The Global Language of Business

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ARTED, Turkey

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Product Tracking System(UTS)Turkey

What to expect from the upcoming product tracking system in Turkey?

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Agenda

- ARTED – brief overview
- Current Regulatory System in Turkey
- Overview of the Product Tracking System Project
- Issues to be further clarified
- Status of the UTS Project

Association of Research Based Medical Technologies Manufacturers

- ARTED has been established in 2009 with the mission of
  - Creating a mutual platform for development of innovative and high technology-focused medical technologies industry in Turkey
  - Ensuring access to new products, information and technologies in order to contribute to the well-being of people living in Turkey
  - Ensuring an ethical, transparent and prestigious position for medical technologies and medical device industry

- ARTED, as of 2011 is a member of Eucomed; as of Jan 2014 among the National Association Members of EDMA and founding member of GMTA.

Association of Research Based Medical Technologies Manufacturers

- ARTED, currently has 17 member companies

Current Regulatory System in Turkey

Turkish Medical Devices National Database (TITUBB)

- Products covered under 93/42/EEC MD, 98/79/EC IVD, 90/385/EEC Directives have to be registered to TITUBB
- No registration dossier
- Registrations are free of charge
- Estimated timeline for registration is 4-6 weeks

Overview of the Product Tracking System (UTS) Project

Definition of the Project

Through this Product Tracking System (UTS) Project, it is targeted to develop a substructure for the purpose of tracking all medical devices and cosmetic products manufactured whether domestically or imported, including their production line, places to where they are sold and/or areas in which they are used.

Medical Device
~4 million product types
(Billions of Singular Products)

Cosmetics
~400,000 product formulas
(Billions of Singular Products)

Overview of the Product Tracking System (UTS) Project

Purpose of the Project

- To **record** medical devices and cosmetic products
- To install a National and Unique substructure in order to **track** the products
- To contribute into the protection of **public health** and provision of patient security
- To provide a substructure for the performance of **auditing** services in a healthy and effective manner
- To ensure that quick **measures** are taken against any dangers that may arise during the use of products

Overview of the Product Tracking System (UTS) Project

Targets

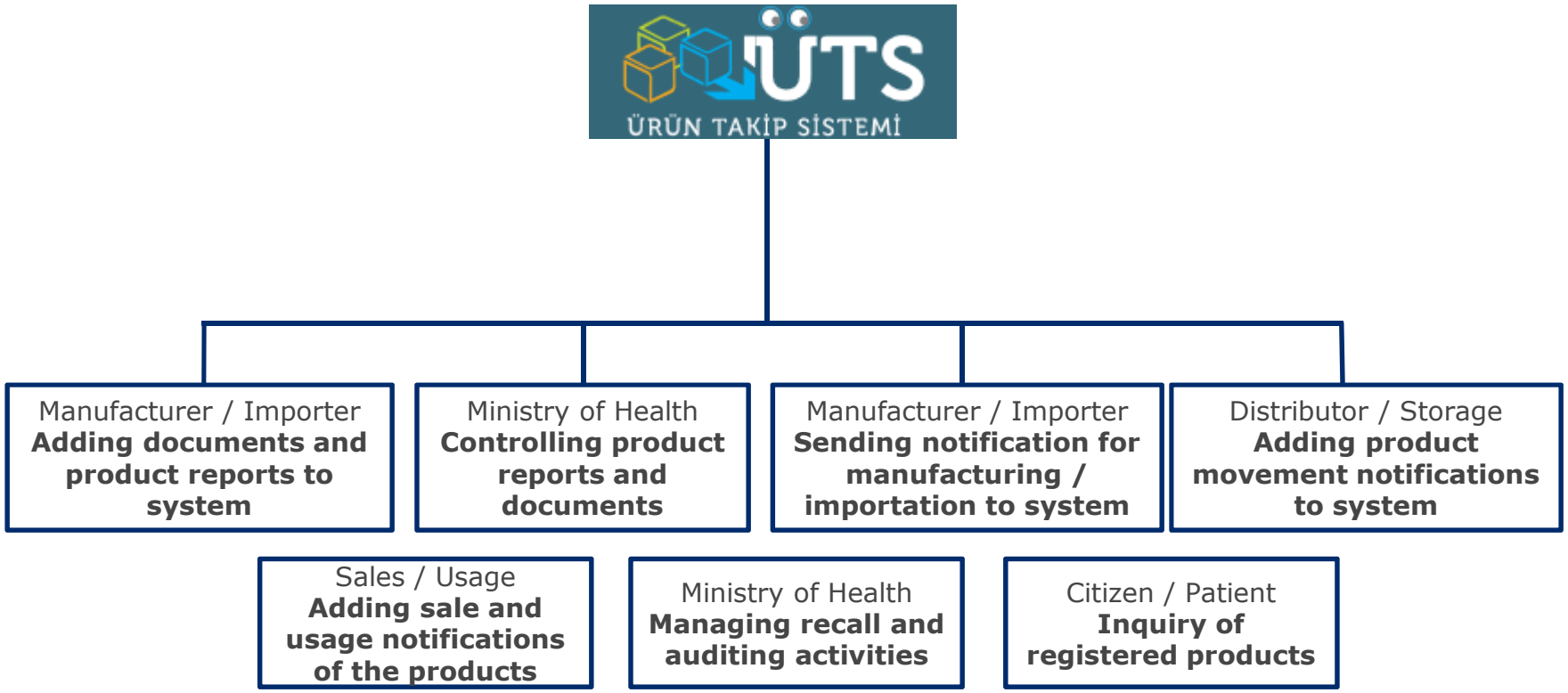
- Secure Access
- Effective market surveillance and inspection
- Define policy
- Economic contribution

Overview of the Product Tracking System (UTS) Project

UTS Users

- Manufacturer and Importer Companies
- Distributors / Warehouses
- Turkish Medicines and Medical Devices Agency (TITCK)
- Social Security Institution (SSI)
- Turkish Public Hospitals Agency (TKHK)
- National Poison Information Center (UZEM)
- Turkish Public Health Agency (THSK)
- Turkish Atomic Energy Authority (TAEK)
- Turkish Republic Ministry of Economy

Overview of the Product Tracking System (UTS) Project



Issues to be further clarified

- Which **product groups** to start with and **timelines**?

  MoH declared to be working on the product groups
- **Singular product identification** – for which products will it be an obligation, and for which products lot number-based tracking is acceptable?

  MoH declared to be working on the product groups
- **2D barcoding** - an obligation or not? On which products?

  Linear barcodes to be accepted?

  MoH declared that product groups that will have to have 2D barcodes are planned to be announced within this year
- **Date of manufacture** – a requirement on the barcode or information to be sent during production/import notifications?
- **Direct marking** – required on which products?

Status of the Project

2016

- Test is completed for cosmetic products' version
- Medical device version testing started as of March 11th
- User access given to companies chosen for test version – 9 ARTED members
- UTS expected to be up and running in June 2016 – For adding documents and product reports to system
- MoH is planning 2 more workshops

2017

- Final Acceptance
- **GO LIVE on June 2017**

Status of the Project

Started on Jan 7th 2014

Aimed to be completed by June 2017

There will be 25 modules of the system;

- ✓ **14 modules are completed**
- ✓ **5 modules are in development process**
- ✓ **6 modules' development process will start**

ARTED, through its Regulatory Committee,

is closely following up the process; gathering benchmark information and documents; attending MoH workshops and sharing feedback and testing the currently available modules.

THANK YOU