TURKISH PHARMACEUTICS & MEDICAL DEVICES

NATIONAL DATA BANK PROJECT

Doruk GÖKŞİN, BA
Project Manager
Presentation Plan

1. Goal
2. Previous Situation
3. Recommended & Applied Model
4. Issued Performance
5. Current Data
6. National Data Bank - Public Procurement Authority Integration
The primary goal of the National Data Bank Project for Pharmaceutics & Medical Devices is to create a common language, to share data electronically between all relevant parties like; Manufacturers, Exclusive Dealers, Distributors, Purchasers, Users, Surveillance Authority and Reimbursement Agency.

This project is under the protection of MoHealth, MoLabor & Social Insurance & MoFinance of Turkish Republic with a signed protocol dated July 14, 2004.
PREVIOUS SITUATION
Previous Situation

Exclusive Dealer

Turkish Manufacturer

Distributor

Hospitals
(Procurement, Stock Control, Internal Consumption)

Reimbursement Agency (SIA)

Surveillance Authority (MoH)

Medical Doctors, Patients

Vendors

Forwarding Companies

Previous Communications Methods between Procurers & Relevant Parties to Share Product Data
Problems & Difficulties

• Communication does not match to a Standard Model.
  – Phone, fax, internet, e-mail, paper, etc...
  – Sometimes an Exclusive Dealer answers for requested data,
  – Sometimes this data comes from a Third party.
• Requires plenty of communication traffic.
• Different parties have different datas for the same product specifications. No harmony.
• Each party has its own way of Data Recording Model. No synchronisation
• No classification therefore products could not be grouped.
Results

• Does not fulfill the requirements of reimbursement agencies.
  – *Rules are conformed only for a group of products not for every single item*
  – *Difficulty to establish relations between group of product and the item itself*

• Almost impossible to observe and inspect the local market functions and activities.
• Severe threat for patient safety.
• Does not support *e-commerce* procedures.
RECOMMENDED & APPLIED MODEL
Recommended & Applied Model

- Exclusive Dealer
- Turkish Manufacturer
- Distributor

National Data Bank

- Party
- Party
- Party
- Party
- Party

- Hospitals (Procurement, Stock Control, Internal Consumption)
- Reimbursement Agency (SIA)
- Surveillance Authority (MoH)
- Medical Doctors, Patients
- Vendors
- Forwarding Companies
Electronic Procurement

Vendor (Manufacturer & Dealers)  National Data Bank  Parties

- Company Details (PARTIN)
- Product / Service Catalogue (PRICAT)
- Legislation Documents (DLEGAL)
- Purchase Order (ORDERS)
- Transportation Data (DESADV)
- Invoice & Payment (INVOIC)
- Money Order (REMADV)
Data Model

Company

Basic Data Set (PRICAT)

Law Data
Clinical Data
Formula of Drug
Price

Mandatory Data Set for Country Scale Data Synchronization

Everyone uses his requests with PRICAT document.
Most Important Data Field

• Universal Product Number (UPN) or Global Trade Item Number (GTIN)
  – Specifies the item uniquely all around the world.
  – Uniqueness of number is not sufficient,
  – Shall be reached by all parties upon request spontaneously.

UPN or GTIN number is on the item as well as in the Data Bank

UPN Number written by Linear Barcode Technology

EAN-13
HIBC
İLAÇ VE TIBBÎ ÇİHAZ TANIMLAMA FORMU

PRICAT

---|---|---|---
11.05.2006 | PRICAT | 8191 | İLK KAYIT

5. Veri Geçerlilik Başlangıç Tarihi: 11.05.2006
6. Veriyi Giren Kişinin TC Kimlik Numarası: 17355252010
7. Firma Tanımlayıcı No: 2687280000138
8. Tedariki Firma Adı: Şengel Tıbbi Araç ve Geräcler Ltd. Şti


12. Etiket Adı: F11.4 HUBREGTSE ENDO SET 9CM  

13. Marka Adı: HUBREGTSE  
14. Tedarikçi Ürün Dahili Referansı: 7006110000

15. UNSPSC Kodu: 42000000  
16. UNSPSC Sınif Adı: Tibbi Dönem ve Aksesuarları ve Malzemeleri

17. İthal/İmal: İTHAL  
18. Renk:  
19. Ambalaj Türü:  
20. Ambalaj İç Miktarı:  
21. Ambalaj Miktarı Birimi:  

22. Genişlik(mm):  
23. Yükseklik(mm):  
24. Derinlik(mm):  
25. Raf Omru (oy):  

BU BÖLÜM SADECE TIBBİ ÇİHAZLAR İÇİNDİR

26. GMDN Kodu: 03442  
27. GMDN Adı: Sınıflandırılmamış

28. Art Öluşu Yönetmeliği:  

Form No: TITUBB-P003-F005  
Revizyon No: 1

Düzelte Ürün İptal Yeni Barkodla Kaydet  
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11. Ait Olduğu Yönetmelik: 93/42/EEC

44. Üretici Firma Numarası (GLN): 
45. Üretici Firma Adı: 
46. Hana (Üretildiği) Ülke Kodu: 
47. Hana Ülke Adı: 
48. İthal Edildiği Ülke Kodu: 
49. İthal Edildiği Ülke Adı: 
50. GTIP Numarası: 
51. Sınıf/Lokasi: Sınıf I Diğer

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| 86. Belge Göçerilik Başlangıç Tarihi: |
| 87. Belge Göçerilik Bitiş Tarihi: |

| 88. Ürünün İlişki Olduğu Ek Yönetmelik: |
| 89. Belgeleniren Kuruluş Kimlik No: |
| 90. Belgeleniren Kuruluş Adı: |
| 91. Belge Numarası: |
| 92. Belge Göçerilik Başlangıç Tarihi: |
ISSUED PERFORMANCE
Issued Performance

• Decision of a common data set for Pharmaceutics & Medical Equipment to collect the necessary data.
  (July 21 - Oct 03, 2005)

• Decision of another necessary data to collect for Pharmaceutics & Medical Equipments.
  (Oct 03, 2005 - Feb 14, 2006)

• Design of Forms for Data Entries
  (Oct 03, 2005 - Feb 14, 2006)

• Preparation of Manuals for Utilisation of Relevant Forms & Procedures
  (Oct 03, 2005 - Feb 14, 2006)
Issued Performance

• System Development Kick-Off.  
  (Start: Feb 15, 2006)
• Translation of UNSPSC (United Nations Services and Products Standard Codes) Classification System.  (Completion: Mar 03, 2006)
• Translation of Recent Release of GMDN (Global Medical Device Nomenclature) System.  
  (Completion: Apr 06, 2006)
• Implementation of First Release  (Apr 10, 2006)
General Specification

- Works fully in an electronic environment. (www.huap.org/ubb)
- All product data entries are submitted via web only by Accredited Users acknowledged by the Companies.
- The uploaded data are inspected and approved by Authorized Staff of MoH & SIA after a period of acceptance.
- Detailed registrations of all procedures are stored with different message numbers.
Universal Standards Used for Medical Equipment

- EAN Suggestions & Standards for PRICAT Data Model.
- EAN-13 & HIBC Codes for UPN / GTIN.
- Self Validating Numbering System for Company Accreditation Numbers.
- UNSPSC (United Nations Services and Products Standard Codes) & GMDN (Global Medical Device Nomenclature) for Medical Equipment Classification.
Universal Standards Used for Pharmaceutics

• ATC (Anatomic-Therapeutic-Chemical) for Drug Classification System and NFC (New Form Codes) System.
• Unit of Measurements: ANSI-UOM (regarding EAN suggestion)
• WHO-INN Standard for Active Ingredients
• ISO-3 Digits for National Country Codes
CURRENT DATA
Current Data
(as of February 12, 2008)

• 2432 Accredited Company.
• 13,823 Accredited Subsidiary.
• Appr. 590,000 each of registered Medical Device.
• 588,263 Medical Device controlled & approved by SIA (Social Insurance Association)
NATIONAL DATA BANK – PUBLIC PROCUREMENT AUTHORITY INTEGRATION

(e-Procurement Platform)
The “Medical Device Company” shall present all details of electronically and from PPA webpage into its computer. (actual status shall include address of tenderer and indication of medical item to be stated in tender) in soft PDF for the instrument. With same software; barcode, quantity and offered price shall be entered.
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A Very Special Thanks to Management for their valuable support