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Turkish MoH
Turkish Practice on Medical Device UDI

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Introduction

- Turkish Medical Device legislation is translation and adoption of related EU legislation (93/42, 98/79, 90/385).
- Turkey has a customs union with EU.
- Turkey can designate Notified Bodies.
- Turkish manufacturers do not need to have authorized representatives in EU; Turkey can be chosen as the local site for ARs for EU market.
Ministry of Health of Turkey
General Directorate of Pharmaceuticals and Pharmacy

Social Security Agency

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Total Land: 783,562 km² (37th)
2010 census: 73,722,988 (18th)
GDP (PPP): $960.511 billion (16th)
: $13,464 per capita

Total Expenditure on Health Per Capita $~600 USD(2010)
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Introduction

- Turkish medical device market is ~2.5-3 billion €/per year purchase.
- The majority of the market (%80) is occupied by imported products.
- Majority of the health expenditure (%80) is funded by public resources (public insurance).
- %16 of the registered products by number in the Turkish Medical Device Databank is in the positive (reimbursement) list of SGK.
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**Turkish Drug and Medical Device National Databank**

TITUBB (Türkiye İlaç ve Tıbbi Cihaz Ulusal Bilgi Bankası)

- Online registration system for medical devices, manufacturers, importers and distributors
- Operation date 2006
- Used also by Social Security Agency (fifty/fifty) for reimbursement procedures.
- Will be used as the e-catalog for electronic public procurement/tenders (EKAP; Electronic Public Purchase Platform)
TITUBB E-CATALOGUE REGISTRY PROCESS

1. VENDOR DATASET
2. PRODUCT DATASET
3. LEGAL DATASET
4. COMMERCE DATASET
5. TRANSACTIONS

- Trade Name
- Company Profile
- Location
- Category
- User Authentication
- Commercial Registers
- Legal Commercial Certificates
TITUBB E-CATALOGUE REGISTRY PROCESS

1. VENDOR DATASET
2. PRODUCT DATASET
3. LEGAL DATASET
4. COMMERCE DATASET
5. TRANSACTIONS

- Unique Identification
- Universal Product No.
- UNSPSC ontology based classification
- UNSPSC Class Nomenclature
- Medical Branch Codes
- GMDN Categorization
- Smart syndication of best match equivalents
- Ontological harmonization
- One at a life time registration
- Public Accreditation
■ Package Tracking
■ Source and Destination Tracking
■ GTIP No. Traceability
■ Age Sensitivity Control
■ Packaging Data
■ Packaging Quantity
- Online Approval Status Check
- Reimbursement Rules Mapping
- Online Current Retail, Wholesale Price Entry
- Price Effectivity Dates

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Electronically Signed Legal Document Uploads
- EC Certificates
- FDA Certificates
- ISO Certificates
- Compliance Legislation
- Declaration of Conformity
- Calibration Status
- User Manuals
- Technical Specification
- Validity Check
- Effectivity Check
- Warning Notices to Vendors
- Dealer Registration
- Mapping Manufacturer and Dealers
- Monitoring Authorized Dealers
- Online declaration of territorial exclusivities
- Monitoring Fake or Banned Dealers
- Monitoring geographical distribution of actors
- Monitoring of dealer performance
- Collaboration Portal between public authorities
- OLAP over market formation and activity
- Vendor Statistics
- Product Statistics
- Buyer Statistics
- UPN based search engine
- Web services to other e-government suites like customs, tax authority
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Turkish Drug and Medical Device National Databank
TITUBB (Türkiye İlaç ve Tıbbi Cihaz Ulusal Bilgi Bankası)

- Public health services are obliged to ask for registration to purchase a medical device and,
- Social Security Agency do not reimburse products unless registered and have a GTIN(EAN...) or HIBC.
- So every single/unique product must have an identification number...
- GMDN codes declared by the user, is also compulsory to finish the registration
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**Turkish Drug and Medical Device National Databank**

TITUBB (Türkiye İlaç ve Tıbbi Cihaz Ulusal Bilgi Bankası)

- Registration necessity of **every single medical device** in TITUBB, is the basis of UDI practice of Turkey
- And...
- Reimbursement requirements is the main initiative for UDI use in Turkey...
- Social Security Agency uses an electronic system for practical reasons during paying for the medical devices and also wants to fight against counterfeit products.
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**Turkish Drug and Medical Device National Databank**

TITUBB (Türkiye İlaç ve Tıbbi Cihaz Ulusal Bilgi Bankası)

- **MKYS** (Malzeme Kaynak Yönetim Sistemi -Product Management System) is the online stock management system used by the public hospitals; it is integrated with TITUBB

- **MEDULA** (Medikal Ulak -Medical IT System-) is the online insurance and health service provision system and it is also integrated with TITUBB
TITUBB STAKEHOLDERS

- National Authority of Health
- National Authority of Procurement
- National Authority of Reimbursement
- National Authority of Customs

- Approval of Medical Device Registers
- Procurement Rules and Market Vigilance
- Reimbursement Rules and Health System Vigilance
- Import Rules and Market Vigilance

- Vendor & Product Data RFQ & Shipments

- Sellers & Distributors
- Manufacturers

- Healthcare Providers

- TITUBB

- Procurement Transactions
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Turkish Perspectives on UDI

- UDI obligation initiated for the reimbursed products but we felt it is something needed in the medical device management system overall;
  - Market surveillance
  - Vigilance
  - Efficient health service
  - ...

- We do not discuss if it is needed or not...
- How and when...?
Conclusion

- 1.8 million MDs has been registered until now in TITUBB...
- At the beginning %20 of MDs had original UDI number but nowadays %90 of MDs have original UDI number...
- We do not want conflicts with EU in terms of requirements for putting into market and conformity assessment of MDs but; “reimbursement power” will continue to speak...
- We can manage the life cycle of a medical device in many steps...

The End