



# ***TURKISH PHARMACEUTICS & MEDICAL DEVICES***

## ***NATIONAL DATA BANK PROJECT***

**Doruk GÖKŞİN, BA**  
**Project Manager**



**TEPETEKNOLOJİ**



# 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





# 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 Insurance & MoFinance of Turkish Republic with a signed protocol dated July 14, 2004.





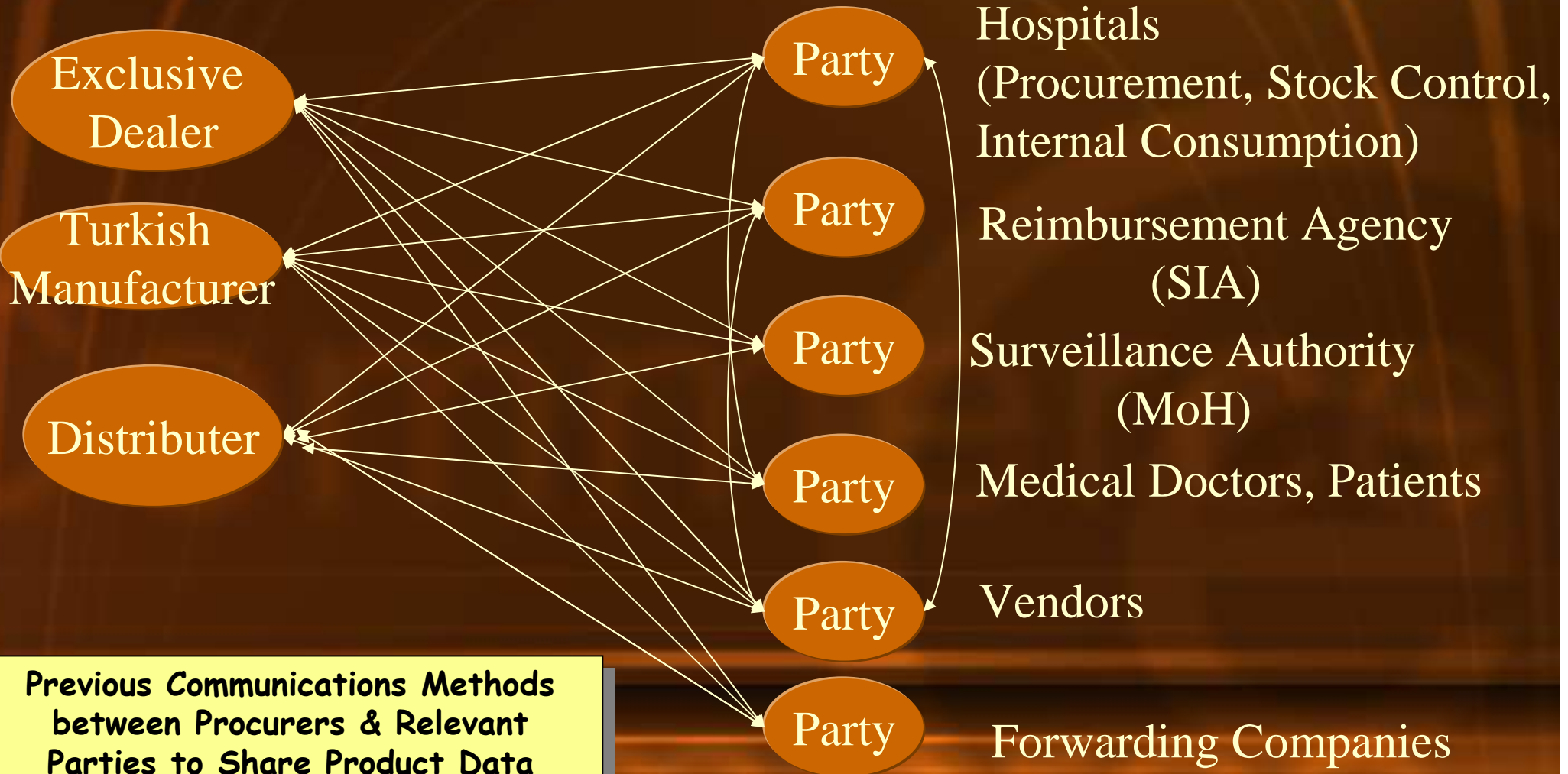
# ***PREVIOUS SITUATION***



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# Previous Situation



**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***



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# Recommended & Applied Model





# Electronic Procurement

National  
Data Bank

Vendor  
(Manufacturer  
& Dealers)

Parties

Company Details (PARTIN)

Product / Service Catalogue (PRICAT)

Legislation Documents (DLEGAL)

Purchase Order (ORDERS)

Transportation Datas (DESADV)

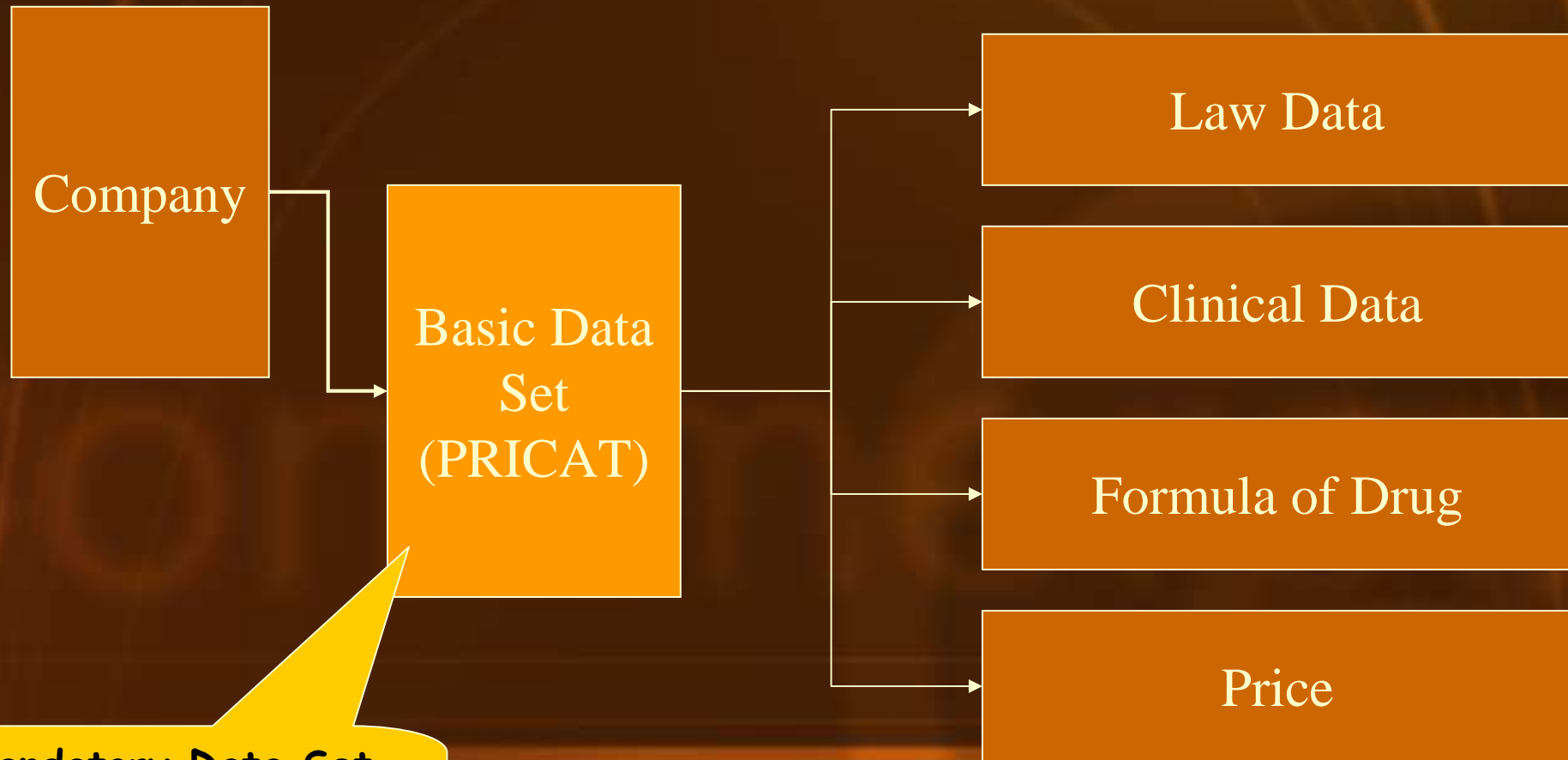
Invoice & Payment (INVOIC)

Money Order (REMADV)





# Data Model



**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.

EAN-13  
HIBC

UPN Number written by  
Linear Barcode Technology

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



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## İLAÇ VE TIBBİ CİHAZ TANIMLAMA FORMU

PRICAT

1. Mesaj Tarihi

2. Mesaj Türü

3. Mesaj No

4. İşlem Kodu

11.05.2006

PRICAT

8191

İLK KAYIT

5. Veri Geçerlilik Başlangıç Tarihi 11.05.2006

6. Veriyi Giren Kişinin TC Kimlik Numarası 17353552810

7. Firma Tanımlayıcı No 2667269000138

8. Tedarikçi Firma Adı Şengel Tıbbi Araç ve Gereçler Ltd. Şti

9. Ürün Numarası 5706025007844

10. Numaranın Türü EAN-13

11. Orjinal Ürün Numarası

12. Etiket Adı F11.4 HUIBREGTSE ENDO SET 9CM

13. Marka Adı HUIBREGTSE

14. Tedarikçi Ürün Dahili Referansı 700911000

15. UNSPSC Kodu 42000000

...

16. UNSPSC Sınıf Adı Tıbbi Donanım ve Aksesuarları ve Malzemeleri

17. İthal/İmal İTHAL

18. Renk

19. Ambalaj Türü

...

20. Ambalaj İç Miktarı

21. Ambalaj Miktar Birimi

22. Genişlik(mm)

23. Yükseklik(mm)

24. Derinlik(mm)

25. Raf Ömrü (ay)

*BU BÖLÜM SADECE TIBBİ CİHAZLAR İÇİNDİR*

26. GMDN Kodu 38442

...

27. GMDN Adı Sınıflandırılmamış

28. Ait Olduğu Yönetmelik

Form No: TITUBB-P003-F005

Revizyon No: 1

Düzeltil

Ürün İptal

Yeni Barkodla Kaydet

Mevzuat Bilgisi Ekle



catheter

Ara

Türkçe Tanım  İngilizce Tanım  Kod

Arama Sonuçları

Detay

- 17787-Adaptör/konnektör, anjiyoplasti balonu dilatasyon kateteri
- 32340-Adaptör, kateter, [belirtin]
- 44036-Adaptör, intravenöz kateter için
- 35944-Adaptör, peritonal diyaliz kateter için
- 31973-Adaptör üreteral kateter için
- 39245-Adaptör, ureteral kateter
- 16430-Anestetik iletim kateteri
- 44476-Anjiyoplasti balon dilatasyon kateteri adaptörü/konnektörü
- 44516-Anjiyoplasti kateter balon şişiricisi
- 44480-Anjiyoplasti yönlendirici kateter
- 31081-Balon kateter
- 34587-Balon kateter şişirme cihazı
- 43482-Berman kateteri
- 32086-Safra kateter
- 17799-Safra manometrik kateteri
- 31666-Kanül, kateter
- 40012-Kateter (gastrik, colonic, etc.), irigasyon (yıkama) ve aspirasyon
- 39934-Kateter ve tıp, emme
- 32067-Kateter ve tüp, suprapubic
- 31665-Kateter balon onarım kiti
- 10676-Kateter bakım kiti
- 31742-Kateter yönlendirme ünitesi
- 37819-Kateter boşaltma kapağı
- 15320-Kateter boşaltma kapağı, kesintisiz
- 40312-Kateter, preterm membrane rüptürü (PPROM) için

17787- Adaptör/konnektör, anjiyoplasti balonu dilatasyon kateteri

AÇIKLAMA:  
YOK

KATEGORİLERİ:  
10- Tek kullanımlık cihazlar

TÜRÜ: EŞ ANLAMLI TERİM

TERCİH EDİLEN TERİM  
36177- Konnektör, kateter, anjiyoplasti balon dilatasyonu

339 adet GMDN kodu bulundu.

Seç

Vazgeç



## TIBBİ CİHAZ MEVZUAT BİLGİLERİ TANIMLAMA FORMU

1. Mesaj Tarihi

2. Mesaj Türü

3. Mesaj No

4. İşlem Kodu

31.05.2006

DLEGAL

İLK KAYIT

5. Veri Geçerlilik Başlangıç Tarihi

31.05.2006

6. Veriyi Giren Kişinin TC Kimlik Numarası

36697697070

7. Firma Tanımlayıcı No

2667269000138

8. Tedarikçi Firma Adı

Şengel Tıbbi Araç ve Gereçler Ltd. Şti

9. Ürün Numarası

5706025007844

12. Ürün Etiket Adı

F11.4 HUIBREGTSE ENDO SET 9CM

28. Ait Olduğu Yönetmelik

93/42/EEC

44. Üretici Firma Numarası (GLN)	<input type="text"/>	45. Üretici Firma Adı	<input type="text"/>
46. Menşe (Üretildiği) Ülke Kodu	<input type="text"/>	47. Menşe Ülke Adı	<input type="text"/>
48. İthal Edildiği Ülke Kodu	<input type="text"/>	49. İthal Edildiği Ülke Adı	<input type="text"/>
80. GTIP Numarası	<input type="text"/>	81. Sınıf/Listesi	Sınıf I Diğer <input type="button" value="v"/>
82. AT Belgesi (CE Certificate) Türü	EK 7 <input type="button" value="v"/>		

EK 7

83. Belgelendiren Kuruluş Kimlik No	<input type="text"/>
84. Belgelendiren Kuruluş Adı	<input type="text"/>
85. Belge Numarası	<input type="text"/>
86. Belge Geçerlilik Başlangıç Tarihi	<input type="text"/>
87. Belge Geçerlilik Bitiş Tarihi	<input type="text"/>

88. Ürünün İlgili Olduğu Ek Yönetmelik	<input type="text"/>
89. Belgelendiren Kuruluş Kimlik No	<input type="text"/>
90. Belgelendiren Kuruluş Adı	<input type="text"/>
91. Belge Numarası	<input type="text"/>
92. Belge Geçerlilik Başlangıç Tarihi	<input type="text"/>



# ***ISSUED PERFORMANCE***



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# Issued Performance

- Decision of a common data set for Pharmaceuticals & Medical Equipment to collect the necessary data.  
(July 21 - Oct 03, 2005)
- Decision of another necessary data to collect for Pharmaceuticals & 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](http://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 Pharmaceuticals

- 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***



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# 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)



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***NATIONAL DATA BANK –  
PUBLIC PROCUREMENT  
AUTHORITY INTEGRATION  
(e-Procurement Platform)***



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Hospital

Tender Announcement



Public Procurement Authority

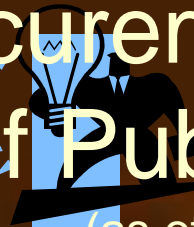


# Medical Device Procurement Milestones of Public Hospitals

National Data Bank  
T.C. İlaç ve Tıbbi Cihaz Ulusal Bilgi Bankası



Medical Device Company



(as of January 01, 2008)

The "Medical Device Company" shall load all details of electronic tendering into PPA webpage. The Hospital announce the tender documents via PPA webpage. Tender details shall be entered via software, and hospital details shall be displayed on the tenderer's website. The details shall be displayed on the tenderer's website. The details shall be displayed on the tenderer's website. <http://documenta.ppa.gov.tr/ukkk/extension>

With same software; barcode, quantity and offered price shall be entered.



Social Insurance Association



# Official Tender Result

UrunKodu	<input type="text"/>	<input checked="" type="checkbox"/> NULL	BaslangicTarihi	<input type="text" value="23.01.2007"/>	
BitisTarihi	<input type="text" value="07.02.2008"/>		IdareKodu	<input type="text"/>	<input checked="" type="checkbox"/> NULL
1 of 1 100% Find   Next Select a format Export					
<b>Ürün Alım Bilgileri - İdare Kırılımlı</b>					
İdare Adı	Ürün	Adet	Fiyat	Tarih	Alım Sekli
<input checked="" type="checkbox"/> ÇERKEŞ DEVLET HASTANESİ		110001.00			
<input checked="" type="checkbox"/> ÇERKEŞ DEVLET HASTANESİ/ÇANKIRI		1146.00			
<input checked="" type="checkbox"/> DENEME İDARE		2.00			
<input checked="" type="checkbox"/> DÖNER SERMAYE İŞLETME MÜDÜRLÜĞÜ		120.00			
	<input type="checkbox"/> 0607567106086 -DATASCOPE FIDELITY 8 FR 40CC IABC	120.00	1800.00		
		120.00	1800.00	04.02.2008	IHALE
<input checked="" type="checkbox"/> GEBZE FATİH DEVLET HASTANESİ		81201.00			
<input checked="" type="checkbox"/> KONYA NUMUNE HASTANESİ BAŞHEKİMLİĞİ		20000.00			





# A Very Special Thanks to



Management for their valuable support



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