



**ARTED**

# Healthcare Transformation in Turkey:

*Impact on product traceability and patient safety*

Sinem Yaman

*ARTED Regulatory Steering Committee Chairman*

- ◆ Update on ARTED
- ◆ National Databank (TITUBB) by Industry 's conception
- ◆ Universal Standarts used in National Databank
- ◆ Actions taken by ARTED
- ◆ Improvement Areas & Recommendations

# ARTED Mission



- ◆ Adding value to Health Industry's future by proactive approach
- ◆ Increasing awareness in Health Economy, Law & Logistics among the medical device market & citizens
- ◆ Contribution to the access of patients in Turkey, to contemporary and innovative treatment
- ◆ Strongly emphasizing compliance with business ethics

# ARTED Founders



- ◆ 3M
- ◆ Abbott
- ◆ Eczacıbaşı Baxter
- ◆ Alcon
- ◆ Boston Scientific
- ◆ Covidien
- ◆ GE Healthcare
- ◆ Johnson & Johnson
- ◆ Medtronic

# Short Name & Logo



- ◆ Short Name: ARTED
- ◆ Abreviation from “Asc. of Research based Medical Technology Manufacturers”



# Board of Directors

- ◆ Chairman: Umit Dereli (Johnson & Johnson)
- ◆ Vice-Chairman: Goksin Ozel (Covidien)
- ◆ Vice-Chairman: Zafer Okatan (Medtronic)
- ◆ Treasurer: Vural Isiker (BSCI)
- ◆ Member: Burak Dagdanas (Abbott)
- ◆ Member: Esra Yildirim (GE Healthcare)

# Steering Committees



- ◆ Regulatory: chaired by Sinem Yaman(Covidien)
- ◆ Ethics & Compliance: chaired by Altay Akbulut (Baxter)
- ◆ Health Economics: chaired by Umit Dereli (J&J)
- ◆ Corporate Communications: chaired by Vural Isiker (BSCI)

# National Databank by ARTED's conception



- ◆ Web based system to enable all respective parties, to conduct the tender proposal, order, shipment, procurement, inventory, patient order, invoicing and payment processes in an electronic environment.
- ◆ Create e-commerce baseline & add value to industry by means of decreasing the cost, resource need and centralising the process.
- ◆ Creates opportunity in tracing (distributor notifications)
- ◆ Creates control on the products in the market



# What we did as ARTED



- ◆ We have had several meetings with the workgroup that was sponsoring and leading the TITUBB project .
- ◆ Worked on the branch tree project that will be alternative product categorisation tool to GMDN.
- ◆ Shared our improvement area ideas & concerns about the current TITUBB version and upcoming planned one and agreed on the modifications.

These improvement areas from ARTED's  
conception were.....

Though GTIN specifies item uniquely all around the world;

In the TITUBB,

Entries can be done only with GTIN 13 & HIBC.



# “Only” GTIN-13 acceptance pain areas

- ◆ In order to register a product with a physical GTIN-14, it is required to convert GTIN-14 to GTIN-13 by the converting tool in TITUBB and register the product with that converted number.

**Barkod Dönüştürücü -- Web Page Dialog**

**Girilen barkodla, kontrolden geçen barkod birebir aynıysa, girilen barkod GEÇERLİ bir barkoddur.  
Eğer farklıysa girilen barkod kontrol edilmelidir veya sisteme önerilen şekilde girilebilir.**

Kontrol Edilecek Barkod:

Kontrolden Geçen (Önerilen) Barkod:

<http://www.huap.org.tr/ubb/MidBarkodDonustur.aspx> Internet

*Barcode that will be controlled*

*Barcode that has passed the control & recommended*

## Risks:

### ◆ Risk on patient safety

- ◆ Lack of product traceability
- ◆ Lack of package configuration information
- ◆ Lack of unique GTIN number usage in all steps of supply chain process.
- ◆ Hospitals request the converted GTIN-13 barcode on the product
- ◆ Hospitals request to deliver the exact amount in the tender list which results in breaking the package configurations in the deliveries.

ORIGINAL PRODUCT NUMBER (GTIN 14)

10614141000071

CONVERTED PRODUCT NUMBER (GTIN 13)

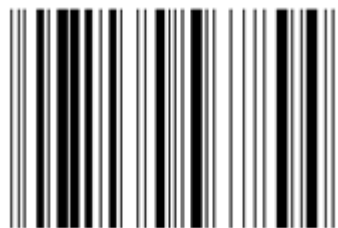
0614141000074

ORIGINAL BARCODE ON THE PRODUCT LABEL



(01) 10614141000071 (17) 101231 (10) ABCD12345

ADDITIONAL BARCODE THAT THE HOSPITALS REQUEST



0614141000074 >

# Recommendations



- ◆ Recommendation 1: Acceptance of GTIN-14 in the system to allow to register the products with the right & accurate package configuration information.
- ◆ Recommendation 2: To be able to give quotations in the tenders without breaking the package configuration in the e-commerce software. For that e-commerce software should include the package configuration calculations. Hospitals need to accept not the exact but the nearest quantity according to the manufacturer package configurations.

# Entries with the same GTIN number by different companies



- ◆ Any company can import and put in the market any product they want.
- ◆ Risk in product traceability and patient safety as there is a possibility of having some products in the market without the manufacturer authorisation.
- ◆ In a possible vigilance case, tracking will be harder



# Entries with the same GTIN number by different companies



## ◆ Recommendation:

Manufacturer authorisation letter should be requested

# Exercises on GTIN acceptance



- ◆ In the requirements of the tender document, the companies should give their tender offers indicating the product identification number ( which is the GTIN)
- ◆ As we all know, in some cases there is a possibility of GTIN change by the manufacturer for the same catalogue number till the product delivery (new language addition to the label etc.)
- ◆ In this case, this is not accepted and the companies are under a risk of being tender banned.

# Recommendation



- ◆ In e-commerce;  
how to accept different GTINs should be defined taking into consideration the cases with changed GTIN for the same catalogue code/product

- ◆ GMDN will be used as an alternative tool for sorting the product categories and tenders will be announced according to GMDN categories in e-commerce.

- ◆ GMDN list in the TITUBB does not include all the GMDN codes.
- ◆ It should be updated periodically if it will be used in the new TITUBB version.

- ◆ Like GMDN, the UNSPSC list in the software should be updated periodically.
- ◆ If the 3 categorisations; GMNDN, UNSPSC & branch tree will be used in the future, it will be useful if a correlation can be created between these 3 categories, instead of entering them seperately.

# We know that;



- ◆ TITUBB database is an useful software for the industry
- ◆ Sponsored and managed by an easy to communicate, reachable, industry oriented team
- ◆ Is going through ongoing improvement
- ◆ All the fixations will be done in a planned manner to eradicate the product traceability and patient safety risks

THANK YOU