IIHMR UNIVERSITY

Thesis Presentation

An Overview of the Turkish Healthcare and Pharmaceutical Industry

Chaitanya Dadhich (0138)
ZS Associates, Gurgaon

Guided by
Dr. Alok Mathur

Introduction

About ZS Associates

ZS is the world's marketing and sales consultancy firm focused on the pharmaceutical and medical device industry majorly in the US and Europe. ZS delivers impact through its vast and varied expertise ranging from from customer insights and strategy to analytics, operations and technology. ZS has 23 worldwide locations with over 4000 employees.

Research Questions

1. What is the structure of the Turkish healthcare delivery and financing system?
2. What is the process of obtaining marketing authorization for a new drug in Turkey?
3. What is the process of drug pricing and reimbursement in Turkey?
4. How is drug procurement carried out in Turkey?
5. What are the key factors that will affect the Turkish health and pharmaceutical industry?

Aim

To obtain an overall comprehensive understanding of the healthcare system and pharmaceutical market of Turkey in terms of structure, functioning and future prospects.

Introduction

Objectives

1. To study the existing structure and functioning of the healthcare system
2. To study the system of healthcare financing
3. To understand the drug approval process and pharmaceutical pricing and reimbursement
4. To understand the distribution channels and pharmaceutical industry trends

Study Design

- Descriptive, desk-based secondary research
- A cross-sectional study was undertaken with emphasis on credible recent data
- Geographic scope was limited to Turkey
- Type of data- Publicly available secondary research data sources were deployed to obtain following information:
  - Demographic and economic indicators
  - General national statistics (employment, education, etc.)
  - Information about health system design
  - Information about healthcare resources
  - Organization hierarchies
  - Various processes, flowcharts, expert opinions, interviews, analyst reports, etc.

Country Overview

Demographics

	Indicator	Value
1	Population (2015)	**78.74 million**
2	Life expectancy at birth, total (years, 2015)	**77**
3	Death rate, crude (per 1,000 people, 2015)	**5%**
4	Birth rate, crude (per 1,000 people, 2015)	**17%**

Economics

	Indicator	Value
1	Total GDP (2015)	**$ 820.82 billion**
2	GDP growth (2015, %)	**4.00**
3	GDP per capita (2015)	**$ 10,706**

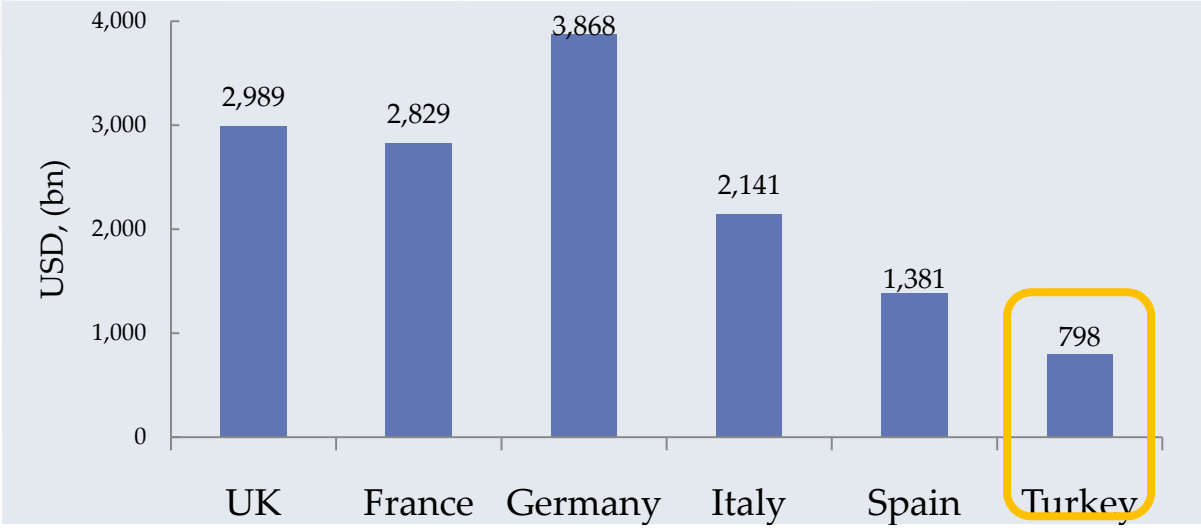
Health Care Spending

	Indicator	Value
1	Health Expenditure, total (USD, 2014)	**39.79 billion**
2	Health expenditure, private insurance (% of total, 2014)	**4.80%**
3	Health expenditure, public (% of total, 2014)	**77.45%**
4	Out-of-pocket expenditure (% of total expenditure on health, 2014)	**17.75%**

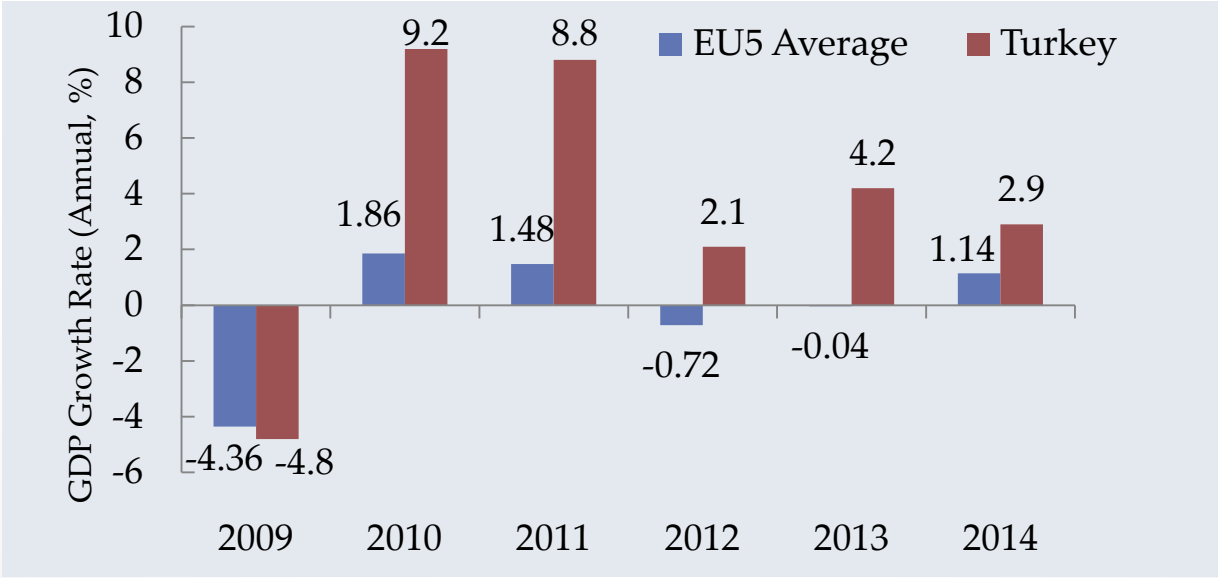
Delivery of Care

	Indicator	Value
1	Hospital beds (per 1,000 people, 2014)	**2.66**
2	Physicians (per 1,000 people, 2014)	**1.74**
3	Nurses (per 1,000 people, 2014)	**1.80**

Comparative Analysis – Economic Indicators

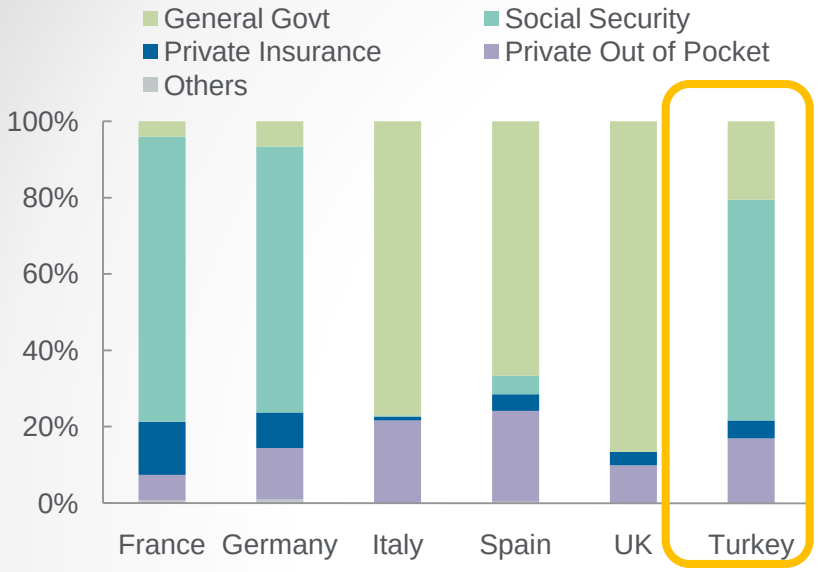


GDP Comparison with EU-5 (2014, USD, bn)

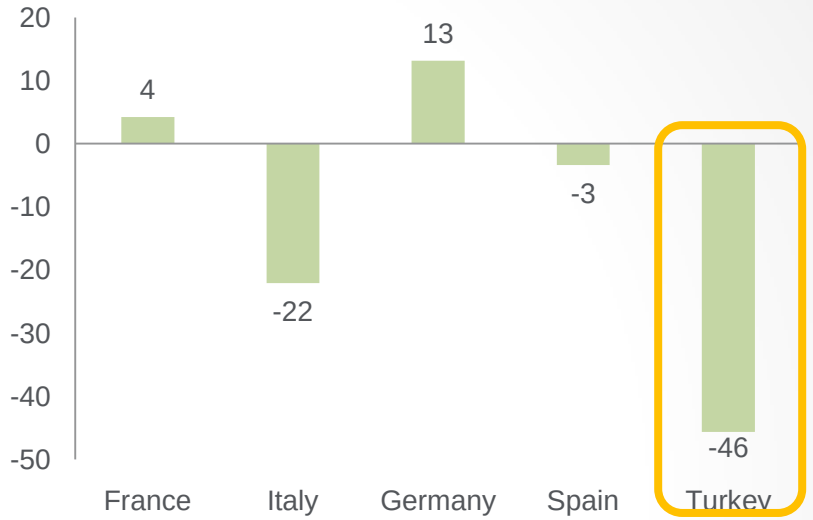


GDP growth rates for Turkey and EU5 countries
(2009-2014, Annual %)

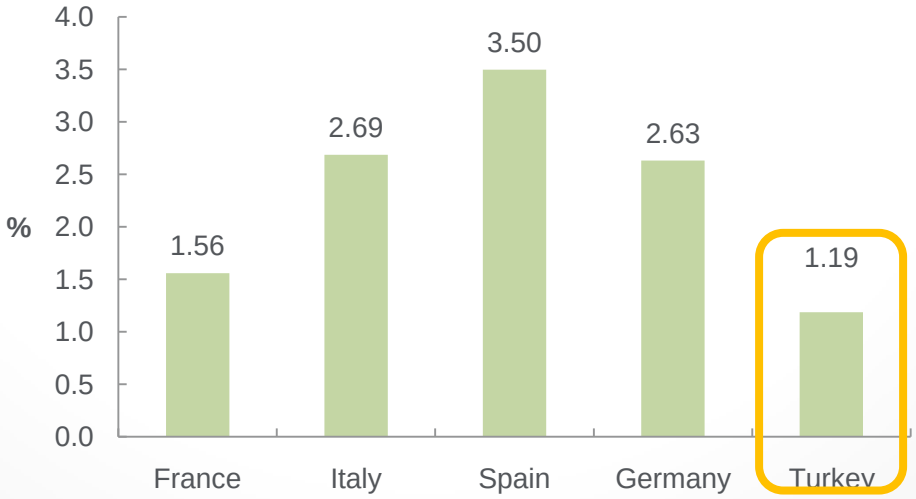
Comparative Analysis – Healthcare Expenditure



Health Expenditure Financing Agent Type, 2011

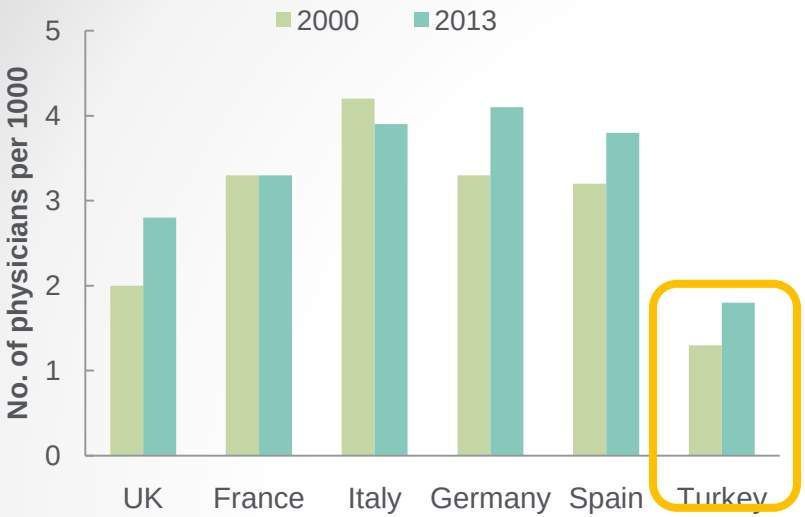


% Change in Out-of-pocket Expenditure as share of Total Health Expenditure, 2000 to 2013

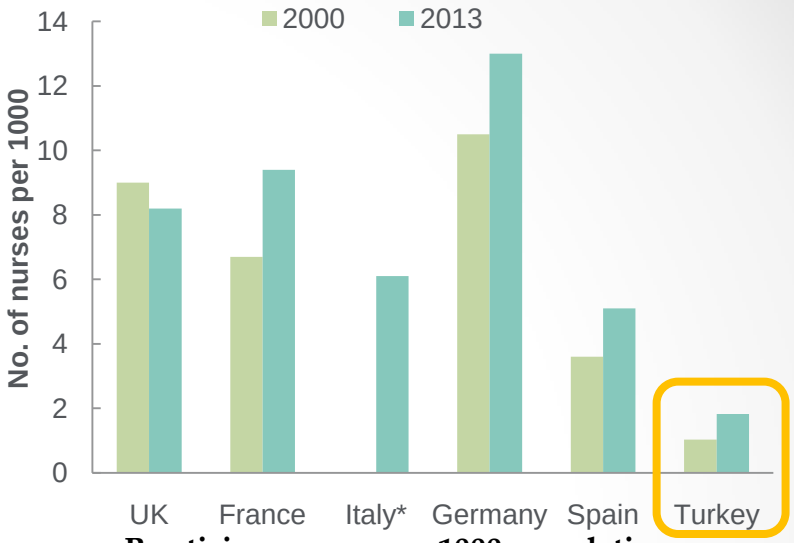


Out-of-pocket Medical Spending as a share of Final Household Consumption, 2013

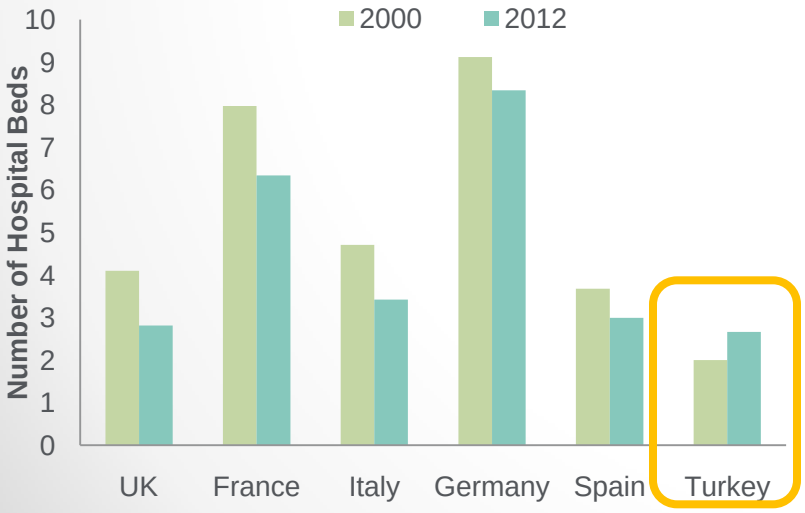
Comparative Analysis – Healthcare Resources



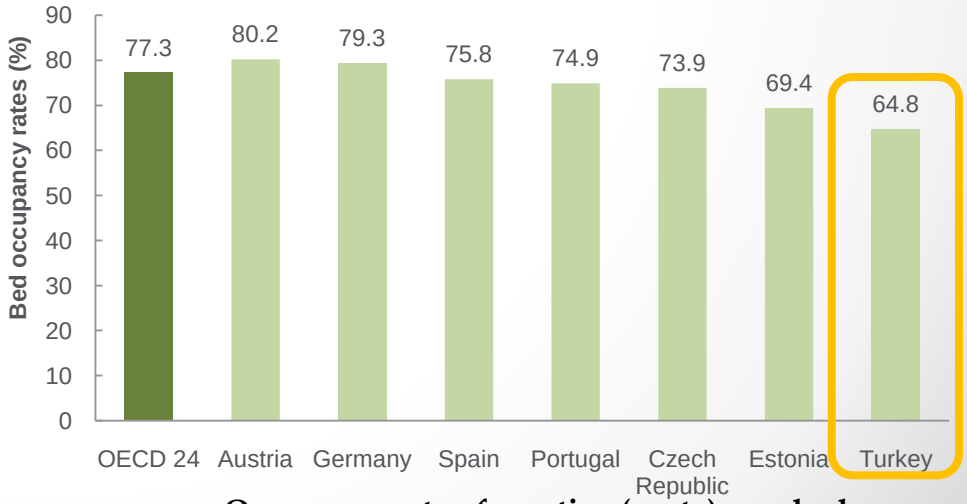
Practicing physicians per 1000 population
Year 2000 and 2013



Practicing nurses per 1000 population
Year 2000 and 2013



Number of Hospital Beds
(Per 1000 population, 2000 and 2012)[4]



Occupancy rate of curative (acute) care beds
Year 2013[1]

Healthcare System Overview

Key Stakeholders in the Turkish Health System

Ministry of Health
Largest health service provider
Sole regulator and policymaker

University Hospitals
Super specialized tertiary care providers and centers of medical research

Social Security Institution (SGK)
Collects contributions from population
Negotiates service contracts with MoH, University Hospitals and private institutions

Affiliated Institutions
4 bodies created in 2012 to decentralize regulation and policy implementation – to become autonomous in the future

Healthcare Transformation Program (HTP) 2003

- Healthcare before HTP - fragmented, hierarchical and lacked equity.
- Informal payments and corruption were rampant.
- HTP unified the four funds leading to universal health coverage (GHIS) under the SGK.
- Shifted focus to family medicine in the primary healthcare setup.
- This vastly improved access to healthcare, affordability and improved utilization of health services.

Affiliated Institutions

- **Public Health Institute** - Responsible for providing and regulating primary healthcare services.
- **Public Hospitals Institute** - Responsible for running all public hospitals (under MoH) and regulates the 87 hospital unions that control the 87 provincial hospitals
- **Pharmaceuticals & Medical Devices Institute (TITCK)**- Regulates four key areas – pharmaceuticals, medical devices, cosmetics and laboratories. Deals with marketing authorization, etc.
- **General Directorate of Health for the Borders and Coastal Areas** – responsible for health monitoring and maintenance in the coastal and border regions of Turkey

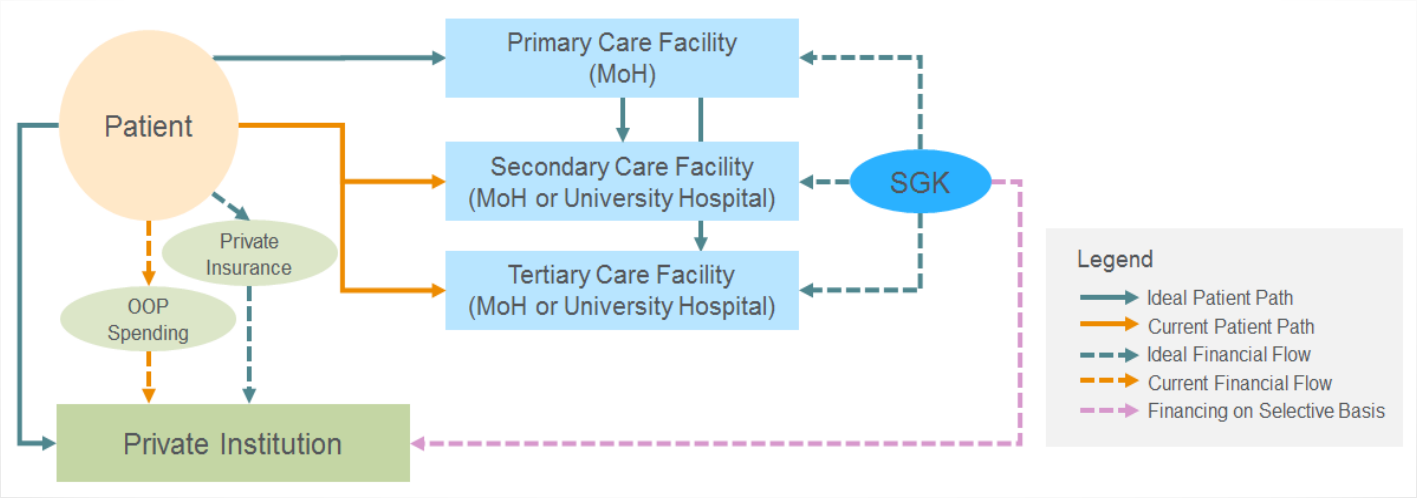
Healthcare System Overview

Primary Care Provision

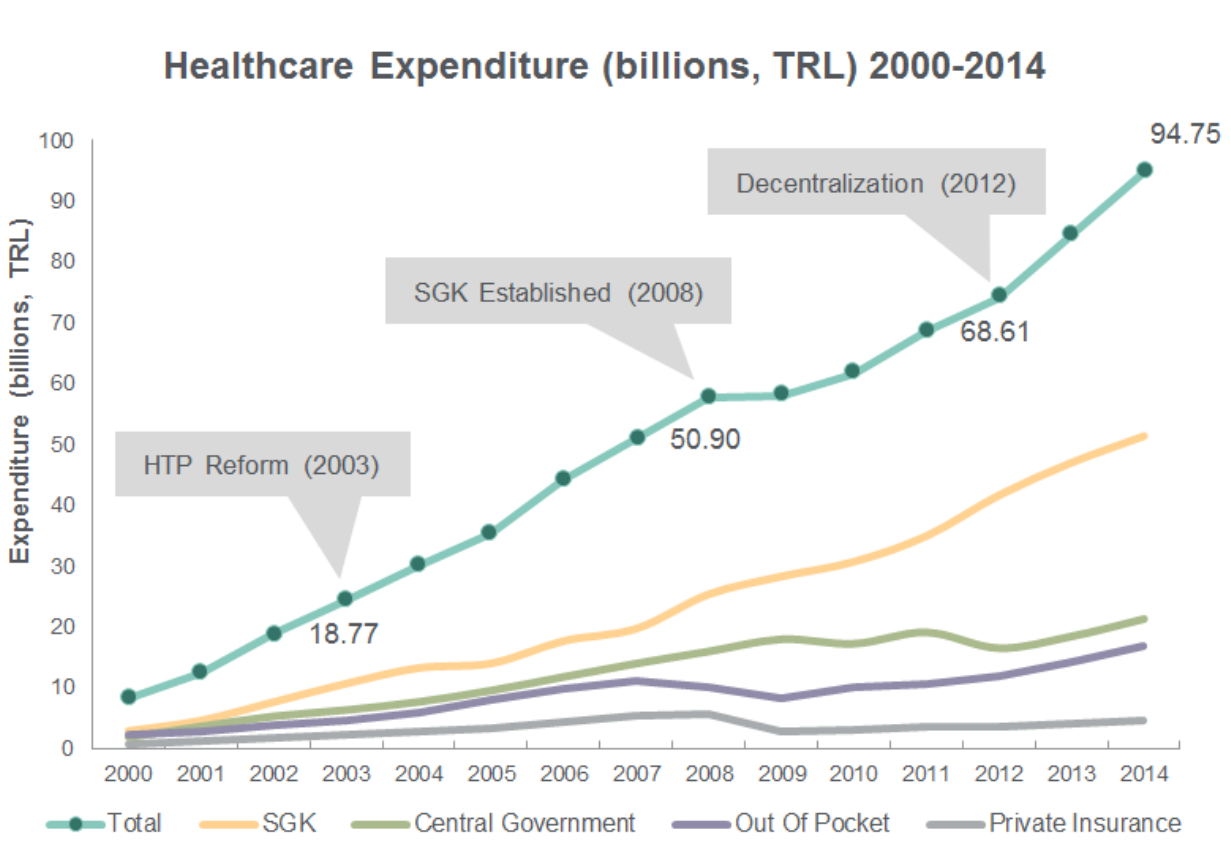
- **Family Health Center (FHC)**
  - Each FHC has at least one Family Physician (FP) responsible for a named list of 3000-4000 people.
  - FHCs offer preventive, diagnostic, curative, rehabilitative and counseling services, maternal and child health services, family planning counseling. There were 6330 FHCs as of 2015.
- **Community Health Center (also called Population Health Center)**
  - CHCs are aligned with the public health aspects of primary care and hire public health experts.
  - CHCs are involved in the design, evaluation, implementation and monitoring of public health programs for preventive health. There were 986 CHCs as of 2015.

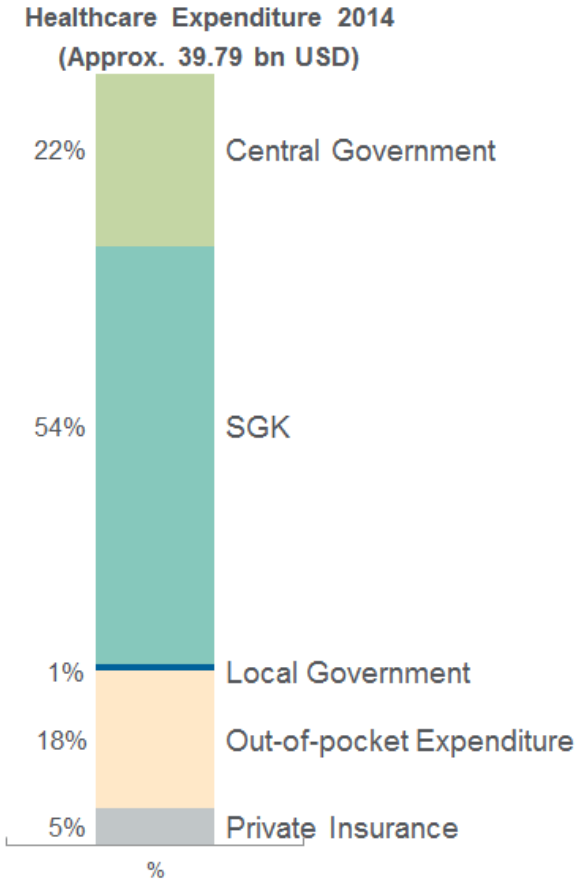
Secondary and Tertiary Care Provision

- High level specialized care is provided by MoH hospitals, University hospitals and private institutions.
- The MoH is the leading provider of secondary and tertiary care services through its General Hospitals and Teaching Hospitals respectively.
- University Hospitals and private hospitals also provide secondary and tertiary care.



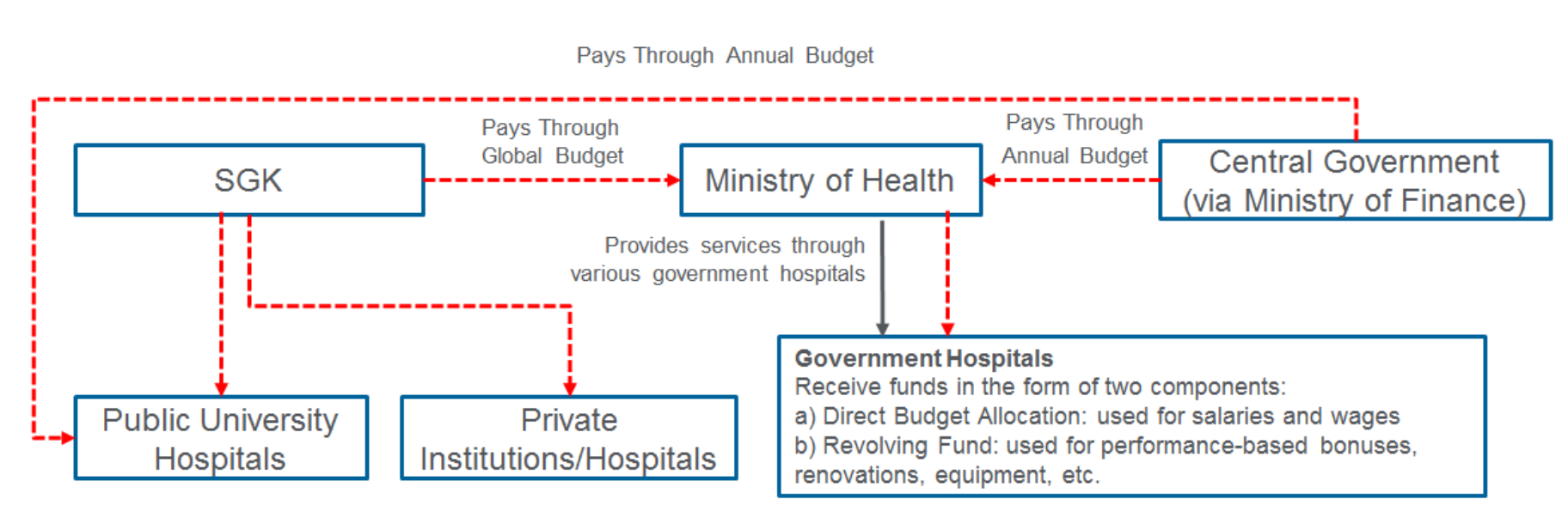
Healthcare Financing





- Payer-provider split was established.
- SGK is the single largest payer - has significant bargaining power
- SGK raises funds through fixed monthly contributions from all citizens - employers pay 7% and employees pay 5% to contribute a total of 12% (12.5% for private sector employees) towards the GHIS.
- Citizens who cannot afford to pay are enrolled in the Green Card program

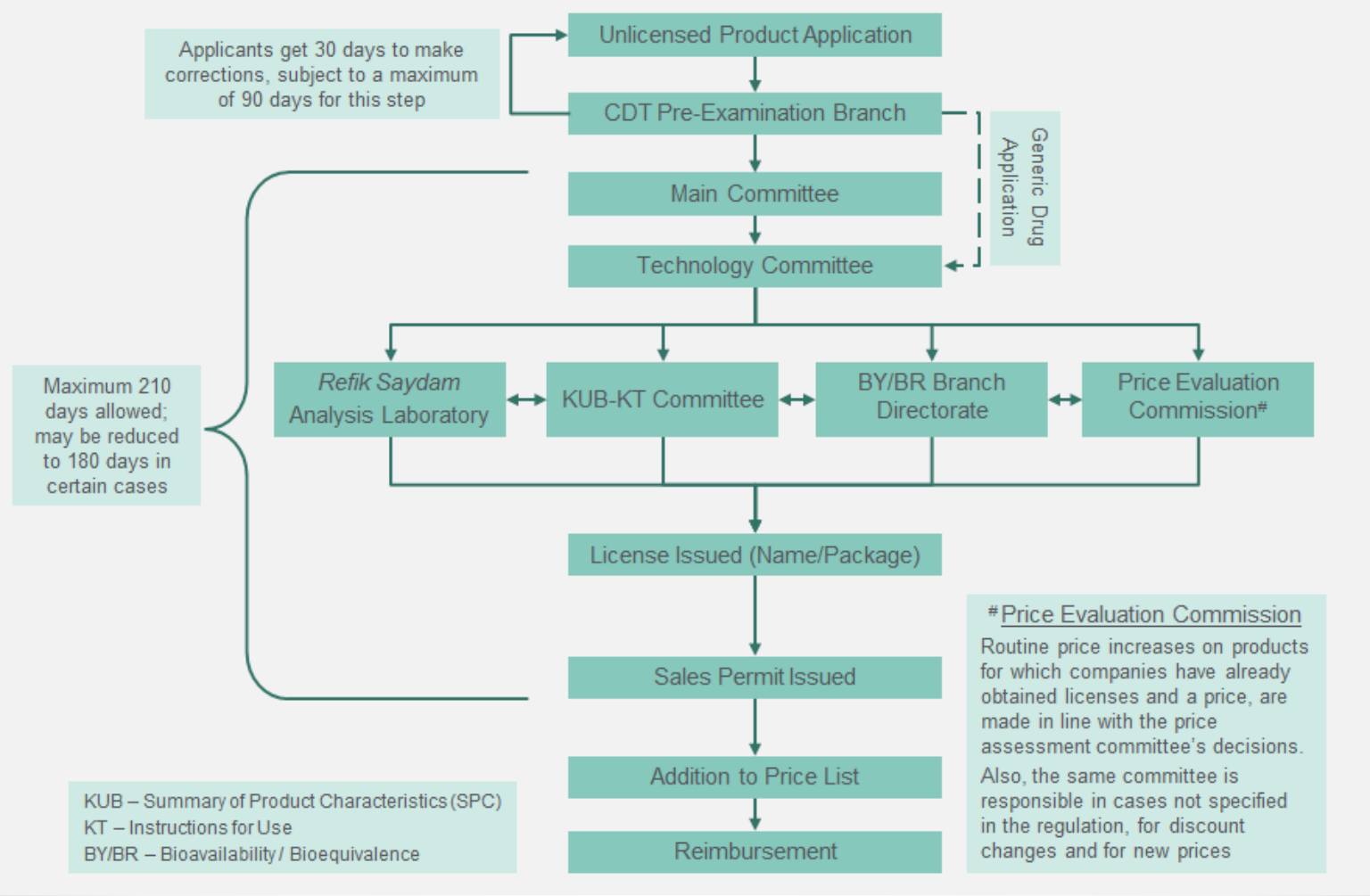
Financial Flows in the Healthcare System



- Public hospitals are paid by the MoH while other hospitals like university and private institutions negotiate individual contracts with the SGK.
- The MoH distributes the total fund among its hospitals in as two components – the revolving fund and the direct budget allocation.
- Private hospitals are allowed extra billing to compensate for the higher costs and better quality of care.
- Hospitals are classified - Class A to Class E

Marketing Authorization

- Marketing authorization is issued by the TITCK after evaluating an application in the Common Technical Document (CTD) format.
- The applicant must show that the drug is safe, effective and conforms to quality standards.
- The approval process is supposed to take 210 days, but often gets delayed up to 1000 days



Marketing Authorization

Delays in Drug Approval

- Of all the new drugs launched in 2007 -2013 in the US or EU, only 24% were also launched in Turkey
- Excessive delays led to a 33% reduction in new drug applications in 2012.
- Some key reasons for these delays are:
  - Delays in the laboratory analysis procedures which are critical steps of the review process.
  - Communication to the manufacturer about the deficiencies in their application are sent one-by-one instead of a complete review.
  - Since December 2009, the MoH has required pharmaceutical exporters who send products to Turkey to obtain a Good Manufacturing Practices (GMP) certificate from the Turkish MoH

Recent Reforms and Changes

- Turkey has applied for membership in the PIC/s which would make it to have mutual recognition
- Applicants for fresh GMP certificates can now apply to get priority in their GMP inspection dates based on criteria such as:
  - The product being innovative
  - The product being a first generic
  - The product being important from a public health perspective
  - Product could significantly reduce health expenditures
- Turkey now allows patients to request named imports – life saving drugs may be imported for a particular patient even if it does not have marketing authorization in Turkey.
- Certain steps of the process are now being performed parallel to each other to save time.

Pharmaceutical Pricing and Reimbursement

External Reference Pricing

- Drug pricing is a part of approval process, done by TITCK. Free pricing not allowed.
- External reference pricing is used – reference countries are France, Spain, Italy, Portugal and Greece
- The lowest price out of all the reference countries is set as the ex-factory price of the drug in Turkey.
- Depending on the type of drug (original/ generic/ patented) further discounts are applied.
- Fixed mark-ups are applied along the supply chain (wholesalers and retailers).

Drug Reimbursement

- Companies must apply to the SGK to be placed on the positive list
- Statutory discounts are applied on top of the reference pricing discounts.
- Level of statutory discount depends on the type of drug.
- The MoH consecutively increased statutory discounts after 2011 to balance the health budget.

Issues in Pricing and Reimbursement

- Steep price cuts have led to stagnation in the industry as profit margins have reduced.
- The EUR-TRL exchange rate for reimbursement was fixed at 1.9595 in 2009.
- The inclusion of Greece in the reference country list has led to very low prices.
- The low drug prices have led to shortage of essential drugs as they are being smuggled out of Turkey.

Pricing and Reimbursement

Recent Policy Changes and Improvements

- Some statutory discounts were rolled back in 2013-14.
- In 2015, the exchange rate was revised to 70% of the average exchange rate of the previous year.
- Pharmaceutical track-and-trace implemented to deter smuggling

Co-payment and Co-insurance

- Only applicable for out-patients.
- Fixed co-payments – TRL 3 per item for the first three items and TRL 1 for each item after that.
- Co-pays on pharmaceuticals are waived off in chronic diseases
- Co-insurance of 20% of the total pharmacy bill (10% for retirees).
- In-patient pharmaceuticals are fully reimbursed.
- There is no deductible in Turkey.

Statutory discounts applied by pharmaceutical companies and pharmacists in public procurement

Type of Drug	Retail Price	Condition	2009	2010	2011	2012	2013	2014
Originator	Below TRL 5.22	No Generic Product	4	4	4	4	0	0
	Between TRL 5.23 and TRL 9.97		24	23	32.5	41	20	20
	Between TRL 9.98 and 14.97		24	23	32.5	41	41	41
	Above TRL 14.98		24	23	32.5	41	41	41
Originator with a Generic Product and the Generic Product	Below TRL 5.22		4	4	4	4	0	0
	Between TRL 5.23 and TRL 9.97		11	11	20.5	28	20	20
	Between TRL 9.98 and 14.97		11	11	20.5	28	28	28
	Above TRL 14.98		11	11	20.5	28	28	28
Twenty Year Old Drug	Below TRL 5.22		4	4	4	4	0	0
	Between TRL 5.23 and TRL 9.97		11	11	11	11	7	7
	Between TRL 9.98 and 14.97	Local	-	-	-	28	20	20
		Reference Price Available	11	11	20.5	28	20	20
		No Reference Price	24	23	32.5	40	20	20
	Above TRL 14.98	Local	-	-	-	28	28	28
		Reference Price Available	11	11	20.5	28	28	28
		No Reference Price	24	23	32.5	40	40	40

TRL – Turkish Liras

Ex-Factory Price Calculation Methodology

Pharmaceutical Supply Chain

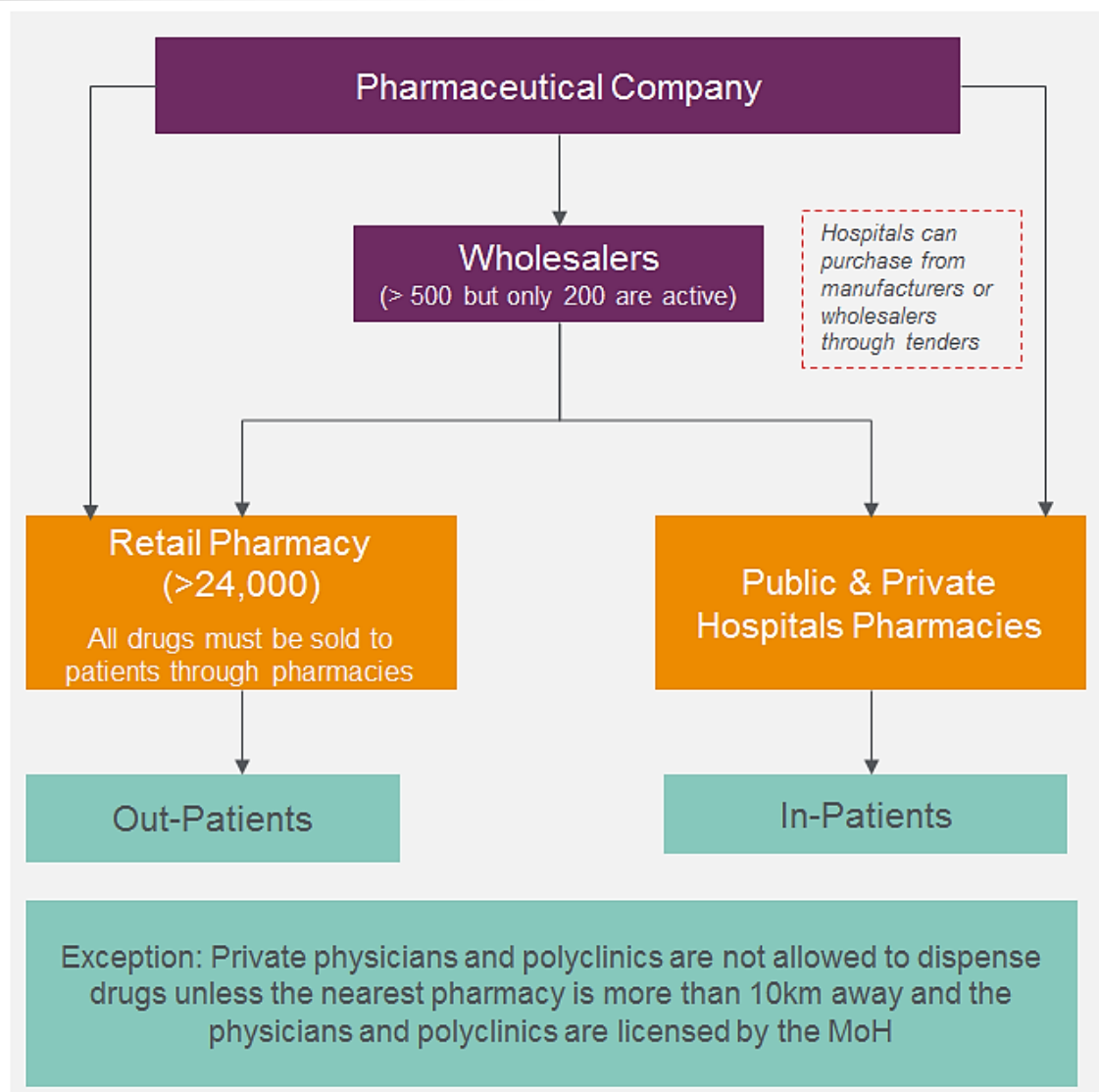
Distribution Channels

- Manufacturers or importers can sell their products to wholesalers or to retailers.
- Medicines can be sold to patients only through hospital or retail pharmacies.
- Two wholesalers have around 90% market share in terms of sale value.
- There are approximately 24,000 retail pharmacies in Turkey.
- Online pharmacies and mail-order pharmacies are not allowed.
- Turkish Law allows discounts at all stages of the distribution chain, as long as all these discounts are determined by the value of the commercial relationships and are not promotional strategies.

Pharmaceutical Procurement

- Public institutions procure drugs by tendering and follow regulations of the Public Procurement Act.
- Hospitals buy their medicines through a tendering process from either wholesalers or directly from manufacturers.
- Private hospitals follow their own tender-based procurement system with their own rules.
- Hospital pharmacy sales are growing rapidly at 20% in 2015 compared to 8% growth in retail pharmacies in the same year due to increasing utilization of health facilities.
- In Public procurements valued at more than USD 10 million, the government can require participants to provide innovation, localization, and technology transfer in the relevant industry.

Pharmaceutical Supply Chain



- In 2014, policy changes were introduced to boost the local pharmaceutical R&D and manufacturing sector.
- A 15% price advantage is now granted for domestically produced pharmaceuticals
- In the near future, more protectionist policy changes are expected as financial incentives for local production and R&D.
- The changes have received some criticism from international economists and pharmaceutical companies as they interfere with the free market.
- The changes could lead to reduced competitiveness of Turkish exports which might face retaliation from trading partners.
- The policies may also violate the GATT if applied for non-public procurements.

Healthcare and Pharmaceutical Growth Factors

Healthcare Industry Factors

- Healthcare spending is gradually increasing, but the growth rate is expected to stabilize.
- Rising incomes, economic growth and overcrowding at public facilities have led to increased demand for private healthcare services.
- The private sector has grown due to referrals from public hospitals and reimbursement by the SGK.
- Private hospitals are also growing to capitalize on healthcare tourism from the Middle East and Europe.

Pharmaceutical Industry Factors

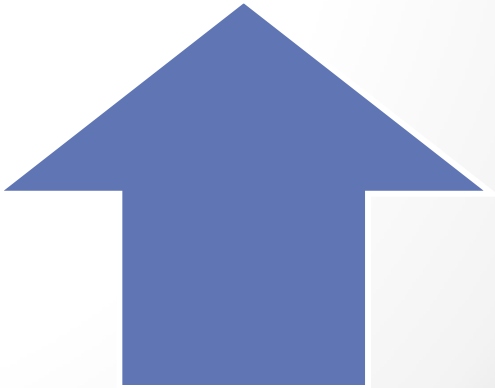
- Pharmaceutical sales steeply declined in 2010-2013 due to several price controls
- The use of a fixed exchange rate, weakened currency, complex reimbursement system and lengthy marketing approval process has led to stagnation in the pharmaceutical industry.
- Domestic manufacturing and R&D is being encouraged by preferential reimbursement of domestic drugs and removal of imported drugs from the reimbursement list.

Generic Drug Sales – Drivers and Resistors

- Turkey has one of the highest generic drug market penetrations in Europe.
- Generic drugs made in Turkey had a market share of 49% by volume and 28% by value in 2014.
- Majority of the current R&D activities in Turkey are performed for generic development.

- Lack of incentive for pharmacies to dispense generics
- Negative attitude of prescribers towards generic drugs
- Lack of awareness about generics and confusion between prescribers and pharmacists on their roles in the process of generic substitution

- Government has a positive outlook towards generic manufacturers
- Upcoming patent expiries on leading drugs
- Lower price is an incentive for patients
- Generic drugs have quick access to the Turkish market
- Lack of SPC is a favorable factor for early entry of generics

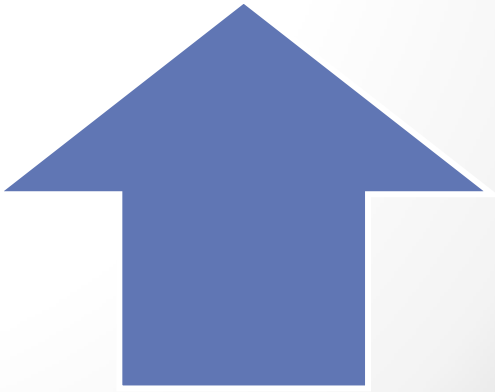


Biosimilar Drug Sales – Drivers and Resistors

- A biosimilar is a 'copied' version of a biological product that has the same pharmacological efficacy, quality and safety which is manufactured and marketed after the patent protection on the biological drug has expired.
- The cost of biologicals can be prohibitively high – especially in emerging economies like Turkey where demographic transition is leading to an aging population plagued by NCDs.
- Biosimilars offer a cost-effective alternative to treat these diseases

- Drug approval process is complex and lacks transparency
- Preference for local biopharmaceutical companies
- Lack of local manufacturers could lead to direct imports

- Rise of non-communicable diseases in Turkey
- Lack of competition from local manufacturers
- Reimbursement coverage by the SGK
- Several Turkish manufacturers are making biosimilars a priority area



Healthcare and Pharmaceutical Industry Trends

Healthcare Industry Trends

- PPP is booming in Turkey. In 2013, the value of all PPP contracts went from USD 2 bn to USD 46 bn.
- The MoH is building 34 city hospitals through PPP during 2015-2018.
- The Bilkent Integrated Health Campus, Ankara will be the largest hospital in the world with 3,680 beds
- MoH has created 'free zones' for healthcare with tax incentives for hospitals and allied institutions
- PPP projects follow the build-lease-transfer model.
- Each free zone is expected to generate USD 38 to 47 bn over a 25 year lease.

Pharmaceutical Industry Trends

- Turkey has been classified as one of the 17 Pharmerging Markets which have great growth potential.
- Pharmerging markets are expected to consume two-thirds of the global volume of medicines by 2020.
- The MoH has made it a national goal to be a world leader in pharmaceutical R&D and manufacturing.
- Aiming to spend 3% of its GDP on R&D and increase pharmaceutical exports to USD 500 bn by 2023.
- The TITCK aims to increase the number of centers for Phase 1 clinical trials and bioequivalence studies by 25% every year until 2023.
- By 2018, 60% of all drugs and 20% of all medical devices to be consumed in Turkey will be produced domestically, and sales are expected to reach USD 23.3 billion by 2023

Conclusion

- Healthcare was revolutionized by the HTP – universal health coverage and family medicine model.
- Payer-provider split was established.
- Affiliated institutes set up to decentralize regulation and implementation
- TITCK is a key stakeholder for the Turkish pharmaceutical industry:
  - Responsible for drug approvals
  - Responsible for pricing & reimbursement
  - Regulates the supply chain
  - Monitors drug movement through track-and-trace system
- Local products are getting financial incentives to kick-start the domestic pharmaceutical industry.
- Generics and biosimilars increasingly being favored due to the low cost of reimbursement
- The overall outlook is positive as the government is receptive to the impact of its price cuts and is implementing reforms to reverse the damage. The PPP model is being highly favored in Turkey.

Business Impact for ZS

- This project will serve as an internal reference document for teams that will work with clients or on-shore teams on any project related to Turkey.
- It is an up-to-date comprehensive document with exhaustive coverage of the systems and processes central to the Turkish healthcare sector, and will serve as a foundation for expertise on Turkey which is an area of interest for several multinational drug companies as the next emerging European economy.


Thank You