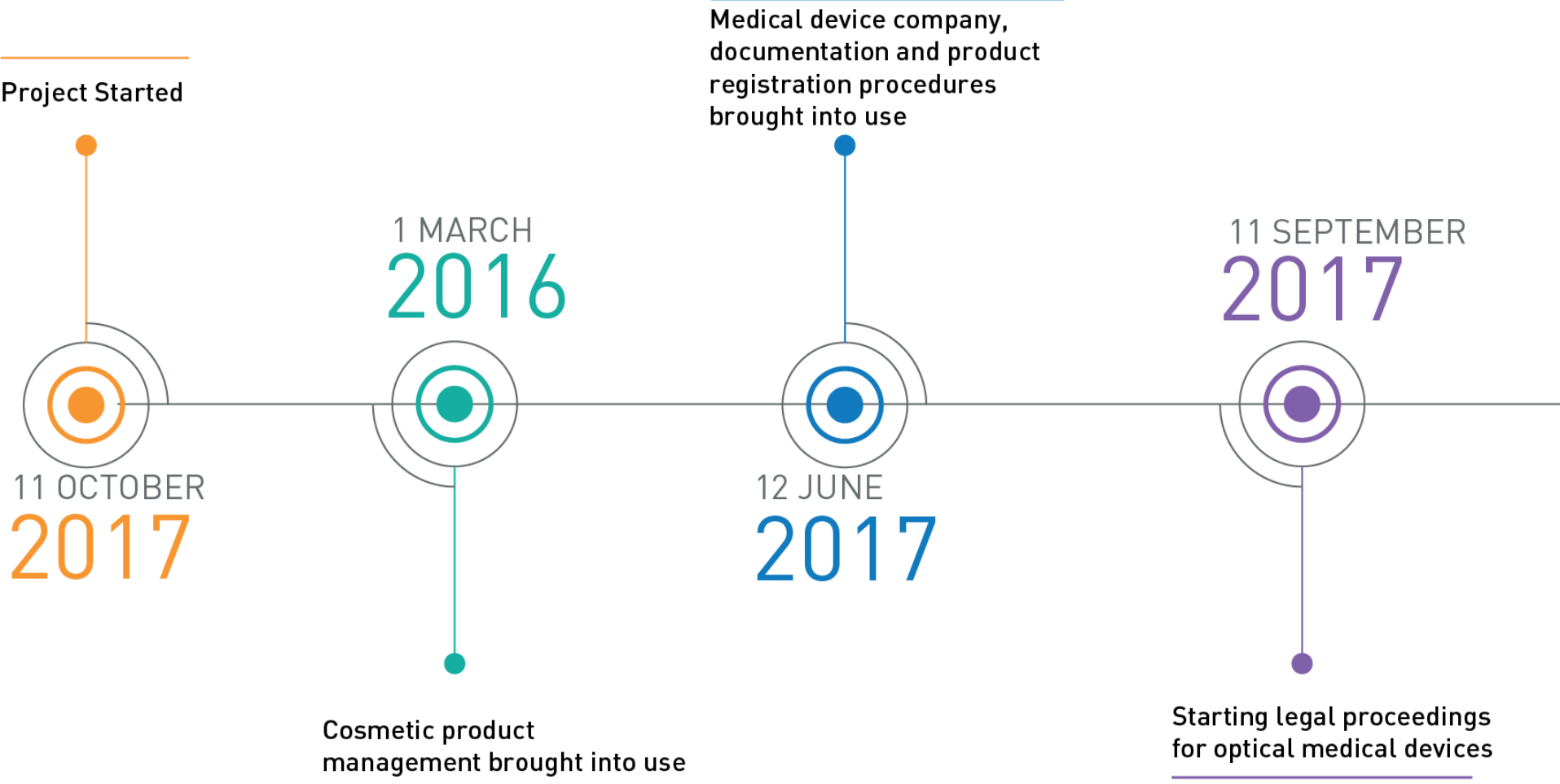
# Single Product Traceability



## ÜRÜN TAKİP SİSTEMİ



# ÜTS Timeline - 1



# ÜTS Timeline – 2



Market surveillance, audit and warning procedures brought into use

Tracking started for Class III medical devices

11 OCTOBER  
2017

2 JULY  
2018

1 OCTOBER  
2018

27 DECEMBER  
2018

Tracking started for 90/385/EEC medical devices


Project Completed



# ÜTS Tracking Transition Plan



MD Class	Start Date	
<b>Optics</b>	<b>11.09.2017</b>	● <b>Started</b>
<b>AIMD</b>	<b>02.07.2018</b>	● <b>Started</b>
<b>Class III</b>	<b>01.10.2018</b>	● <b>Started</b>
Class IIb	2019	● Planned
Class IIa	2019	● Planned
Class I	2019	● Planned

A large green arrow pointing downwards, positioned to the right of the 'Planned' status for Class I.

# Statistics - 1



As of October 2018:

Company	QTY
Manufacturer/Importer/ Dealer	6,300
Healthcare Providers	1,554
<b>Total (including others)</b>	<b>29,315</b>

Document	QTY
<b>CE Certificates</b>	13,849
<b>DoC</b>	95,719
<b>IFU</b>	71,445
<b>Total (including others)</b>	<b>189,965</b>

Product	QTY
Class I	1,845,790
Class IIa	259,918
Class IIb	460,697
Class III	225,919
IVD	39,871
<b>Total</b>	<b>2,902,134</b>

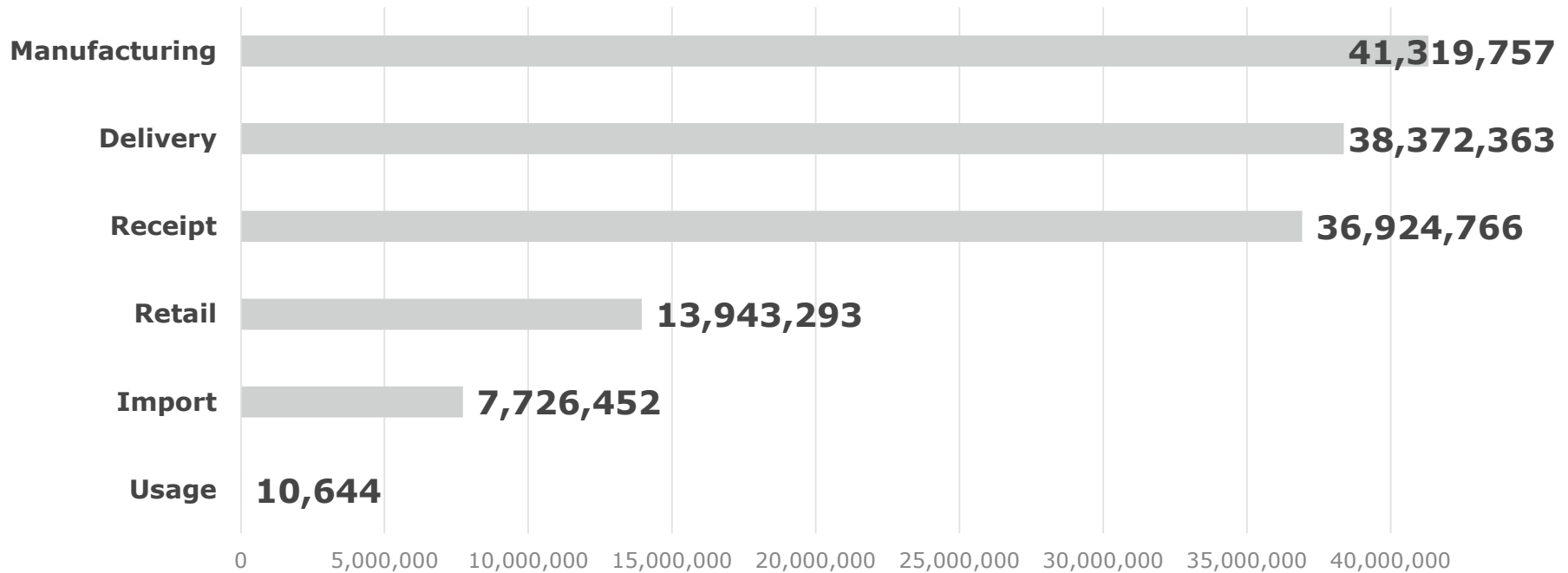
# Statistics - 2



As of October 2018:

Total Movement Notification is **140,200,065**

## SINGLE NOTIFICATIONS



# ÜTS Portal



- Information about the new versions, training materials, news on workshops conducted and up to date information about the project are published in the portal.

<http://uts.saglik.gov.tr/>

**ÜTS**  
URUN TAKIP SISTEMI

HOME ABOUT MODULES TRAINING NEWS CONTACT TR

User, Institution and Authorization Management

Product Management

Market Surveillance and Vigilance

Clinical Engineering

Monitoring and Tracking

Citizen-Oriented Services

Business Intelligence

Supporting Functions

**National and Original Product Tracking and Monitoring Model**  
Developing infrastructure in order to track medical devices and cosmetic products manufactured in our country or imported from other countries from the production line to places where they are sold and used

**Participatory Project Management Approach**  
Analyzing needs and expectations of all stakeholders.  
Organizing project workshops with participation of industry and public institutions

**Citizen Oriented Services**  
Product inquiry and Application for complaints by citizens

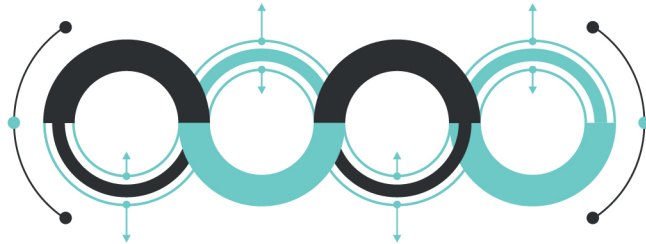


# To Sum Up



EFFECTIVE  
AUDIT

TACKLING INFORMAL  
ECONOMY



**2,9 Million**  
Registered Medical Device  
(October 2018)

**50 Million**  
Unique Product  
(October 2018)

**350,000**  
EXTERNAL  
SYSTEM  
QUERY

**400**  
DOCUMENT  
RECORD

DETERMINE  
HEALTHCARE POLICIES

ACCESS TO SAFE  
PRODUCT

**8 Million**  
TRANSACTION

**ÜTS  
IN A DAY**

**15,000**  
MEDICAL DEVICE  
RECORD

**550,000**  
MOVEMENT NOTIFICATION

**250,000**  
UNIQUE PRODUCT  
RECORD



# Contact Information



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**THANK YOU**



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