TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND
MEDICAL DEVICES AGENCY

PHARMACEUTICAL TRACK AND TRACE SYSTEM (İTS)

İlaç Takip sistemi

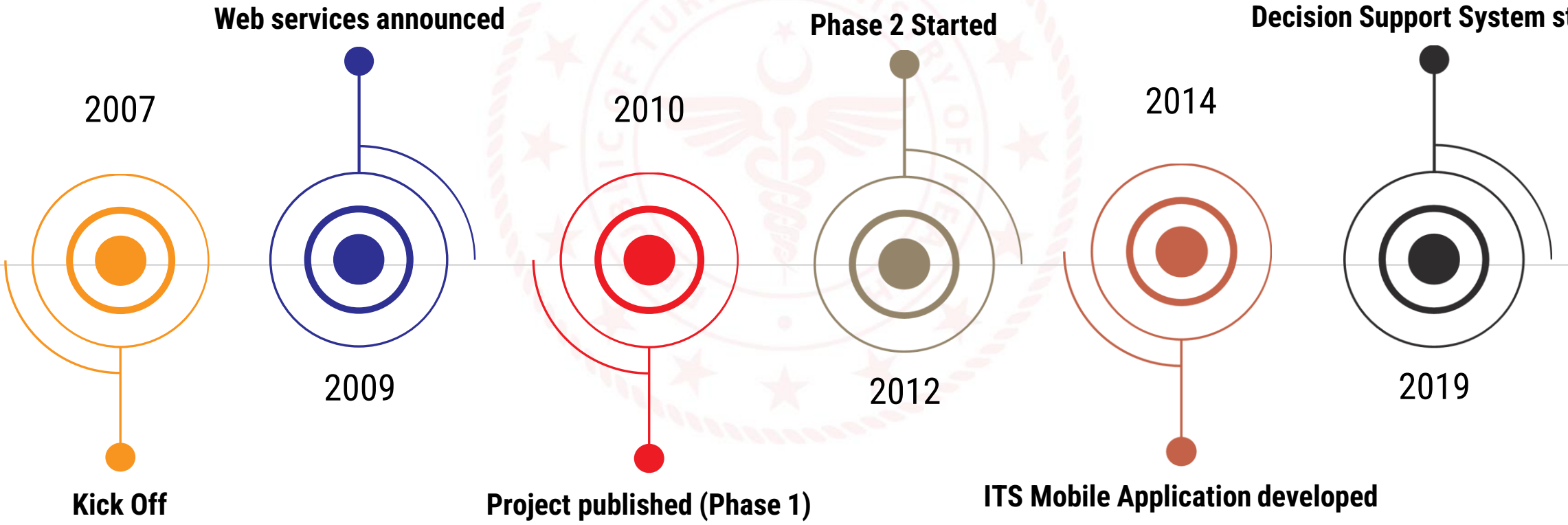
Information Systems Department
Pharmaceutical Track & Trace System Unit

www.titck.gov.tr

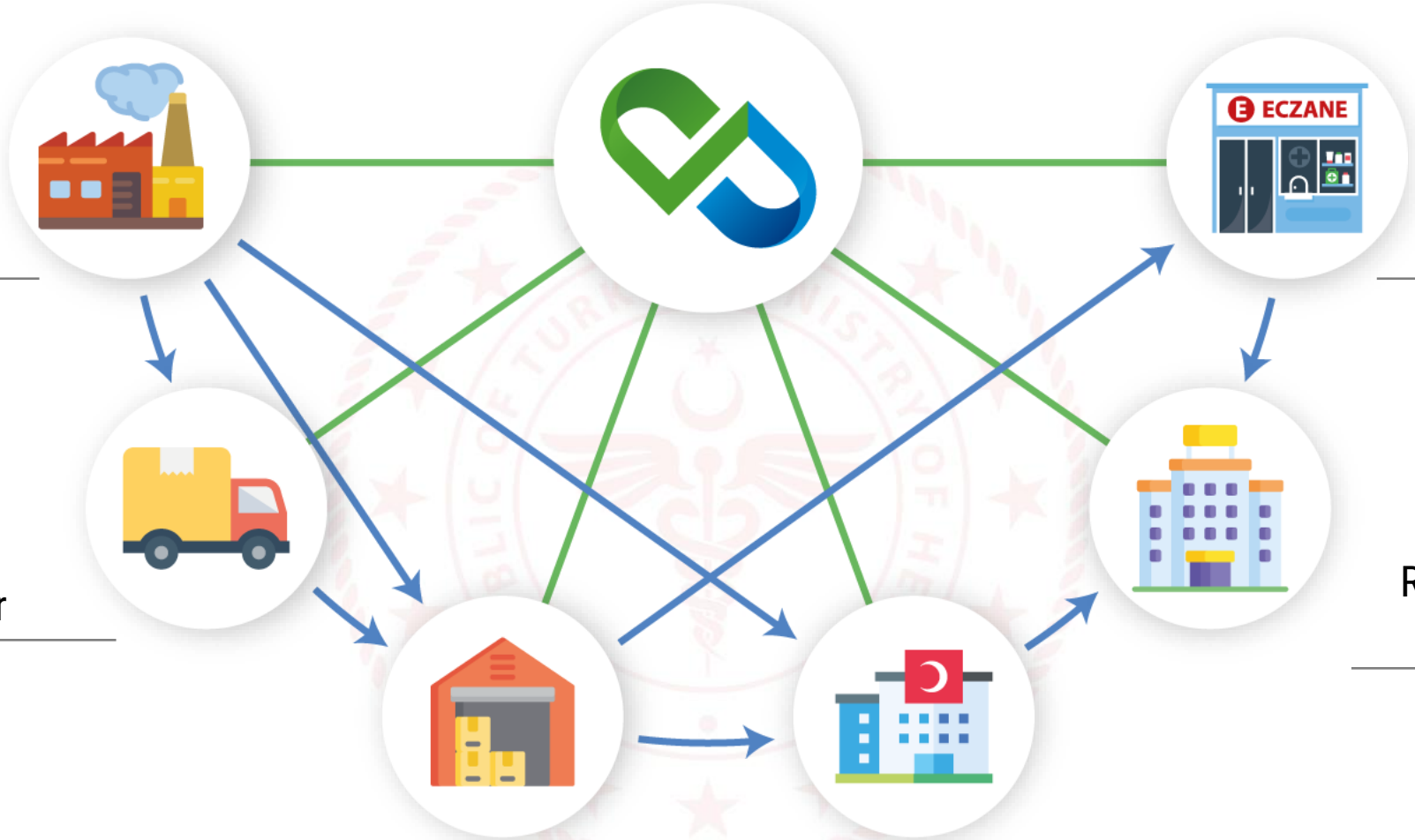
WHAT IS PHARMACEUTICAL TRACK AND TRACE SYSTEM?

Desciption

Pharmaceutical Track & Trace System is the infrastructure designed for track and trace all medicine in supply chain of Turkey. System covers every medicine box in all steps of supply chain, from production / import until consumption.



PHARMACEUTICAL TRACK & TRACE SYSTEM



Licence Holder

409

Exporter

71

Pharmacy

28.456

Reimbursement Agency

53

Pharmaceutical Warehouse

662

Consumption Center

18.022

Notification to ITS

Package Transfer

RIGHT PLACE

ITS system monitors all transactions or transaction cancellations in real time.

- Licence Holders
- Pharmacies
- Warehouses
- Consumption Centers

Medicine stocks can be monitored on the system.

MARKET CONTROL

- Various limitations and rules can be applied by İTS due to the Ministry politics.

For Example

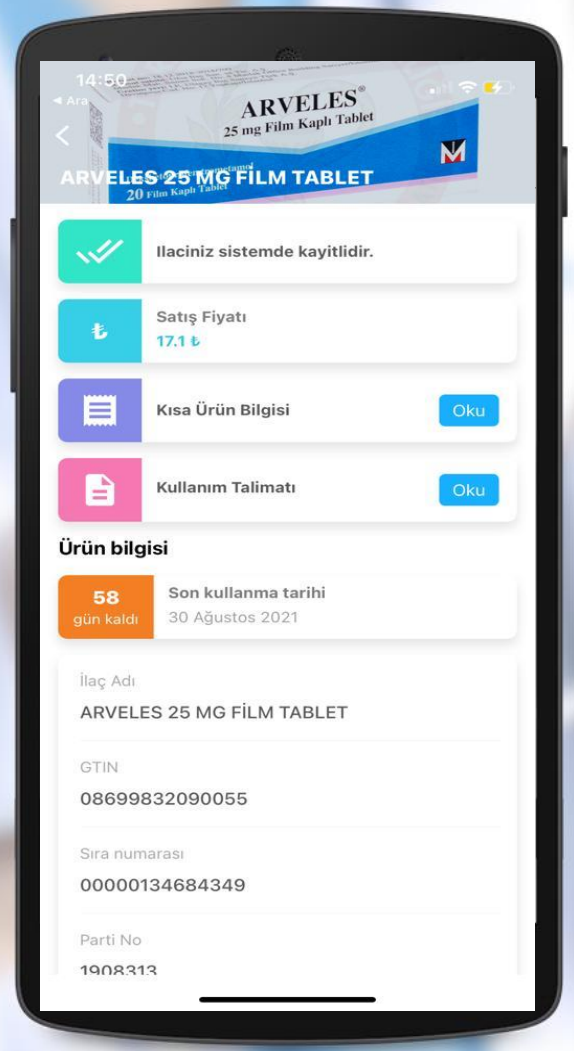
Selling of controlled medicine is limited depending on the risk groups.

RIGHT PRODUCT

1. İTS allows all kind of movements of **safe medicine** in supply chain. It protects patients and whole supply chain from counterfeit products.
2. İTS prevents **resale** of medicine.
3. İTS expedites **recalling** of medicine.
4. İTS prevents sale of **expired** medicine.

PARAMETERS

TOTAL STAKEHOLDERS	≈ 47.668
MEDICINE TYPES	≈ 10.714
MEDICINE UNITS	≈ 18.871.377.102
MEDICINE UNITS SOLD BY PHARMACIES	≈ 13.736.095.589
MEDICINE UNITS RECALLED	≈ 16.978.178
MEDICINE UNITS IN PHARMACY STOCK	≈ 523.245.611
DAILY AVERAGE TRANSACTIONS	≈ 79.198.651 (March 2022 avg.)
TRANSACTIONS IN A SECOND	≈ 917.4
RESPONSE TIME	< 0.5 Second



FOR OUR PEOPLE: İTS MOBILE

ITS mobile application that developed for public use, is available on AppStore, GooglePlay and Windows Store.

Citizens are able to learn the,

- Data Matrix Information,
- Name,
- Expiration Date,
- Price of the Medicine,
- Instructions for Use,
- If the Medicine is Recalled,
- If the Medicine is Registered on the System.

Also;

- Nearby Pharmacies Query,
- Where is my Medicine Screen,
- Locations of Pharmacies on Duty,

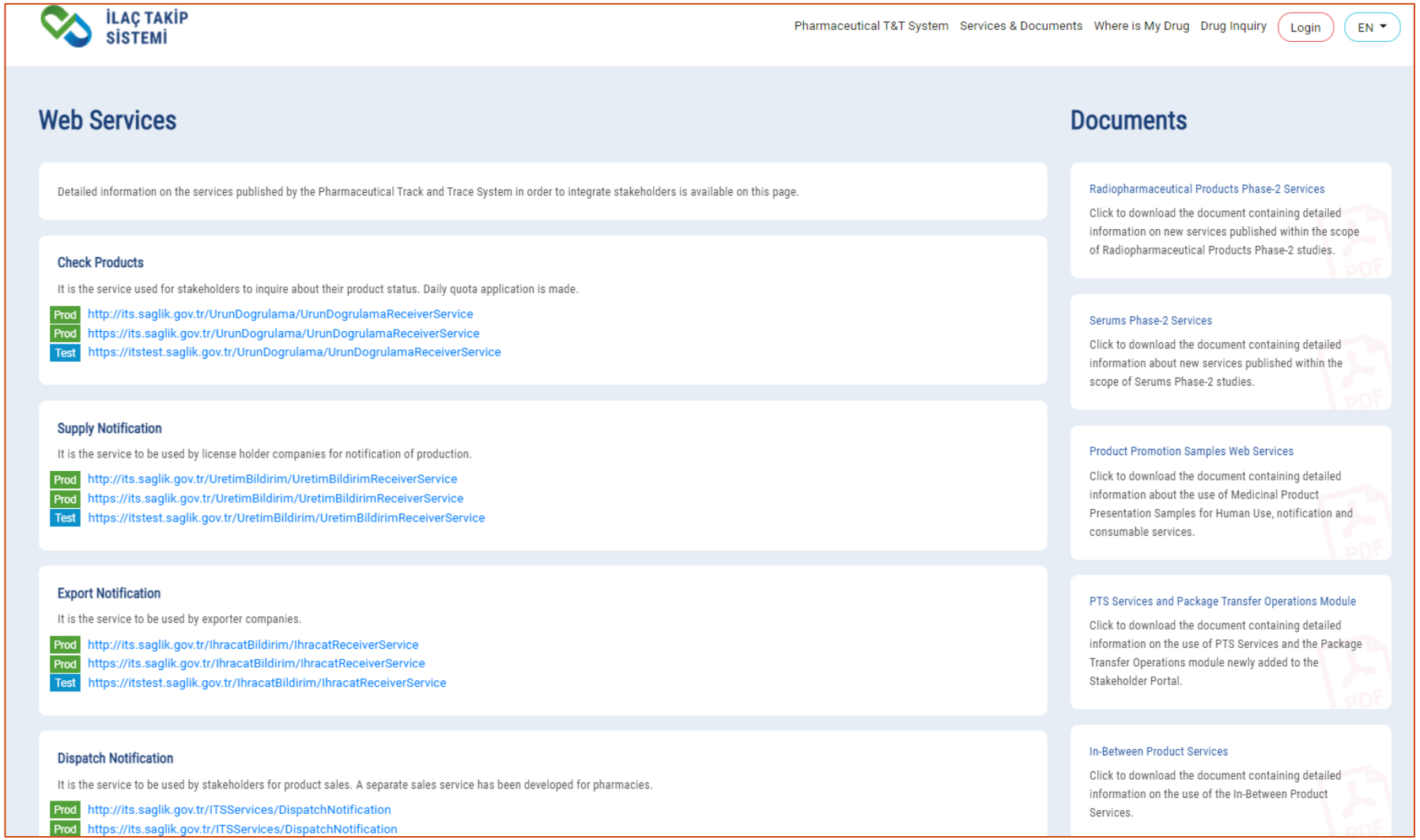
I**nsecure Medicine Notifications** and **Adverse Effect Notifications** can be made by citizens thru İTS Mobile.

identifying pharmaceutical products

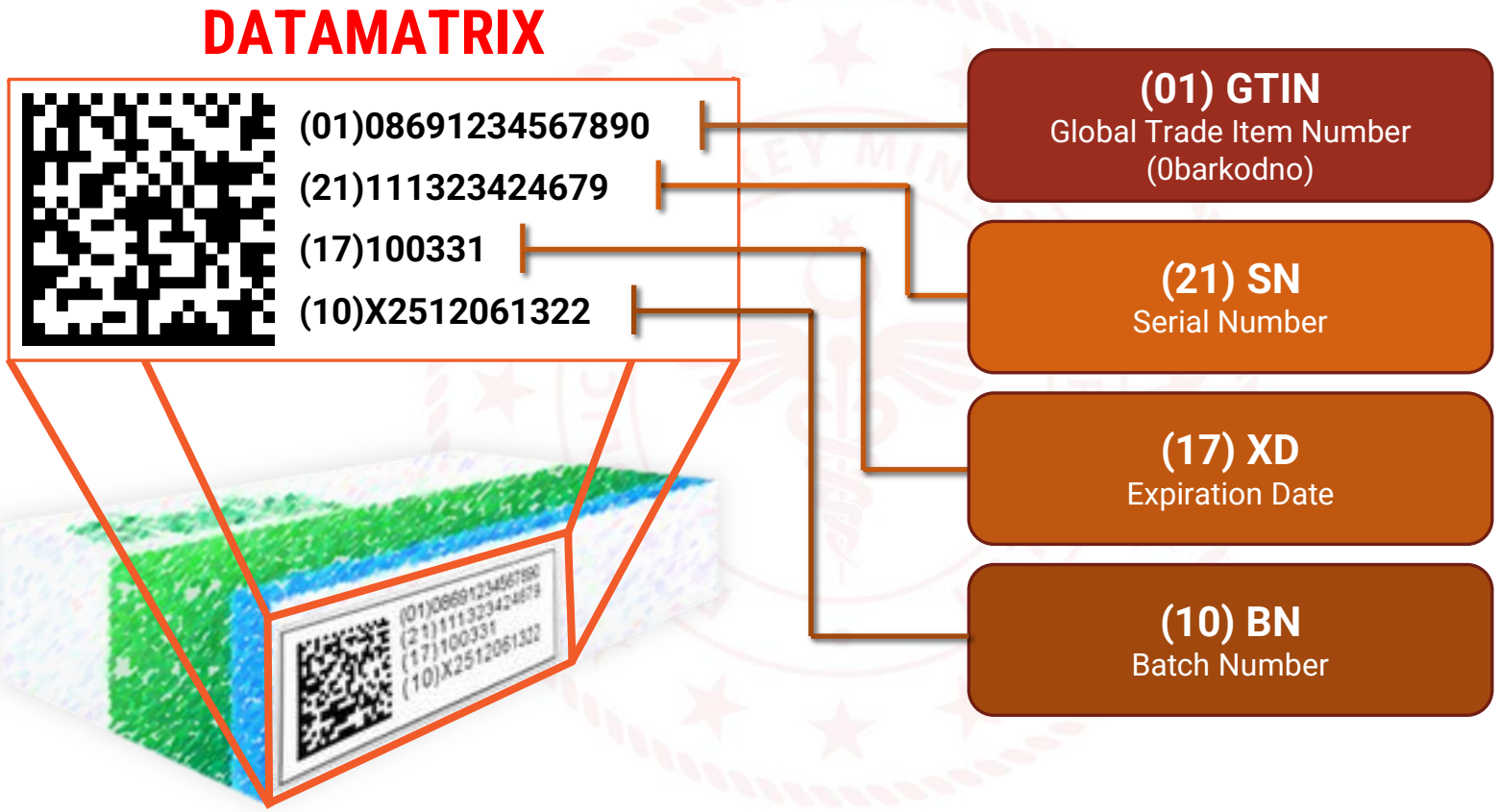
identifying stakeholders.

ITS WEBSITE & TECHNICAL DOCUMENTS

www.its.gov.tr



DATAMATRIX TECHNOLOGY



LEGISLATION

Implementing Regulation on the Labeling, Package Leaflet and Tracing of Human Medicinal Products

(https://www.titck.gov.tr/mevzuat/implementing-regulation-on-the-labeling-package-leaflet-and-tracing-of-human-medicinal-products-27122018173024)

Barcode and DataMatrix Application Guide for Medicinal Products for Human Use

(https://www.titck.gov.tr/mevzuat/beseri-tibbi-urunler-barkod-ve-karekod-uygulama-kilavuzu-27122018173036)

Pharmaceutical Track and Trace System Operating Manual

(https://www.its.gov.tr/Content/pdf/ITS_Isletme_Kilavuzu.pdf)

A REGULATION

By Ministry of Health :

Implementing Regulation on the Labeling, Package Leaflet and Tracing of Human Medicinal Products

SECTION ONE

Objective, Scope, Legal Basis and Definitions

Objective

ARTICLE 1- (1) The objective of this Implementing Regulation is to set the procedures and principles regarding the information which must be available on labeling, package leaflet of authorized or permitted human medicinal products and allow more effective efforts against defective and falsified human medicinal products by tracing and registration system in supply chain to handle public safety.

Scope

ARTICLE 2- (1) This Implementing Regulation shall comprise the minimum compulsory information that must be placed on the labeling, package leaflet and also the real persons and legal entities and institutions and organizations that are in supply chain of human medicinal products and responsible for making compulsory notifications throughout the chain.

Legal Basis

ARTICLE 3- (1) This Implementing Regulation has been prepared on the basis of Law No. 1262 on Pharmaceutical and Medicinal Preparations, dated 14 May 1928, clause (k) of paragraph one in article 3 of Principal Law No. 3359 on Health Services, dated 7/5/1987 and article 24 of Law No. 6197 on Pharmacies and Pharmacists, dated 18 December 1953 and article 27 of Decree-Law No. 663 on Organization and Duties of Ministry of Health and its Affiliated Agencies dated 11 October 2011.

Definitions

ARTICLE 4- (1) For the purposes of this Implementing Regulation, the following definitions shall apply:

a) Labelling: Information on the immediate or outer packaging.

b) Human medicinal product:

1) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings or,

2) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis,

c) Name of the human medicinal product: The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorization holder,

ç) Strength of the human medicinal product: The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form,

d) Notification: Process of inputting actual movement and state of each unit of human medicinal product into Pharmaceutical Track and Trace System through related stakeholders,

e) Outer packaging: The packaging into which is placed the immediate packaging,

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THANK YOU

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