

TCHEALTH



TiTUBB

Turkish National Databank
Project For Pharmaceuticals &
Medical Devices

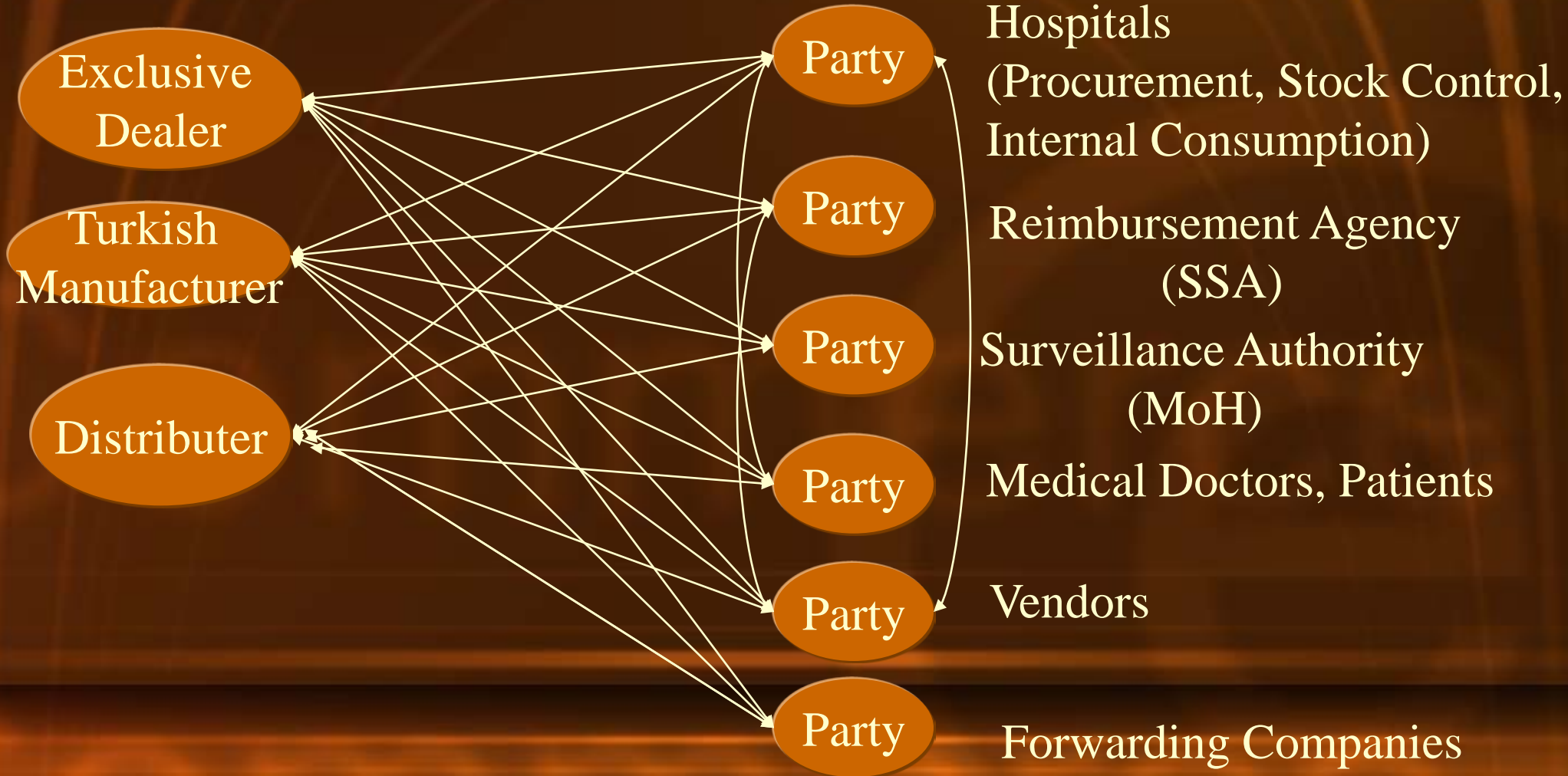
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GOAL

The primary goal of the National Data Bank Project for Pharmaceuticals & 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



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



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

GMDN Kodu	Toplam TUTAR	% oranı	GMDN Adı	Kat	Kategori Adı
35669	59.479.856	6,30%	Protez, diz, internal, tibial bileşen	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
35668	52.422.199	5,56%	Protez, diz, internal, femoral bileşen	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
37272	46.656.848	4,95%	Sabitleme (fiksasyon) sistemi, internal, spinal, faset vidası	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
43257	42.095.073	4,46%	Sabitleme (fiksasyon) sistemi, internal, spinal, pedikül vidası	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
35666	36.666.381	3,89%	Protez, kalça, internal, femoral bileşenli	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
35667	30.886.317	3,27%	Protez, diz, internal, toplam	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
16966	26.107.744	2,77%	Protez, kemik Grefi	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
34163	21.192.729	2,25%	Protez, omurga, disk	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
35643	20.150.298	2,14%	Stimülatör (uyarıcı), elektrikli, işitsel, koklear	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
34179	19.349.301	2,05%	Stent, kardiyovasküler	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
35661	17.601.893	1,87%	Protez, kalça, internal, asetabular bileşenli	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
34219	17.423.845	1,85%	Protez, kalça	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
12913	16.109.930	1,71%	Pacemaker, kardiyak, implante edilebilir	1	Aktif vücuda yerleştirilebilir cihazlar
38161	15.515.142	1,64%	Spinal kafes	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
36315	15.480.830	1,64%	Protez, kalça, internal, toplam	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
13180	14.773.217	1,57%	Protez, implantasyon cihazı, ortopedik	9	Tekrar kullanılabilir araçlar
35590	14.437.674	1,53%	Protez, valf, kardiyak	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
16101	14.166.876	1,50%	Sabitleme (fiksasyon) vidası, kemik	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
35642	13.433.084	1,42%	Sabitleme (fiksasyon) sistemi, internal, fraktür (kırık)	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
35852	13.409.762	1,42%	Defibrilatör, implante edilebilir, otomatik	1	Aktif vücuda yerleştirilebilir cihazlar
35281	12.907.072	1,37%	Gref, vasküler	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
35647	11.756.533	1,25%	Sabitleme (fiksasyon) sistemi, eksternal, fraktür (kırık)	9	Tekrar kullanılabilir araçlar
35241	11.682.835	1,24%	Sabitleme (fiksasyon) plakası, kemik	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
37265	10.973.570	1,16%	Defibrilatör, implante edilebilir, otomatik, iki odalı	1	Aktif vücuda yerleştirilebilir cihazlar
35833	10.048.372	1,07%	İnfüzyon uygulama seti, infüzyon pompası	11	Engelliler için teknik yardımcımlar
16405	9.368.277	0,99%	Aferez ünitesi	4	Elektromekanik tıbbi cihazlar
43084	9.285.401	0,98%	Sabitleme (fiksasyon) sistemi, internal, spinal, intervertebral gövde (disk)	7	Aktif olmayan vücuda yerleştirilebilir cihazlar
32369	9.140.664	0,97%	Uygulayıcı, cerrahi, zimba	9	Tekrar kullanılabilir araçlar

e-trade Project

- 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.
- TITUBB 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 TITUBB.

Actors of TİTUBB



Custom



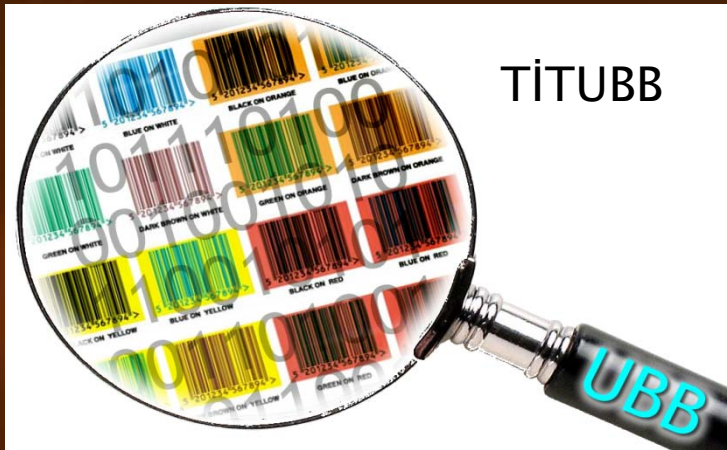
MoH



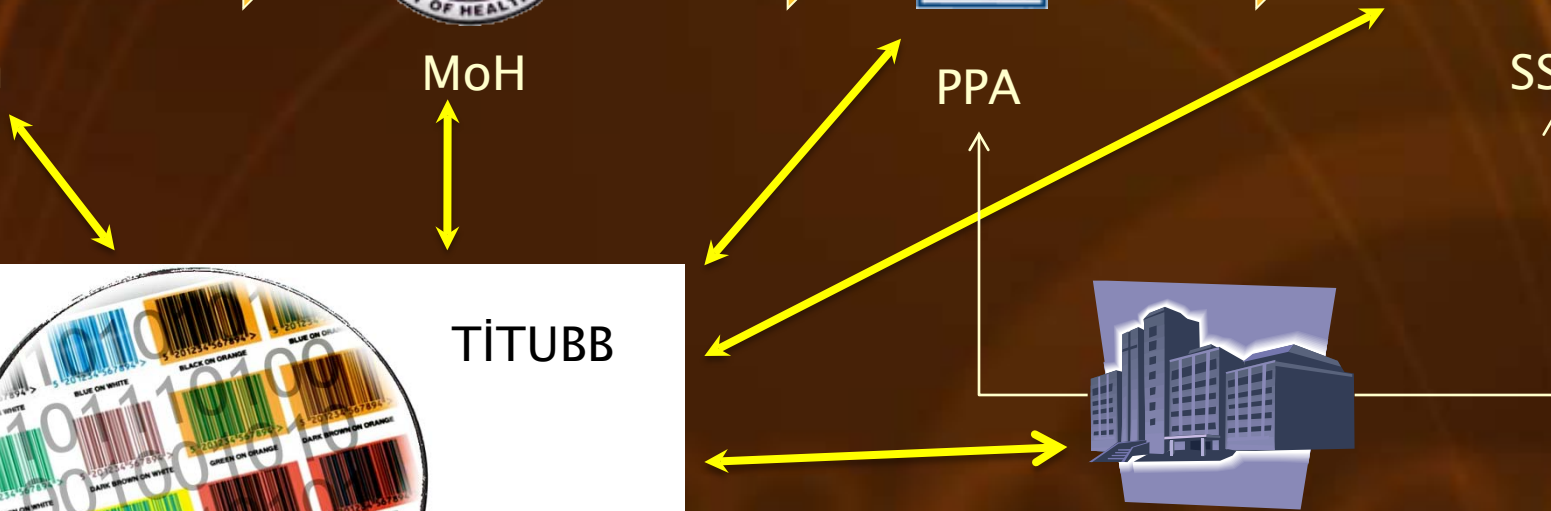
PPA



SSA



Hospital



A common language is created.

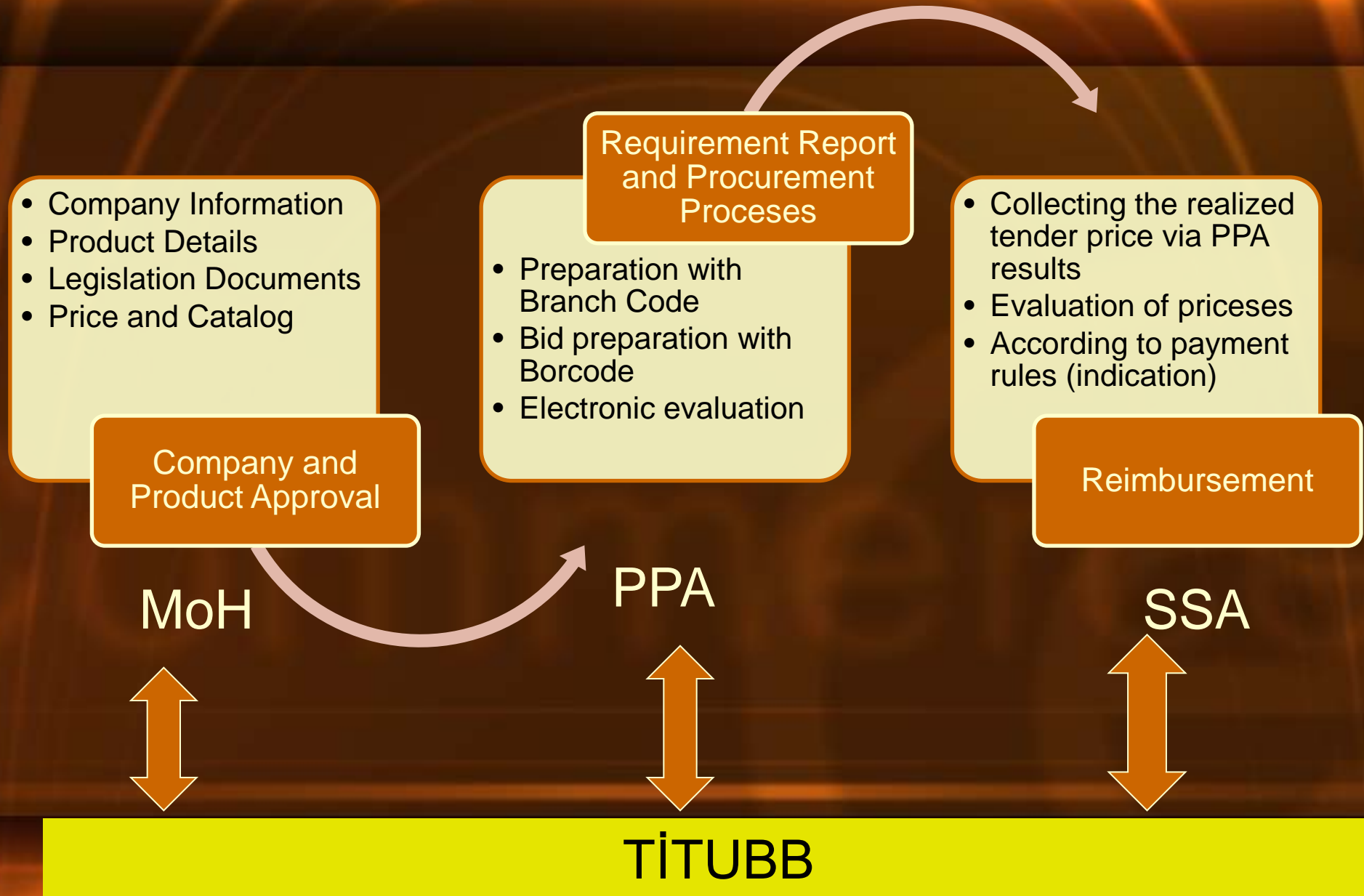
All parties could reach any requested data of each medical device. Electronic catalog.

Any traceability 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



New Design of TITUBB

- 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 TITUBB 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 TITUBB

- 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 TITUBB

- Implementing of e-signature for all approval mechanism
- Registration and approval of foreign Manufacturer Info's to TITUBB by MoH
- Exclusive Dealershipness System
- Uploading of Product Manuals, 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 Expenche

~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.

(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
- Comparing TITUBB data with other DB's
- Selection of GDSN pilot project
- Allowness of each medical device data by manufacturers.

Expectations

From Manufacturers

- Existence 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 TITUBB.

From EU & Notified Bodies

- Standardisation of each quality certification & document
- Provision of electronic data via webservice to TITUBB

Please Visit

www.huap.org.tr/ubb

for TITUBB

www.huap.org.tr/reports

for realized tender results (1200 hospitals)

(*username: kikrapor - password: raporkik*)

Call Center

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ISSA AWARD



CERTIFICATE OF MERIT

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

For Turkish National Drug and Medical Device Database (TMDDB)

In Warsaw, Poland, 1 March 2010


Marek Harek
Secretary General


Andrzej Banaś
President



TiTUBB TEAM



Quality is never an accident.
It is always the result of intelligent effort.

John Ruskin