TiTUBB

Turkish National Databank Project For Pharmaceutics & Medical Devices

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Project Manager
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 Security & MoFinance of Turkish Republic with a signed protocol dated July 14, 2004.
Previous Situation

- Exclusive Dealer
- Turkish Manufacturer
- Distributer
- Hospital (Procurement, Stock Control, Internal Consumption)
- Reimbursement Agency (SSA)
- Surveillance Authority (MoH)
- Medical Doctors, Patients
- Vendors
- Forwarding Companies
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 vigilance & 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

- Exclusive Dealer
- Turkish Manufacturer
- Distributor

National Data Bank

- Hospitals (Procurement, Stock Control, Internal Consumption)
- Reimbursement Agency (SSA)
- Surveillance Authority (MoH)
- Medical Doctors, Patients
- Vendors
- Forwarding Companies
Most Important Data Field

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

UPN Number written by Linear Barcode Technology
Standards

- GMDN (Global Medical Device Nomenclature)
- UNSPSC (United Nations Service & Products Supply Codes)
- International Medical Device Directives.
- National “Branch Tree & Codes” for every single Medical Device.
General Specifications

• Works fully in an electronic environment. 
  (www.huap.org.tr/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 & SSA after a period of acceptance.

• Detailed registrations of all procedures are stored with different message numbers.
Current Data
(as of June 21, 2010)

4,712 Accredited Company.

14,983 Users

Appr. 1,655,000 each of approved Medical Device.
# Reimbursement details by GMDN codes

<table>
<thead>
<tr>
<th>GMDN Kodu</th>
<th>Toplam TUTAR</th>
<th>% oran</th>
<th>GMDN Adı</th>
<th>Kat</th>
<th>Kategori Adı</th>
</tr>
</thead>
<tbody>
<tr>
<td>35669</td>
<td>59.479.856</td>
<td>6,30%</td>
<td>Protoz, diz, internal, tibial bileşen</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>35668</td>
<td>52.422.199</td>
<td>5,56%</td>
<td>Protoz, diz, internal, femoral bileşen</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>37272</td>
<td>46.656.848</td>
<td>4,95%</td>
<td>Sabitleme (fixasyon) sistemi, internal, spinal, faset vidası</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>43257</td>
<td>42.095.073</td>
<td>4,46%</td>
<td>Sabitleme (fixasyon) sistemi, internal, spinal, pedikül vidası</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>35666</td>
<td>36.666.381</td>
<td>3,89%</td>
<td>Protoz, kalça, internal, femoral bileşenli</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>35667</td>
<td>30.886.317</td>
<td>3,27%</td>
<td>Protoz, diz, internal, toplam</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>16066</td>
<td>26.107.744</td>
<td>2,77%</td>
<td>Protoz, kemik Grefi</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>94163</td>
<td>21.192.729</td>
<td>2,25%</td>
<td>Protoz, omurga, disk</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>55443</td>
<td>20.150.288</td>
<td>2,14%</td>
<td>Stimülatör (uyancı), elektrikli, işitsel, koklaraar</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>34179</td>
<td>19.349.301</td>
<td>2,05%</td>
<td>Stent, kardiyovasküler</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>35661</td>
<td>17.601.693</td>
<td>1,87%</td>
<td>Protoz, kalça, internal, otsebular bileşenli</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>34219</td>
<td>17.423.845</td>
<td>1,85%</td>
<td>Protoz, kalça</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>12913</td>
<td>16.109.930</td>
<td>1,71%</td>
<td>Pacemaker, kardiyak, implant edilebilir</td>
<td>1</td>
<td>Aktif vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>38161</td>
<td>15.515.342</td>
<td>1,64%</td>
<td>Spinal kafes</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>36215</td>
<td>15.480.830</td>
<td>1,64%</td>
<td>Protoz, kalça, internal, toplam</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>13180</td>
<td>14.773.217</td>
<td>1,57%</td>
<td>Protoz, implantasyon cihazı, ortopedik</td>
<td>9</td>
<td>Tekrar kullanılabılır araçlar</td>
</tr>
<tr>
<td>35930</td>
<td>14.437.674</td>
<td>1,53%</td>
<td>Protoz, vaf, kardiyak</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
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<tr>
<td>16101</td>
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<td>Sabitleme (fixasyon) vidası, kemik</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>35842</td>
<td>13.433.084</td>
<td>1,42%</td>
<td>Sabitleme (fixasyon) sistemi, internal, fraktür (kırık)</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>35852</td>
<td>13.409.762</td>
<td>1,42%</td>
<td>Defibrilatör, implant edilebilir, otomatik</td>
<td>1</td>
<td>Aktif vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>35281</td>
<td>12.907.072</td>
<td>1,37%</td>
<td>Gref, vasküler</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>35647</td>
<td>11.756.533</td>
<td>1,25%</td>
<td>Sabitleme (fixasyon) sistemi, eksternal, fraktür (kırık)</td>
<td>9</td>
<td>Tekrar kullanılabılır araçlar</td>
</tr>
<tr>
<td>35241</td>
<td>11.682.835</td>
<td>1,24%</td>
<td>Sabitleme (fixasyon) plakası, kemik</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>37265</td>
<td>10.973.570</td>
<td>1,16%</td>
<td>Defibrilatör, implant edilebilir, otomatik, iki odalı</td>
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<td>Aktif vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>35833</td>
<td>10.048.372</td>
<td>1,07%</td>
<td>Infüzyon uygulama seti, infüzyon pompası</td>
<td>11</td>
<td>Engelliler için teknik yardımcılar</td>
</tr>
<tr>
<td>36405</td>
<td>9.388.277</td>
<td>0,99%</td>
<td>Aferez ünitesi</td>
<td>4</td>
<td>Elektromekanik tıbbi cihazlar</td>
</tr>
<tr>
<td>43084</td>
<td>9.285.401</td>
<td>0,88%</td>
<td>Sabitleme (fixasyon) sistemi, internal, spinal, intervertebral gövde (disk)</td>
<td>7</td>
<td>Aktif olmayan vücuta yerleştirilebilir cihazlar</td>
</tr>
<tr>
<td>32369</td>
<td>9.140.664</td>
<td>0,97%</td>
<td>Uygulayıcı, cerrahi, zumba</td>
<td>9</td>
<td>Tekrar kullanılabılır araçlar</td>
</tr>
</tbody>
</table>
By 2009, Turkish government has decided to apply all their public issues in electronic way to minimize the bureaucracy.

One of the essential goal of this e-government project is to do also all public procurement via a platform called **EKAP** (Electronic Public Procurement Platform) by Public Procurement Authority.

TİTUBB project has been awarded by PPA Turkey to be the pilot implementation e-tender project on medical device sector.

Today, beta tests are on the air for the first medical device e-tender scheduled to be performed by the end of July 2010 with all data to be provided from TİTUBB.
A common language is created. All parties could reach any requested data of each medical device. Electronic catalog. Any tracebility function could be performed. Retail price per unit and tender unit prices could be followed. Placing into the market & market requests to decide national politics.
Role of Actors

Company and Product Approval:
- Company Information
- Product Details
- Legislation Documents
- Price and Catalog

Requirement Report and Procurement Processes:
- Preparation with Branch Code
- Bid preparation with Barcode
- Electronic evaluation

Reimbursement:
- Collecting the realized tender price via PPA results
- Evaluation of prices
- According to payment rules (indication)

MoH
PPA
SSA

TİTUBB
New Design of TİTUBB

- Registration of UPN in GTIN-8, GTIN-12, GTIN-13, GTIN-14 & HIBC unless they provide uniqueness for a single item
- New architectural design of TİTUBB will also cover;
  a) Registration of Allografts (Human Cells, Tissue and Organ Transplants)
  b) Registration of DBM (Demineralized Bone Matrix)
  c) Registration of Hemogenic products. (covering any items for blood)
- Optical Databank (all glasses & frames) for national stock management
- Custom made devices.
New Design of TİTUBB

• Determination and projection of geographic locations of any Healthcare Service Providers like Hospitals, Pharmacies, Hemodialysis Centers, Physical Therapy & Rehabilitation Centers, etc.

• Including to different type of GTIN & HIBC entry for UPN, (Universal Product Numbers) there will be other fields to be entered manually like the data of serial numbers, lots and batch numbers of every dedicated medical devices.

• Same fields will be compatible for the electronic data entry by 2D datamatrix barcoding.

• Allowance of barcode entries of different types of packaging in GTIN-14 format.
New Design of TİTUBB

- Implementing of e-signature for all approval mechanism
- Registration and approval of foreign Manufacturer Info’s to TİTUBB by MoH
- Exclusive Dealershipness System
- Uploading of Product Manuels, Pictures, Labels and Other Relevant Quality Certificates
- Custom Integration (third quarter of 2011)

To register the quantity of medical device with its barcode imported to Turkey to prevent the sale of same item more than one time.
2009 Statistics

Population
71,517,100

Total Income
~34,000,000 EURO

Total Expense
~48,000,000 EURO

Gap
~14,000,000 EURO
(Compansated by Treasury)
Benefits

- Vigilance, surveillance & recall procedures.
- Cost utility analysis. (payables & non-payables items)
- Management of local market.
- Decision making for national health policies.
- Database for academic researches.
- Database for research & development.
- Defining the estimated value during purchasing process.
Expectations From GS1

(All member countries offices shall via GEPIR)

• Recording the UPN’s to DB.
• Tracibility of any medical device informations,
• Global Location Numbers and Manufacturer’s details
• Compairing TİTUBB data with other DB’s
• Selection of GDSN pilot project
• Allowness of each medical device data by manufacturers.
Expectations

From Manufacturers

• Existance of GMDN codes on EC Certificates
• Describe all GMDN codes received from agency to Turkish dealers and distributors.

From GMDN

• Sharing any information of each codes with TİTUBB.

From EU & Notified Bodies

• Standardisation of each quality certification & document
• Provision of electronic data via webservice to TİTUBB
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for TİTUBB

www.huap.org.tr/reports
for realized tender results (1200 hospitals)
(username: kikrapor - password: raporkik)

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ISSA GOOD PRACTICE AWARDS
EUROPE COMPETITION 2010

THE CERTIFICATE OF MERIT IS AWARDED TO:
SOCIAL SECURITY INSTITUTION
(GENERAL DIRECTORATE OF
UNIVERSAL HEALTH INSURANCE),
TURKEY

For Civilian National Dental and Medical Service System (DITASIK)

Issued: Istanbul, 31 March 2010

[Signatures]

[ISSA Logo]
Quality is never an accident.
It is always the result of intelligent effort.
John Ruskin