PHARMACEUTICAL
MANUFACTURERS
ASSOCIATION
OF TURKEY

PARTNERING WITH THE GOVERNMENT TO GLOBALIZE THE TURKISH PHARMACEUTICAL INDUSTRY

prepared by

THE BOSTON CONSULTING GROUP

November, 2011

Agenda

Current state of Turkish pharma industry

Objectives and targets of Turkish pharma industry

Proposed industry strategy and actions

Action plan

Executive summary (I/II)

Current situation of the Turkish pharma industry

Increasing national wellness in Turkey

Health and well-being have been improving in Turkey

- Life expectancy has increased by 1.9 years, infant mortality decreased by 52% (14 in 1.000 live births) since 2002
- Incidence of various infectious diseases have been decreasing

Drivers of change

Social security coverage expanded rapidly across Turkey

- 96% of population covered by some form of social security in 2011

Physician and hospital bed availabilities have been increasing

- Physicians per 1,000 population increased from 1.44 in 2002 to 1.65 in 2009
- Hospital beds per 1,000 population increased from 2.46 in 2002 to 2.71 in 2009

Hospital visits more than doubled in the last decade

- 124 mn visits in 2002 vs. 295 mn visits in 2009

Primary Care facility visits more than tripled in the last decade

- 60 mn visits in 2002 vs. 198 mn visits in 2009

Number of prescriptions issued has been on an upward trend

- 4% CAGR between 2007 – 2010 to reach 306 mn prescriptions in 2010

Immunization coverage has increased significantly

- Average immunization of 79% in 2002 vs. 96% in 2009

Source: TUIK, Ministry of Health, BCG analysis

Executive summary (II/II)

Current situation of the Turkish pharma industry

Resulting position

Public satisfaction with healthcare services being provided in Turkey has increased

- 40% satisfaction in 2003 vs. 73% satisfaction in 2010

Crucial differences remain between Turkey and developed nations in terms of vital statistics

- Life expectancy of 73.7 years in 2009 vs. 78.1 in United States and 82.1 in Japan
- Infant mortality of 13.1 per 1.000 live births in Turkey in 2009 vs. 6.2 in United States and 2.8 in Japan

Sustainable Turkish Pharma Industry

Turkish pharma industry must be set on sustainable foundations for continued improvement in vital statistics. However in recent years ...

... Turkey is losing the chance to become a pharma production base

- MNCs are delaying production investments in Turkey
- Pharma imports increasing – 34% of pharma market (by value) imported in 2002 vs. 52% in 2010
- Low capacity utilization in local production – 62% in finished product capacity utilization in 2010
- Turkey relies on imports in therapeutic areas with high average prices

... Turkey is moving away from becoming a pharma independent country

- Pharma industry accounted for ~10% of total trade deficit in 2010
- Pharma share in total exports of Turkey is low compared to many other countries
- Turkey is not fully utilizing its pharma export potential

... Pharma sector does not have a specific Government endorsed industrial development strategy

- Pharma industry treated as a sub-sector of chemicals

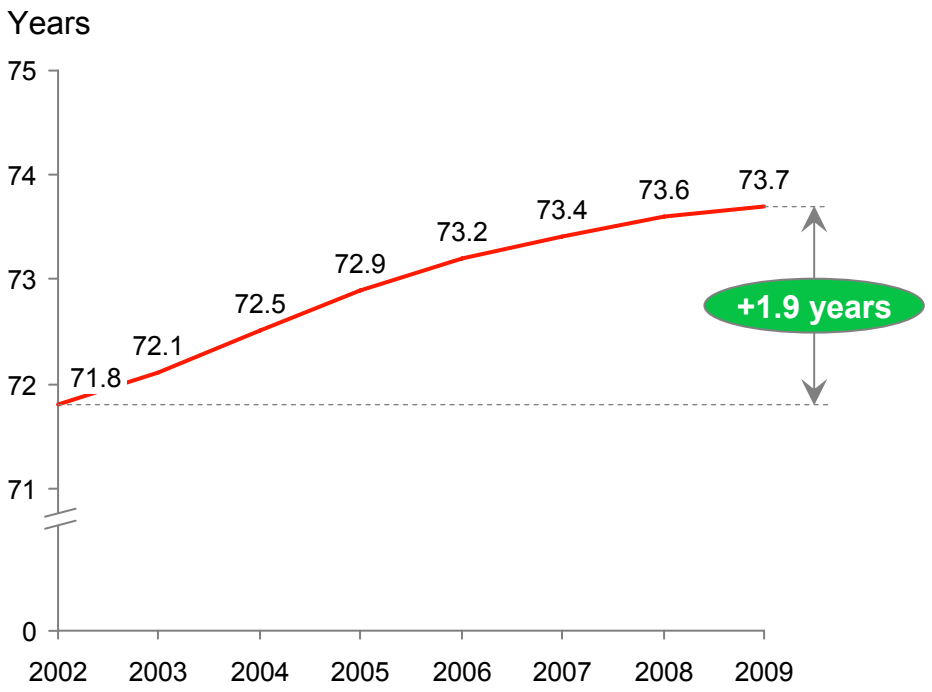
Sustainability of the Turkish pharma sector must be considered in conjunction with its strategic importance

Source: TUIK, Ministry of Health, BCG analysis

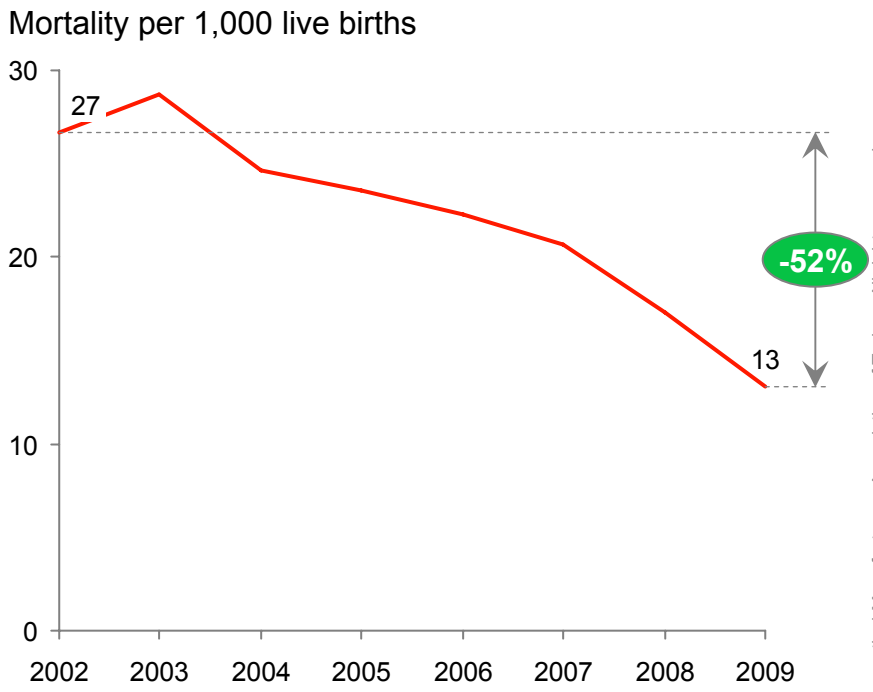
Health and well-being have been improving in Turkey ...

Life expectancy & infant mortality

Life expectancy at birth by years



Infant mortality rate by years[1] (per 1,000 live births)



Infant mortality decreased dramatically while life expectancy increased by around two years

1. 1993, 1998, 2009 data from Ministry of Health, 2002 – 2008 data from OECD
Source: Ministry of Health statistics, OECD statistics

... as reflected in the incidence of various infectious diseases

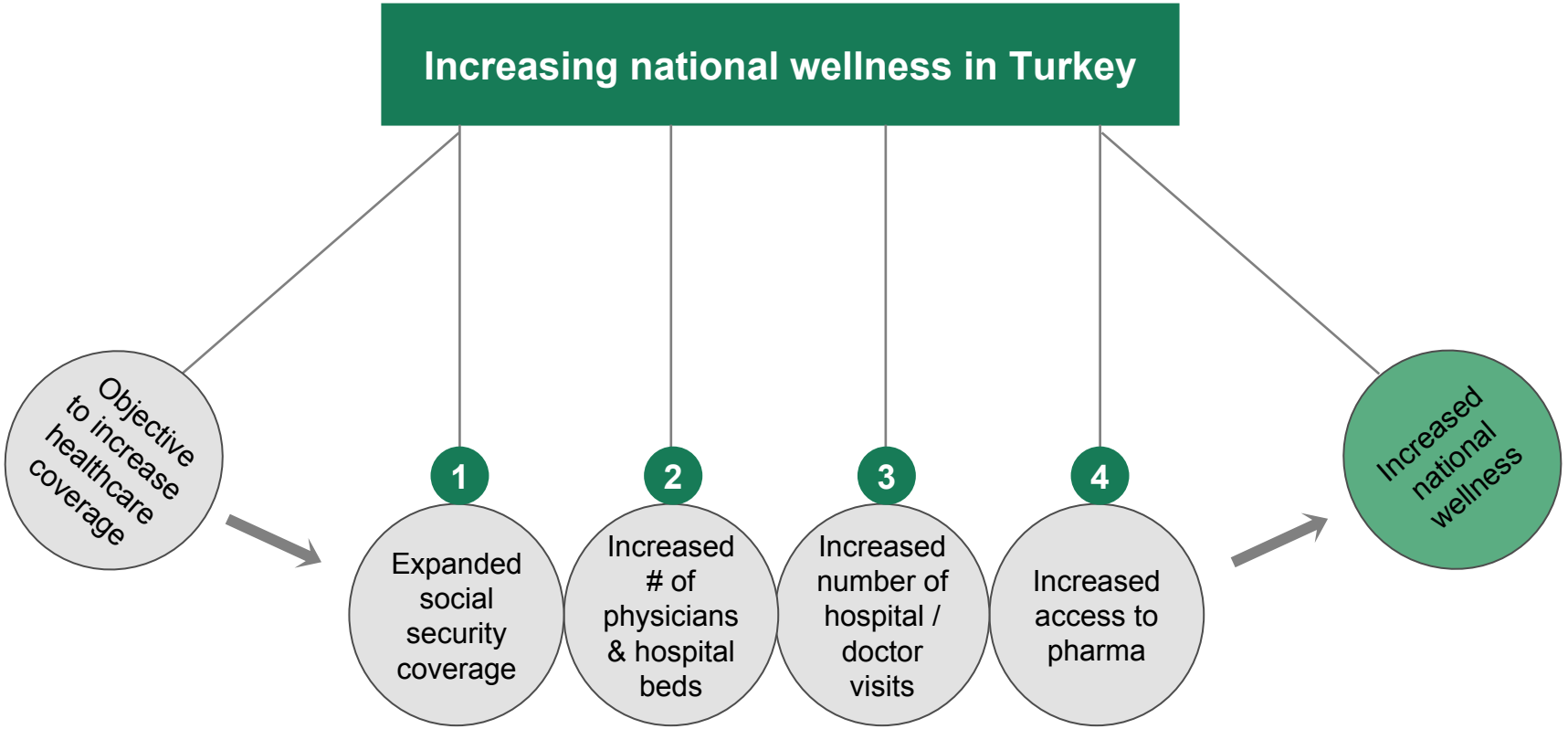
Incidence of selected infectious diseases by years (per 100,000 population)

Disease	2002	2006	2007	2008	2009
Measles	11.09	0.05	0	0.01	0.01
Tetanus	0.02	0.02	0.02	0.02	0.02
Neonatal Tetanus	2.35	1.34	0.37	0.53	0
Pertussis	0.27	0.09	0.07	0.03	0.01
Hepatitis B	8.26	10.05	9.14	8.18	6.9
Tuberculosis	40	32	31	30	29
Malaria	14.7	1.2	0.5	0.3	0.05

Incidence of infectious diseases has decreased significantly over a relatively short period of time

Source: Ministry of Health statistics

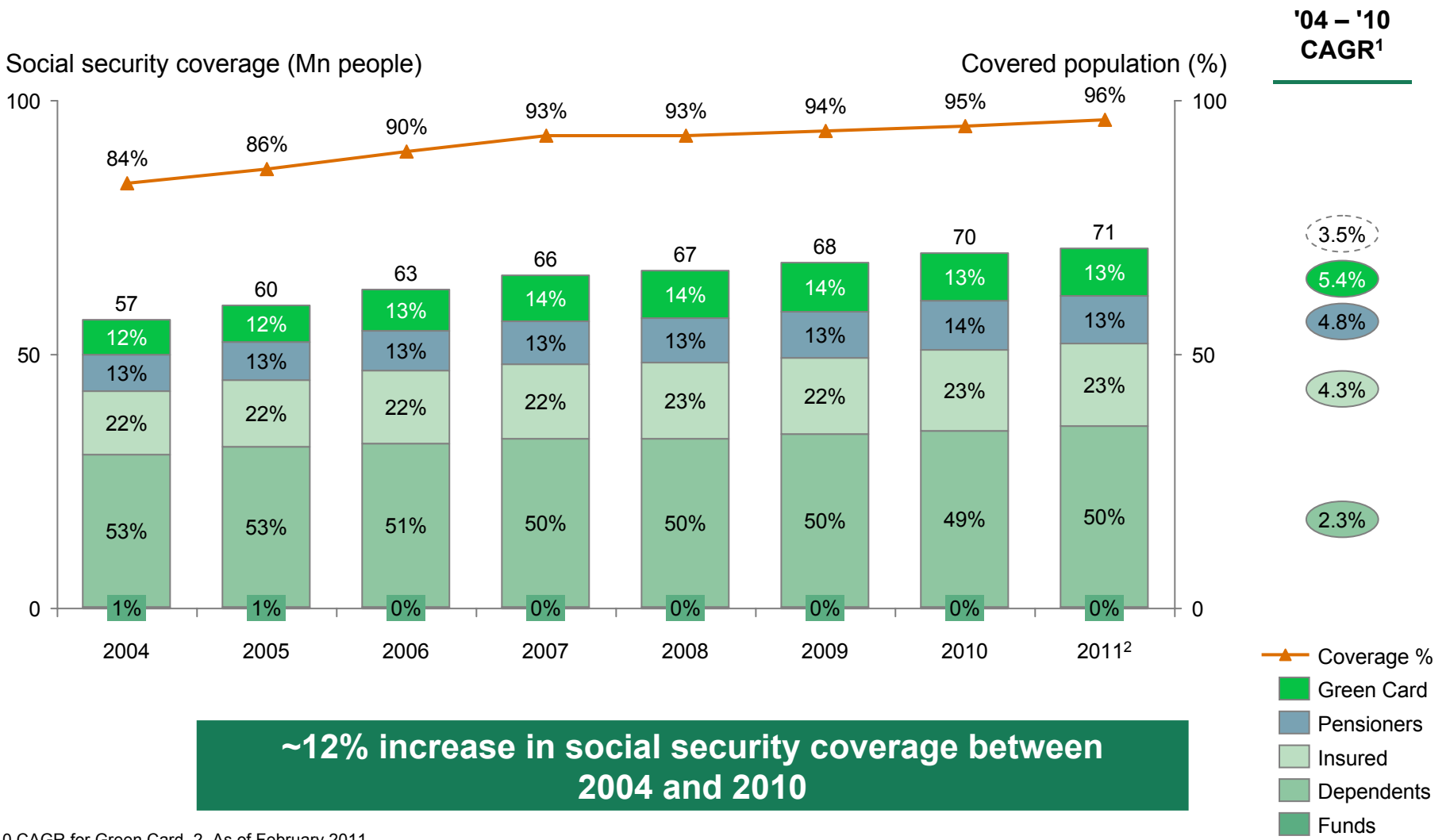
Increased access to healthcare and pharmaceuticals are key drivers of improving national wellness



Source: BCG analysis

Social security coverage expanded rapidly across Turkey

Almost the entire population covered by some form of social security

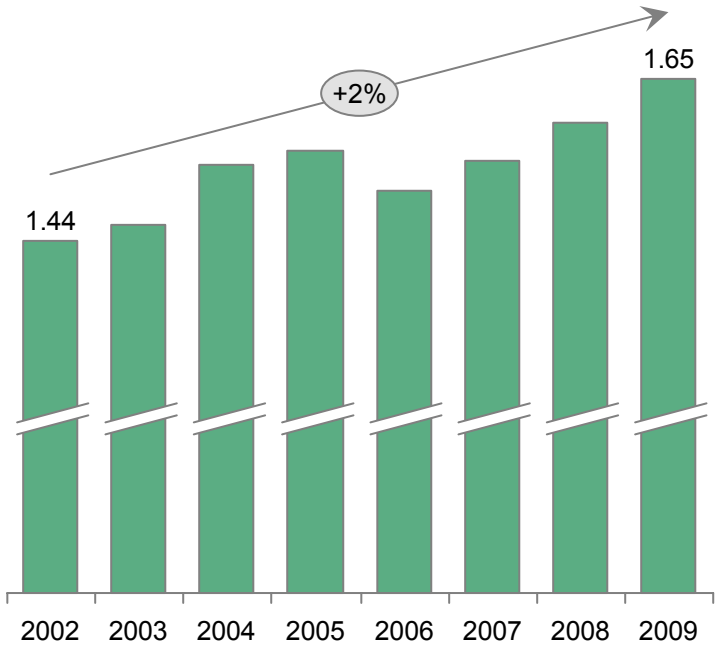


~12% increase in social security coverage between 2004 and 2010

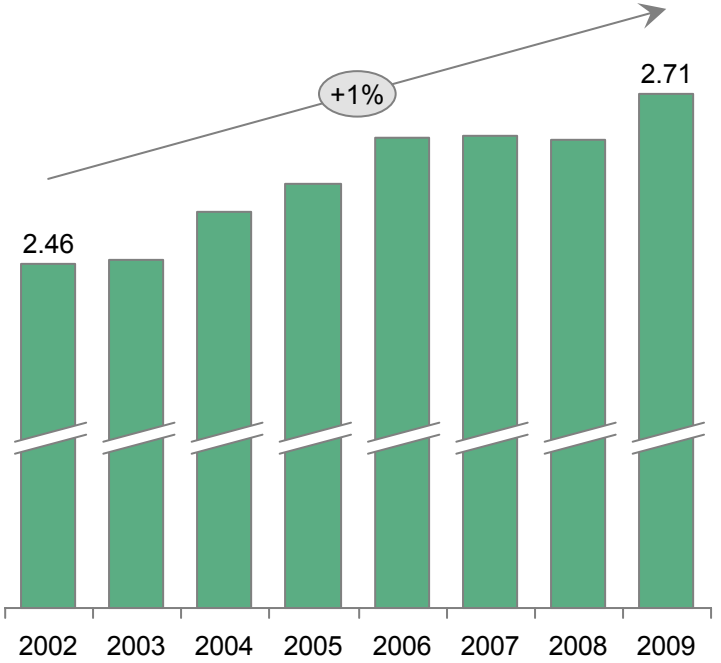
1. '04-'10 CAGR for Green Card 2. As of February 2011
Source: Social Security Institution statistics

Physician and hospital bed availabilities have been increasing

Physicians per 1,000 population



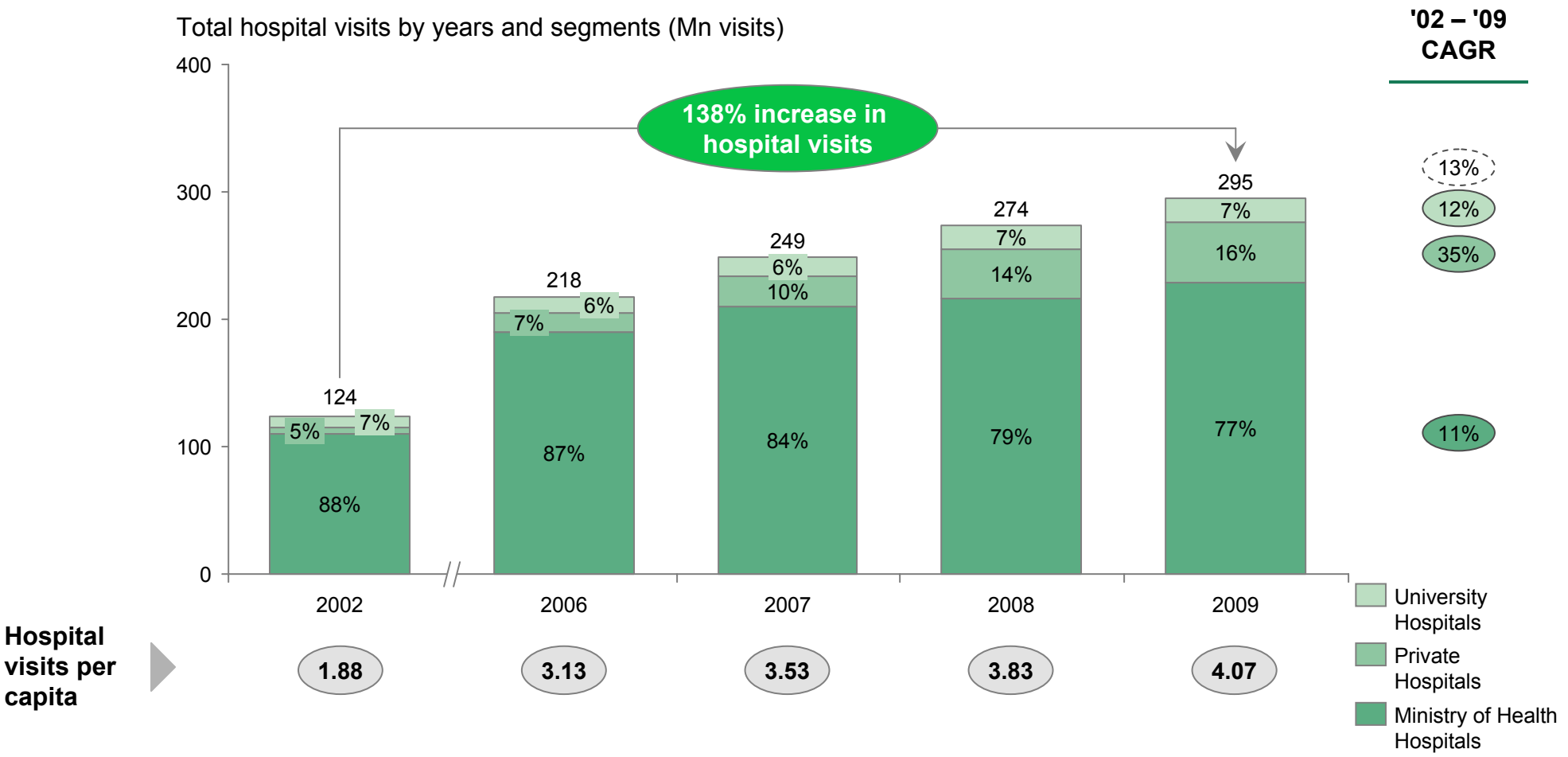
Hospital beds per 1,000 population



Physicians per 1,000 population was 1.44 in 2002, reached 1.65 in 2009
Hospital bed availability was 2.46 in 2002, reached 2.71 in 2009

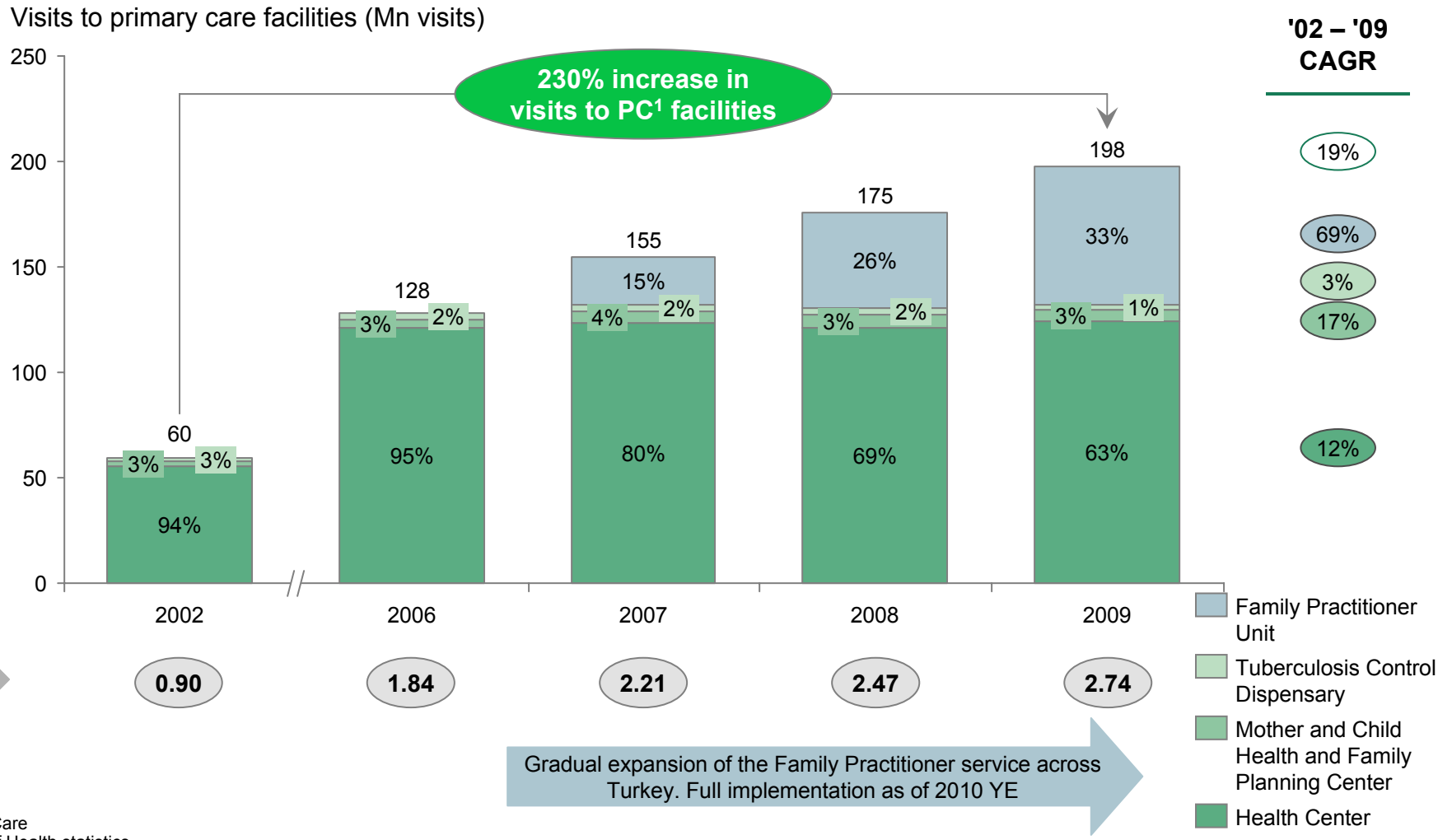
Source: TUIK

Hospital visits more than doubled in the past decade



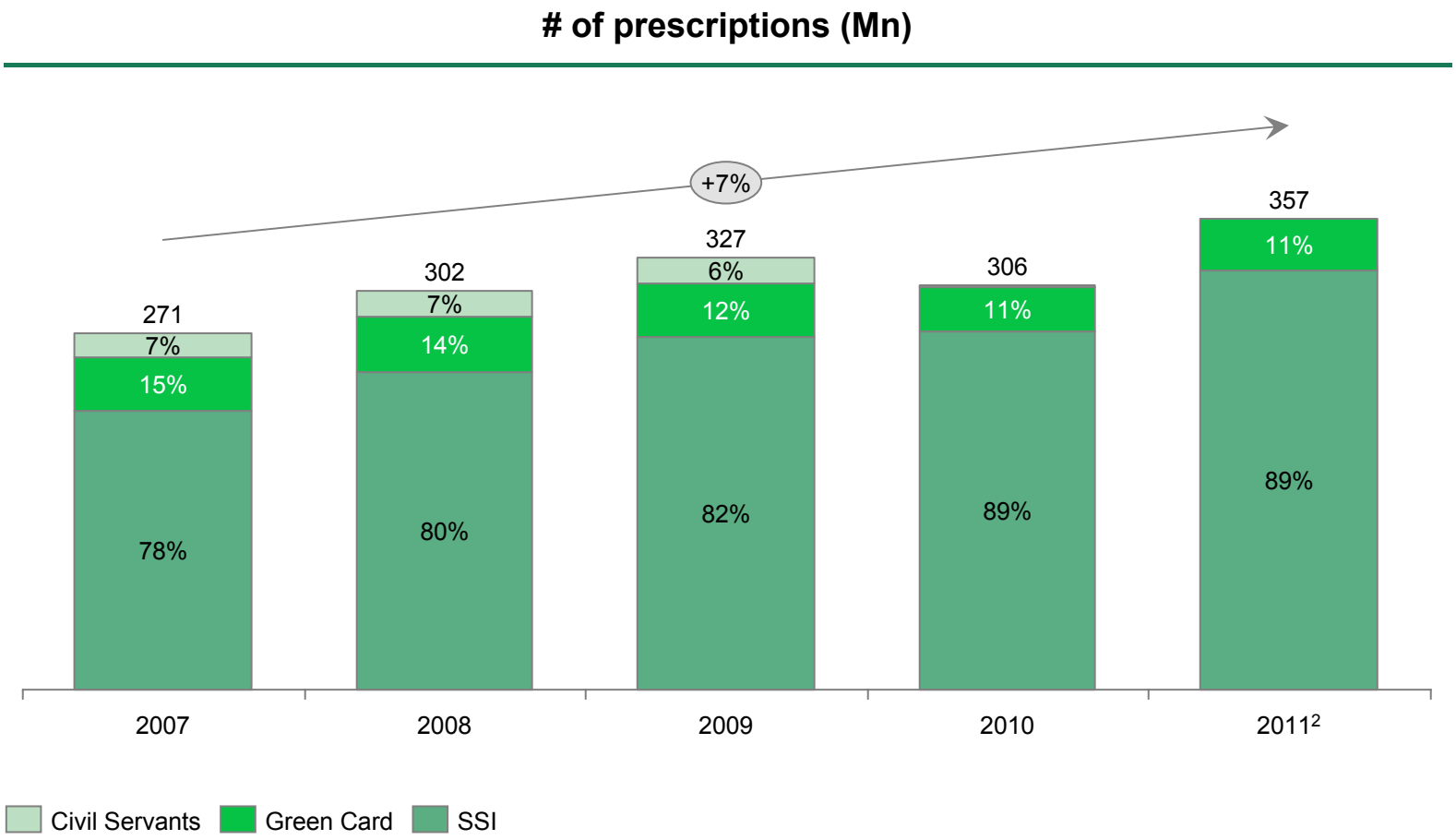
Note: Ministry of Defence hospitals are not included. The limited number of hospitals belonging to local administrations have been included in private hospital visits. Visits to SII (Social Insurance Institution) hospitals in 2002 (~44 Mn) were included in MoH hospital visits.
Source: Ministry of Health statistics

Visits to primary care facilities more than tripled; mainly due to the start of the family practitioner system



1. PC = Primary Care
Source: Ministry of Health statistics

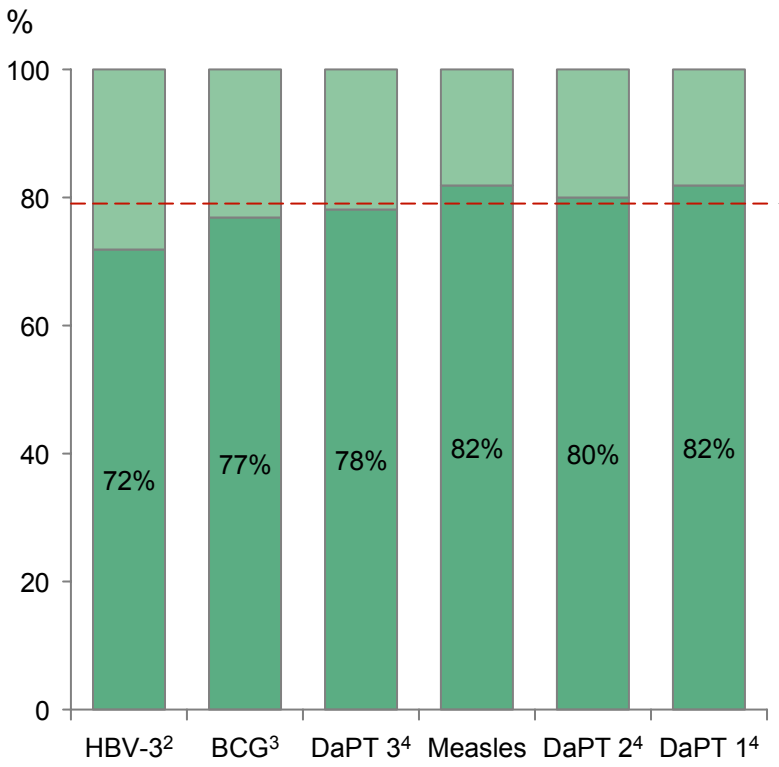
Number of prescriptions issued has been on an upward trend



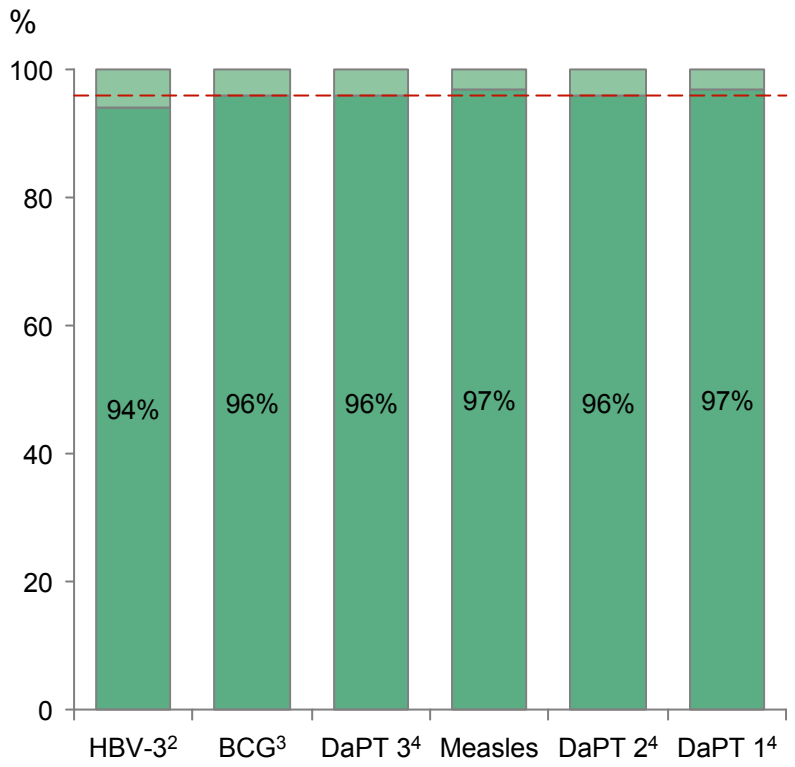
1. In 2010, civil servants prescriptions were added to SSI 2. Forecasted based on first 5 months of available data
Source: Social Security Institution

Immunization coverage has increased significantly as access to physicians and hospitals increased

Immunization coverage[1], 2002



Immunization coverage[1], 2009



Average immunization

1. As % of the targeted population by the Ministry of Health 2. Hepatitis B Vaccination 3. Bacillus Calmette-Guerin Vaccination (Tuberculosis) 4. Diphtheria Pertussis Tetanus Vaccination
Source: Ministry of Health statistics

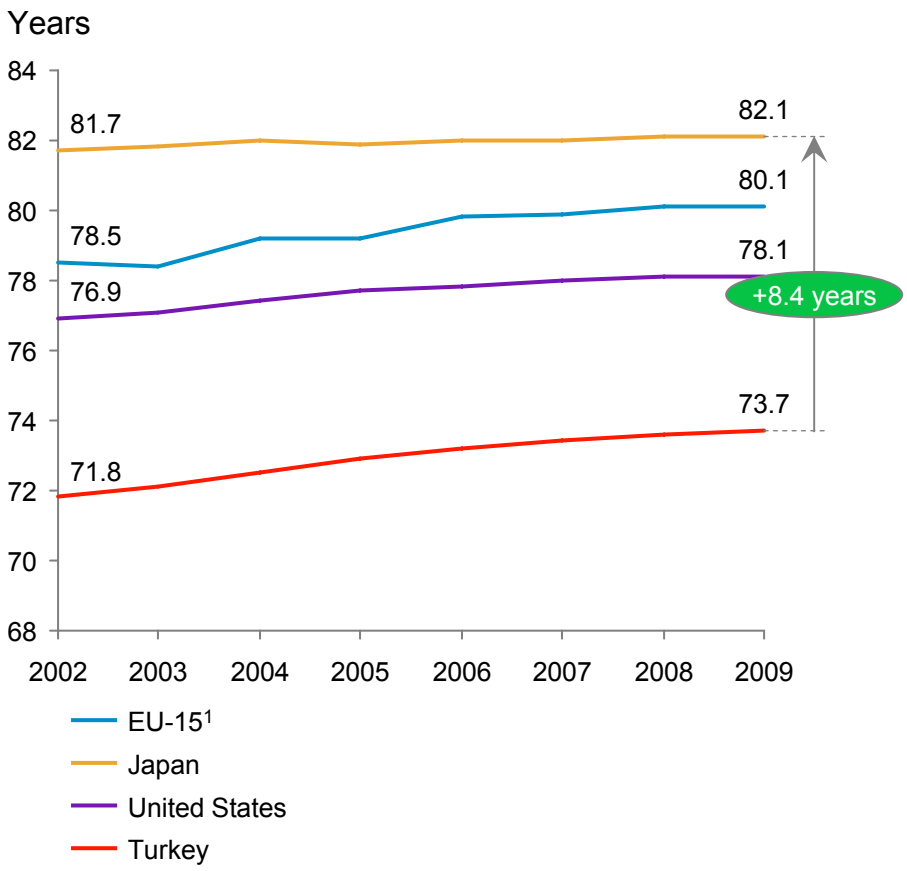
As an overall result, public satisfaction with healthcare services provided in Turkey increased

Results of the TUIK survey on satisfaction with healthcare services

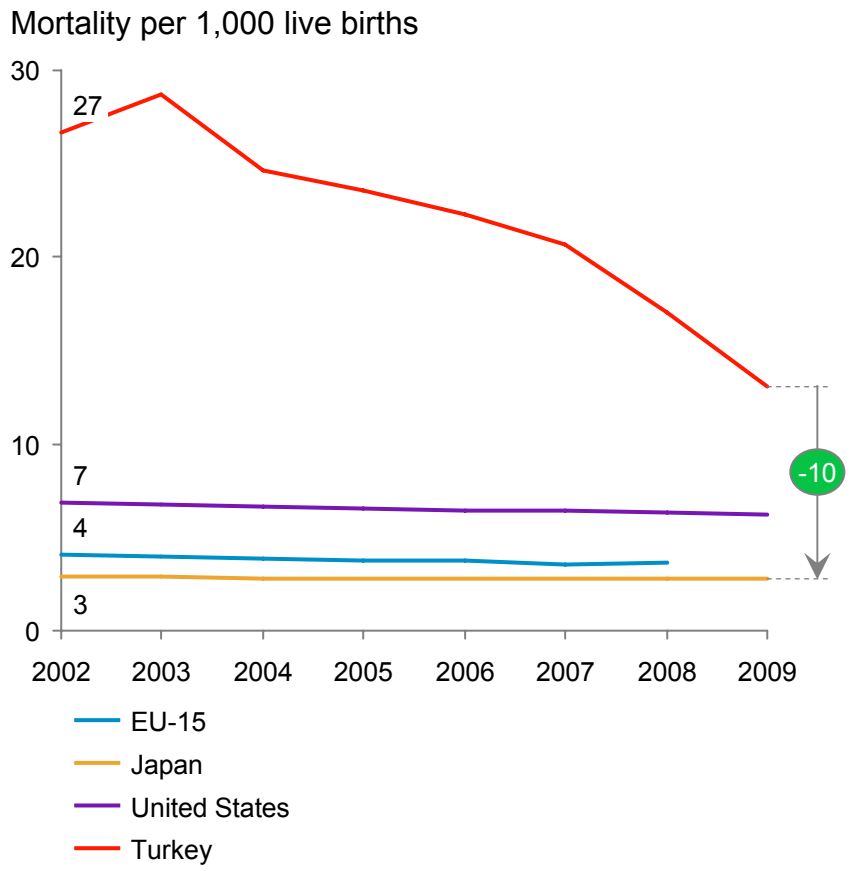
Source: TUIK

However, Turkey still has ground to cover in reaching developed nation levels, both in terms of vital statistics ...

Life expectancy at birth by years

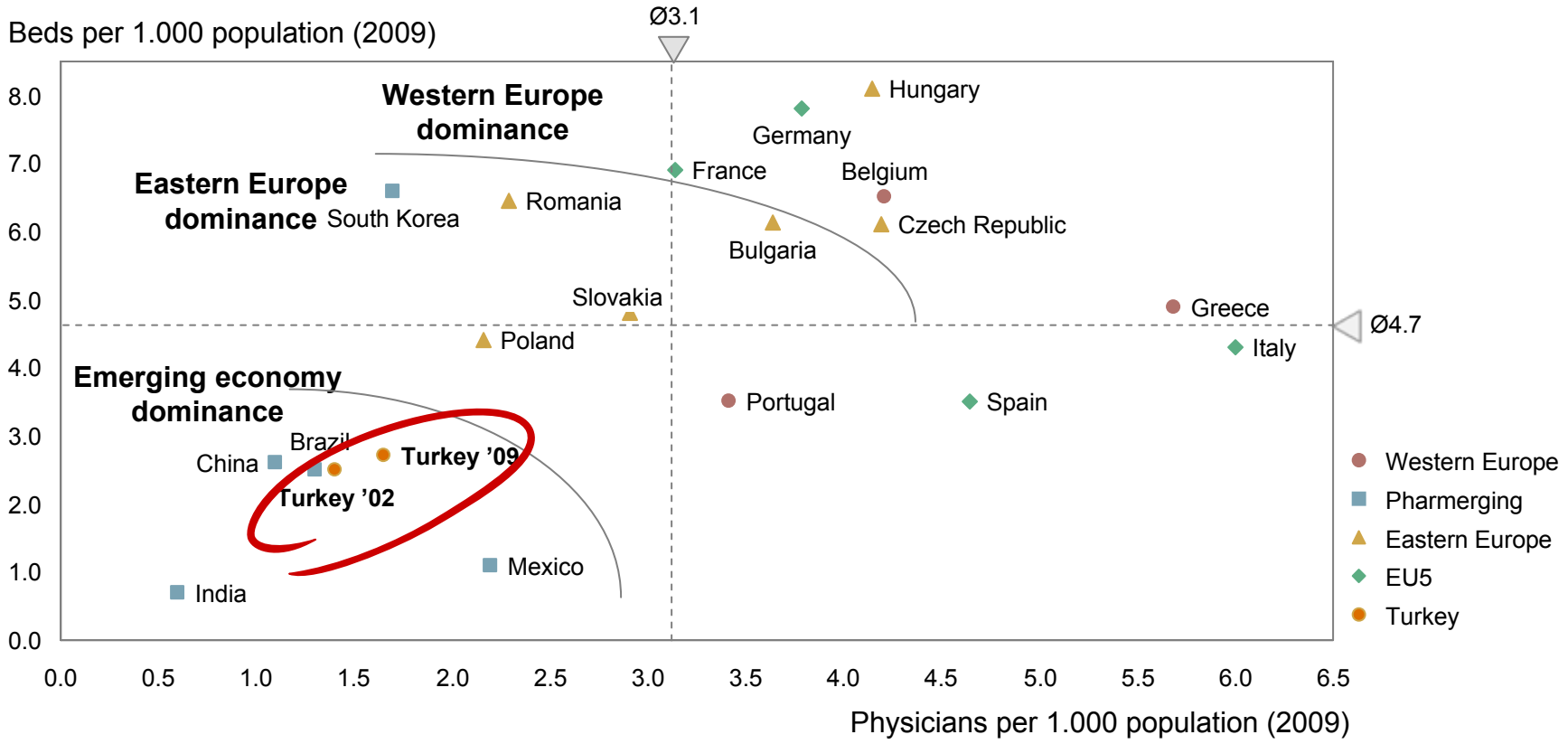


Infant mortality rate by years[1] (per 1,000 live births)



1. 2009 data not yet available, assumed equal to 2008
Source: Eurostat, EIU,TUIK

... and in terms of healthcare infrastructure & personnel



Turkey can move closer to European countries with higher hospital bed & physician ratio

Source: EIU, BCG analysis

To further improve nation's wellness, Turkey should build a sustainable pharma industry

Current issues of the pharma industry in being sustainable

1 Turkey is losing the chance to become a pharma production base

- MNCs are delaying production investments in Turkey
- As pharma production loses its appeal, imported drugs are replacing locally produced drugs
- Production unable to shift to technologically advanced high value added products
- Low capacity utilization among pharma producers
  - Finished product capacity utilization of 62%[1] in 2010

2 Turkey is moving away from becoming a pharma independent country

- Trade deficit in pharma is increasing, pharma is one of the key industries causing Turkey's overall trade deficit
- High dependence on imports for raw materials and ingredients
- Turkey is not fully utilizing its pharma export potential

3 Pharma sector does not have a specific Government endorsed industrial development strategy

- Treated as a sub-sector of chemicals

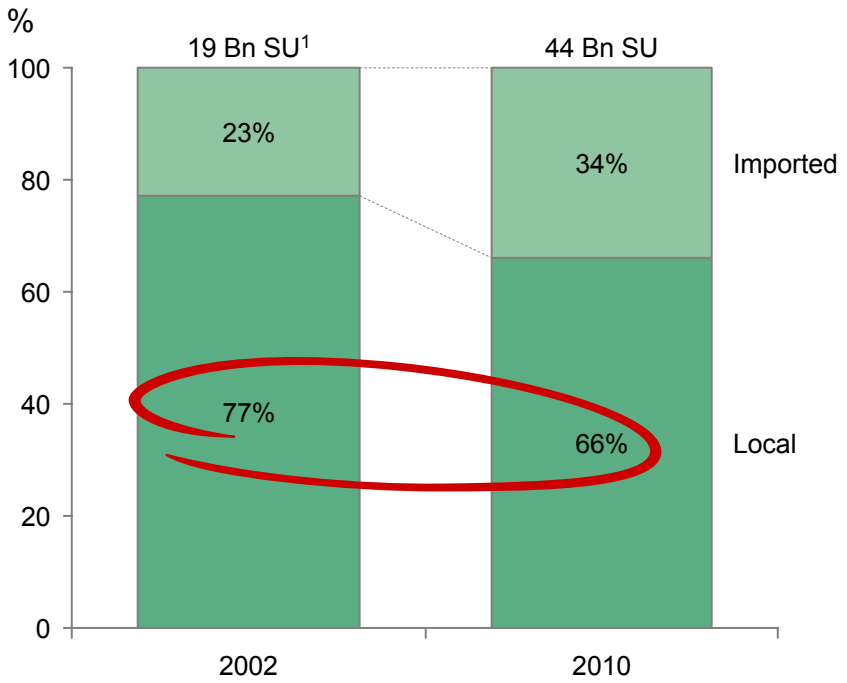
Despite issues, Turkish pharma industry should develop itself a vision for sustainable growth

1. Based on responses of IEIS members
Source: BCG analysis, AIFD Sector Survey (April 2011)

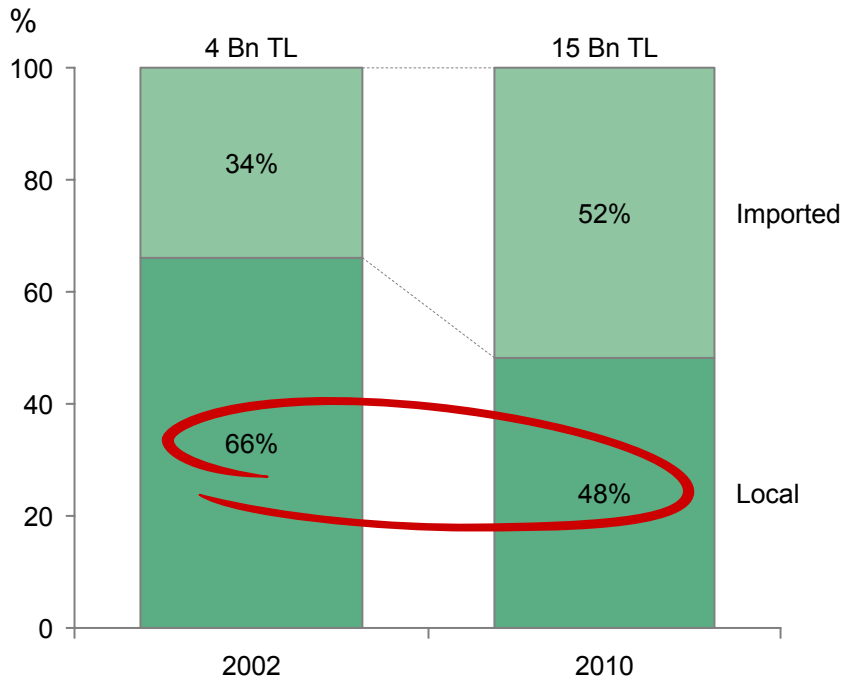
1 Local pharma production has been losing ground to imports

Local production increased ~5 Bn TL over last 8 years; but imports grew ~7 Bn TL over same period

Turkish pharma market by volume



Turkish pharma market by value



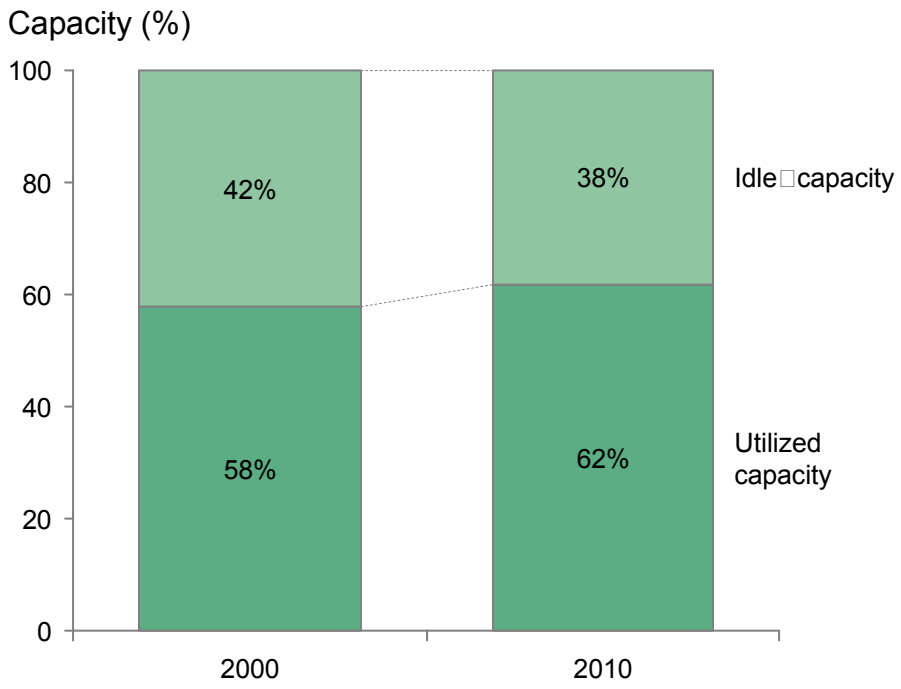
Share of local production decreased 11% by volume and 18% by value over eight years

1. SU = Standard Unit
Source: IEIS, IMS, BCG analysis

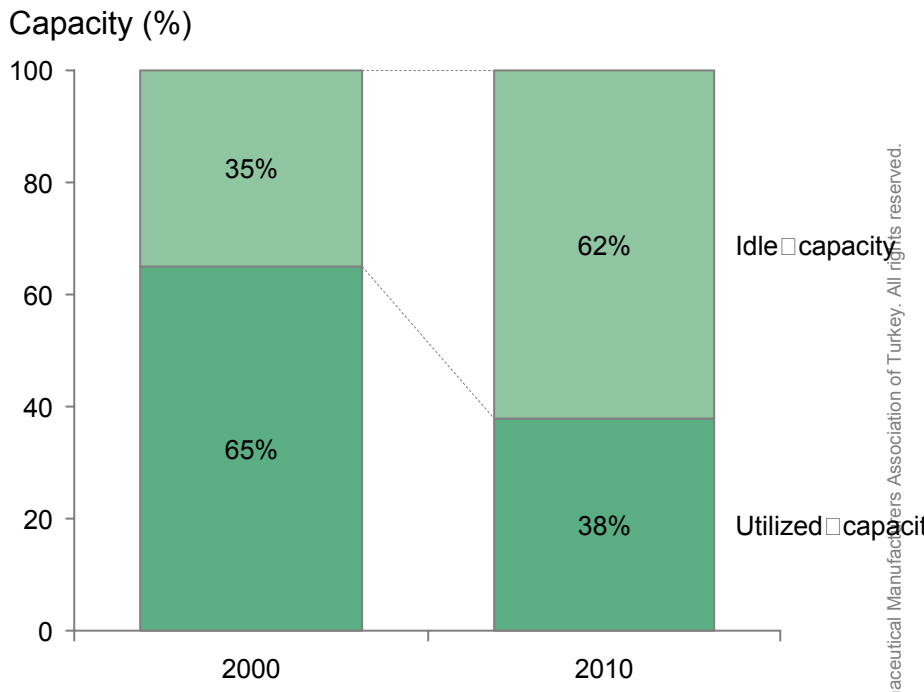
1

Low capacity utilization among local pharma manufacturers is a major issue ...

Formulation capacity utilization



Raw material capacity utilization



Raw material production capacity utilization has been decreasing

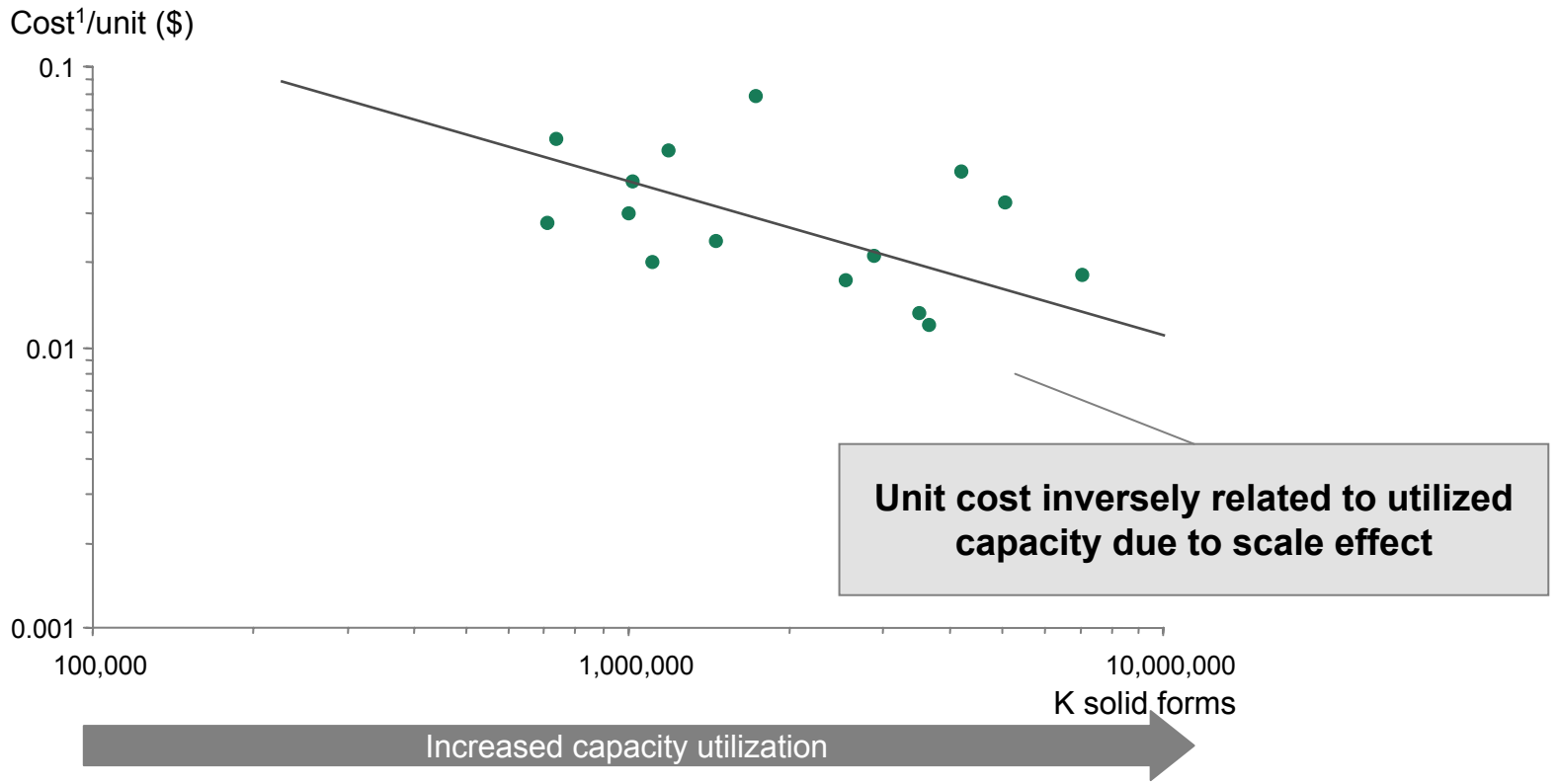
Source: Based on responses of IEIS members

1

... which leads to higher unit production costs

Conceptual

Solids manufacturing scale curve (global plants)



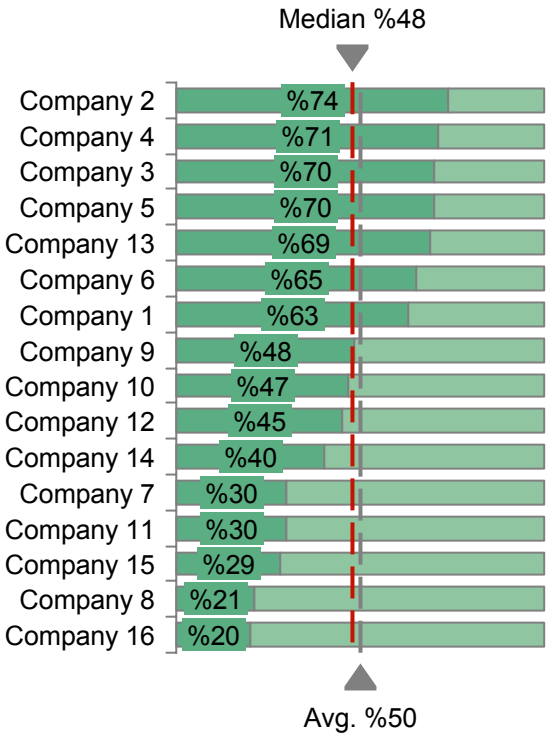
Increased capacity utilization allows lower unit production costs and hence higher competitiveness in exports

1. Cost measured net of utilities and materials (API)
Source: BCG experience

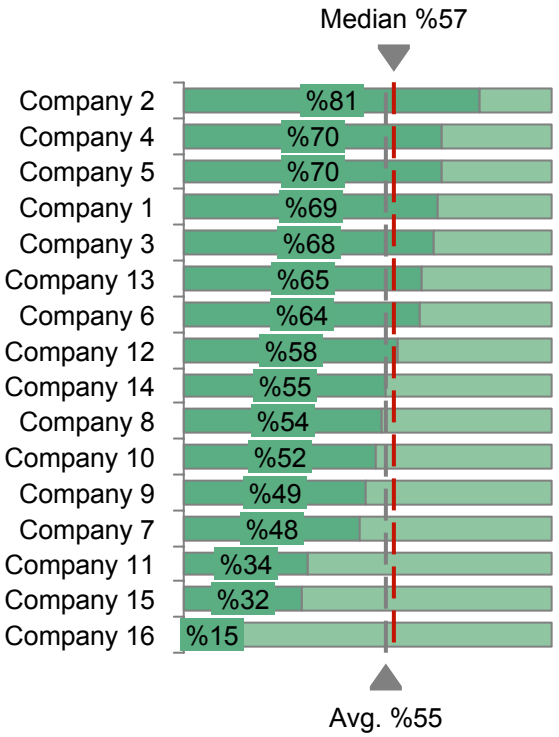
1

Significant variations exist among local manufacturers in capacity usage

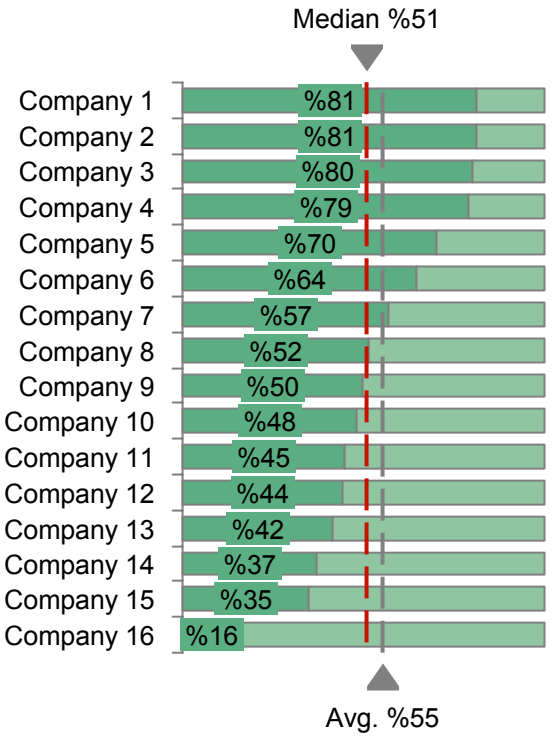
Finished product capacity utilization, 2000



Finished product capacity utilization, 2005



Finished product capacity utilization, 2010



Variation in capacity usage among companies has been on the rise

Note: Calculations are according to data provided by IEIS members
Source: IEIS member companies that responded to questionnaire

1

Turkey relies heavily on imports in high value-added TAs with high technology investment needs

Therapeutic areas	Share of imports	Indexed Price[1]	Indexed Sales[2]
T DIAGNOSTIC AGENTS	%99.3	244	2%
L ANTINEOPLAST+IMMUNOMODUL	%97.8	3.154	9%
V VARIOUS	%93.8	87	2%
S SENSORY ORGANS	%90.7	19	2%
H SYSTEMIC HORMONES	%71.6	102	1%
B BLOOD + B.FORMING ORGANS	%65.0	120	4%
R RESPIRATORY SYSTEM	%55.5	60	11%
G G.U.SYSTEM & SEX HORMONES	%52.4	233	5%
N NERVOUS SYSTEM	%52.1	95	11%
C CARDIOVASCULAR SYSTEM	%47.8	114	12%
A ALIMENTARY T.& METABOLISM	%46.1	84	14%
D DERMATOLOGICALS	%31.4	54	3%
J SYSTEMIC ANTI-INFECTIVES	%26.9	331	15%
M MUSCULO-SKELETAL SYSTEM	%26.7	84	8%
P PARASITOLOGY	%2.5	48	0%

%60

%40

Avg. index price level: **621**

Avg. index price level: **117**

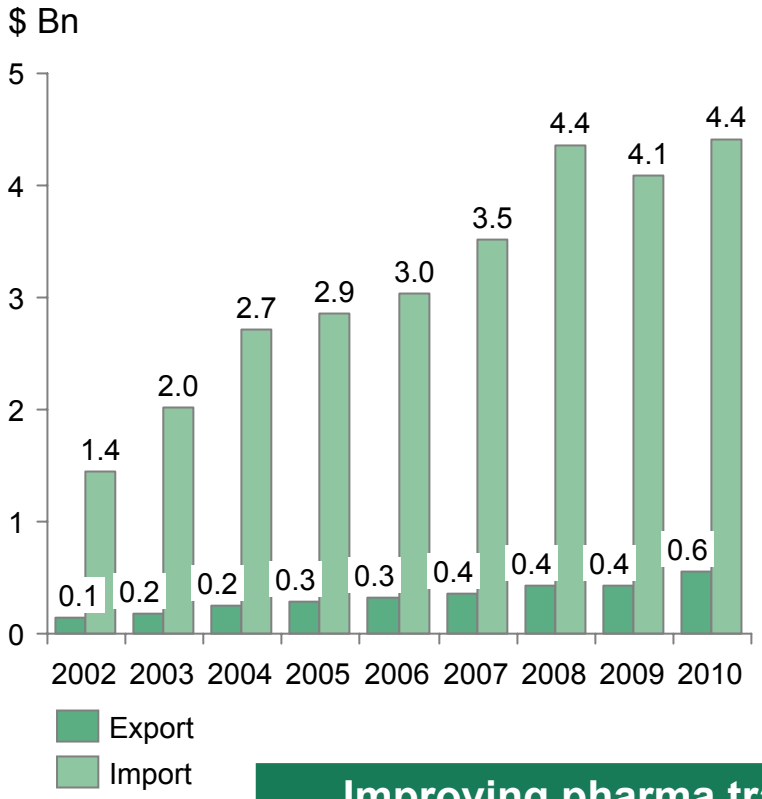
Avg. index price level: **129**
(Avg. excl. antiinfectives = 62)

1. An average price has been determined for each Therapeutic Area (TA) by dividing 2010 sales value with volume. These average prices were indexed by setting the arithmetic average of the 15 TAs as 100 2. Sales of the 15 TAs were taken as 100% and the share of each TA within the total are listed in percentages
Note: Hospital solutions have been excluded
Source: İEİS, BCG analysis

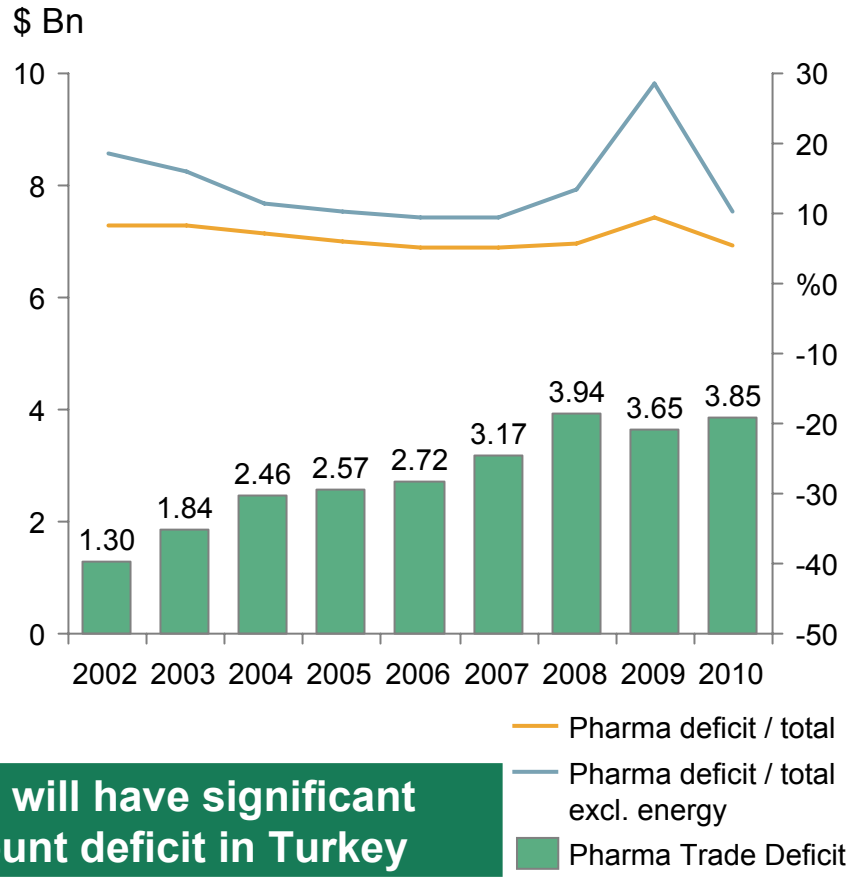
2

Pharma industry accounted for ~10% of total trade deficit in 2010; excluding energy industry

Pharma export and imports



Pharma trade deficit and its share in total trade deficit of Turkey

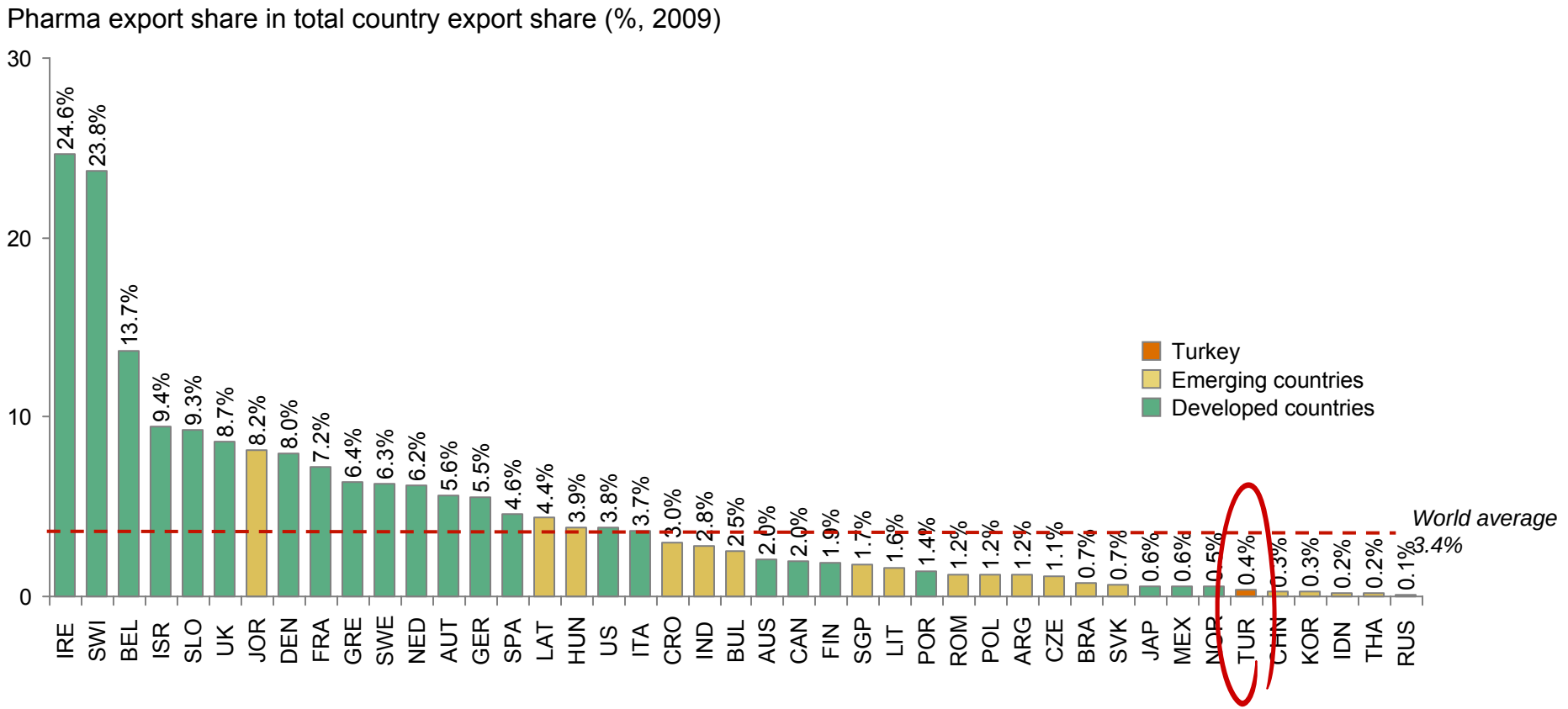


Improving pharma trade balance will have significant impact on reducing current account deficit in Turkey

Source: TUIK, BCG analysis

2

Pharma share in total exports of Turkey is low compared to many other countries



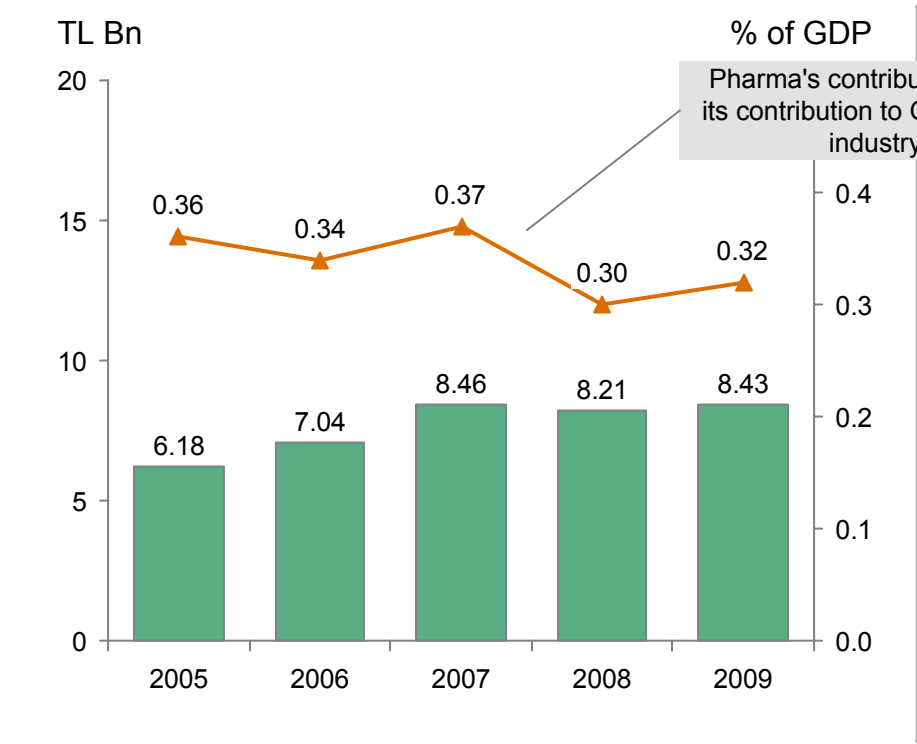
Relatively low share of pharma exports in total exports indicates potential for growth

Note: Pharma exports taken from ITC code #30 only to be comparable with Turkey statistics. 2009 figures used for India and Singapore due to lack of data
Source: Intracen, BCG analysis

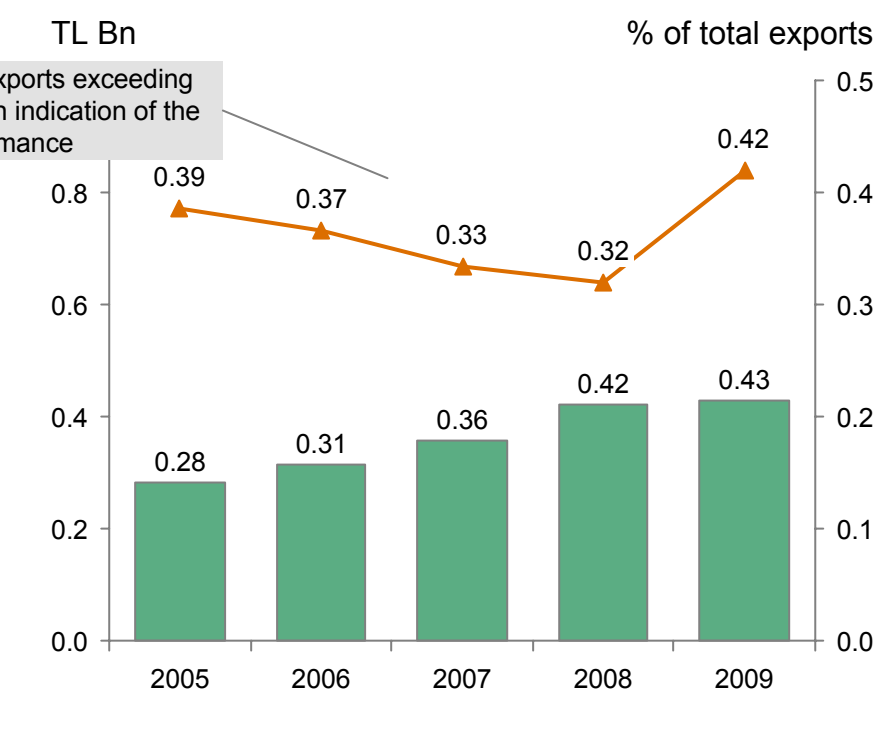
2

Comparison between industry's contribution to GDP and its export share shows export potential

Pharma's contribution to Turkish GDP[1] is approximately 0.3% ...



... yet pharma manages to capture greater share of Turkey's exports



Pharma's contribution to exports exceeding its contribution to GDP is an indication of the industry's performance

Pharma share in GDP

Value of pharma production

Investing in the pharma industry will increase pharma exports. Industry proves its export potential.

Pharma share in total exports

Pharma exports

1. Pharma share in GDP = (Manufacturing share in GDP) x (Pharma share in total manufacturing)

Source: TUIK, BCG analysis

3

Turkish pharma sector does not have a unique strategy, treated as a sub-sector under the chemical industry

Ministry of Industry and Trade does not have a strategy paper for pharma

Ministry of Industry and Trade has been developing sector strategies

- As indicated in the 2010 – 2014 Strategic plan of the ministry

Strategy papers on the automotive and machinery sectors have already been published

- Strategy papers on electronics, wood products, paper and furniture are to be published

Pharma is treated as sub-sector of chemical industry

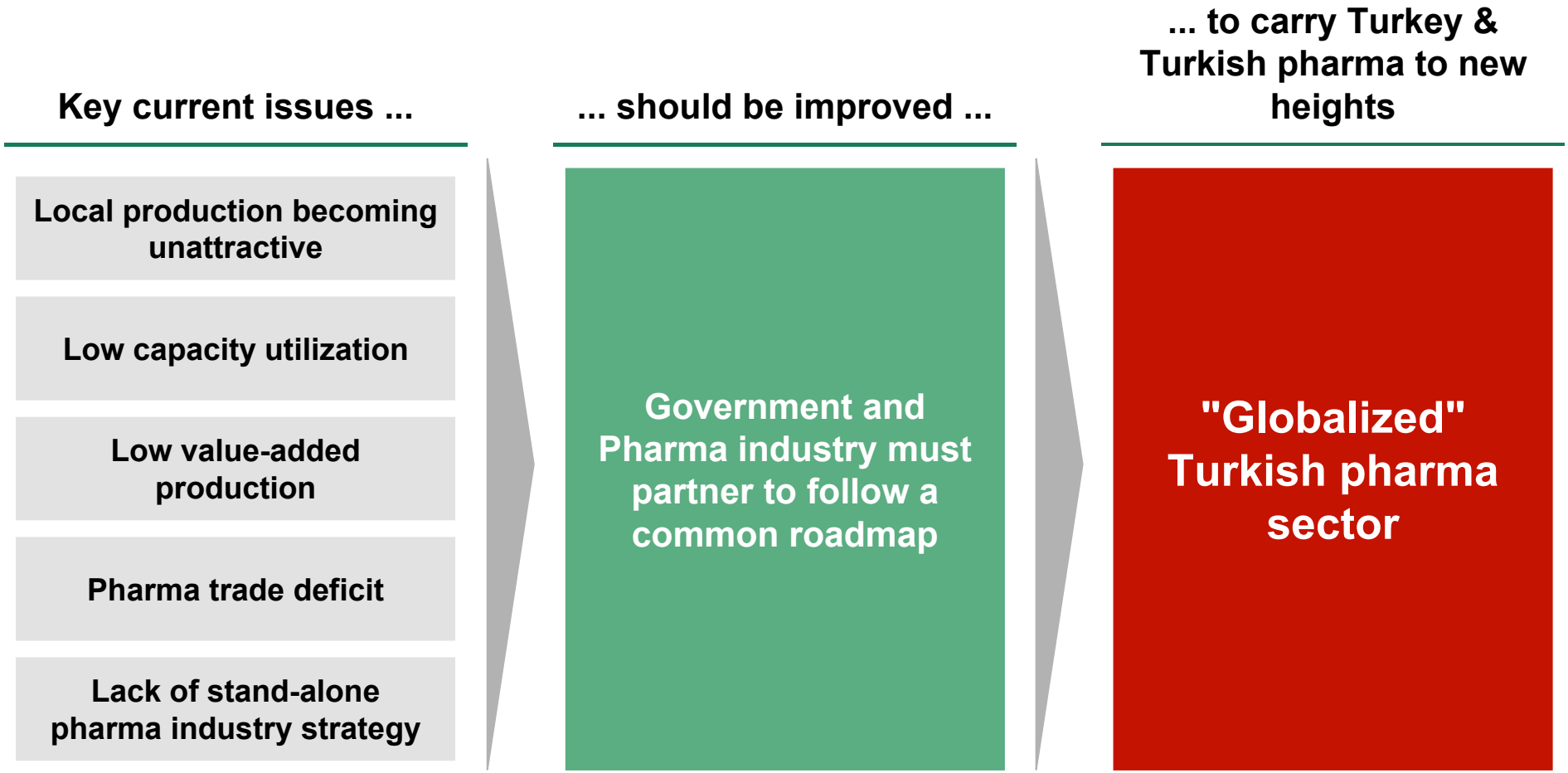
Gov't currently does not cover the pharma sector uniquely in terms of strategy and target development

- Covered in "Chemicals Sector Report[1]" of the Ministry of Industry & Trade along with paints, cosmetics and plastic industries
- Sub-sector of "Chemicals" in TIM's "2023 Turkey Export Strategy" report, along with organic-inorganic chemicals, mineral fuels, paints, detergents, cosmetics, plastic industries

Pharma has very different dynamics compared to chemical industry and Government should have a standalone pharma industry strategy

1. "Kimya Sektör Raporu"
Source: Turkish Exporters Assembly (TIM)

Government and industry should partner to transform pharma into a sustainable industry competing in global markets



The pharma industry has the necessary capabilities to reach globalization target

Turkish pharma industry has a long history of production at international quality standards

- Currently there are 49 pharma production facilities in Turkey

The industry currently exports to more than 100 countries

- Turkish pharma industry is able to produce according to the high standards of many different countries ...
- ... including regulated markets such as EU and USA

Local pharma companies play an important role in the industry

- Currently there are ~300 local pharma companies in Turkey
- In terms of sales revenues, the 1st and 3rd companies in the market are local producers

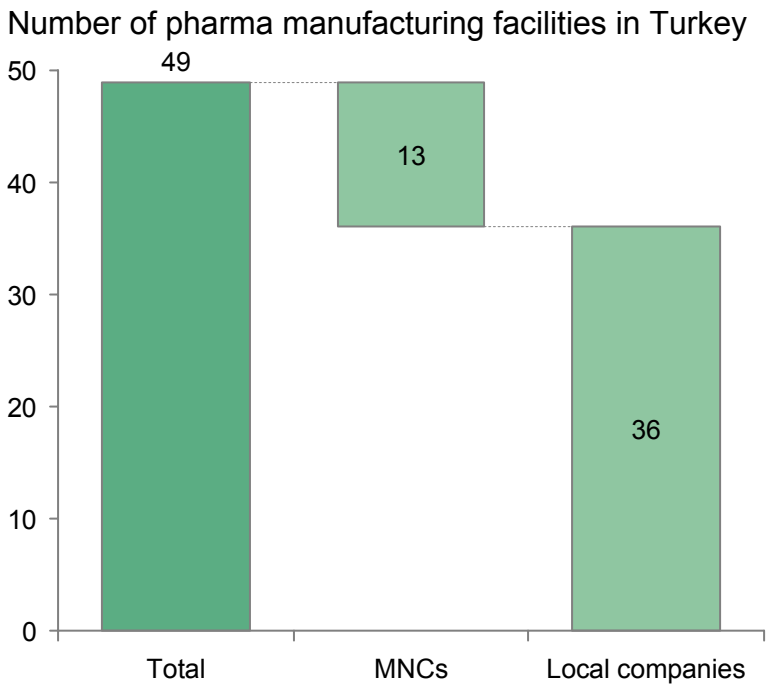
Global pharma giants also play a major role in the Turkish pharma industry

- Many leading MNCs have production capabilities in Turkey

Source: International Trade Center statistics, BCG analysis

Established pharma manufacturing facilities in Turkey have good technical and quality standards

49 pharma manufacturing facilities in Turkey ...



... of which majority compliant with global manufacturing standards

Compliance to GMP guidelines is a pre-requisite for pharma exporting

- WTO's GMP guidelines applied in 100+ countries
- EU and US has similar but separate guidelines to WTO's guideline

Majority of manufacturing facilities in Turkey are compliant with GMP guidelines

- MoH regularly audits facilities in Turkey for quality and technical compliance

Majority of traditional formulations and technologies can be manufactured at current facilities

- Exceptions are sophisticated biotechnological drugs and some other forms that are not economically feasible for local production

Source: Literature research, interviews, IEIS, BCG analysis

Agenda

Current state of Turkish pharma industry

Objectives and targets of Turkish pharma industry

Proposed industry strategy and actions

Action plan

Executive summary

Pharma should be considered as a strategic industry for Turkey; just as telecom, banking, defence and energy industries

- Pharma industry supports improvement of human health and well-being of population; reduces disease incidences and increases average life expectancy
- Pharma is one of the most value generating industries in the world
- Pharma is a highly technological and R&D-focused industry; allocates highest share of sales to R&D compared to other industries

Turkey is one of the largest pharma markets in Europe and the world; and expected to grow further due to aging population, increased access to healthcare services and average life expectancy

- 6th largest market in Europe and 14th largest pharma market in the world by 2010 figures

However, Turkish pharma industry hasn't taken its fair share in Turkey's exports and global pharma market; causing limited contribution to Turkish economy

- Pharma exports account for 0.5% of Turkey's total exports in 2010
- Turkish pharma exports represent 0.1% of global pharma trade in 2009

Moreover, import-dependency in pharma products causing increase in Turkey's trade deficit

- Pharma imports climbed to $4.4 Bn in 2010; export to import ratio floating at ~10% levels in the last decade

In light of these, Turkish pharma industry set its 2023 objective to globalize and become one of the major pharma countries in the world ...

- ... And increase its contribution to the Turkish economy while improving industry's trade balance

Pharma should be a strategic industry for Turkey

Pharma should be a strategic industry

Pharma industry ...

- ... continually strives to **develop and improve medications** targeting various diseases and health problems
- ...is strategic for **national safety during emergency periods** i.e epidemics, natural disasters, wars, etc.
- ... is a **high value-added and R&D intensive sector**
- ... utilizes **high-skilled labor** in various corporate functions

Public benefits for Turkey

- Improved public welfare in conjunction with increased public access to HC services
- Increased availability of medication at times of elevated demand due to emergencies
- Creates value for the economy and contributes to nation's R&D capabilities
- Increased number of employment opportunities for university graduates

Source: BCG

Emerging countries place the pharma industry as a strategic component of national development

Selected examples

Brazil

Development of a national "Health Industrial Complex" is a priority for Government

- Aim to foster development of pharmaceutical, equipment, and health technologies industry
- Oriented by Secretariat of Science and Technology, under MoH[1]

Substantial investment and support provided to strengthen local manufacturing and R&D

- Government invested in Health Industrial Complex ~$3 Bn between 2003-2010
- Government supports investments and exports; special credits provided by national development bank

Russia

Pharma set as one of the five innovative industries for Russia

"Instead of primitive extraction of natural resources, we will create a smart economy that produces unique knowledge, new things and technologies useful for people"

President Medvedev,
Address to the Parliament, Nov 2009

Pharma 2020 strategy developed by MoI&T[1]

- With the goal of transition to innovation development model of Russian pharma

~$5-6 Bn investment requirement for 2009-2020 period estimated by Government

- Main investment items are transition to GMP standards, development of medications and training of pharma specialists

1. MoH = Ministry of Health 2. MoI&T = Ministry of Industry and Trade
Source: Espicom, Press research, Pharma 2020 website, BCG analysis

Considering pharma as a strategic industry, the Brazilian Government has a policy to develop the local industry

Pharma seen as a strategic industry by Government

"There is an understanding in federal government that healthcare technology is strategic for the country and can help boost the development of many other complementary industries"

Franco Pallamolla President of ABIMO[1]

"... For more expensive drugs, we understand that it is an economic asset for the country to have the technology. We are willing to pay a little more to have the capacity to produce..."

Reinaldo Guimarães, Secretary of Science & Technology at MoH

Government institutions partnering with private sector to build and transfer know-how

State-owned Fiocruz is one of the most prominent healthcare and pharma research institution in Latin America

Activities of Fiocruz include not only R&D but also drug development

- Farmanguinhos[2] produces drugs against AIDS, tuberculosis, malaria, leprosy, hypertension and several kinds of cancer, among others

In drug development, Fiocruz forged 20+ public-private partnerships in recent years

- Both with local producers (e.g., Ache) and with MNCs including Novartis and GSK

Government policy is to foster locally based production of high-value pharma, even it costs more than importing

1. ABIMO = Brazilian Medical Device Manufacturers Association 2. Medicines and Drug Technology Institute under Fiocruz
Source: Press research, expert interviews, BCG analysis

Government in Russia developed Pharma 2020 strategy aiming to modernize industry and increase local drug share

ФАРМА 2020

Pharma 2020 program focusing on local industry and innovation ...

Increase share of local production through a series of preferences
- Pharma production clusters
- Import substitution with locally produced analogues

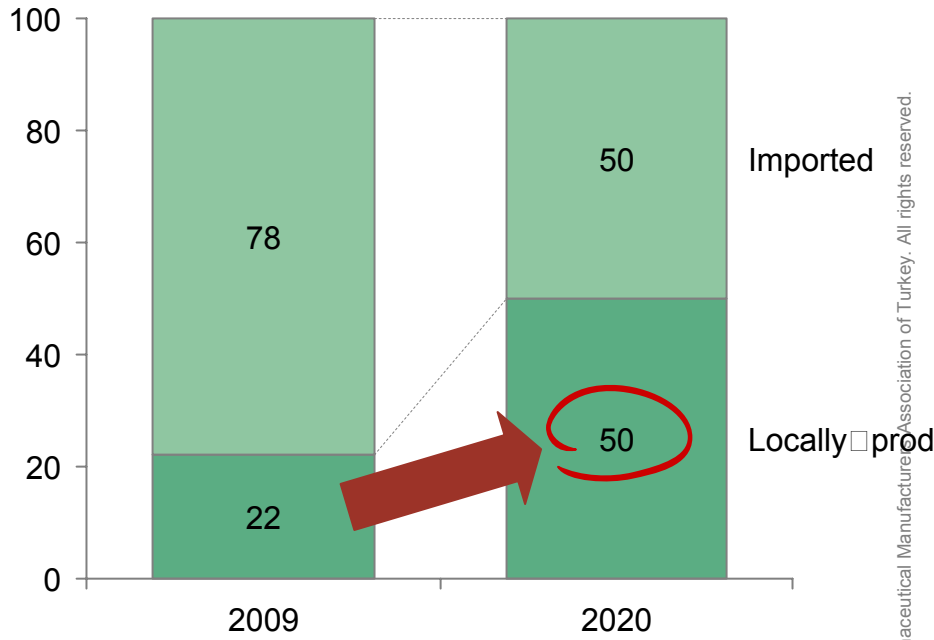
Increase share of local innovative drugs
- Localization of innovative drugs production

Build local industry also oriented for export; increase export x8 higher compared to 2008
- Switch to GMP standards

Increase investments into technology and R&D via local R&D centers
- Localization of high-tech and innovative substances production

... To increase share of locally-produced drugs share in market and decrease import-reliance

Pharma market split by origin (% of value)

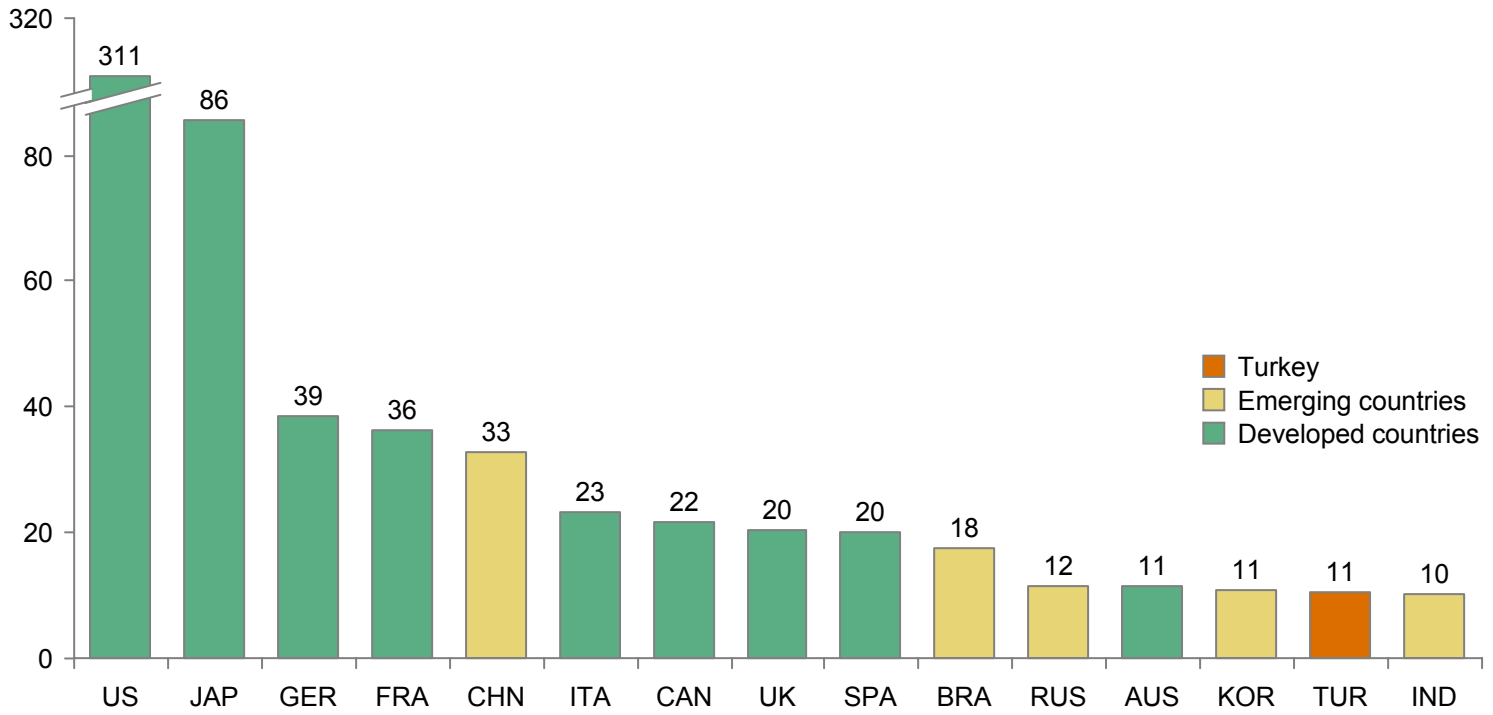


Government targeting not only increasing local share in domestic market but also to export 8 times higher vis-á-vis 2008 figures

Source: Pharma 2020, press research, expert interviews, BCG analysis

Turkey is among the largest pharma markets

Top 15 countries according to pharma market size ($ Bn, 2010)

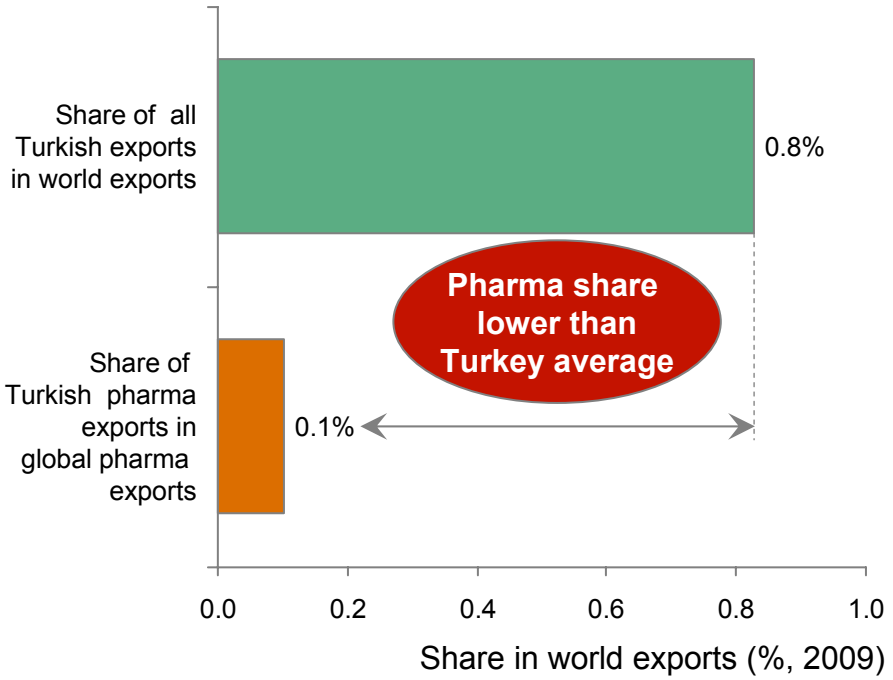


Turkey is 6th largest pharma market in Europe and 14th largest pharma market in the world

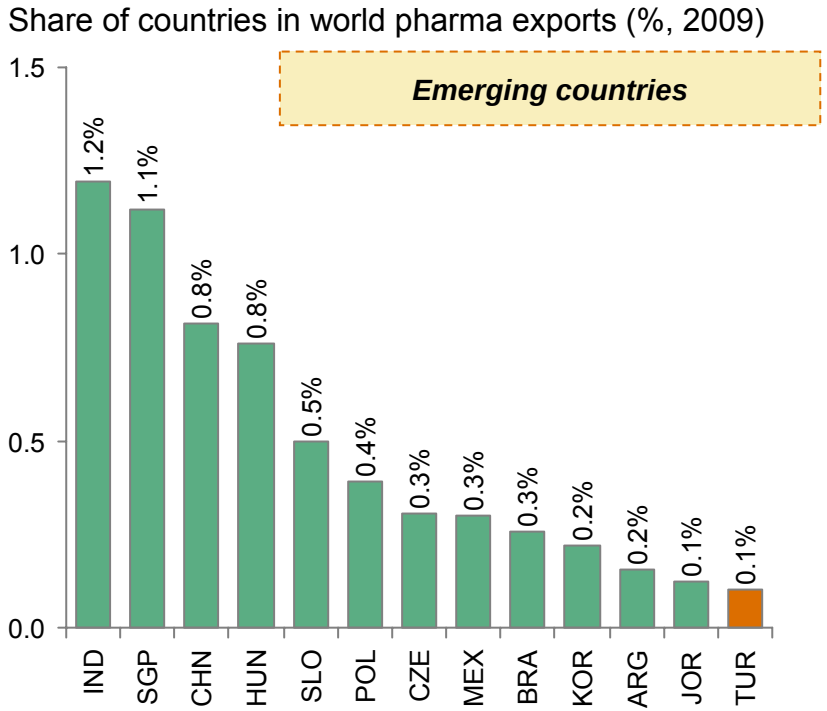
Note: Market at ex-manufacturer prices
Source: IMS, BCG analysis

However, internal and external comparisons indicate that local pharma industry is not leveraging its potential

Turkish pharma industry has much lower share in international trade vis-á-vis Turkey average



Turkish pharma exports has relatively lower share in global pharma trade compared to other emerging countries

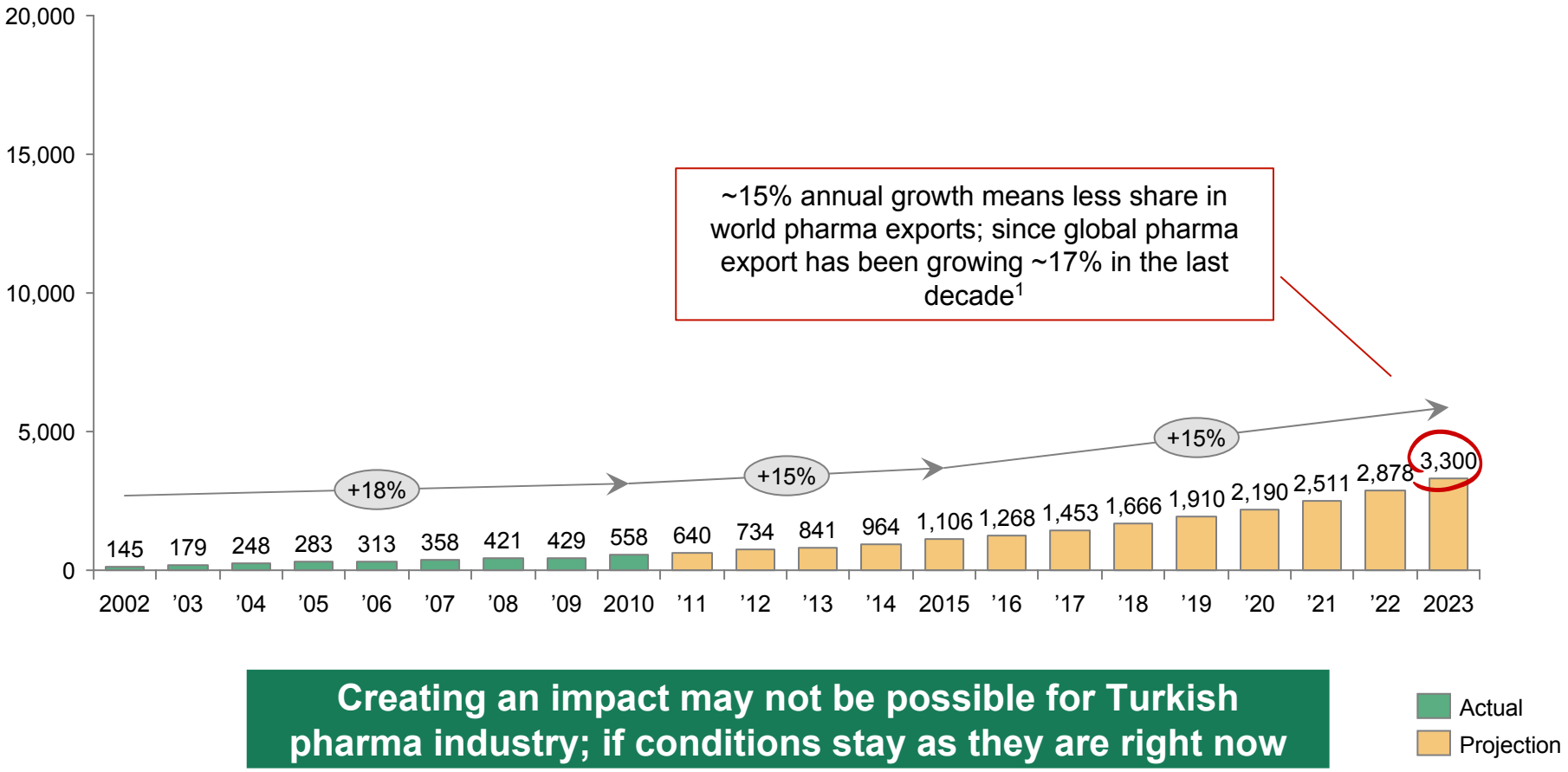


Note: Only products classified under HS code #30 taken into consideration for pharma exports
Source: Intracen, BCG analysis

Turkish pharma exports would reach ~$3 Bn by 2023; according to TIM's export strategy report ...

SCENARIO: TIM EXPORT STRATEGY REPORT

Pharma goods exported by Turkey[2] ($ Mn)



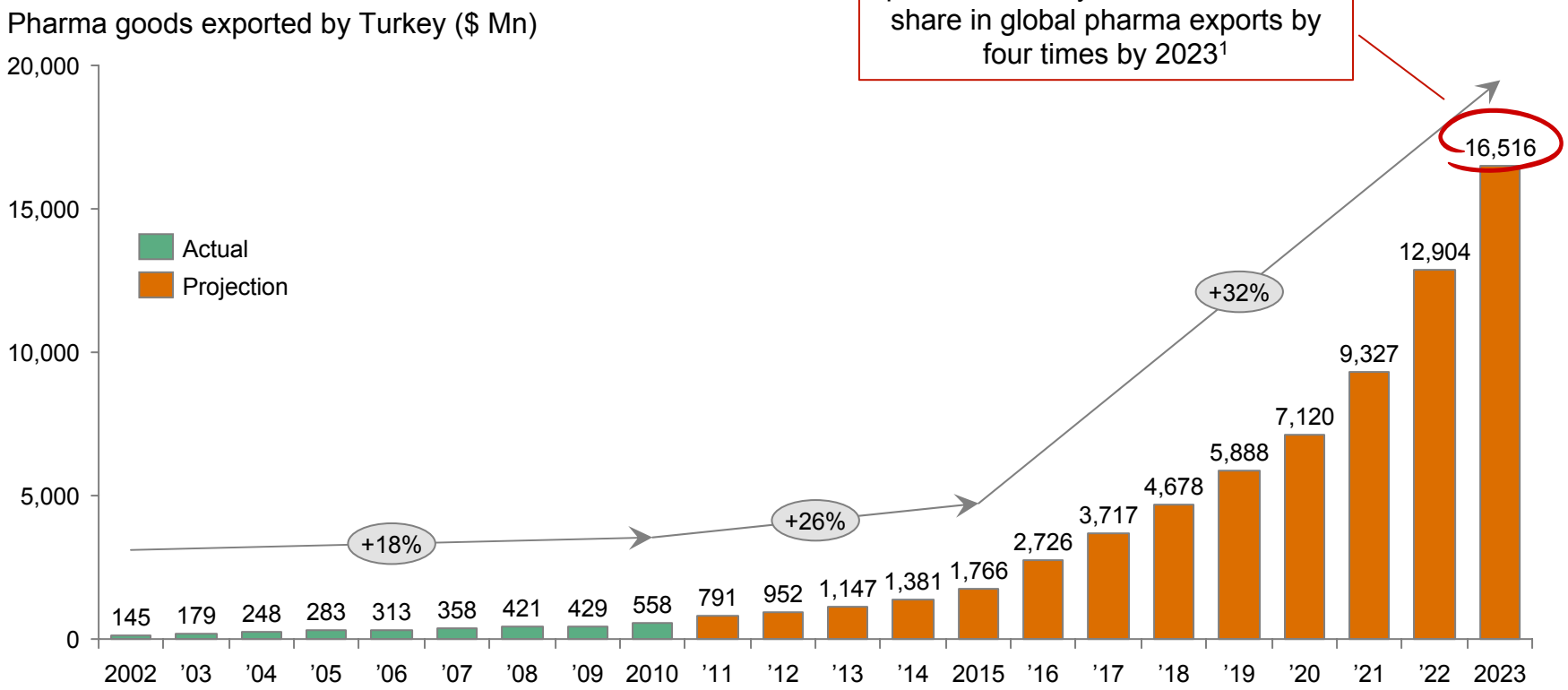
Creating an impact may not be possible for Turkish pharma industry; if conditions stay as they are right now

1. 17% annual growth experienced during 2001-2009 2. Export value projection for 2023 taken from TIM 2023 Export Strategy Report; the years between 2010 and 2023 projected by using the compound annual growth rate of 15%
Note: For pharma export figures; only products classified under HS code #30 taken into consideration.
Source: Intracen, IMF, TIM (Turkish Exporters Assembly) 2023 Export Strategy Report, BCG analysis

... However, the pharma industry globalization initiative can deliver a $17 Bn export target by 2023

SCENARIO: MAXIMUM POTENTIAL

If this scenario is targeted, Turkish pharma industry would increase its share in global pharma exports by four times by 2023[1]

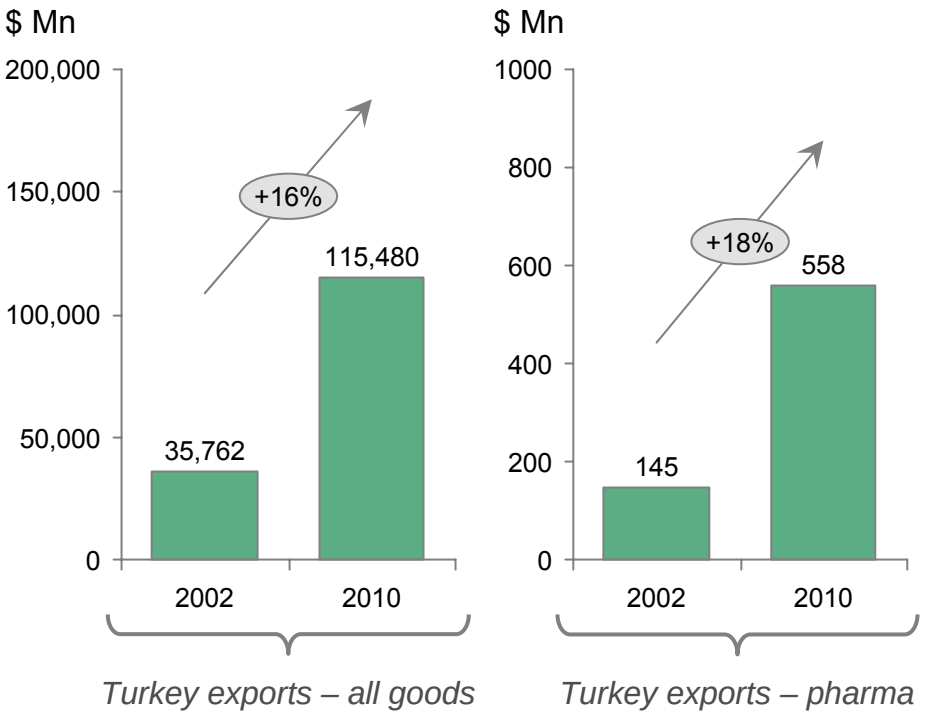


Pharma industry and Government should work together to reach $17 Bn target

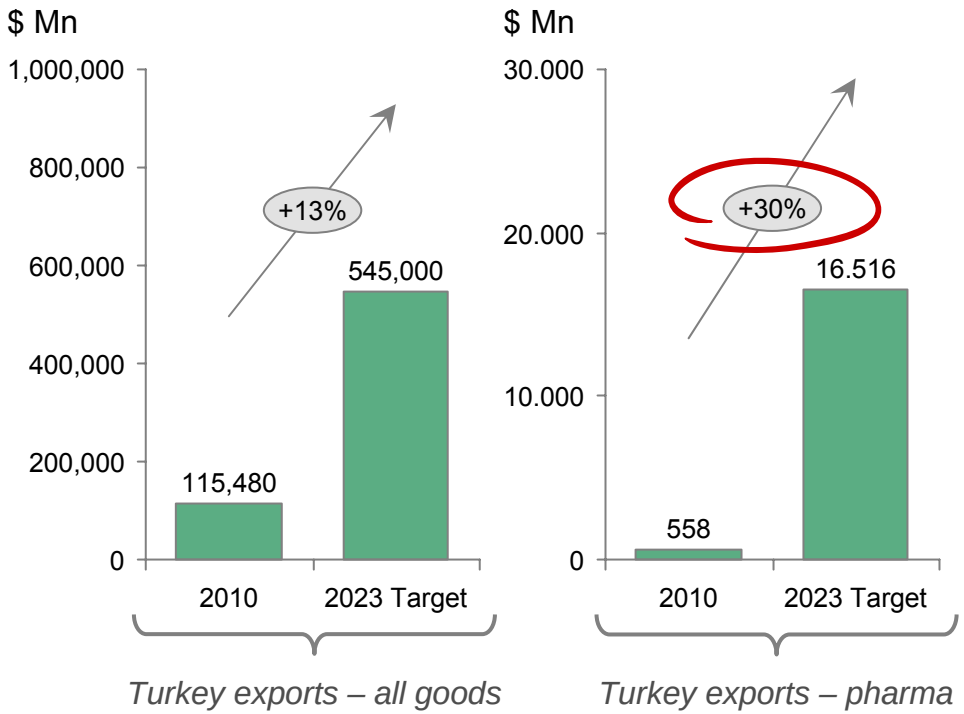
1. Assuming world pharma export value will grow ~17% per annum; as it has grown during 2001-2009
Note: For pharma export figures; only products classified under HS code #30 taken into consideration
Source: Intracen, IMF, TIM 2023 Export Strategy Report, BCG analysis

$17 Bn export target implies pharma exports growing twice as fast compared to total exports of Turkey

Growth in pharma exports outpaced Turkey's total export growth during 2002-2010 ...



... And will be more than double till 2023

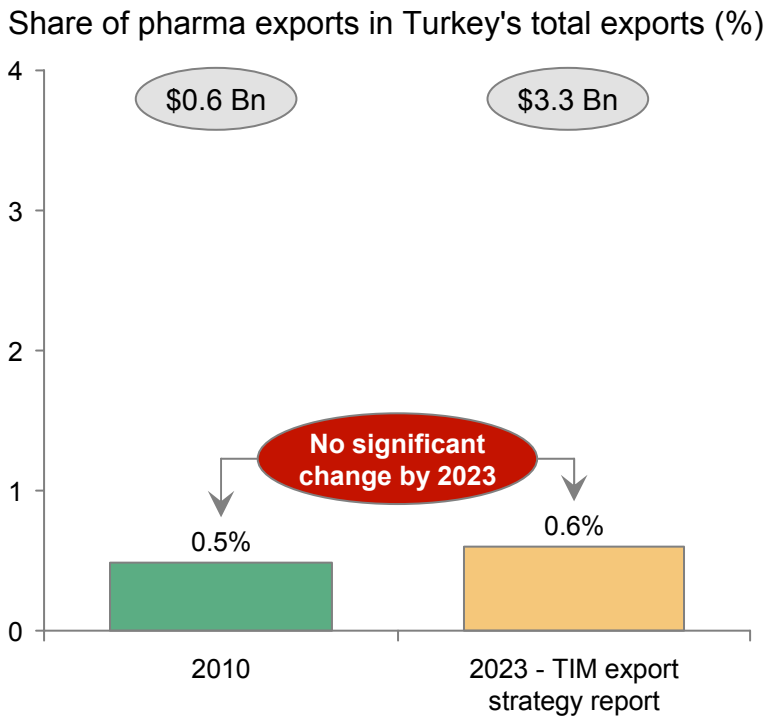


Aggressive growth target set by Turkish pharma industry

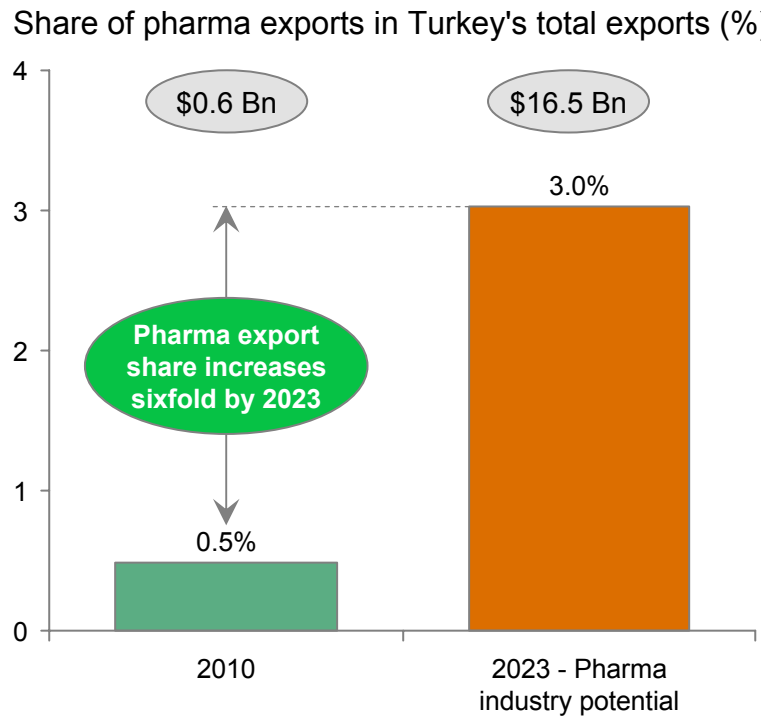
Note: Export target for all goods taken from TIM's export strategy report. For pharma, only products classified under HS code #30 taken into consideration
Source: Intracen, TIM 2023 Export Strategy Report, BCG analysis

Pharma industry targeting to get six times higher share in Turkey's total exports by 2023 ...

Pharma export target for 2023 declared in TIM's report would not change pharma industry's current position



Pharma industry plans to extend contribution of pharma exports substantially

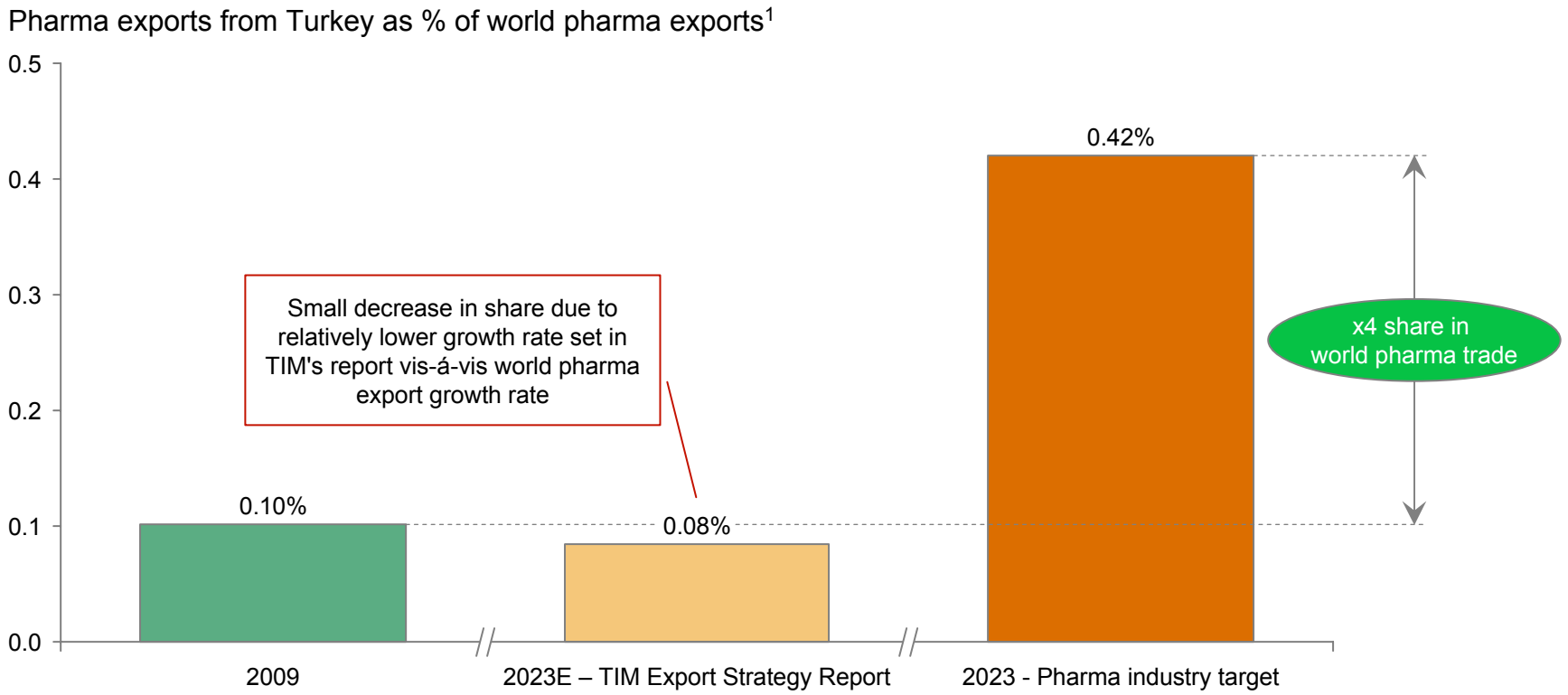


Pharma industry aiming to become one of the main export industries of Turkey

x Pharma export by value

Note: Share of pharma industry in Turkey's total exports calculated by assuming total export value will reach $545 Bn as stated in TIM's "Turkey Export Strategy" report.
Source: TIM "Turkey Export Strategy" report, Intracen, BCG analysis

This implies Turkey quadrupling its share in global pharma exports by 2023



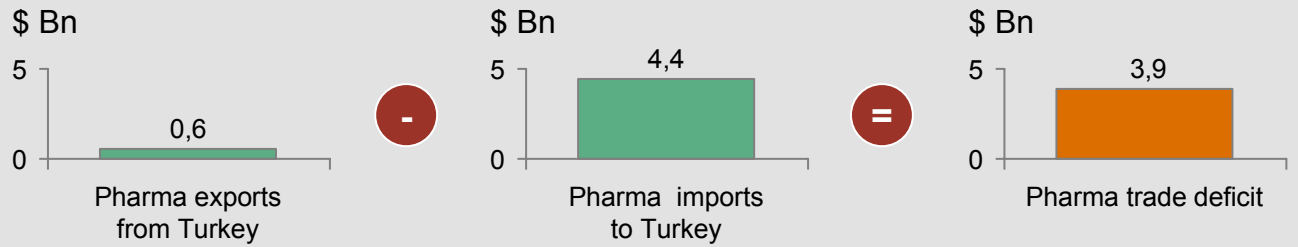
Turkish pharma industry will gradually increase its share in global pharma trade

1. Turkey's share in global pharma trade calculated based on the assumption that world pharma exports will grow 17% in 2009-2023 as it grew at that rate during 2001-2009.
Note: Only products classified under HS code #30 taken into consideration
Source: Intracen, TIM Export Strategy Report, BCG analysis

2023 pharma export target will reduce dependence on imports and will contribute more to the Turkish economy

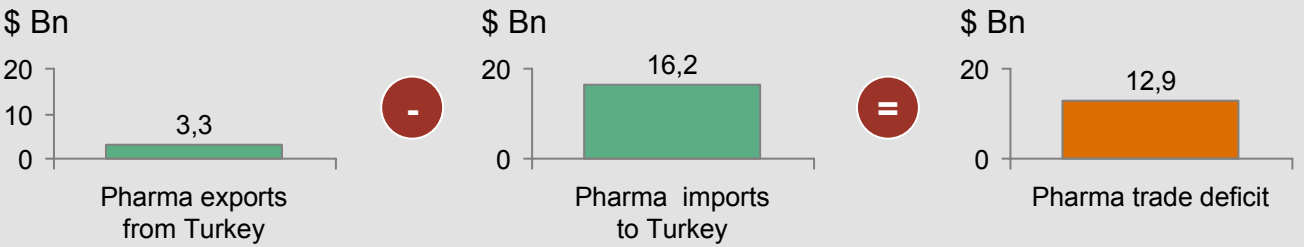
2010 - Actual

$3,9 Bn pharma trade deficit in 2010



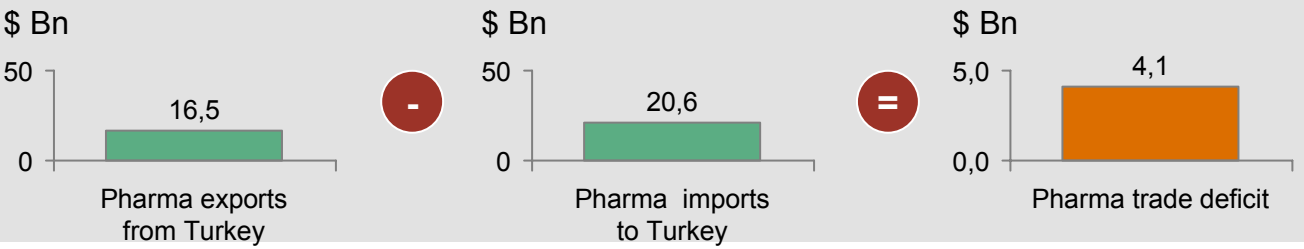
2023 – TİM Export Strategy

Trade deficit expected to reach $12.9 Bn if TİM export target is achieved



2023 – Pharma industry target

... while the pharma industry export target is expected to keep the pharma trade deficit at $4 Bn



Pharma trade deficit envisioned to be $8.8 Bn lower in 2023 thanks to the industry export target

Assumptions used to forecast 2023 pharma imports to Turkey
1. Local products will constitute 65% of local market (by value) 2. Raw materials and intermediates constitute 40% of finished dosage sales value 3. 90% of raw materials and intermediates used in local production are imported (by value) 4. 92% of exported pharmaceutical goods are finished forms
Source: Intracen, TİM Export Strategy Report, BCG analysis

Agenda

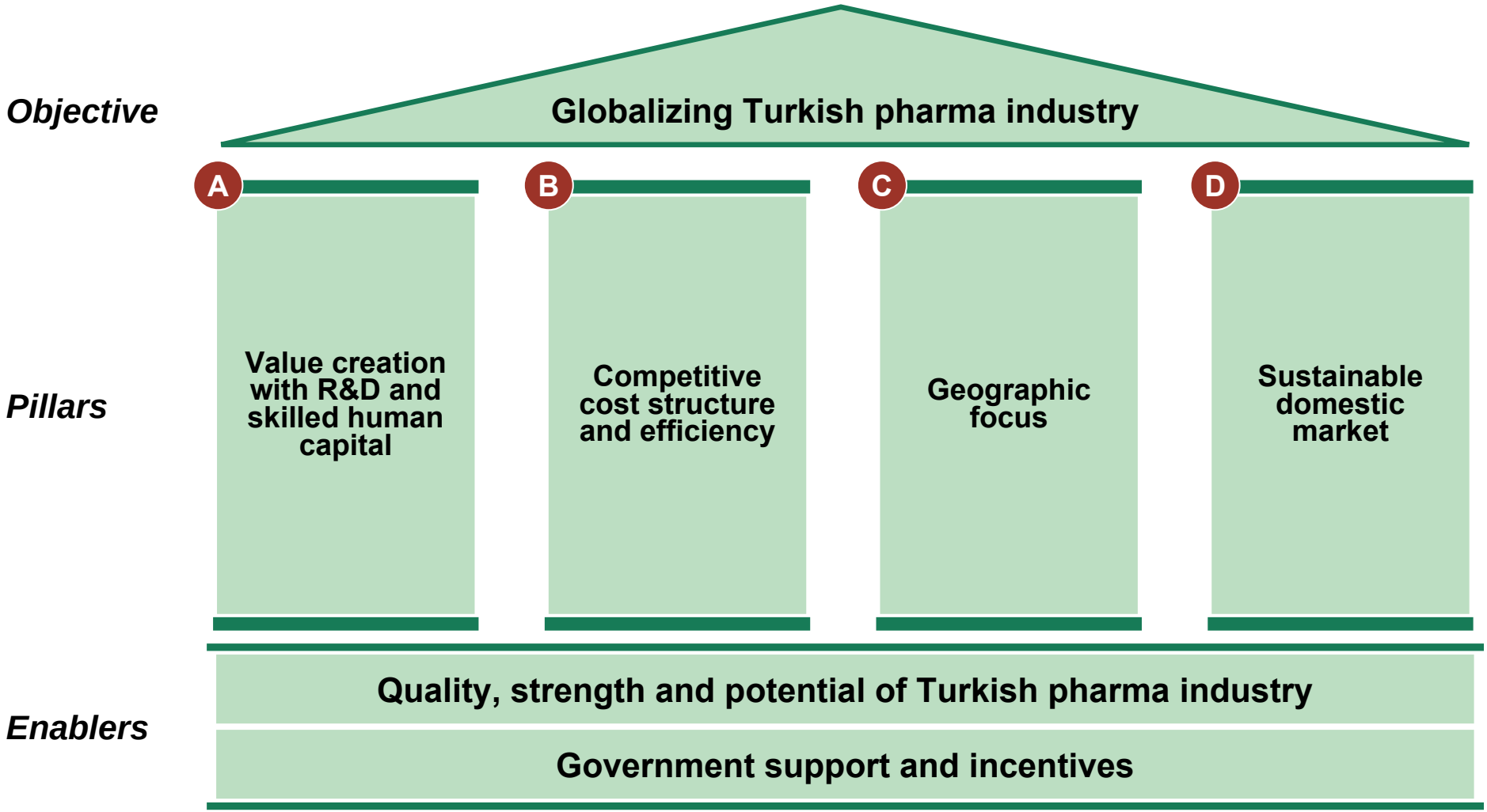
Current state of Turkish pharma industry

Objectives and targets of Turkish pharma industry

Proposed industry strategy and actions

Action plan

Reaching globalization target dependent on implementation of 4 key pillars with industry efforts and Government support



Source: BCG analysis

Turkish pharma industry has set its objective as globalizing and gaining an important position in the global pharma sector

	2011-2014	2015-2020	2021-2023
	Short-term	**Medium-term**	**Long-term**
Manufacturing	• Increased global competitiveness in manufacturing (e.g., increased capacity utilization, lower input costs) • Technical and regulatory compliance with requirements of major international markets		• Further investment in state-of-art manufacturing facilities in Turkey
R&D and human capital	• Developed capabilities in drug development process for value-added Gx drugs	• World-wide capabilities in drug development process for value-added Gx drugs	
	• More contribution to global innovative R&D activities		
	• Increased collaboration with universities and research organizations to develop capacity for R&D		
International trade	• Amplified export growth in regulated markets such as EU and North America		
	• Increased export penetration in semi-regulated markets in close neighborhood such as MENA and CIS via current portfolio		• Start of offering value-added Gx portfolio to MENA and CIS

Turkish pharma industry would like to partner with the Government during the globalization journey

21 actions identified to globalize Turkish pharma industry (I)

A — Value creation with R&D and skilled human capital

- **A1**: Focus efforts to improve capabilities in development (e.g. formulation and process development) and clinical trials
- **A2**: Revise current R&D legislation (Law #5746) to reduce 50 R&D employee threshold to receive R&D center license to 10 R&D employees
- **A3**: Ease legislation to grant "R&D visa" or work permits to international pharma R&D staff
- **A4**: Increase collaboration with research entities linked to universities or to techno-centers via pharma industry funded projects
- **A5**: Develop pharma manufacturing and R&D oriented curriculum in pharmacy faculties
- **A6**: Establish dedicated institution for higher education and advanced research in pharmaceutical sciences with support of the industry
- **A7**: Form a workgroup to provide advisory services to member companies regarding the utilization of R&D incentives provided by public institutions

B — Competitive cost structure and efficiency

- **B1**: Introduce new measures to incentivize local manufacturing; in line with international agreements
- **B2**: Form a workgroup to provide support services to member companies regarding the usage of current incentives
- **B3**: Remove discrepancies in VAT system causing uneven competition for local pharma manufacturing
- **B4**: Develop pharma specialized industry zones enabling clustering with solid infrastructure and access to ports and inland transportation
- **B5**: Investigate possibility of building alliance for purchasing of pharma ingredients and utilities (e.g., electricity, gas)
- **B6**: Investigate investment opportunities for pharma ingredient manufacturing to increase backward integration (e.g., acquisition of API manufacturers in other countries)

21 actions identified to globalize Turkish pharma industry (II)

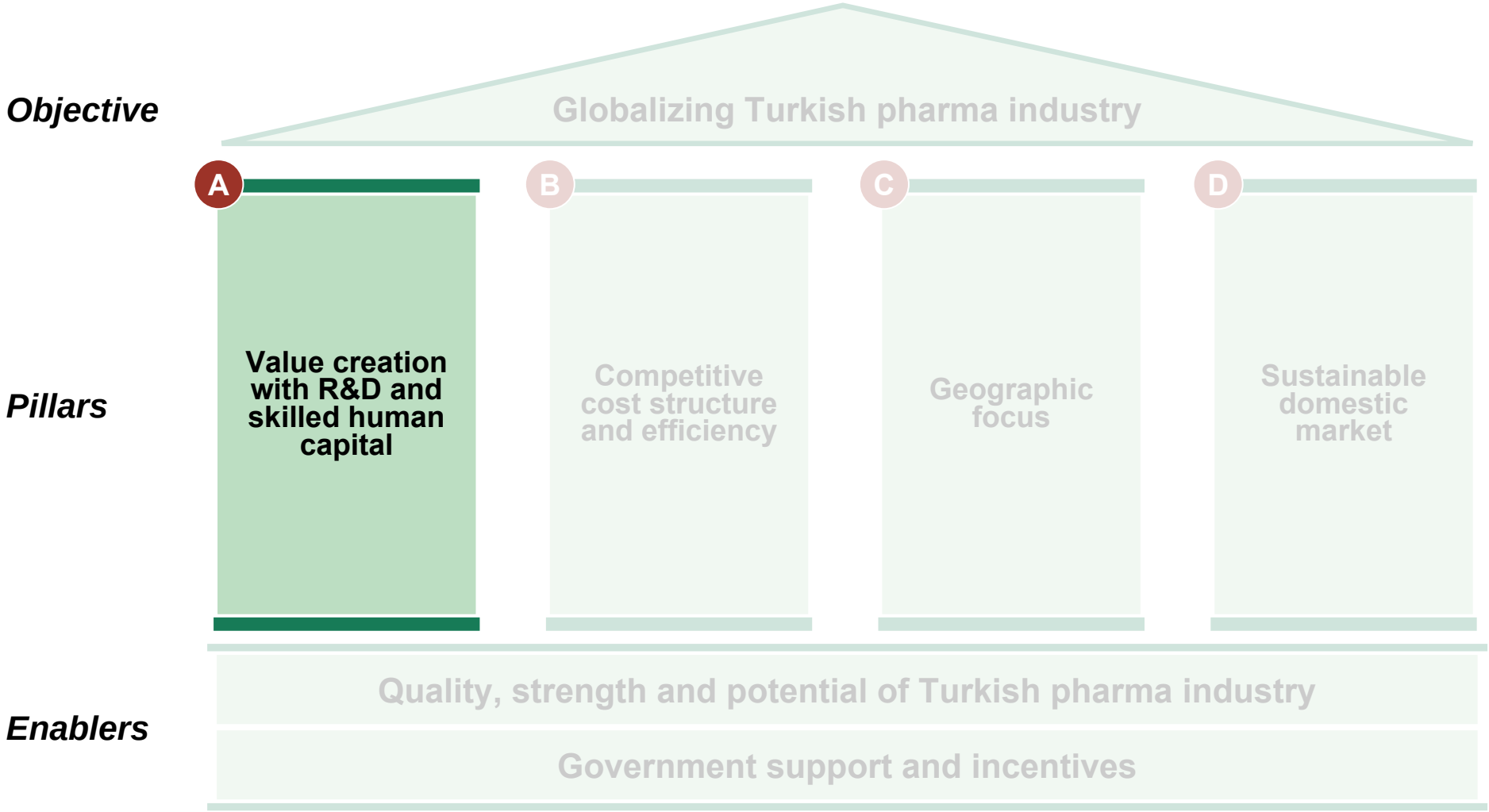
C **Geographic focus**

- **C1**: Ease market authorization and regulatory compliance monitoring in target regions/ countries
- **C2**: Establish pharma export promotion agency
- **C3**: Organize roadshows to target regions to promote Turkish pharma industry and overcome challenges
- **C4**: Leverage off-set trade negotiations for energy imports to increase pharma export (i.e., include export of pharma goods to negotiations for energy import from CIS and MENA countries)
- **C5:** Improve organizational capabilities of local pharma producers in order to increase their competitiveness in international markets (e.g. setting up representative offices in target markets or strengthening of HR structures)

D **Sustainable domestic market**

- **D1**: Promote rational use of drugs via treatment guidelines
- **D2**: Setting of pharma budget application on a more sustainable basis while also keeping the natural growth of the sector in perspective
- **D3**: Redistribution of the public pharma expenses to a broader base via the revision of co-payment scheme and OTC regulations
- **D4**: Investigate ways to increase private medical insurance penetration

Reaching globalization target dependent on implementation of 4 key pillars with industry efforts and Government support



Source: BCG analysis

Executive summary

Value creation with R&D and skilled human capital

Government aiming to increase Turkey's R&D share in GDP by increasing contribution from private sector to R&D spending

- Turkey's R&D spending reached ~8 Bn TL (0.85% of GDP) in 2009; of which ~40% is from the private sector
- Government's target is to raise total R&D spending in Turkey to 3% of GDP by 2023

Cross-industry incentive schemes for R&D expenditure already in place in encourage private sector R&D spending

- TÜBİTAK received 10,000+ applications and granted ~2 Bn TL to projects developed by private sector in 2000-2010

R&D expenditure of Turkish pharma industry is still not at a substantial level

- Only 113 projects of pharma industry supported under TUBITAK R&D incentive scheme between 2000-2010; equaling to 1.7% of all projects supported under TUBITAK schemes

In its path for globalization by 2023, Turkish pharma industry aiming to increase R&D activities to move up in pharma value-chain via ...

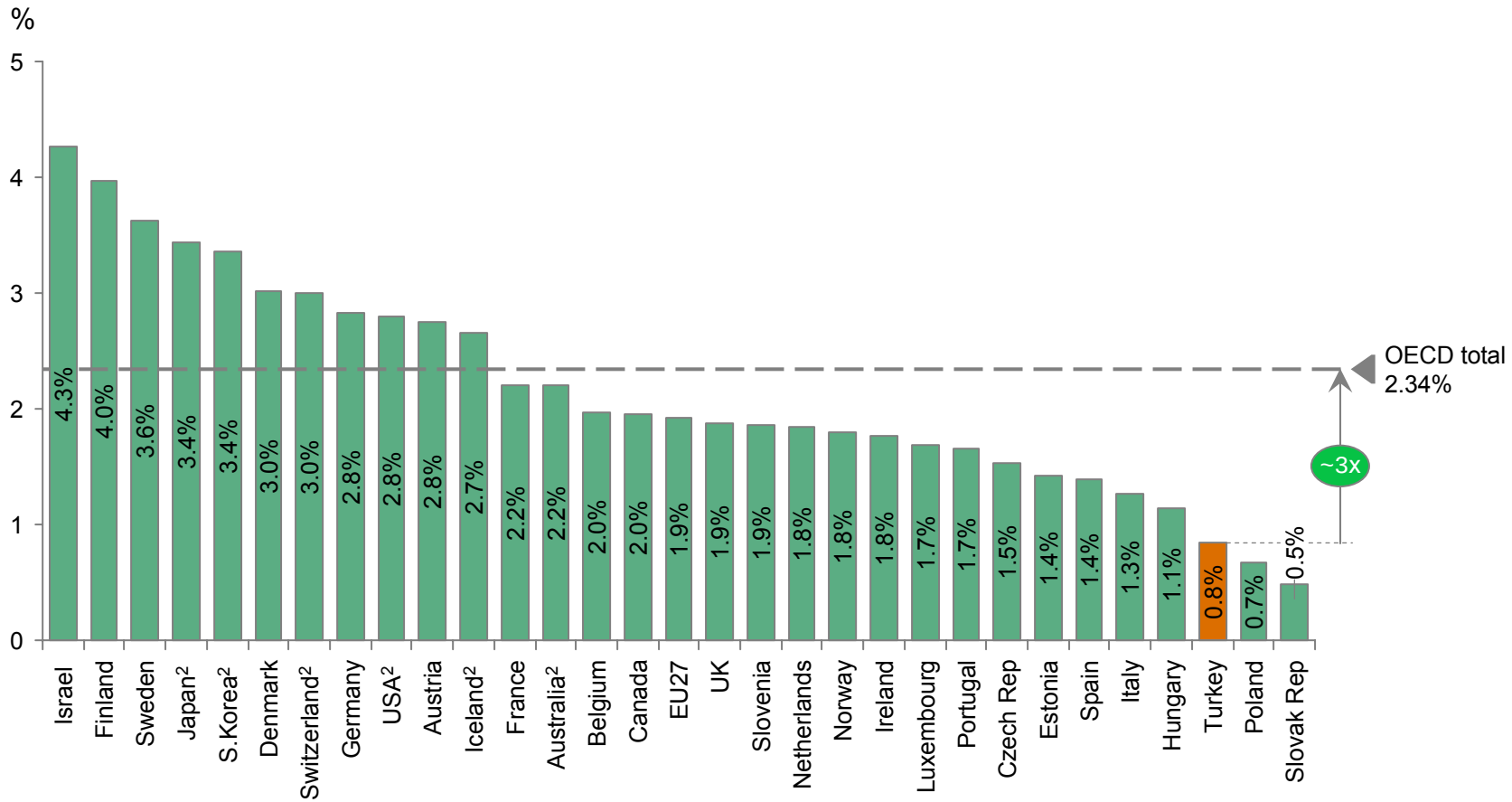
- Increase focus on new process, formulation and combination development

Note: R&D employee numbers are preliminary figures based on statements of AIFD and IEIS
Source: Interviews, BCG analysis, Eurostat, TUBITAK

Country-wide R&D spending

Turkey currently does not spend as much on R&D as other OECD countries

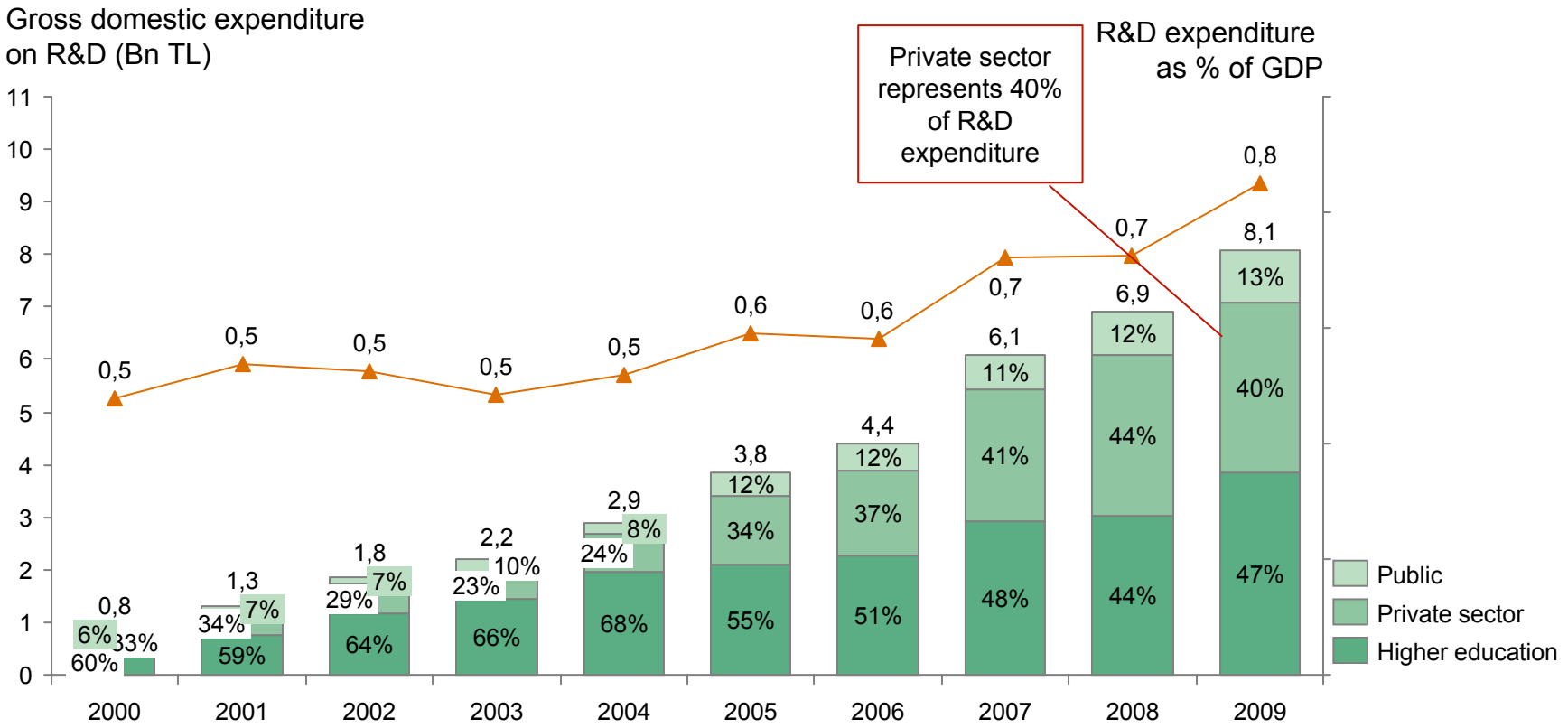
R&D spending as % GDP, OECD countries, 2009[1]



Note: Chile, Greece, Mexico, New Zealand have been left out since neither 2008 nor 2009 data are available for these countries.
1. 2008 data used for countries where 2009 data is not available. 2. 2008 data used
Source: TUIK, OECD

R&D spending has been improving steadily in recent years

Government has set an ambitious R&D target that is competitive with leading developed nations



Government targets to increase R&D expenditure to ~3% of GDP by 2023

Note: Gross domestic expenditure on R&D including operational expenses and capital expenditure
Source: TUIK, BCG analysis

Government incentivizing R&D expenditure by private sector through various TÜBİTAK support programs ...

The Scientific and Technological Research Council of Turkey

Technology & Innovation Support Programs Directorate

Vision
- To support Turkish private sector R&D, technology management and innovations in reaching globally competitive levels and to become a well-known organization whose procedures are followed around the world

5 programs

Industry R&D Projects Support Program (#1501)

Aim to increase the R&D capabilities of Turkish industry

Grants provided to companies on specific R&D projects
- Grants of up to 60% of total project cost

Project Markets Support Program (#1503)

Support for events to bring universities, R&D institutions and private sector together to discuss project possibilities

Maximum 20 K TL for local events, 25 K TL for events with international participation

Technology Transfer to SMEs Program (#1505)

Aim to transfer R&D knowledge developed in universities to SMEs
- 75% of project budget covered by TUBITAK, 25% by SMEs
- Maximum project size of 300 K TL, project support period of 18 months

SME R&D Initiation Support Program (#1507)

Aim to support SMEs get their R&D projects initiated
- Maximum project size of 400 K TL, project support duration of 18 months

International Industrial R&D Support Program (#1509)

Aim to support R&D projects of companies entering international project programs e.g.
- EUREKA
- EUROSTARS

Projects supported via grants of ...
- ... up to 60% for large-scale companies, 75% for SMEs

Note: TUBITAK's technology venture support program (TEKNOGİRİŞİM) has been omitted since it is not being implemented currently
Source: TUBITAK

A Various public agencies are also incentivizing R&D expenditure

Ministry of Industry & Trade and State Planning Organization examples

Ministry of Industry and Trade

Ministry gives support to R&D projects in the following formats (Law #5746):

- Income tax, stamp tax and employee insurance premium support given to companies founded in R&D Centers
- Various forms of grants and tax incentives to companies running or operating in Technology Development Zones
- Ministry covering 75% of costs of R&D projects developed by private sector – university collaborations (SAN-TEZ)
- Up to 100 K TL capital injection support granted to entrepreneurs willing to found technology related companies (Teknogirişim)
- Tax incentives to pre-competition collaboration projects initiated by multiple companies

State Planning Organization (SPO)

Organization gives support to Turkish universities for creation of the following facilities

- Research laboratories
- Thematic research centers

As of 2010, SPO supported establishment of research laboratories in 57 universities around Turkey

SPO received ~200 project applications in 2010 with average per project size of 4 Mn TL

Various other institutions also provide support to R&D e.g., TTGV[1], KOSGEB, Turkish Patent Institute

1. TTGV = Technology Development Foundation

Source: State Planning Organization, Ministry of Industry and Trade, Press research

Government incentives are mainly project & SME oriented

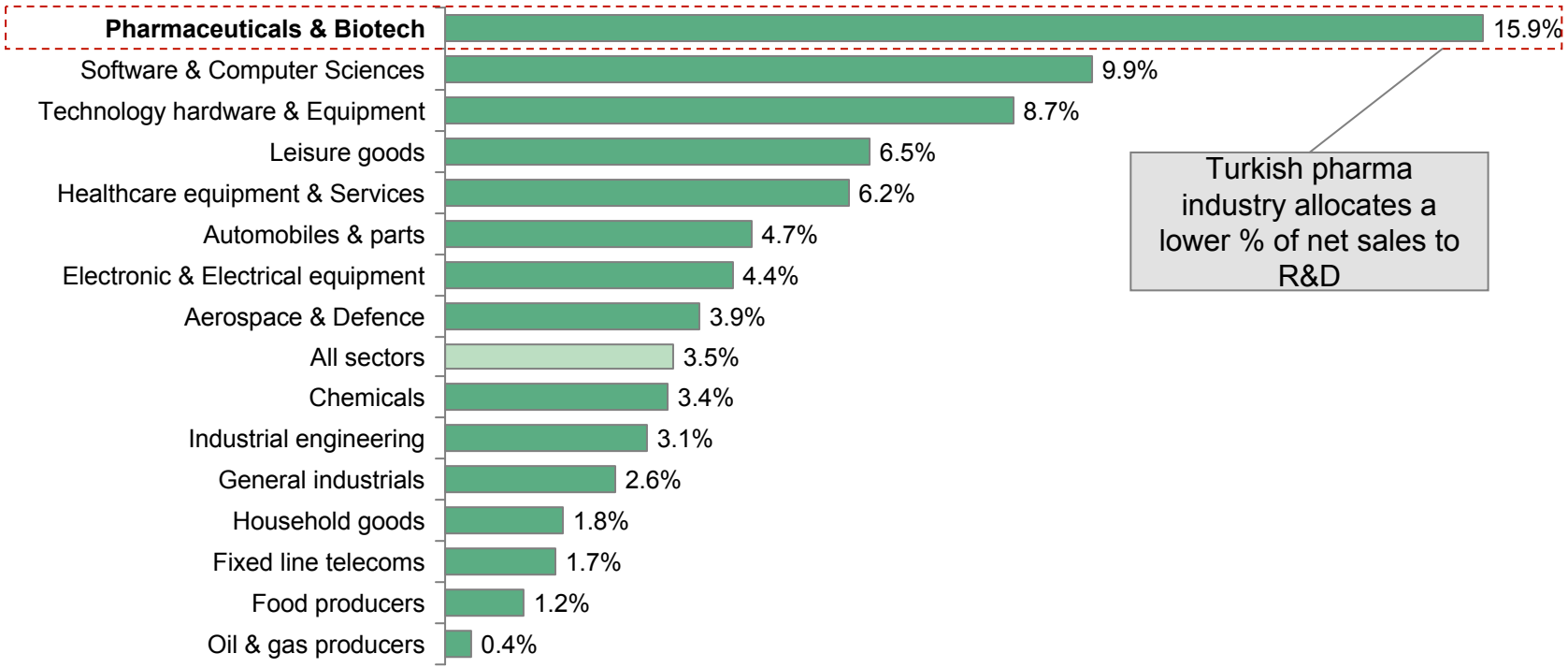
Only 1 program that supports R&D organization establishment

Major Government Initiative Programs	Project-based vs. Setup support	Scale of support	Comments
Ministry of Industry & Trade			
• R&D Centers	Setup	Large scale	• Already being used by pharma
• Technology Development Zones	Setup	SME	• Designated R&D zones w/incentives
• SAN-TEZ	Project	SME	• Support for MS or Ph.D theses
• Teknogirişim	Setup	SME	• Business setup for new grads
• Pre-competition projects	Project	Large scale	• Support for joint industry projects
TÜBİTAK			
• Industry R&D Projects Support Program (#1501)	Project	Large scale	• Already being used by pharma
• Project Markets Support Program (#1503)	Project	n/a	• Support for industry events e.g., fairs, symposiums
• Technology Transfer to SMEs Program (#1505)	Project	SME	• Transfer of academic projects to SMEs for commercialization
• SME R&D Initiation Support Program (#1507)	Project	SME	• Support for SME R&D projects
• International Industrial R&D Support Program (#1509)	Project	Large scale & SME	• Support for projects entering international programs

Source: Ministry of Industry and Trade, TUBITAK

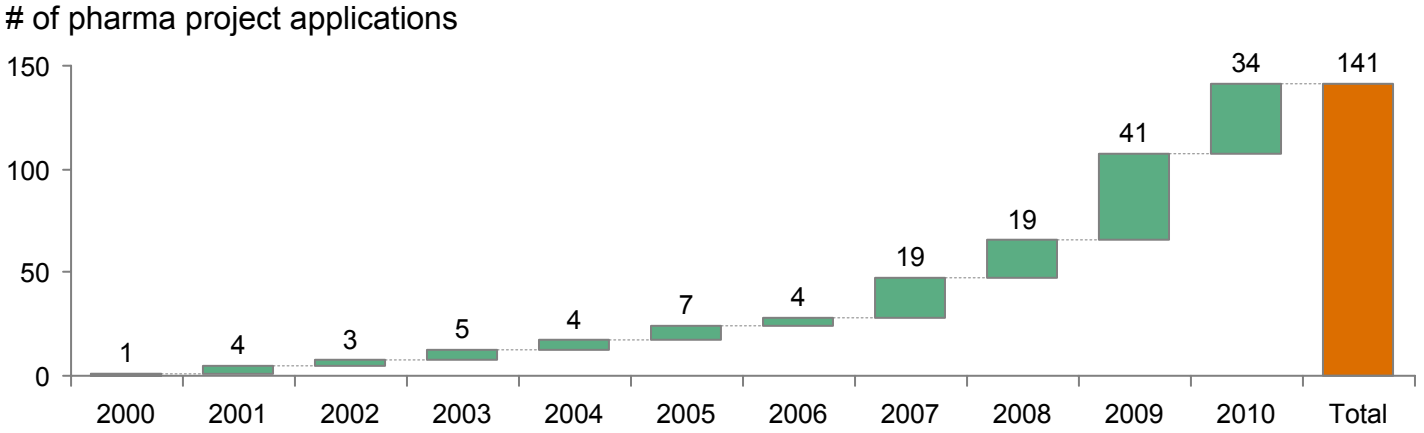
Pharma is one of the most R&D-intensive industries globally

Global R&D spending by industry as % of Net Sales, 2009



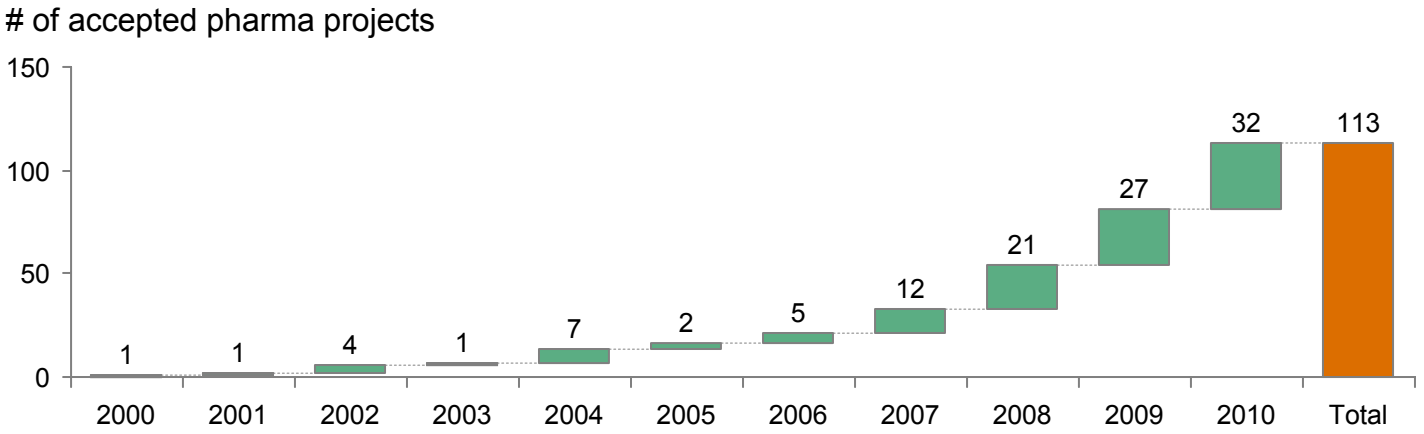
Source: EFPIA "Pharmaceutical Industry in Figures – 2011"

Although increasing, applications by the pharma sector for TÜBİTAK R&D support have been limited in the last decade



1.3%

of all applications[1] between 2000 -2010



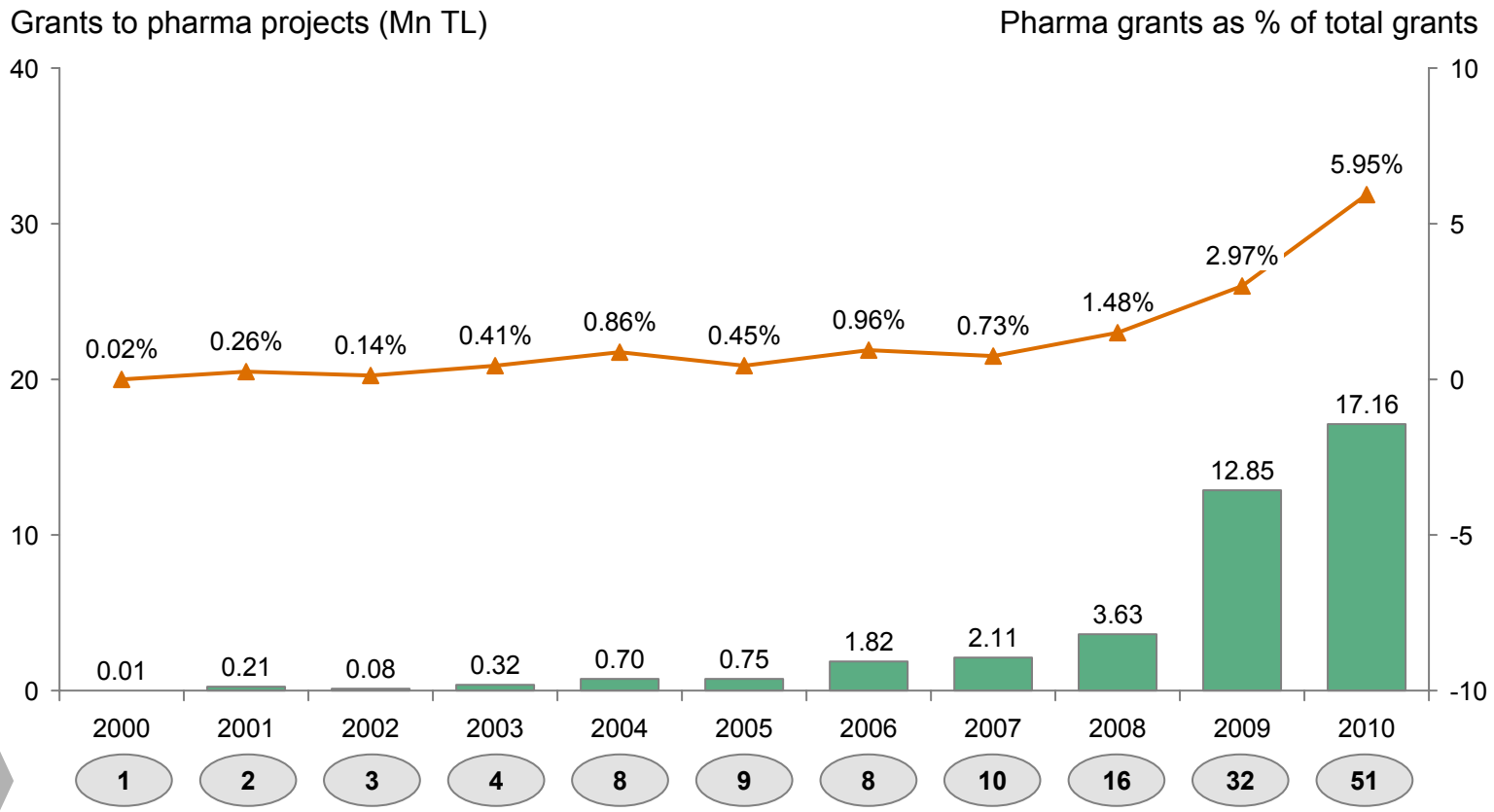
1.7%

of all accepted applications[2] between 2000 -2010

1. Total of 10,733 2. Total of 6,568
Source: TUBITAK

R&D grants given to the pharma industry have also been limited but increasing

Grants for Pharma R&D projects by TUBITAK - TEYDEB



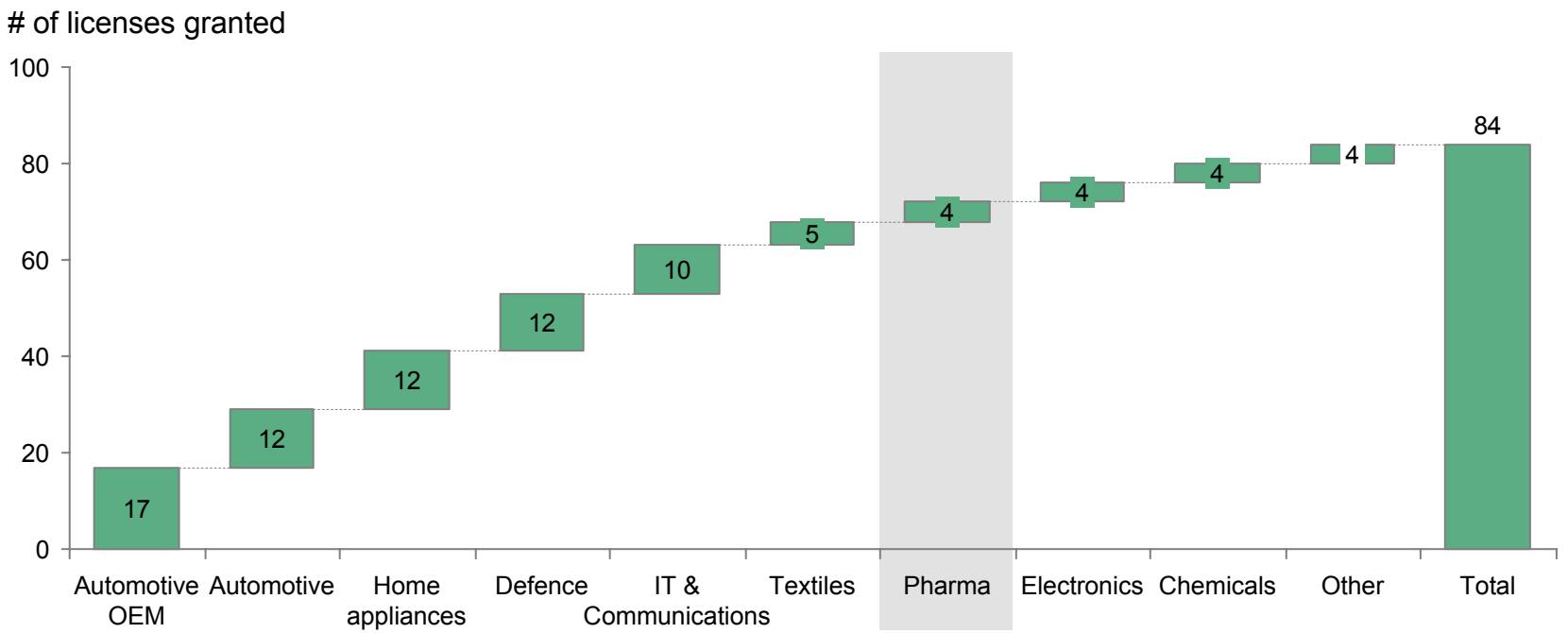
# of pharma projects receiving grants within each year[1]

40 Mn TL granted to 84 unique pharma projects between 2000 – 2010, 2% of total grants[2] within the same period

1. If a project receives grants in multiple years, it is recorded under all the years in which it received grants 2. 1.9 bTL between 2000 - 2010
Source: TUBITAK

Pharma producers received 4 of the 84 "R&D Center Licenses[1]" granted by the Ministry of Science, Industry & Technology

"R&D Center Licenses" granted as of March 2011 according to industry



1. "Ar-Ge Merkezi Belgesi" given in accordance with Law #5746 regarding Government support for R&D activities 2. Includes 1 Islamic bank, 1 furniture producer, 1 jeweler, 1 glass and ceramics producer
Note: A company may have acquired multiple licenses e.g. Arçelik acquired 7 of the 12 licenses in home appliances
Source: Ministry of Industry & Trade

A

R&D centers

Currently, pharma producers with R&D centers mostly focus on "development" rather than "primary research"

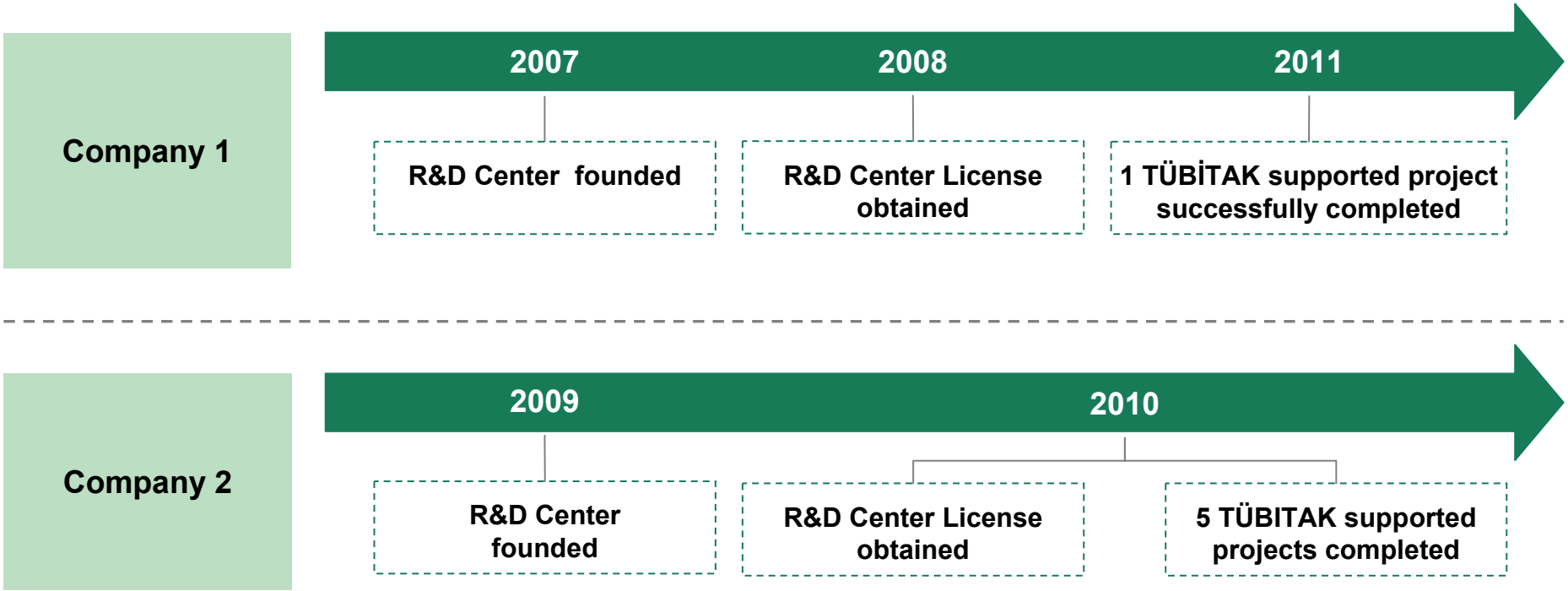
	Company 1	Company 2	Company 3	Company 4
Patent	✓	✓	✓	✓
API	✓	✓	✗	✓
Formulation Dev.	✓	✓	✓	✓
Analytical Dev.	✓	✓	✓	✓
Optimization	✓	✓	✓	✗
Stability	✓	✓	✓	✓
Technology	✓	✓	✓	✗
Pilot production	✓	✓	✓	✓

No new molecule development capabilities currently

Source: Interviews, company websites, BCG analysis

Establishment of R&D centers support project creation

Industry examples from two companies that have R&D centers



1. Good Manufacturing Practice 2. Good Laboratory Practice 3. Sanayi Ar-Ge Projeleri Destekleme Programı
Source: Abdi İbrahim, Deva websites, Press research

Recommended actions

In this context, seven main actions are identified to create value with R&D and human capital

Lever	Action	Owner
Shift focus to value-added R&D	A1 Focus efforts to improve capabilities in "development" (e.g., formulation and process development) and clinical trials	Pharma industry
Modify legislations to accommodate R&D needs	A2 Revise current R&D legislation (Law #5746) to reduce 50 R&D employee threshold to receive R&D center license to 10 R&D employees	Ministry of Science, Industry & Technology
	A3 Ease legislation to grant "R&D visa" or work permits to international pharma R&D staff	Ministry of Labour and Social Security
Increased collaboration with universities, R&D companies/ organizations	A4 Increase collaboration with research entities linked to universities or to techno-centers via pharma industry funded projects	Pharma industry
	A5 Develop pharma manufacturing and R&D oriented curriculum in pharmacy faculties	Council of Higher Education
	A6 Establish a dedicated institution for higher education and advanced research in pharmaceutical sciences with support of the industry	Council of Higher Education
Other R&D incentives (e.g. low-interest loans)	A7 Form a workgroup to provide advisory services to member companies regarding the utilization of R&D incentives provided by public institutions	Pharma industry

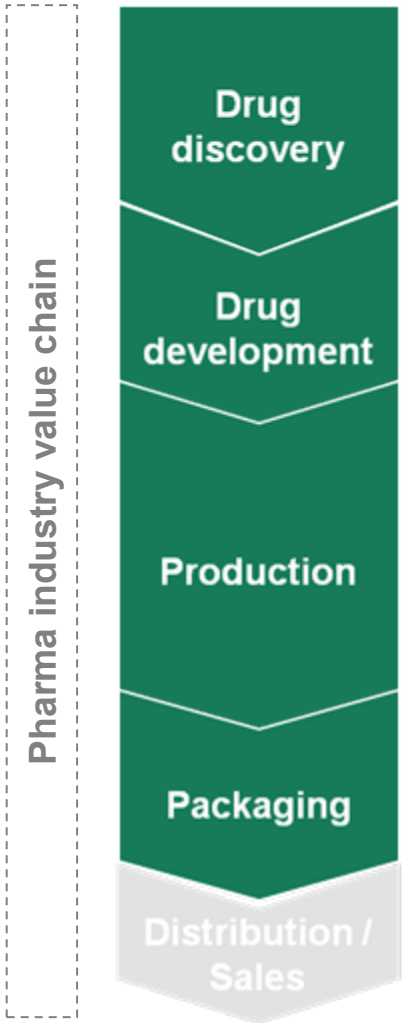
Priority actions detailed in the following pages

Source: Interviews, BCG analysis

A1

Shift focus to value-added R&D

Turkish pharma would differentiate from low-cost competitors by focusing on development of new formulations and processes



Main activities	Focus for Turkish pharma	Rationale
Molecule discovery • Target selection, validation, screening etc.		**Low feasibility for Turkish companies** • Very high capital requirements • Requires global chain of R&D centers • Low success rates
Preclinical & clinical testing • Test compounds on animals • Test compounds on patients (Phases I to IV)		**More relevant for MNCs, which can shift part of global clinical studies to Turkey** • Some MNCs already increased clinical trials in Turkey e.g. GSK's vaccine trials
Process development • Process patents		**Can give an edge via increased production efficiency** • Can also support clinical trials via pilot production
New formulation and form development		**Drug formulation and product development to be main points of differentiation** • For "high value added" Gx products
Packaging • Forming, filling, sealing, print, carton		**Not a priority since value-add is relatively low** • Can be focused to reduce dependency to 3rd parties

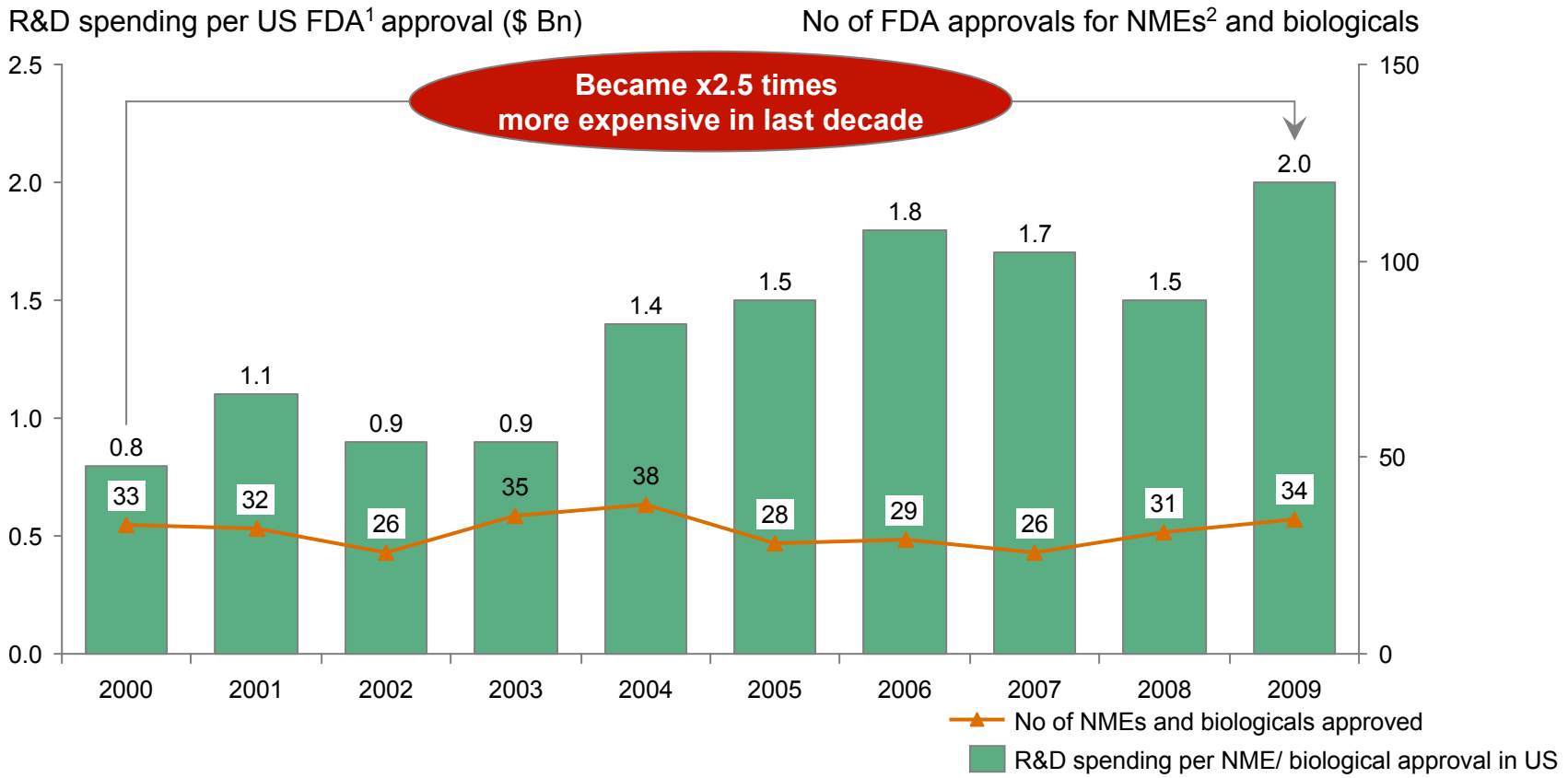
Focus areas

Source: Literature research, BCG

A1

Shift focus to value-added R&D

Commercialization of an innovative drug becoming more and more costly



Cost of innovative research is above the financial capabilities of local pharma industry

1. US FDA = United States Food and Drug Administration 2. NME = New Molecule Entity
Note: US accounts for approximately 40% of the global drugs market, so an assumption has been made that a corresponding ratio of global R&D investment happens in the country
Source: EvaluatePharma analysis

A1

Shift focus to value-added R&D

Innovative pharma companies perform innovative research through their multiple R&D centers in various countries

Innovative company 1

Each R&D location

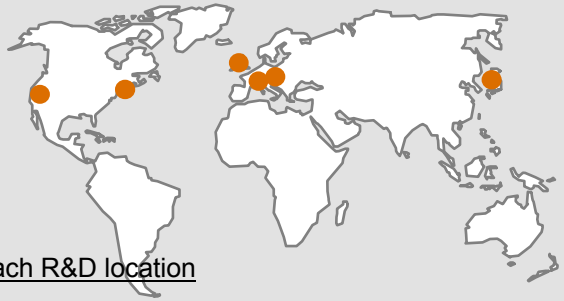
Each research unit is located in a single geographic location

Innovative company 2

Each R&D location

Each R&D site specializes in a few TAs

Innovative company 3

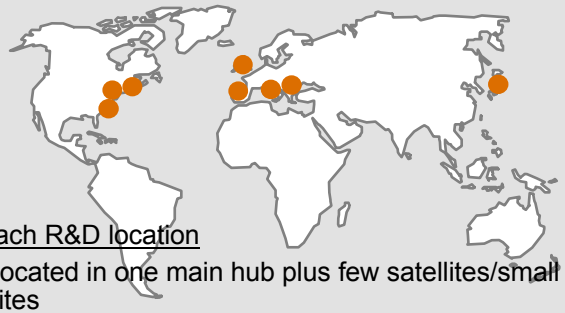


Each R&D location

Houses multiple TAs and platforms

- Each TA & platform can be in many locations

Innovative company 4



Each R&D location

Located in one main hub plus few satellites/small sites

- Employs ~350 scientists: 71-85% Biologists and Chemists, remainder MDs, Clin. Researchers

Innovative company 5

Each R&D location

11,000 people in R&D

- 4,500 staff in at Alderley Park, England
- 4,000 staff employed at Lund, Molndal and Sodertalje, Sweden

Innovative company 6

Each R&D location

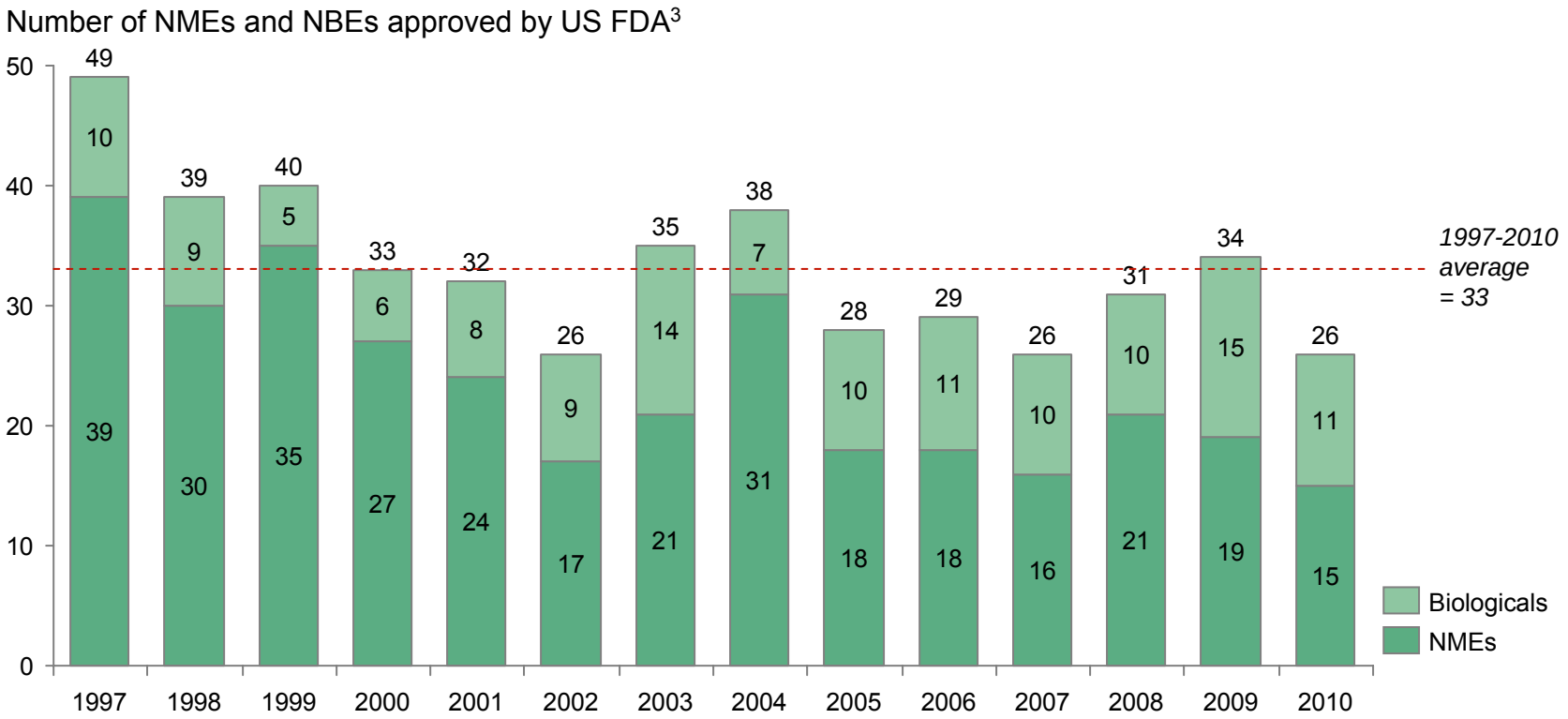
Research HQ in Europe and US
Development in various sites

Innovative research requires a global network

Source: Company annual reports, BCG

However, success is decreasing in innovative research

Decreasing trend in number of approved NMEs[1]/NBEs[2]



Market authorization becoming harder for innovative drugs

1. NME = New Molecule Entity 2. NBE = New Biological Entity 3. US FDA = United States Food and Drug Administration
Source: EvaluatePharma

Shift focus to value-added R&D

Clinical trials constitute a significant part of pharma R&D activity

Drug discovery → **Drug development** → **Production** → **Packaging** → **Distribution/ sales**

Preclinical testing

- Test compounds in animal models for:
  - Safety
  - Efficacy
  - Pharmacokinetics
  - Pharmacodynamics
  - Toxicology
  - …

Clinical testing

- Test compounds on patients
- Clinical trials process require:
  - Clinical trial management
  - Clinical trial monitoring
  - Biostatistics
  - ...

Application for clinical trials: Investigational New Drug (IND)

Registration: New Drug Application (NDA)

Approval for market launch

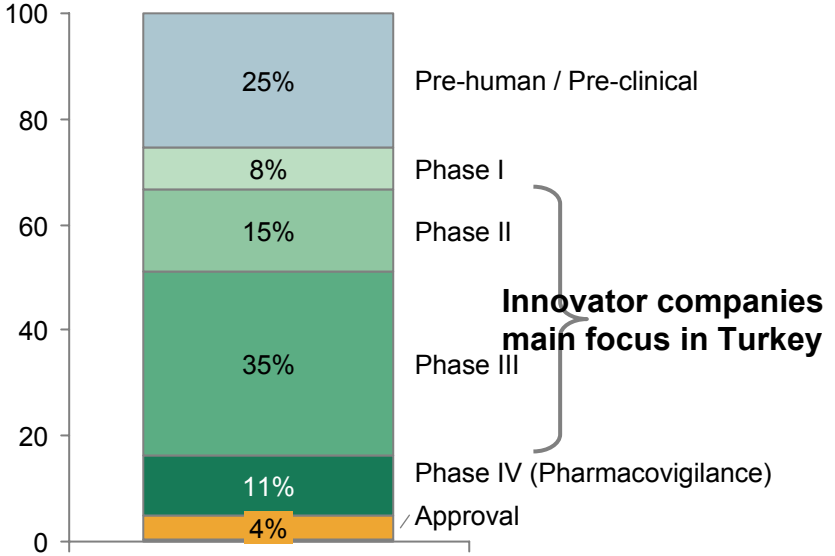
Phase I	Phase II	Phase III	Phase IV (Pharmacovigilance)
What is the tolerated dose?	What is the dosing ensuring safety and efficacy? Any additional effect?	Is there any additional effect?	What are the previously unknown or inadequately quantified adverse reactions?
Test on healthy volunteers[1] (20-30) • Pharmacology • Safety • Acute toxicity • Maximum tolerated dose	Test on patients (500) • Efficacy • Chronic toxicity • Dose versus Response	Test on patients (1,000-3,000)[2] • Efficacy • Therapeutic profile • Compliance • Interactions • Side effects	All treated patients • Efficacy under market conditions • Extension of indications • Readjustment of dosage • Side effects

1. Not for oncology and HIV drugs. These are only given to diseased patients 2. Sometimes >20,000 patients
Source: BCG analysis

Turkish pharma R&D has room to grow in clinical trials, where activities by MNCs are already increasing

European pharma devotes significant part of of R&D expenses to clinical trials ...

Breakdown of R&D expenses by function (%), 2009



... indicating significant growth potential for Turkey given the current level of clinical trials

Out of of the 72,615 clinical trials conducted in 2009 globally, only 0.72% were conducted in Turkey[1]

Some MNCs already increasing clinical trial activities in Turkey

- GSK recently established "Vaccine Clinical Trials Center" in Hacettepe Teknokent
- Roche established its 6th clinical trials center globally in Turkey in 2009

Solution of legislative issues will make clinical trials more attractive in Turkey

- Problems with the clinical trial legislation led to period of uncertainty, which was later cleared by the approval of the new legislation
- Implementation of the procedures and durations in the new legislation and monitoring by the MoH expected to increase the predictability researchers need and to increase the number of clinical trials carried out in Turkey

1. "Türkiye'nin Avrupa Birliği'ne Üyelik Sürecinde Sağlıkta İnovasyon" by Z. Güldem Ökem, TÜSİAD (February 2011)
Note: Any errors in summations are due to rounding off
Source: EFPIA "The Pharmaceutical Industry in Figures" 2011 update

Process and formulation development would be the core focus of Turkish pharma companies on their path to globalization

Turkish pharma companies currently focusing on "development" R&D, should intensify its focus on this field

- Generics players already focusing on development of new combinations
- Development of drug delivery systems (DDS) and modified release systems should also be a growth path for pharma
- Pharma R&D can shift some of its focus from product to production via developing new processes
- Molecule development can be a long-term target of Turkish pharma industry, once R&D base is developed via focus on "development"

Innovator MNCs operating in Turkey should shift more of their clinical trial activities to Turkey

- Some MNCs already investing in clinical trials in Turkey. Other MNCs should also be driven to Turkey

Entities with <50 full-time R&D employees currently ineligible to receive "R&D Center License"

Incentives given to "R&D Center License" holders

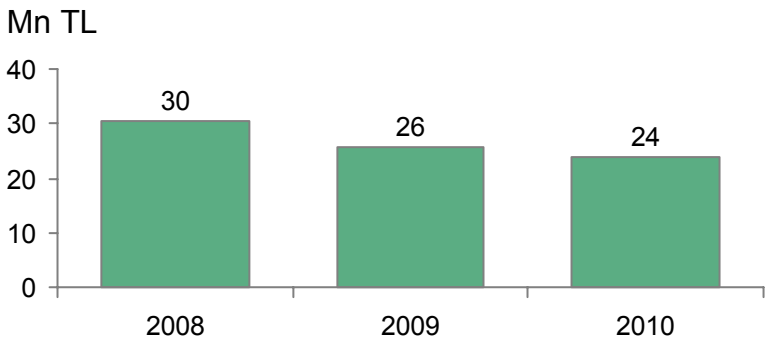
R&D discount:
- R&D related spending by the R&D centers subtracted from the income of the related corporation

Income tax withholding incentive:
- 90% of the wages of Ph.D holding R&D center employees (80% of non-Ph.D employees) exempted from income tax

Social security contribution incentive:
- For each R&D center employee, 50% of employer's social security contribution share paid by the Ministry of Finance for 5 years

Only R&D centers with >50 employees allowed to benefit from these incentives

Yearly planned R&D expenditure per "R&D Center License" holder



Some license-holder companies

arçelik, VESTEL, DIGITURK, avea, RENAULT, dyo

Difficult for small-to-medium scale companies to obtain license

1. Law #5746
Source: Ministry of Industry & Trade

A2

Revision of R&D legislation

South Korea offers cash grants and tax exemption to R&D centers with 10+ R&D personnel

Cash grants

Eligibility

- At least 10 R&D personnel must have academic backgrounds OR masters degree plus at least 3 years of R&D work experience
- Foreign ownership in the R&D center must be at least 30%

Tax exemption

Eligibility

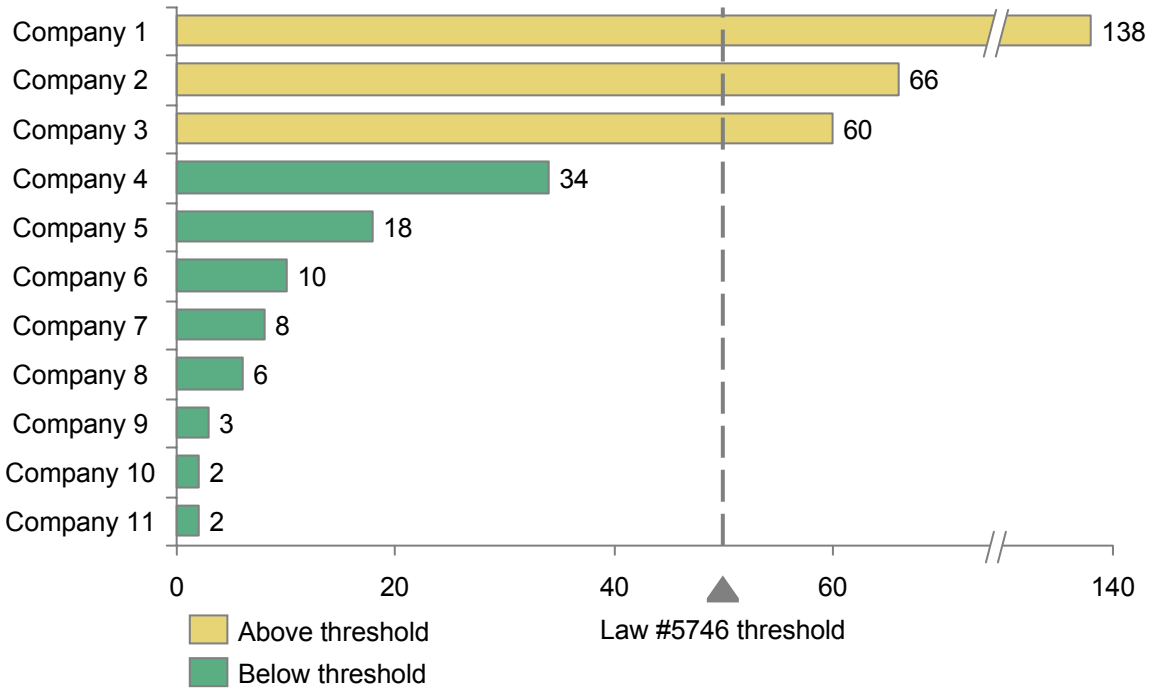
- At least 10 R&D personnel must have academic backgrounds OR masters degree plus at least 3 years of R&D work experience
- Foreign investment is at least 1 m$ for FEZ[1] and 2 m$ for FIZ[2]

South Korea supplements its R&D personnel threshold with additional competency requirements

1. Free Economic Zone 2. Foreign Investment Zone
Source: Literature search

Numerous local pharma producers have R&D activities; but at levels below the threshold to receive R&D center incentives

R&D employees of IEIS members



Implications

Numerous pharma companies with below threshold R&D employees

- "R&D Center Licenses" would allow small R&D teams to grow more easily
- Some MNCs operating in Turkey also run R&D operations, who may expand operations with a R&D center license

Source: IEIS

Employee limit can be lowered to expand license usage; other criteria can be implemented to ensure high standards

Current situation

- **Government keeping high threshold to avoid small & limited capacity corporations from using up resources**
- **Pharma R&D conducted significantly by small research firms with significant know-how**

Desired situation

- **Pharma companies with smaller R&D teams enabled to obtain license; opportunity to grow R&D activity**
- **Expected increase in projects; applications and approvals in project-based incentive programs (e.g., TUBITAK, TTGV[1])**

Proposed action

- **50 employee threshold in Law #5746 to be lowered to 10 employees**
- **Additional criteria included to Law #5746**
- Growth to 50 R&D employees in 5 years OR
- 1 TUBITAK-TEYDEB supported projects for each year

Performance-based criteria more effective than capability-based criteria to best allocate Government resources

1. TTGV = Technology Development Foundation

Source: BCG

Employing foreign R&D personnel currently difficult in Turkey due to limitations on work permits for foreigners

1 Legal constraints to employ foreign pharma R&D employee

Broad definition of "pharmacist" in Turkish laws

- Includes everything from running a pharmacy to working in pharma production facilities

Law regarding Pharmacists and Pharmaceuticals (#6197) does not allow foreign researchers to work on pharma R&D in Turkey

2 Legal obligation to seek Turkish personnel suitable for jobs of foreigners

In the issuance of work permits, current legislation (#4817) requires that if Turkish citizens suitable for the job exist, the work permit shall not be granted

Legal period for seeking Turkish personnel suitable for the job of foreigners is 4 weeks, which create a delay in the application process even if no suitable Turkish citizens are found

3 Long duration of procedure to ensure equivalency of degrees held by foreigners

Foreign R&D personnel are required to have their diplomas & degrees "recognized" by Turkish authorities

Turkish Board of Higher Education[1] gives the final approval for equivalency of foreign diplomas, but meets very few times every year

- Board meets 3 times per year
- Additional meetings can be called by the Chairman or by at least 1/3 of the board members

Local pharma companies require foreign R&D personnel to accumulate know-how and train Turkish R&D employees

1. YÖK
Source: IEIS

Work permits to foreign R&D personnel

South Korea Government offers dedicated visa to foreign nationals bringing technological know-how to corporations

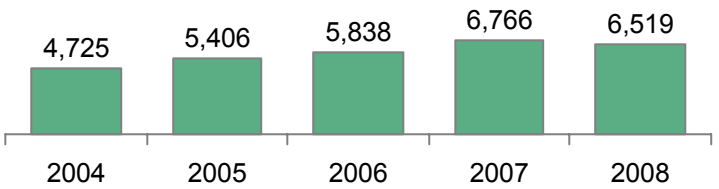
Processing time: 2-4 weeks

Research Visa (E-3)

Given to scientists that are engaged in the study at the institutes mentioned below under the contract with the mentioned organizations in order to develop high technology based on related laws of Technology Development Promotion Act

- Company-attached institute
- Industry Technology Research Corporation under the Industry Technology Research Corporation Promotion Act
- Universities or Colleges under the education law
- National/public institutes
- Technological Supporting Institution under the Formation Law for Industrial Technology
- Non-profit institutes whose foundation is based on a certain law (civil or otherwise).
- Institute of other scientific field or corporation

# of E-3 visas granted by South Korea



Technological Guidance Visa (E-4)

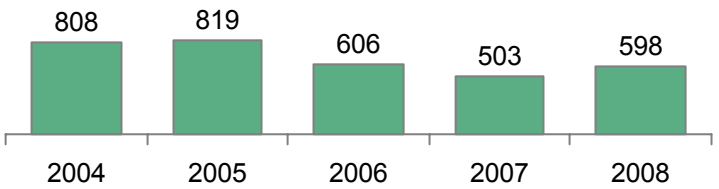
Given to foreign professionals that offer special technology or expertise at a public/private organization

- To Korean nationals or corporations, based on the regulation of Foreigners Investment Promotion Act

Other than above, those that offer special technology or expertise not available in Korea.

- That are dispatched by a foreign corporation
- That are doing so because it had been newly introduced to a Korean corporation

# of E-4 visas granted by South Korea



Source: Korea Immigration Service, KIS Statistics 2009

A3

Work permits to foreign R&D personnel

Regulations can be modified to employ qualified foreign R&D personnel more easily

1 Legal constraints to employ foreign pharma R&D employee

- "Pharmacist" duties described in Law #6197 should be revised differentiating the employees working in pharmacists, pharma production and R&D
- An exception must be included in the legislation to allow employing foreign R&D personnel

2 Legal obligation to seek Turkish personnel suitable for jobs of foreigners

- An exception can be included in Law #4817 to shorten the process (legal obligation to seek Turkish personnel for jobs of foreigners) to employ R&D employees

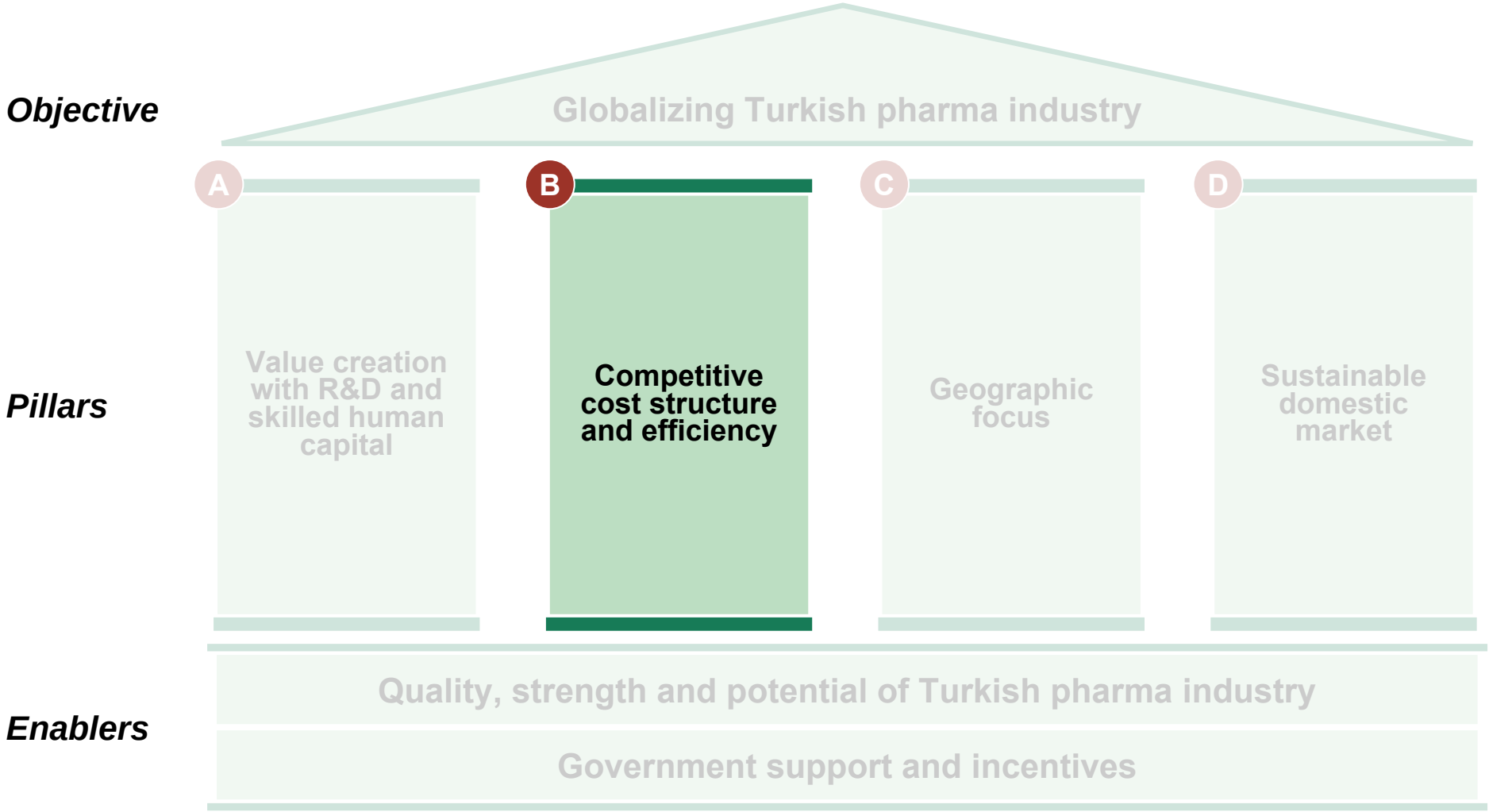
3 Long duration of procedure to ensure equivalency of degrees held by foreigners

- Current legislation allows Turkish Board of Higher Education (YÖK) to meet more than 3 times a year
- Requesting YÖK representatives to accommodate this need will improve the process time

Decreasing bureaucracy in employing foreign R&D employees will speed up know-how transfer

Source: İEİS, BCG analysis

Reaching globalization target dependent on implementation of 4 key pillars with industry efforts and Government support



Source: BCG analysis

Executive summary

Competitive cost structure and efficiency

Turkey has lower manufacturing costs compared to Western countries; however, Turkey is not as competitive as low-cost countries (e.g. China, India, Brazil, Singapore)

Two structural problems limiting competitiveness of Turkish pharma industry

- Lack of backward integration: Local pharma manufacturing is import-dependent for active ingredients and intermediaries; causing a disadvantage in global competition
- Underutilized manufacturing capacity: Capacity utilization in Turkish pharma industry below Turkey manufacturing industry averages; lack of scale in manufacturing is another reason for higher unit costs

In addition to these major issues, discrepancy in VAT rates between imported raw materials and finished drug formulations causing disadvantage for local pharma industry

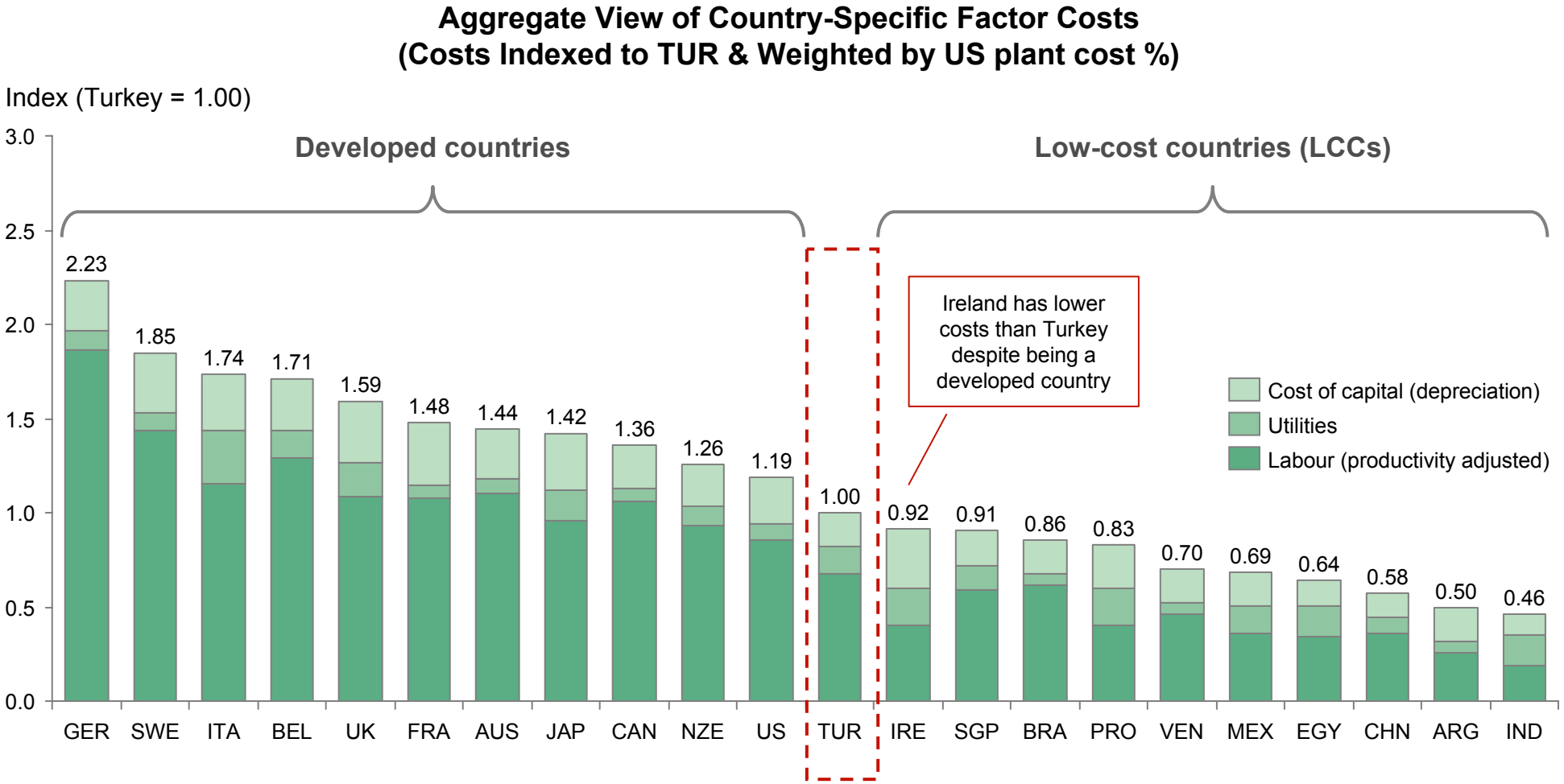
On the other hand, Government providing cross-industry incentives for investments and exports to increase global competiveness and attract FDI

In the light of above mentioned conditions, a set of actions recommended to be taken

- New incentive mechanisms would be introduced to increase utilization of current pharma manufacturing investments
- Turkish pharma industry's utilization of current incentives would be increased
- VAT rates of raw materials and locally-produced finished drug formulations would be aligned
- Development of pharma clusters would be considered in case current manufacturing capacity not adequate
- Purchasing alliances would be formed for purchasing of specific materials or utilities such as electricity
- Feasibility of raw material manufacturing would be investigated in the long run

Source: Interviews, BCG analysis

Manufacturing costs in Turkey are in between developed and low-cost countries ...

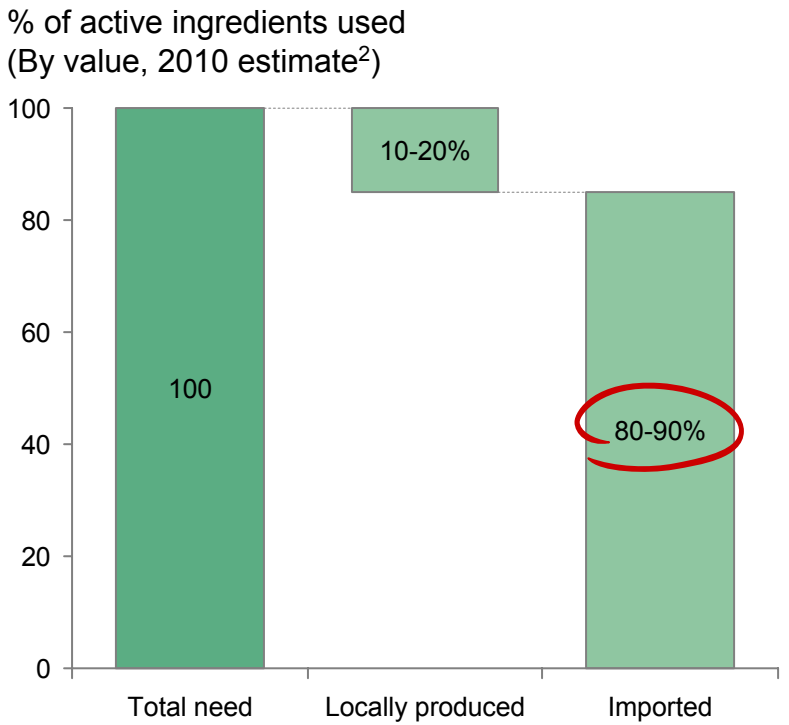


Turkey has cost advantage against developed countries; but has higher manufacturing costs compared to low-cost countries

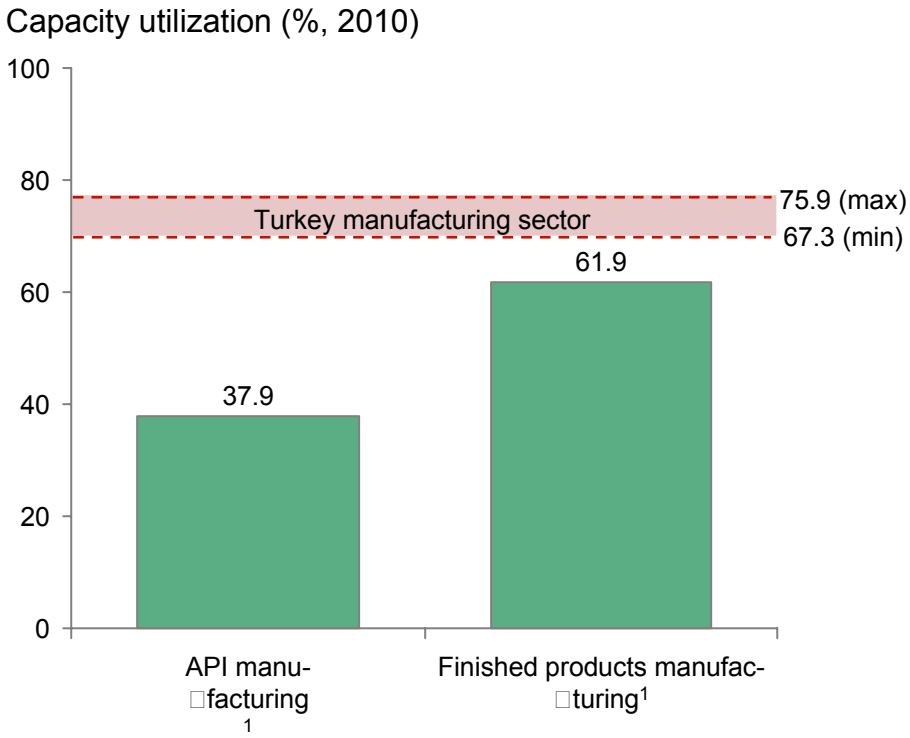
Detail on Weighting: Labor (prod. adjusted) wt = 72% Depreciation wt = 21% Utilities wt = 7%
Source: BCG analysis

... Yet, lack of vertical integration and underutilized capacity limiting cost competitiveness of Turkish pharma industry

Majority of active ingredients imported for local manufacturing



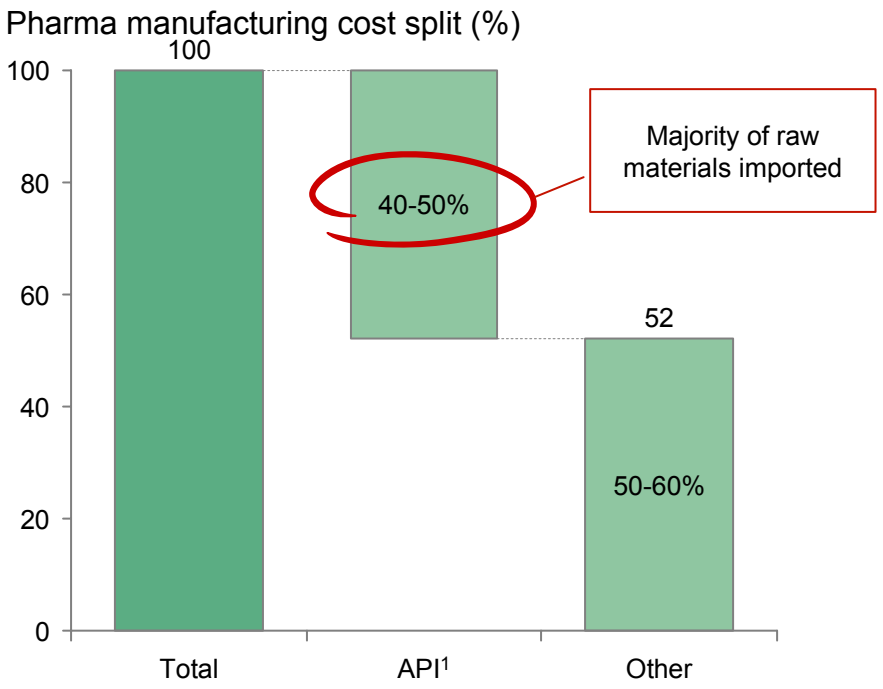
Underutilized manufacturing capacity[1] hindering cost efficiency



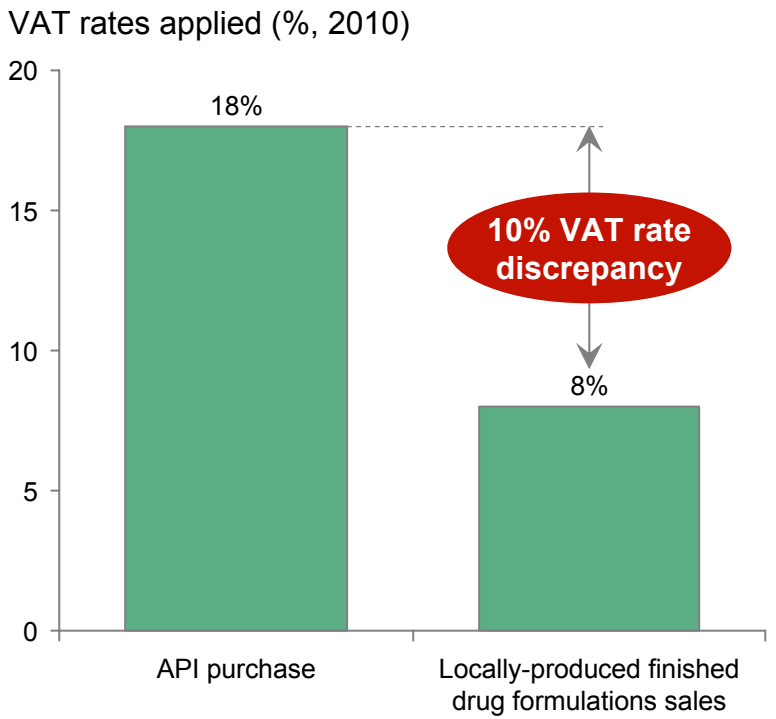
1. Based on responses of IEIS members 2. Based on interviews with industry experts
Source: State Planning Organization Pharmaceuticals report, TUIK, IEIS, BCG analysis

In addition, higher VAT rates applied for active ingredients compared to finished drug formulations

Active ingredients account for 40-50% of manufacturing costs in pharma



VAT rates for active ingredients higher than VAT rates of finished drug formulations



Higher VAT rates for raw materials increases financing costs of local pharma manufacturers

1. API = Active Pharma Ingredient
Note: % of raw material cost in total pharma manufacturing costs rough estimate for overall industry. Cost of raw material highly dependent on type of drug produced.
Source: Interviews

On the other hand, new investments and export supported by Government via incentives in line with international agreements

Incentive program for new investments defined by Undersecretariat of Treasury

Main objectives of incentive program are ...
- ... to reduce regional imbalances in socio-economic development
- ... to support industry clustering by determining key industries in accordance with regions and competitiveness advantages
- ... to promote big projects that would increase global competitiveness and focus on R&D and technology

Program consisting of three main components
- Region-industry based incentive system
- Big project incentive system
- General incentive system

Main incentive levers are ...
- ... corporate tax and VAT reduction, land allocation, low-cost financing, custom duty exemption

Pharma industry incentivized both in region-industry based and big project systems

Export-oriented incentives framed by Undersecretariat of Foreign Trade

Majority of export promotion incentives introduced in 1980s had to be lifted ...
- Due to binding international agreements

... And current cross-industry export support programs have been shaped
- Main goal is to help exporters develop export capabilities and exposure to international markets
- Program consistent with WTO and EU regulations

19 free zones across Turkey to promote export-oriented investment and manufacturing
- Tax advantages, ease in export procedures, infrastructure in international standards provided

Inward processing regime providing custom duty exemption for imported raw materials/intermediaries used for exports

Source: Undersecretariat of Treasury, Undersecretariat of Foreign Trade, literature research, BCG

Undersecreteriat of Treasury offers three incentive systems for investments

Incentive system for large-scale projects	**Projects with certain capital requirement in R&D and technology focused industries classified as "Large Scale Projects" and incentivized in all provinces** • Pharma projects over 100 Mn TL classified as "Big Projects"
Region-industry based incentive system	**Classification of provinces** • Cities grouped under 4 zones compromised of 26 regions according to socio-economic development **Region-industry match** • Industries to be supported in each region determined based on regional potential and feedbacks of local authorities **Minimum capital requirements for investments to be eligible for incentives** • Minimum investment requirements are 0.5 Mn TL and 1 Mn TL according to development level of zones in which investment will be realized **Pharma-relevant[1] investments incentivized in 11 regions covering 27 provinces**
General incentive system	**Projects that are not qualified for region-industry based and large-scaled project incentive systems can benefit from general incentive system** • Exemptions from VAT and custom duty provided to those projects

Investment certificates given to companies qualified for investment incentives

1. US 97 codes 24 and 2423. Investment size would be 5 Mn TL for Zone 1, 4 Mn TL for Zone 2, 3 Mn TL for Zone 3 and 2 Mn TL for Zone 4.
Source: Undersecretariat of Treasury

Large scale investment projects in 12 industries incentivized in all provinces of Turkey; pharma among those 12 industries

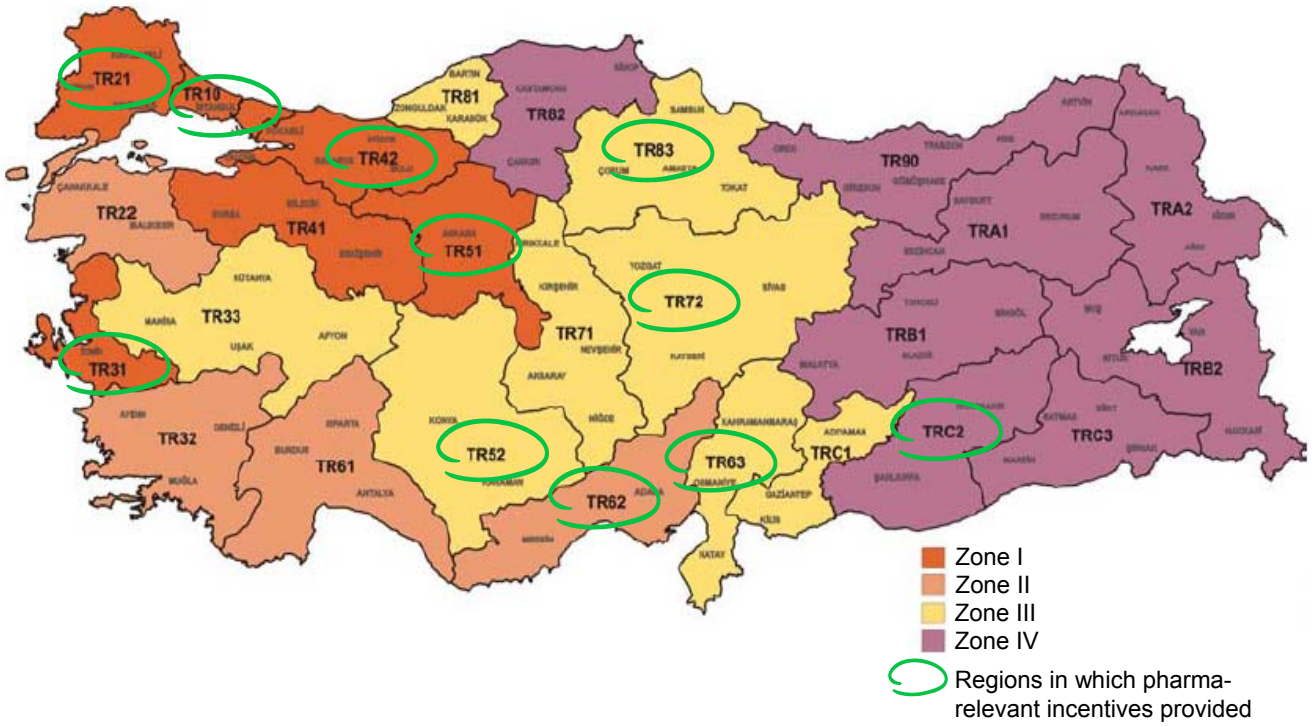
Industry	Minimum fixed investment amount
Production of chemical substances and products	
• Main chemical substances	1,000 Mn TL
• Other chemical substances	300 Mn TL
Production of refined petroleum products	1,000 Mn TL
Pharma production	**100 Mn TL**
Investments in the area of transportation services with transit pipe line	50 Mn TL
Motorized land vehicle manufacturing	250 Mn TL
Railway and tramway locomotives and/or wagons production	50 Mn TL
Port and port services	250 Mn TL
Electronic	
• LCD/Plazma Production	1,000 Mn TL
• Module Panel Production	150 Mn TL
• Laser Television, Three Dimensional Television and OLED Televisions production	50 Mn TL
• Other Electronic Sector	50 Mn TL
Medical Instruments, High Precision and Optical Devices Production	50 Mn TL
Aeronautical Vehicles and Spacecrafts Manufacturing	50 Mn TL
Machinery Production	50 Mn TL
Mining Investments[1]	50 Mn TL

In pharma industry, investments over $100 Mn eligible to be incentivized by big project incentive system

1. Investments for ore processing facilities established for production of metal as end-product concerning IV/c group metallic mines stated in the Mining Law and investments for mine production (extraction and processing) integrated to these facilities. (Except for products included in list annexed to the Turkey-ESCS Free Trade Agreement)
Source: Undersecretariat of Treasury

Region-industry based incentive scheme supporting pharma-relevant investments in 27 cities

Pharma-relevant[1] investment incentives given in 11 regions ...



... Covering 27 cities

1. Adana
2. Amasya
3. Ankara
4. Bolu
5. Çorum
6. Diyarbakır
7. Düzce
8. Edirne
9. Hatay
10. İstanbul
11. İzmir
12. Kahramanmaraş
13. Karaman
14. Kayseri
15. Kırklareli
16. Kocaeli
17. Konya
18. Mersin
19. Osmaniye
20. Sakarya
21. Samsun
22. Sivas
23. Şanlıurfa
24. Tekirdağ
25. Tokat
26. Yalova
27. Yozgat

Investments related to production of pharmaceuticals are incentivized by the Government

1. US 97 codes 24 and 2423
Note: Investment size would be 5 Mn TL for Zone 1, 4 Mn TL for Zone 2, 3 Mn TL for Zone 3 and 2 Mn TL for Zone 4.
Source: Undersecretariat of Treasury

Main incentives are tax benefits, land provision and low cost financing for investments in designated regions

Measure	Upper limits of incentives provided			
	Zone I	Zone II	Zone III	Zone IV
Reduced corporate tax for the earnings from new investment[1]	15%	12%	8%	4%
Exemption on social security premium (employer portion)	-	-	3 years	5 years
Land provision	✓	✓	✓	✓
VAT exemption	✓	✓	✓	✓
Custom duty exemption	✓	✓	✓	✓
Low-cost financing				
• Interest rate reduction (TL loans)			3%	5%
• Interest rate reduction (Fx loans)			1%	2%

1. Reduced corporate tax will be applied till the amount of support on investment reached to 10% (Zone I), 15% (Zone II), 20% (Zone III) and 25% (Zone IV) of total investment for region-industry projects. for "large investment"s, ie. pharma investments over 100 Mn TL, reduced corporate tax will be applied till the amount of support on investment reached to 25% (Zone I), 30% (Zone II), 40% (Zone III) and 45% (Zone IV)
Note: For investments started after 31 Dec 2010
Source: Undersecretariat of Treasury

In terms of export, majority of subsidies introduced in 1980s currently not applicable due to international agreements

1980-1990	1990-2000	2000-2011
Turkey adopted export-oriented growth strategy • Instead of import substitution **Export performance based incentives introduced; e.g.,** • Income tax exemption for export revenues • Custom duty exemption for importing raw materials • Low-cost financing for export **To support financing of export operations, Eximbank founded in 1987**	**Turkey became member of WTO and joined Custom Union with EU** • Turkey became a member of WTO in 1995 • Customs Union with the EU introduced in 1996 **Export performance based incentives gradually phased-out** • Due to regulations came in force with international agreements	**Exporters supported by a set of export-oriented aids by Gov't** • In compliance with international agreements **Cross-industry export supports composed of three elements** • Aids covering several value chains; from production to marketing • Inward processing regime • Eximbank offerings as export credits, insurance and guarantees

Level of Government support to exporters highly restricted

Source: Undersecratariat of Foreign Trade, literature research, BCG analysis

Government currently supports exporters with a set of financial aid to increase competitiveness (I)

Support	Description
Participation in international fairs	Financial support given to companies that participate in international trade fairs • Benefiter: Participating companies
Environmental compliance	Costs incurred for compliance to international environmental standards (e.g., ISO, CE sign) supported up to 50% (max $25 K) • Benefiter: Industrial, agricultural or software companies
R&D	R&D activities supported by Technology Development Foundation (TTGV) of Turkey and TUBITAK • Activities would be relevant to ... – ... New product manufacturing – ... Improvement of product quality or standard – ... New process/ technique development for cost efficiency or quality improvement – .... Technology development or upgrade for international compliance • Benefiter: Industrial and software companies
Employment	Support for wages of experienced and educated managers and employees that are dealing solely with international trade procedures in international trade companies • Wages of experienced and educated manager (one, up to $18 K) and employees (two, up to $18 K total), are paid up to 75% for only one year, provided that the mentioned manager and employees are hired for the first time in the relevant international trade company • Benefiter: International trade companies

Source: Undersecratariat of Foreign Trade

Government currently supports exporters with a set of financial aids to increase competitiveness (II)

Support	Description
Participation to international fairs abroad	Up to 50% (with limits) of participation fee supported by Undersecretariat of Foreign Trade • Benefiter: Companies with industrial and commercial activities or software companies, international trading companies, and sector-specific foreign trade companies, at different levels of support
Trademark registration, office/ store opening	Expenses incurred with regard to presentation of their products in international markets, registration of trademarks, and expenses with regard to entities established for trade of products abroad covered by public funds at varying levels (e.g., 50-60% with max limit around $250 K) • Benefiter: Companies with industrial and commercial activities or software companies, international trading companies, and sector-specific foreign trade companies, at different levels of support
Turquality	Marketing and brand promotion activities supported at various levels under Turquality program • Benefiter: Export unions, manufacturing associations and unions
Market research & market access	Market research and market entry strategy studies supported by Undersecretariat of Foreign Trade and Export Promotion Center • Some of the activities covered are ... – Target market visits – Consultancy services and market research reports – Subscription to e-trade websites

Source: Undersecratariat of Foreign Trade

Government currently supports exporters with a set of financial aids to increase competitiveness (III)

Support	Description
Export capability development	Up to 70% (max $20 K annually) support for training expenses in several topics including EU and WTO regulations, international pricing and contracting, supply chain management and logistics, international marketing • Benefiter: Software and industrial companies, export unions, chambers of commerce in cities, international trade firms
Design support	In order to establish and spread the culture of design in Turkey; advertising, marketing, employment, and consultancy expenses of design companies supported at various levels • Benefiter: Export unions
Technical Consultancy Firms' Activities in abroad	Within the scope of the sponsorship, several sectors supported for expenses for offices located abroad; expenses with regard to marketing research; fees for attending fairs, conferences, and seminars; and expenses for the preparation of feasibility studies and contracts up to the cap designated • Benefiter: Technical consultancy firms, construction firms, fair organizations, seminar and conference organizations

Source: Undersecratariat of Foreign Trade

Inward processing regime as another tool to enhance competitiveness of Turkish exporters

Inward processing regime (IPR)

System allowing manufacturers/exporters to obtain raw materials, intermediate unfinished goods that are used in production of exported goods without paying customs duty and being subject to commercial policy measures

Raw materials & intermediaries without custom duty

for

Exported finished goods

IPR enables importing raw materials used in production of exported goods at world market prices

Source: Undersecretariat of Foreign Trade, BCG analysis

Low-cost financing and export insurance available for Turkish exporters via Eximbank and commercial banks

Eximbank offers specialized financial services to Turkish exporters ...

Loan offerings
- Providing short-, medium- and long-term cash and non-cash loans
- Eximbank loans exempted from taxes and KKDF[1] fee

Country credit and guarantee program
- Providing financing support for projects and export of capital goods undertaken by Turkish companies through medium/long-term loan and guarantee programs

Insurance programs
- Provides cover for exporters, against commercial and political risks by offering variety of insurance programs

... either by its own or through commercial banks in Turkey

Eximbank works closely with commercial banks encouraging them to increase support for exports
- Eximbank credits offered by commercial banks to exporters

Eximbank offers guarantee schemes to commercial banks in order to create a risk free environment for banking sector
- To encourage them to engage directly in export financing

Commercial banks offer Eximbank loans to exporters

Low-cost and tax-free loans provided to exporters

1. KKDF = Resource Usage Support Fund (Kaynak Kullanimini Destekleme Fonu)
1ource: Eximbank, commercial banks websites

In this context, 6 main actions recommended to improve competitive cost structure and efficiency in pharma manufacturing

Lever		Action	Owner
Pharma-specific manufacturing and export incentives	B1	Introduce new measures to incentivize local manufacturing; in line with international agreements (e.g., WTO[1], EU[2])	Economic Coordination Committee
	B2	Form a workgroup to provide support services to member companies regarding the usage of current incentives	Pharma industry
VAT rates for APIs	B3	Remove discrepancies in VAT[3] system causing uneven competition for local pharma manufacturing	Deputy Prime Minister (Economy)
Special economic zones for pharma	B4	Develop pharma specialized industry zones enabling clustering with solid infrastructure and access to ports and inland transportation in the long term	Ministry of Science, Industry and Technology
Purchasing alliance	B5	Investigate possibility of building alliance for purchasing of APIs and utilities (e.g., electricity, gas)	Pharma industry
Backward integration	B6	Investigate investment opportunities for API manufacturing to increase backward integration (e.g., acquisition of foreign API manufacturers)	Pharma industry

Priority actions detailed in the following pages

1. WTO = World Trade Organization 2. EU = European Union 3. VAT = Value-added tax
Source: Interviews, BCG analysis

New measures can be introduced to incentivize local pharma manufacturing and export

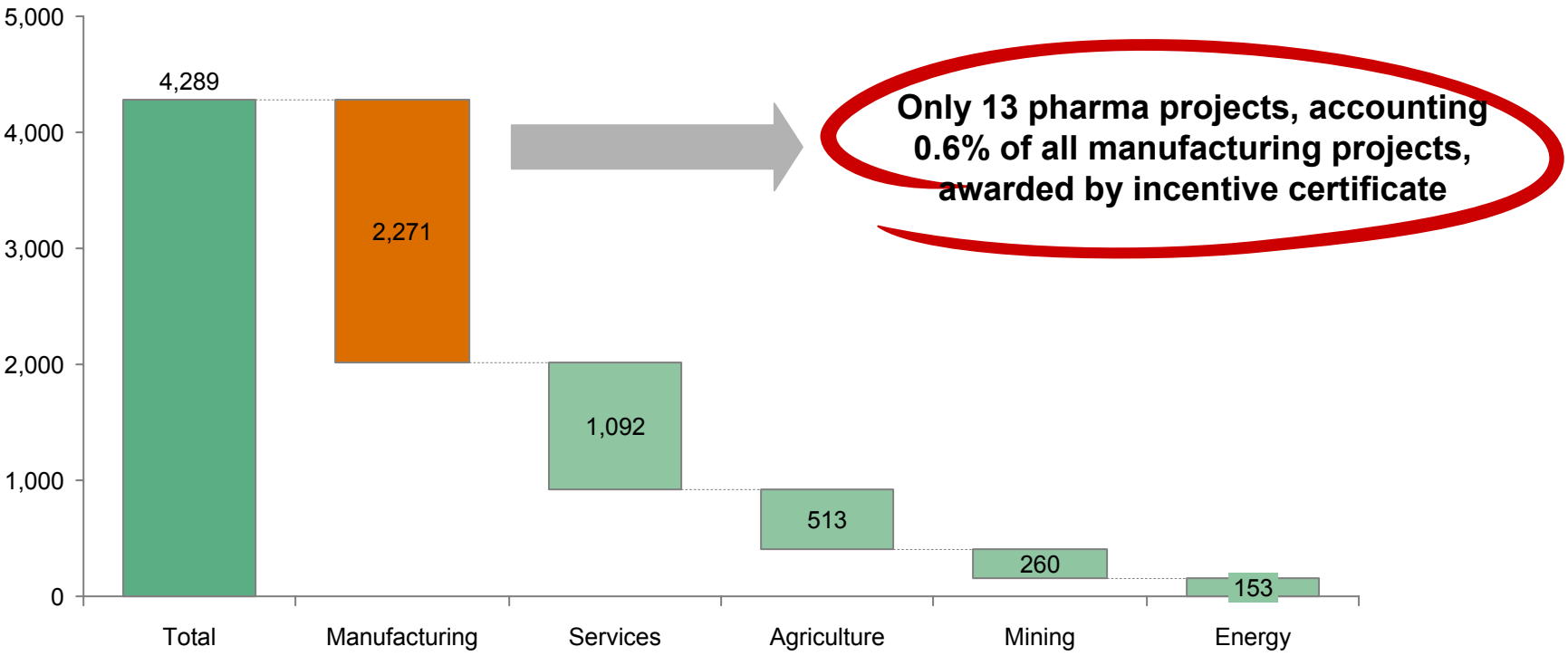
Domain	Possible incentive measures to increase local pharma manufacturing and export
Exemption from loan growth cap	• Exempt loans given to pharma industry for manufacturing investments and export from overall 25% loan growth cap set for banking sector
Tax and KKDF exemption for pharma financing	• Tax and KKDF[1] fee exemption for loans given to pharma companies to ... – ... purchase imported pharma ingredients (e.g., API, intermediaries) – ... finance exporting operations

1. KKDF = Resource Usage Support Fund (Kaynak Kullanimini Destekleme Fonu)
Source: Interview, BCG

Increased use of current incentives

Limited number of pharma investment projects awarded by incentive certificate in 2010

Number of investment projects awarded by investment incentive certificate (2010)



Only 13 pharma projects, accounting 0.6% of all manufacturing projects, awarded by incentive certificate

Three possible reasons of low-utilization of investment incentives:

- **Lack of investments in 2010 due to undesirable market conditions**
- **Lack of applicability of current incentives for pharma industry**
- **Lack of incentive awareness among pharma companies**

Source: Undersecretariat of Treasury, BCG analysis

Industry should guide individual companies to better exploit investment and export incentives

Investment and Foreign Trade Committee (ITC)

- Main objective of ITC is ...
  - ... to increase awareness and usage of current investment and export incentives among member companies
  - ... to support member companies in application process
- ITC would be composed of a joint workgroup of IEIS and member company employees from relevant departments (e.g., finance, regulatory affairs, legal, strategy)

IEIS staff

- Overall coordination and project management
- Content development

Experts from member companies

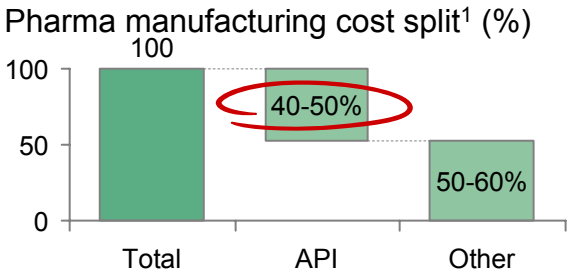
- Advisor and supports content development

Source: BCG

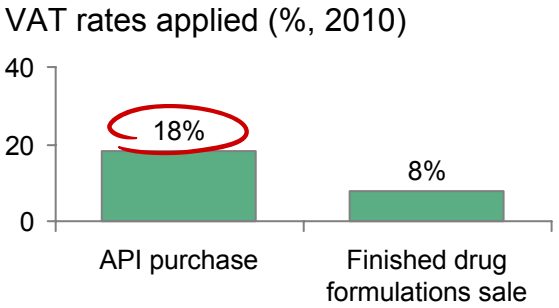
VAT rates of pharma ingredients and finished drugs should be aligned to make local drug manufacturing more attractive

Facts

APIs represent ~40-50% of total manufacturing costs in pharma[1]



Higher VAT rates applied to APIs compared to rates applied to finished drugs



Issues

Discrepancy in VAT rates leading to increasing receivables from Government ...

- Companies' working capital negatively affected due to pending receivables (incl. opportunity cost)

... And creating disadvantage for local manufacturers

- Finished drug importing becoming more attractive than local production

POSSIBLE SOLUTION

Aligning VAT rates of pharma ingredients and finished drug formulations at 8% would be a solution ...

... To reduce pending receivables of local pharma manufacturers

Pharma ingredients of whose VAT rates would be aligned can be easily identified

A license or certificated issued by MoH can be used; as MoH already has the list of ingredients used in drugs

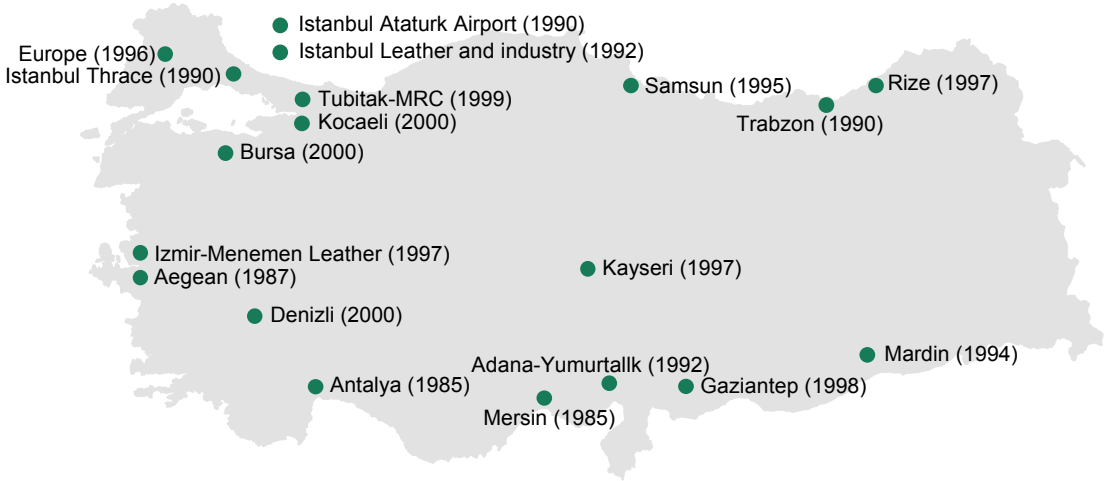
1. Depending on drug specifications

Source: Interviews, IEIS, BCG

Organized industrial zones, enabling clustering, would be developed for manufacturing and exporting of pharma products

Free zones and clusters developed separately in Turkey

19 free-zones operating in Turkey; all of them hosting companies from different industries



On the other hand, Government aiming to make Turkey one of the few countries with national cluster policy

- In line with this objective, a strategy will be developed that will constitute the core of clustering policy

Clustering in free-zone concept would support globalization of pharma industry and reach export targets for 2023

Pharma cluster(s) would be developed in free zone concept ...

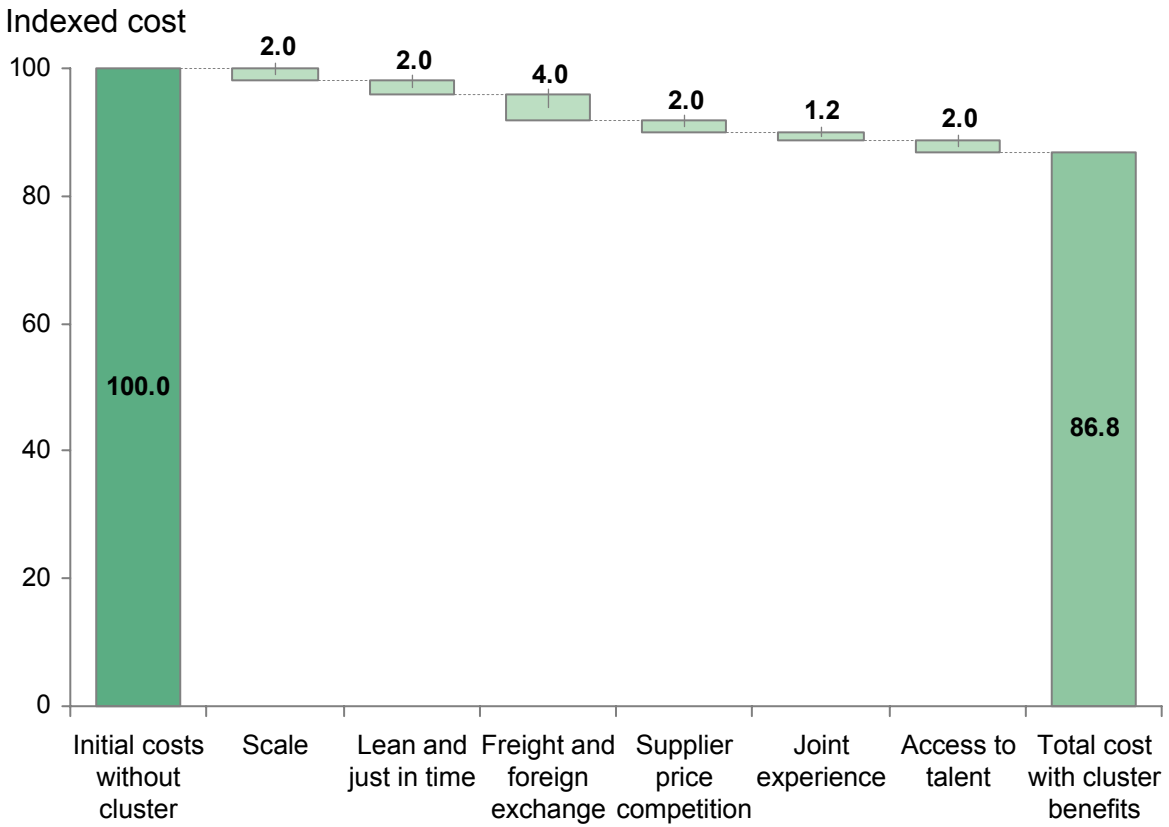
... With similar advantages provided in free zones

- Income or corporate tax exemption for revenue generated from goods manufactured in free zones
- Opportunity to transfer profits
- Eased bureaucracy for export and import
- Custom duty free trade facilities
- Solid infrastructure suitable for commercial and industrial activities
- With easy access to ports and inland transportation

Source: Undersecretariat of Foreign Trade, BCG

Clusters estimated to provide ~13% cost advantage; even without advantages provided within free zones

Example of the value of a cluster location versus an isolated assembly plant[1]



- Scale from network-level sourcing and common processes
- Lean assets, processes, and networks
- Flexible production reduces the impact of logistics and currency costs
- Experience curve effects through sharing of best practices
- Greater access to managerial and production talent

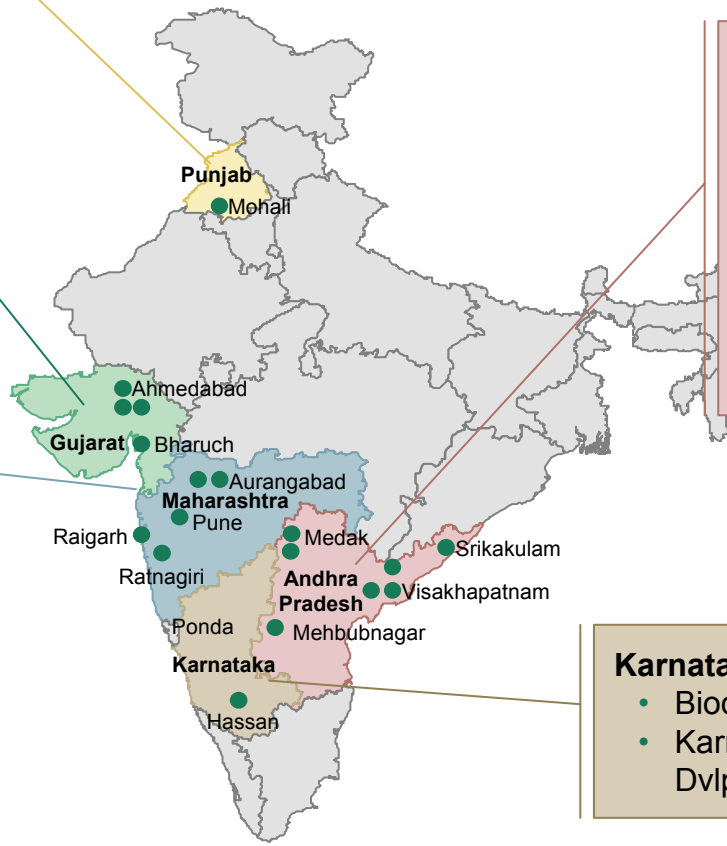
1. Based on an international study conducted by BCG in China
Source: BCG experience

Pharma clusters across India hosting pharma manufacturers and research centers ...

Punjab SEZs
- Ranbaxy Laboratories

Gujarat SEZs
- Zydus
- Jubilant
- CPL Infrastructure
- Dishman Infrastructure
- J B SEZ

Maharashtra SEZs
- Glenmark
- Wockhardt
- Serum Institute of India
- Maharashtra Industrial Dvlpmnt Corp. (MIDC)
- Ajanta Pharma Ltd
- Navi Mumbai SEZ Pvt (Kalamboli Pharma.)



Andhra Prades SEZs
- Dr Reddy's Labs
- Divi's Labs
- Ramky Pharma City
- Hetero Infrastructure SEZ
- Andhra Pradesh Industrial Infrastructure Corp.
- Deccan Infrastructure and Land Holdings

Karnataka SEZs
- Biocon
- Karnataka Industrial Areas Dvlpmnt Board

~53 pharma & biotech SEZs granted approval in India

Note: SEZ = Special Economic Zone
Source: Pharmexcil, India Brand Equity Foundation report, press research, BCG analysis

Pharma specialized industrial zones

... And offer financial incentives and benefits to pharma companies

SEZ structured to meet demands of companies of all sizes...

JB SEZ layout

Large manufacturing

Specialty manufacturing

Housing

... And provide a package of financial incentives and benefits to firms in the location

Customs and excise
- No duty on import/ domestic procurement of goods
- Exemption from special additional duty provided for domestic sales

Income tax
- 100% tax exemption on export income for first 5 years; 50% for next 5 years thereafter

Service tax and central sales tax
- Exemption from service tax
- Reimbursement of central sales tax paid on domestic purchases

Banking and insurance
- Ability to write-off "unrealized" export bills

Loss carrying
- Forward carrying losses for eight years

Ease in bureaucracy
- Simplification of export procedures

Source: India Brand Equity Foundation report, JB SEZ report, BCG analysis

Pharma clusters in China located in four provinces with access to ports and inland transportation

Pharma clusters concentrated mainly in four provinces

Clusters concentrated to consolidate supply base, infrastructure, and local political clout

Regional concentration improves access to qualified suppliers

- Concentrates supplier demand
- Increases supplier monitoring

Regional consolidation focuses infrastructure investment

- Firms are able to pool resources to develop roads, etc.

Regional consolidation aggregates political clout

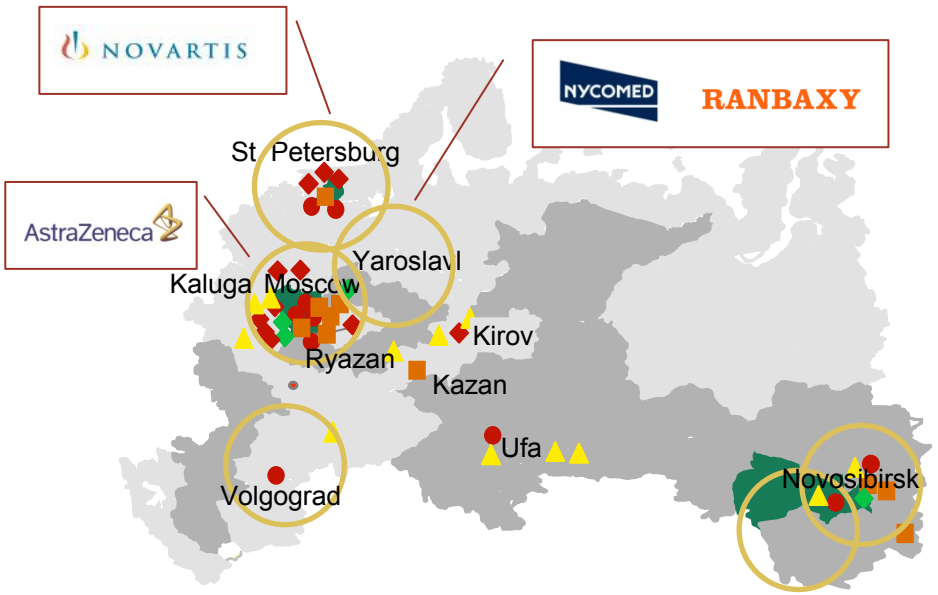
- Greater number of firms coordinating local lobbying

Source: Domestic Market Based Industrial Cluster Development in Modern China by Ding Ke, Factors and Mechanisms Causing the Emergence of Local Industrial Clusters by Thomas Brenner and Andre Muhlig, Korean Institute for Industrial Economics and Trade, Identifying Industrial Clusters in Korea by Dr. Jun Ho and Dr. Jin-Myon Lee, Overview of Industrial Clusters in China from Li and Fung Research Center, Competitive Strategy of Global Firms in Industrial Clusters by Amano Tomofumi, Cluster Development Project, Cluster Pulse, the Competitiveness Institute

Pharma specialized industrial zones

MNCs established manufacturing facilities in financially-incentivized pharma clusters in Russia

MNCs investing to pharma clusters under development



Several incentives promised to stimulate investments to those clusters

Tax Incentives

- Special custom regulation in terms of partial custom duties exemption
- Purchase of a list of equipment that can be imported without duties

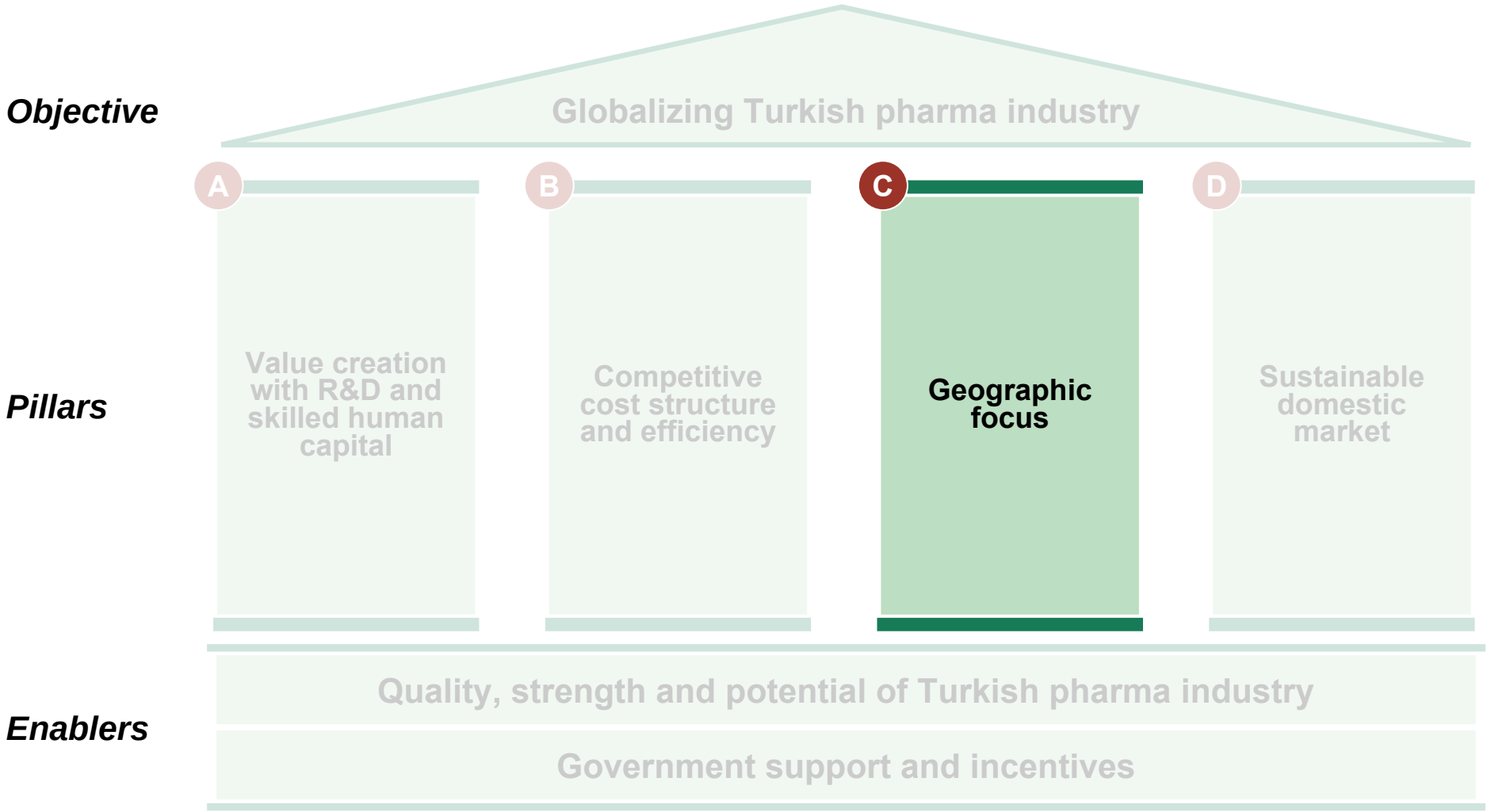
Financing incentives

- Local government support for construction, infrastructure development
- Preferential rent rates for the usage of tenements owned by the Yaroslavl Region

Russia supports development of pharma clusters primarily for domestic market rather than exporting

Source: Press research, company websites, expert interviews, BCG analysis

Reaching globalization target dependent on implementation of 4 key pillars with industry efforts and Government support



Source: BCG analysis

Executive summary

Geographic focus

Pharma exports of Turkey grew 18% per annum and reached ~$560 Mn during 2001-2010

- With 34% share in Turkish pharma exports, developed EU15 countries are the top destinations
- MENA and CIS are following EU15 with 14% and 8% shares in 2010 pharma exports, respectively
- Exports to North America, mainly US, experienced the highest growth rate with 37% per annum

Targeting specific regions and building or enhancing technical, regulatory and commercial competencies in those regions will help pharma industry to reach its export target for 2023

In this context, Turkish pharma industry aiming to focus on three key regions - EU15, MENA and CIS- to reach ~$17 Bn target by 2023

- Developed EU15 countries will continue to be the key driver of Turkish pharma export growth; growth target is 31% per annum till 2023
- Increasing penetration in MENA and CIS will be another lever to boost pharma exports; targeted growth rates are 34% and 35% per annum for MENA and CIS, respectively
- Export to North America aimed to continue growing at a high rate of 42% per annum till 2023

Achieving the export targets set by the Turkish pharma industry will be possible by working closely and collaboratively with the relevant institutions of the Turkish Government

- Collaboration with regulatory agencies in target regions should be increased to reduce technical barriers delaying market authorization (e.g., mutual recognition, participation to PIC/S[1])
- Foundation of a pharma-specific export promotion agency
- Promotion of Turkish pharma industry via roadshows in target countries; with participation and support from Government

1. PIC/S = Pharmaceutical Inspection Scheme

Note: For pharma exports, only products classified under HS code #30 taken into consideration

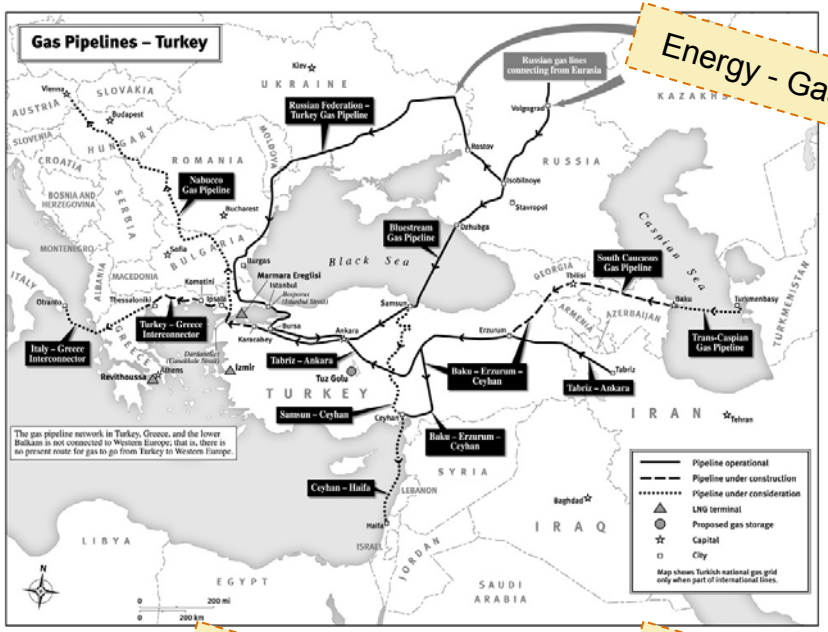
Source: Interviews, Intracen, BCG analysis

Geo-politic importance of Turkey

Turkey strategically located in between EU and CIS, while enjoying proximity to newly emerging countries in MENA

In various sectors ...

Energy - Gas



Telecom – Fiber silk road

Telecom - TTJadi

... Turkey is connected to neighboring regions

EU access negotiations on-going; further harmonization with EU expected in trade and regulations

- Trade-wise Turkey is almost integrated with EU
- Full EU-integration potential is a reality for Turkey

Extremely close to newly emerging countries in CIS and MENA

- Access to West and Central Asian countries
- Offers easy access (proximity) to all such nations without the risk
- Strong cultural ties especially with CIS region

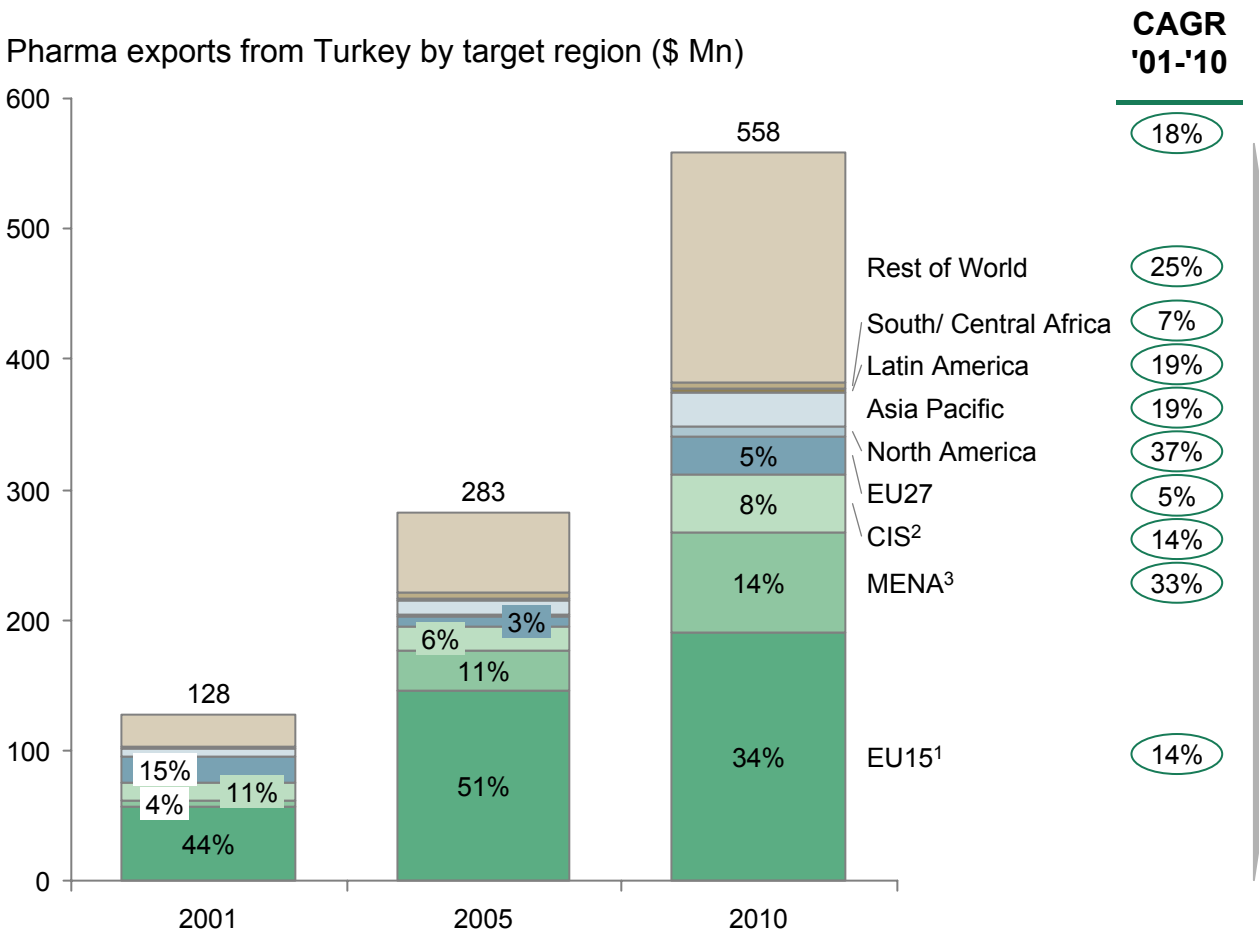
Turkey is a gateway to energy resources such as gas and oil pipelines in the region

Turkey, with Russia, is the leader in Black Sea Economic Corporation

Note: JADI name derives from the initials of the following cities; Jeddah (Saudi Arabia), Amman (Jordan), Damascus (Syria) and Istanbul (Turkey); it is an integrated multi-pass fiber optic network. The silk road is also similar covering Fujairah (United Arab Emirates) going over Riyadh (Saudi Arabia), Amman (Jordan) and Tarsus (Syria) to reach Istanbul. For the first time in Middle East, covering the entire Gulf area and having a total distance of 7750 km with its spare structure, the RCN Project will be the longest terrestrial fiber optic infrastructure in the region between Fujairah and the West
Source: Literature research, BCG analysis

Historical pharma export evolution

Geographic proximity puts EU-15, MENA and CIS as the largest markets for Turkish pharma industry ...



Albeit decreasing, EU15 still has the highest share in pharma exports

- Share decreased due to drops in export value in '06 and '09

MENA experienced 33% growth rate between '01 – '10

- Raised its share to 14% of total exports by '10; up from 4% in '01

Exports to N. America have highest growth rate in '01-'10

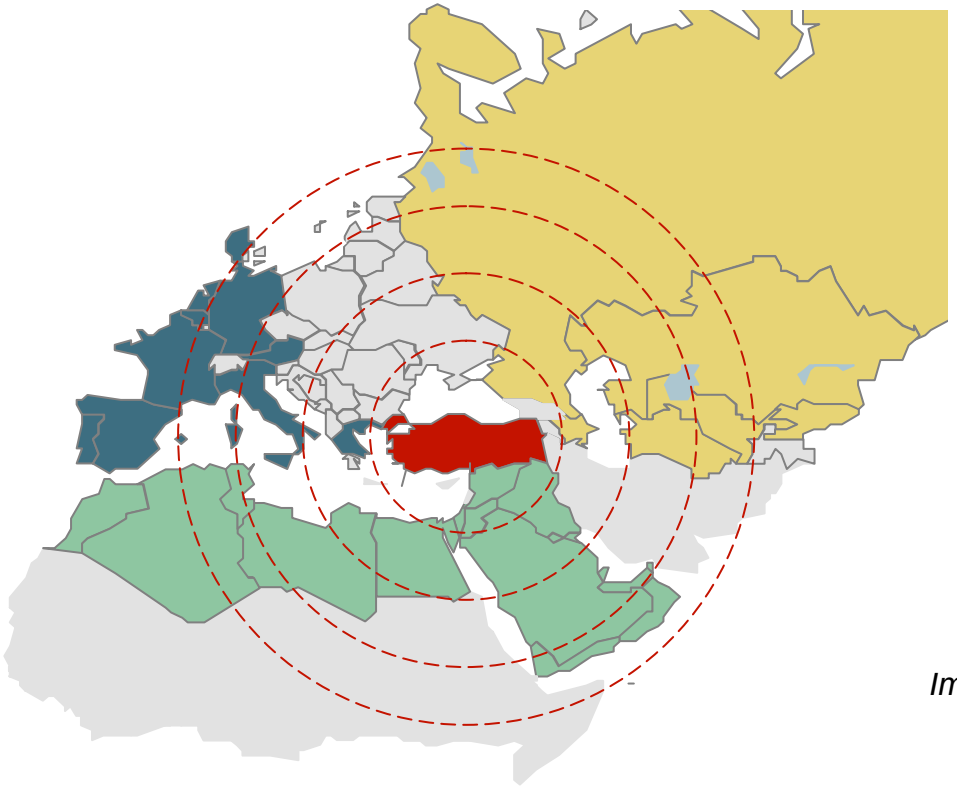
Very low growth export towards EU27

- Partly due to decreasing trend in 2001-2005

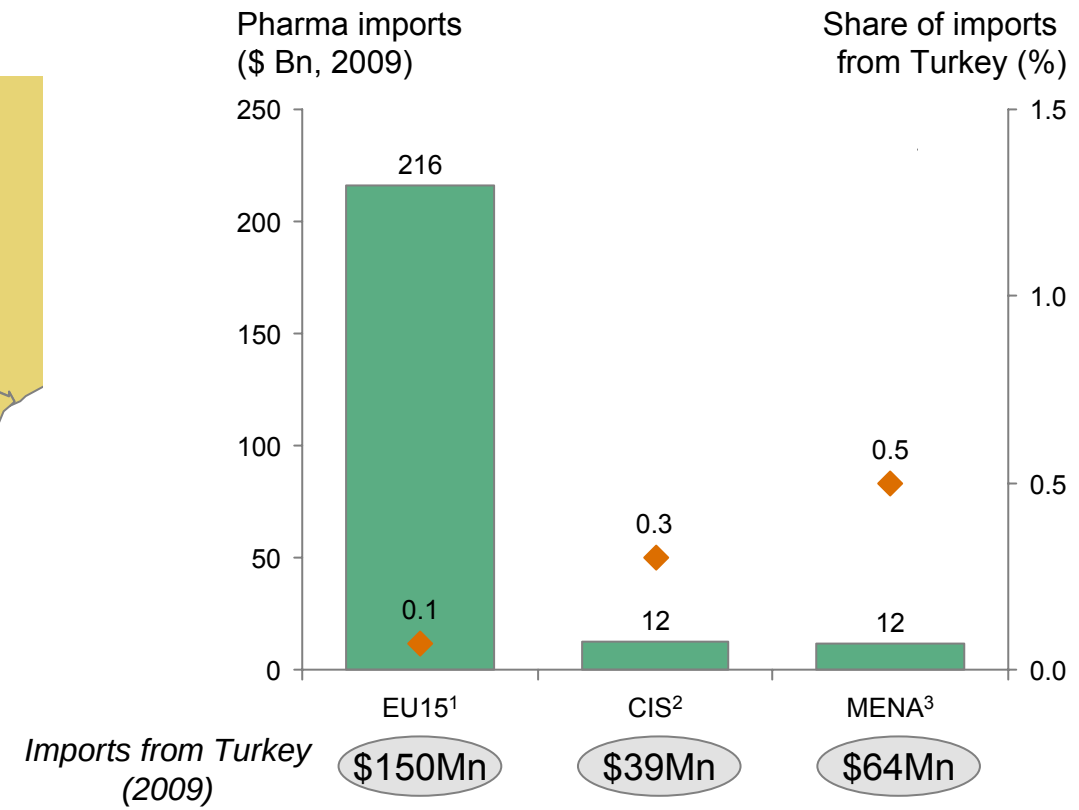
1. Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom. 2. Russia, Kazakhstan, Uzbekistan, Azerbaijan, Kyrgyzstan, Turkmenistan, Tajikistan, Georgia ,Ukraine 3. Saudi Arabia, Algeria, United Arab Emirates, Egypt, Iran, Lebanon, Morocco, Tunisia, Kuwait, Jordan, Iraq, Libya, Sudan, Yemen, Oman, Syria, Qatar, Bahrain
Note: Only products classified under HS code #30 taken into consideration
Source: Intracen, BCG analysis

... However, currently Turkish pharma industry take less than 1% share in EU15, MENA and CIS pharma imports

Turkey has unique position to be pharma manufacturing hub for EU15, MENA and CIS



Current penetration of Turkish pharma industry in these regions at low levels

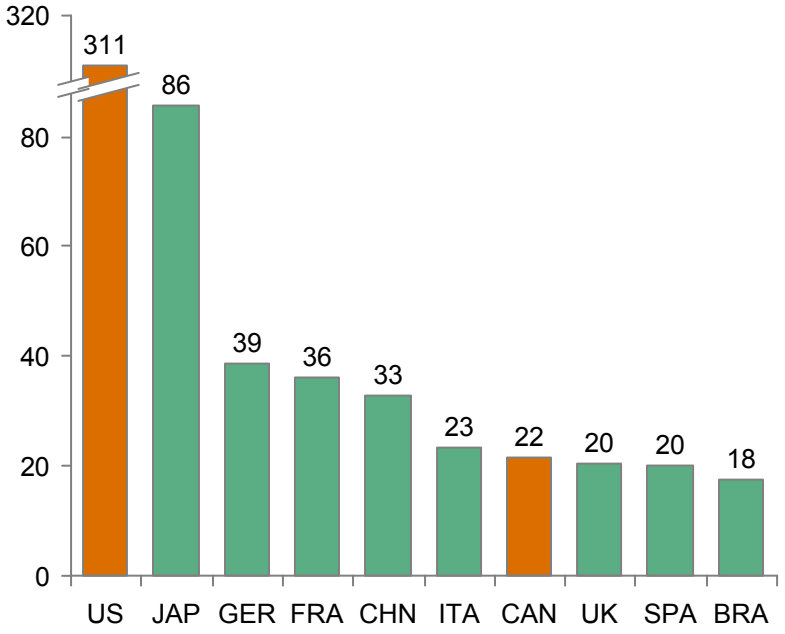


1. Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom. 2. Russia, Kazakhstan, Uzbekistan, Azerbaijan, Kyrgyzstan, Turkmenistan, Tajikistan, Georgia ,Ukraine 3. Saudi Arabia, Algeria, United Arab Emirates, Egypt, Iran, Lebanon, Morocco, Tunisia, Kuwait, Jordan, Iraq, Libya, Sudan, Yemen, Oman, Syria, Qatar, Bahrain
Note: Only products classified under HS code #30 taken into consideration
Source: Intracen, BCG analysis

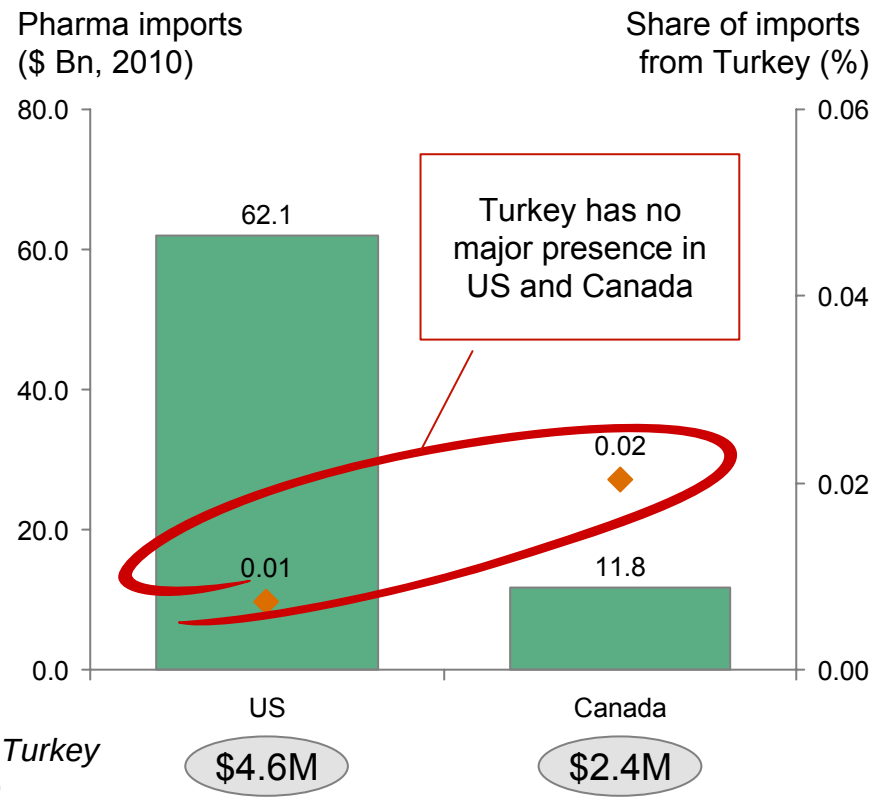
In North America, share of pharma imports from Turkey is very low in comparison to total pharma imports of the region

US and Canada among top 10 pharma markets in the world

Top 10 countries according to pharma market size[1]
($ Bn, 2010)



Turkish pharma does not have significant share in ~$74 Bn valued pharma imports of N. America

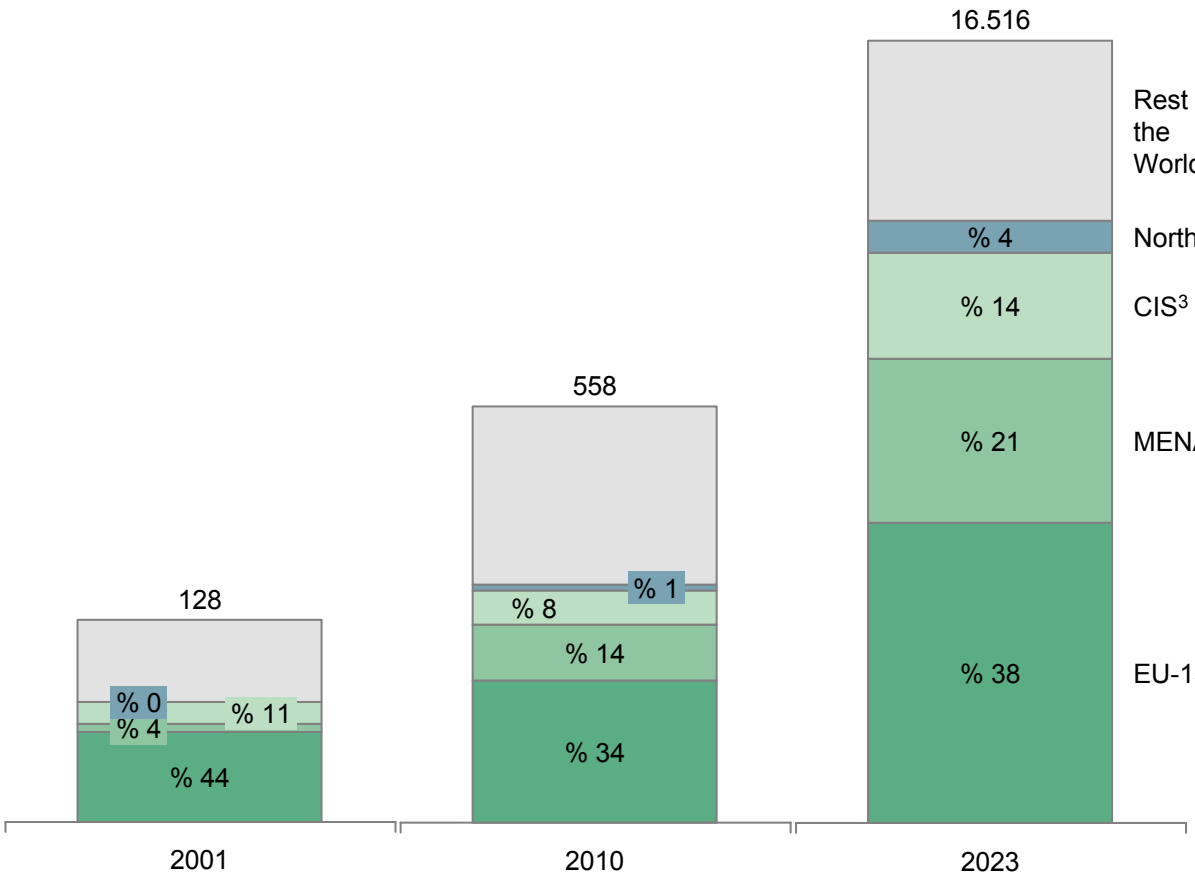


1. At ex-manufacturer prices
Note: Only products classified under HS code #30 taken into consideration
Source: Intracen, IMS, BCG analysis

Region based pharma export target

Exports to four target regions –EU15, MENA, CIS and North America– will represent ~77% of total pharma exports by 2023

Pharma exports from Turkey by target region ($ Mn)



	CAGR '01-'10	CAGR '10-'23
Rest of the World	19%	24%
North America[4]	37%	42%
CIS[3]	14%	35%
MENA[2]	33%	34%
EU-15[1]	14%	31%
	18%	30%

1. Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom. 2. Saudi Arabia, Algeria, United Arab Emirates, Egypt, Iran, Lebanon, Morocco, Tunisia, Kuwait, Jordan, Iraq, Libya, Sudan, Yemen, Oman, Syria, Qatar, Bahrain 3. Russia, Kazakhstan, Uzbekistan, Azerbaijan, Kyrgyzstan, Turkmenistan, Tajikistan, Georgia ,Ukraine 4. US and Canada
Note: Only products classified under HS code #30 taken into consideration
Source: Intracen, BCG analysis

Recommended actions

In given conditions, five main actions proposed to increase penetration in target regions

Lever		Action	Owner
Ease market authorization in target regions	C1	Ease market authorization and regulatory compliance monitoring in target regions/ countries (e.g., mutual recognition, PIC/S[1] participation)	Ministry of Health
Promote Turkish pharma industry in international markets	C2	Establish pharma export promotion agency	Ministry of Economy
	C3	Organize roadshows to target regions to promote Turkish pharma industry and overcome challenges	Ministry of Economy
	C4	Leverage off-set trade negotiations for energy imports to increase pharma export (i.e., include export of pharma goods to negotiations for energy import from CIS and MENA countries)	Ministry of Economy
Improvement of export and foreign trade capabilities	C5	Improve organizational capabilities of local pharma producers in order to increase their competitiveness in international markets (e.g. setting up representative offices or strengthening presence in target markets)	Pharma industry

Priority actions detailed in the following pages

1. PIC/S = Pharmaceutical Inspection Cooperation Scheme
Source: Interviews, BCG analysis

Technical barriers on registration and inspection processes can be reduced by Government agreements with target countries

Market authorization is a technical barrier in international trade of pharmaceuticals

Global standards defined in pharma industry to ensure safety, efficacy and quality

- WHO plays an active role in definition of quality standards in pharmaceuticals (e.g., GMP[1], GLP[2], GCP[3])

Regulatory agencies apply strict market authorization regulations to maximize benefits to human health and reduce risks at the same time

- Agencies responsible for coordinating inspections in connection with market authorization applications; these inspections may cover clinical studies and production

Market access has to be approved by applying to regulatory agencies in countries

- Length of market authorization process can be an important factor in commercial success of pharma drugs

Possible levers that can be used to ease market authorization procedures:

- Mutual recognition agreements would be established with regulated countries; namely EU and US, to reduce the time lost and costs incurred during lengthy registration and inspection processes
- GDDP[4] would be a part of international regulatory organizations such as PIC/S to increase harmonization with international regulations, to increase information sharing and to increase trustworthiness of Turkish pharma industry
- GDDP would position itself as a role model and support its counterparts in MENA & CIS countries

1. GMP = Good Manufacturing Practices 2. GLP = Good Laboratory Practices 3. GCP = Good Clinical Practices 4. General Directorate of Pharmaceuticals and Pharmacy in Turkey
Source: Literature research, BCG analysis

Harmonization of market authorization on-going in EU and MENA; individual country authorization running in parallel

Regions	Regulatory environment
EU	**Four regulatory ways of approving market authorization of drugs in EU** • Centralized procedure: – European Medicines Agency (EMEA) responsible for scientific evaluation and marketing authorization of medicines – The centralized procedure is mandatory for biologicals, cancer, HIV, diabetes and neurodegenerative disorder product, orphan drugs • Decentralized procedure – Companies can apply for the simultaneous authorization in more than one EU country of a medicine that has not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure • Mutual recognition among EU members – Companies that have a medicine authorized in one EU member state can apply for this authorization to be recognized in other EU countries • National drug authority – Companies can apply for authorization to regulatory body (e.g., BfARM (Germany), MHRA (UK), AIFA (Italy), AFSSA (France)) in single EU country
MENA	**Joint committee, Gulf Central Committee for Drug Registration (GCC-DR), established in 1999 between Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the UAE** • Market authorization, inspection of manufacturing facilities for GMP compliance are some of the activities of GCC-DR • GCC-DR runs concurrently with domestic regulatory bodies and is unlikely to replace them in the short term **Each individual country has also its own regulatory agency for marketing authorization of pharma drugs**

Source: EMEA, Business Monitor International, literature research, BCG analysis

Marketing authorization under control of regulatory agencies in individual countries in CIS and North America

Regions	Marketing Authorization and Inspections
CIS	**In general lengthy and bureaucratic marketing authorization in CIS countries** • In Russia, Roszdravnadzor responsible for market authorization of pharma drugs • Protectionist approach adopted hardening market authorization of imported drugs **Efforts to harmonize regulatory system on-going between CIS Custom Union members Russia, Belarus and Kazakhstan** • Targeted to be completed by 2011; delay expected
North America	**Food and Drug Administration (FDA), within US Department of Health and Human Services, responsible for marketing authorization and inspection of pharmaceuticals in US** • Center for Drug Evaluation and Research (CDER) is the regulatory authority to approve novel chemical compounds and evaluates bioequivalence for generic compounds • Center for Biologics Evaluation and Research (CBER) is the branch that approves biologics and vaccines **Canadian Agency for Drugs and Technologies in Health (CADTH) is the regulatory agency responsible for marketing authorization and monitoring of safety, efficacy and quality**

Source: Business Monitor International, literature research, BCG analysis

International agreements can ease the marketing authorization process and thus increase pharma exports: Mutual recognition

Mutual recognition agreement (MRA)

Bilateral agreements between countries aiming to benefit a specific industry by providing easier access via recognizing one another's conformity assessments

MRAs reduce barriers in international trade by using exporting country's tests and standards

Basis of MRA is the use of the exporting country's tests and standards

- Such MRAs allow an importing country's regulatory agencies to use tests and standards of the exporting country in evaluating products

In pharma, scope of MRAs can be registration as well as GMP/ GLP compliance

- Harmonization of inspection and approval procedures not necessary; but it can be complementary to MRAs

MRAs actively leveraged to smoothen international trade of pharma drugs

EU signed MRAs for GMP compliance with six countries

- Australia: fully operational since 1999
- Canada: in operation[1] since 2003
- Japan: operational since May 2004 with limited scope
- New Zealand: fully operational since 1999
- Switzerland: fully operational since 2002
- US: not in operation

Indian works on bilateral or multilateral agreements with CIS nations to improve pharma exports

MRAs are the primary tools to remove technical barriers, shorten durations and hence increase exports

1. Except for preapproval inspections and medicinal products derived from blood or blood plasma

Source: European Union website, EMEA, literature research, BCG analysis

International agreements can ease marketing authorization and inspection processes and thus increase pharma exports: PIC/S

Type of agreement	Description
Pharmaceutical Inspection Cooperation Scheme (PIC/S)	**A co-operative agreement to improve cooperation in GMP issues (training of inspectors, mutual quality standards, etc.)between regulatory agencies in different countries** • Initially funded in 1970 (as Pharmaceutical Inspection Convention, PIC) by European Free Trade Association • In 1990s, it was realized that PIC is incompatible with European law; as European law does not permit individual EU countries to sign such agreements with countries outside EU • As a consequence PIC/S formed in 1995 as an informal agreement between regulatory agencies instead of a formal treaty between countries • Purpose of PIC/S is to facilitate networking between participating agencies and maintenance of mutual confidence, exchange of information and experience in GMP **More than 35 regulatory agencies, including US FDA and almost all agencies of EU countries, are members of PIC/; GDPP in Turkey is not participating to PIC/S** • Long-term planning required for PIC/S participation as the process lasts around 6-7 years

There is no doubt PIC/S membership will increase confidence to quality of Turkish pharma industry

Source: Pharmaceutical Inspection Co-operation Scheme website, interviews, BCG analysis

Ambitions of Turkish pharma industry necessitate establishment of pharma-specific export promotion agency

Export promotion agency

Public organization aiming to increase international competitiveness of national industries by supporting export development and promotion

Pharma-specific export promotion agency ...

Export promotion center (IGEME) under Secretariat of Foreign Trade providing cross-industry services to Turkish industry

However, pharma-specific export promotion agency required ...

- ... To coordinate pharma specific export development activities (e.g., helping companies to reach market specific information, etc.)
- ... To promote Turkish pharma industry in target markets
- ... To increase collaboration between Government and pharma industry in export-relevant topics

... with clear governance and responsibilities

Governance	• Agency would be an external arm of Government with independent board drawn largely by industry
Interaction with key stakeholders	• Agency would work closely with industry associations, IGEME and individual pharma companies in pursuit of particular export opportunities
Respon-sibilities	• Trainings (e.g., export capability development) • PR activities (e.g., representation at international trades) • Marketing authorization and market research support • Cooperation with other trade promotion agencies

Source: Literature research, BCG

Pharma export promotion agency

Indian Government established export promotion agency to support local manufacturers' globalization efforts

pharmexcil
PHARMACEUTICALS EXPORT PROMOTION COUNCIL
(Set up by Ministry of Commerce & Industry, Govt. of India)

A joint council by Government and industry ...

Arising need for one voice

- MoC&T[1] established Pharmexcil to meet needs of growing industry in a separate setup

Activities administrated by a committee consisting of industry and Government representatives

- e.g., Dr. Reddy'y, Ranbaxy, Sun Pharma, Central Government and Government of Andhra Pradesh

... Actively representing Indian pharma industry in India and abroad

Selective list of international events Pharmexcil participated in 2009-2010

- Trade delegation to ASEAN and CIS countries
- India Brand Promotion in African countries
- Catalogue Show at Vietnam and Saudi Arabia
- Arab Health 2010 at Dubai

Selective list of national events Pharmexcil attended in 2009-2010

- Seminar on export opportunities for pharma and herbal industries
- Seminar on vendor registration process with UN agencies

1. MoC&T = Ministry of Commerce and Trade
Source: Pharmexcil website, BCG analysis

Roadshows to target regions

Government-level lobbying in MENA and CIS would help reducing barriers and promote Turkish pharma industry

MENA

CIS

Major issues faced in neighboring countries …

- Protectionist approach adopted by target countries
- Lengthy and bureaucratic marketing authorization processes
- Lack of awareness for Turkish drugs
- Lack of knowledge regarding "quality" of Turkish drugs
- Finding successful and reliable partners

… Would be solved by active support of Government lobbying activities in roadshows

Moreover new business opportunities would be created

- Triggering participation of Turkish pharma companies to public tenders
- Leveraging off-set trade of pharma drugs for in response to energy import of those countries

Roadshows to MENA and CIS countries would be an effective method to demonstrate support of Government to pharma industry

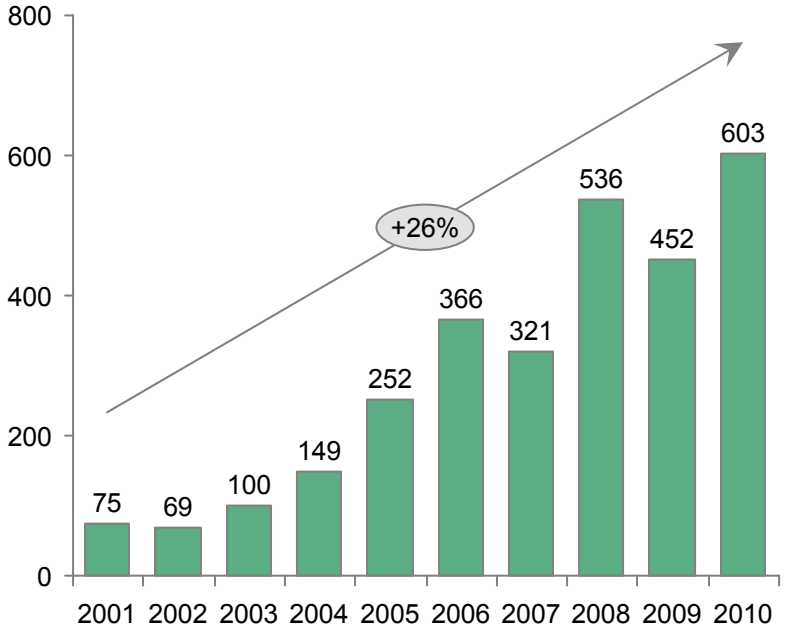
Source: BCG

Roadshows to target regions

India lobbying at top Government level and demanding better market access for pharma industry to Russia

India aiming to further increase pharma exports to Russia ...

Russian pharma imports from India ($ Mn)



... Via mutual recognition of standards and procedures in pharma

Main topics on discussion covering ...

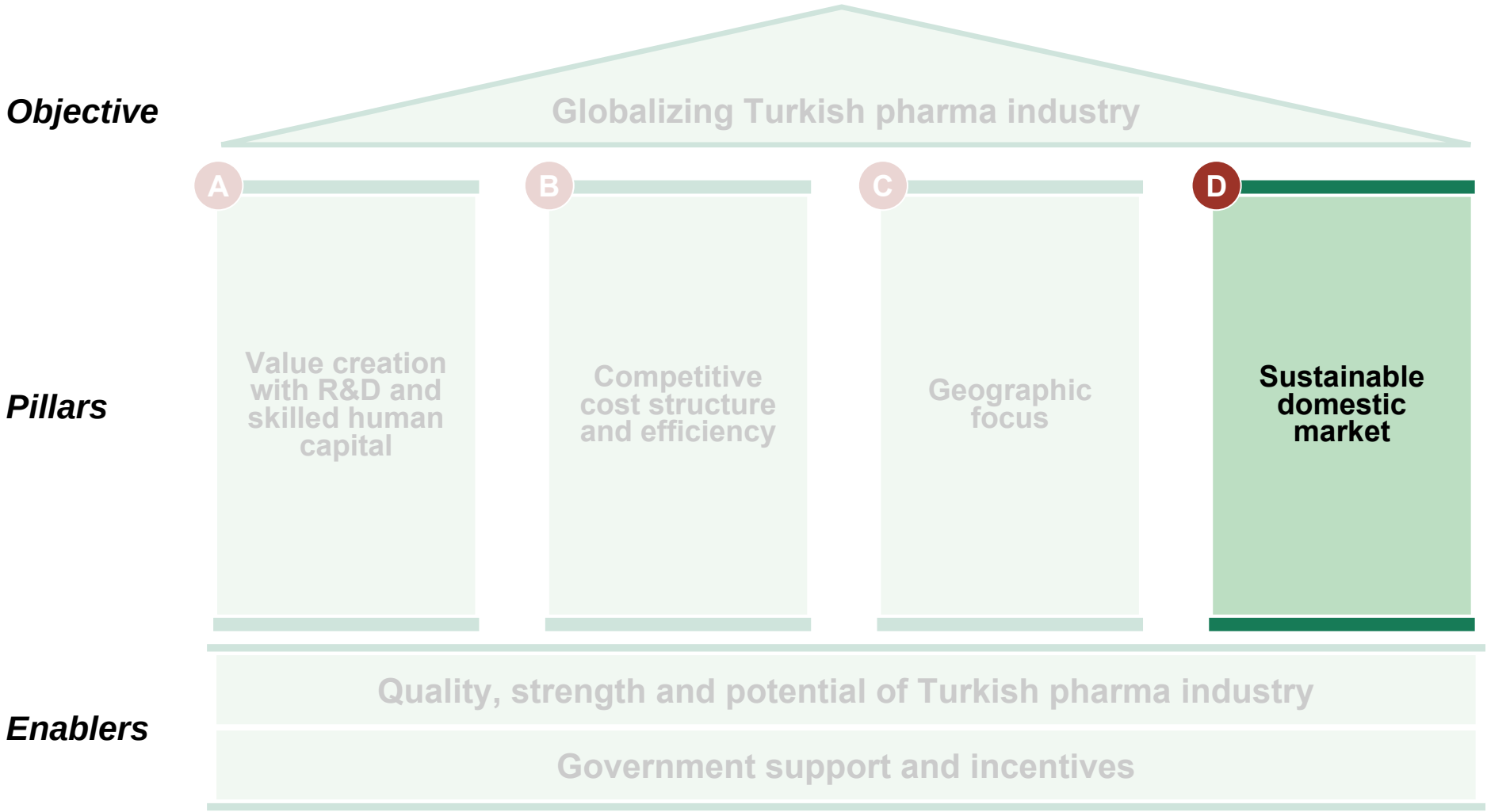
- ... mutual recognition of standards and institutions
- ... simplified work permits and business visas

"Indian exports would get a major boost if Russia and India could mutually recognize each other's pharma sectors"

Ambika Sharma,
Deputy Secretary General of Indian Chambers of Commerce & Industry, June15th, 2011

Source: Intracen, literature research

Reaching globalization target dependent on implementation of 4 key pillars with industry efforts and Government support



Source: BCG analysis

Executive summary

Sustainable domestic market

Turkish pharma spending has been increasing in the recent years, driven mainly by changing social policies and key socioeconomic variables

- Changing social policies led to increasing primary care and hospital visits and social security coverage
- Aging population, increasing life expectancy and increasing GDP per capita are key socioeconomic trends

Government contained pharma market growth by introduction of several price cuts under pharma budget capping

- Gov't is the payor of ~85% of total pharma spending[1], keeps public HC expenditures at 15% of all expenditures
- "Price cuts" under budget capping is the main policy to contain pharma spending.

A comparison of drug prices among 34 countries indicate lower prices in Turkey than most countries

~80 Bn TL Turkish pharma market size[2] expected in 2023 with natural demand at pharmacy prices; with current pharma budget calculation government can only pay less than half of the pharma spending

- With current methodology, pharma budget will amount to 41% of 80 Bn TL expected market size in 2023

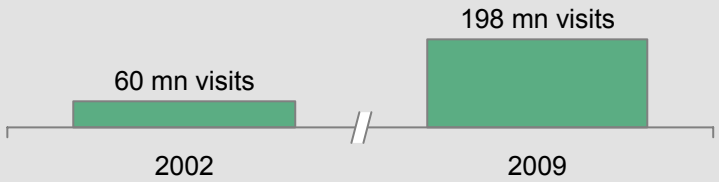
Government has various options to align pharma budget size and pharma market growth. Creating a win-win situation for all stakeholders should be the key goal

- Continued price cuts would endanger the sustainability of the market and reaching industry targets
- Main options include promotion of rational drug use, revision of pharma budget calculation methodology, revised co-payment scheme and increasing private insurance penetration

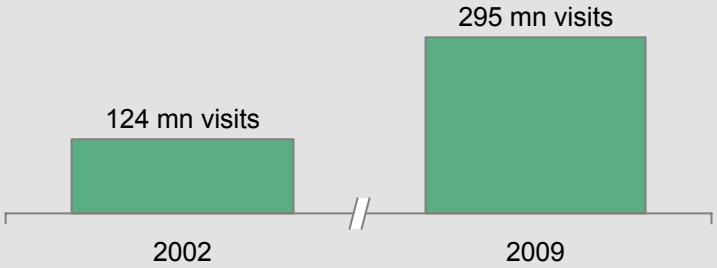
1. At ex-manufacturer prices 2. At pharmacy retail prices
Source: Interviews, BCG analysis

Increased coverage and access to healthcare services are the main enablers of growth in pharma demand

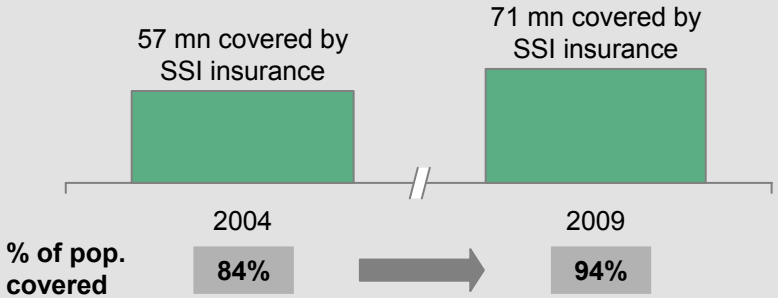
Increased access to PC facilities[1]



Increased access to hospitals[2]



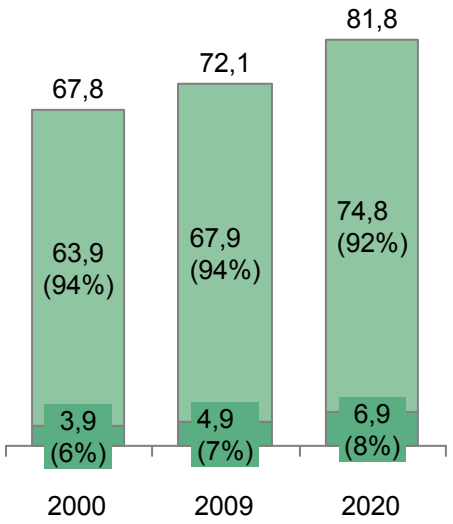
Increased social security coverage[3]



1. Family Practicioner Units + Tuberculosis Control Dispensaries + Mother & Child Health and Family Planning Centers + Health Centers 2. MoH hospitals + Private hospitals + University hospitals
3. Green Card + Pensioners + Insured + Dependents + Funds
Source: MoH statistics, SSI statistics

Changing demographics and increasing income per capita have also caused a natural growth in demand

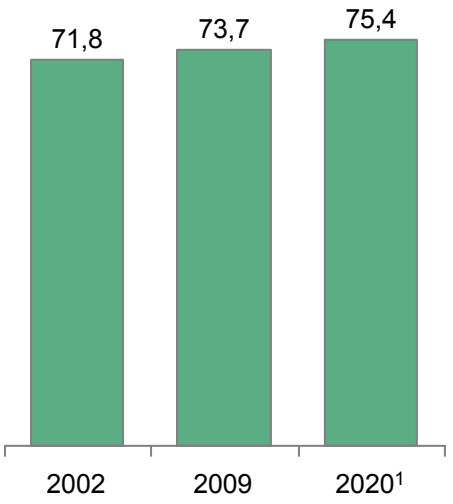
Aging population



Total population (mn)

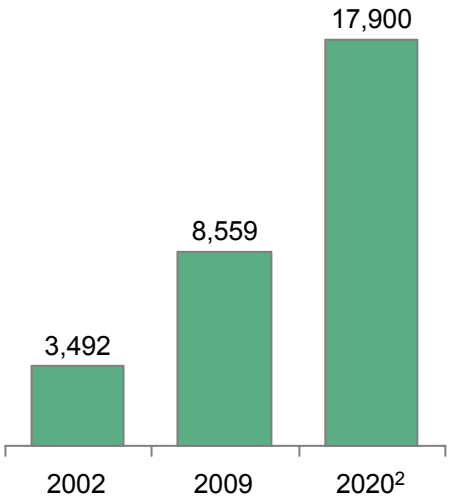
< 65 years
> 65 years

Increasing life expectancy



Life expectancy at birth (yrs)

Increasing GDP per capita

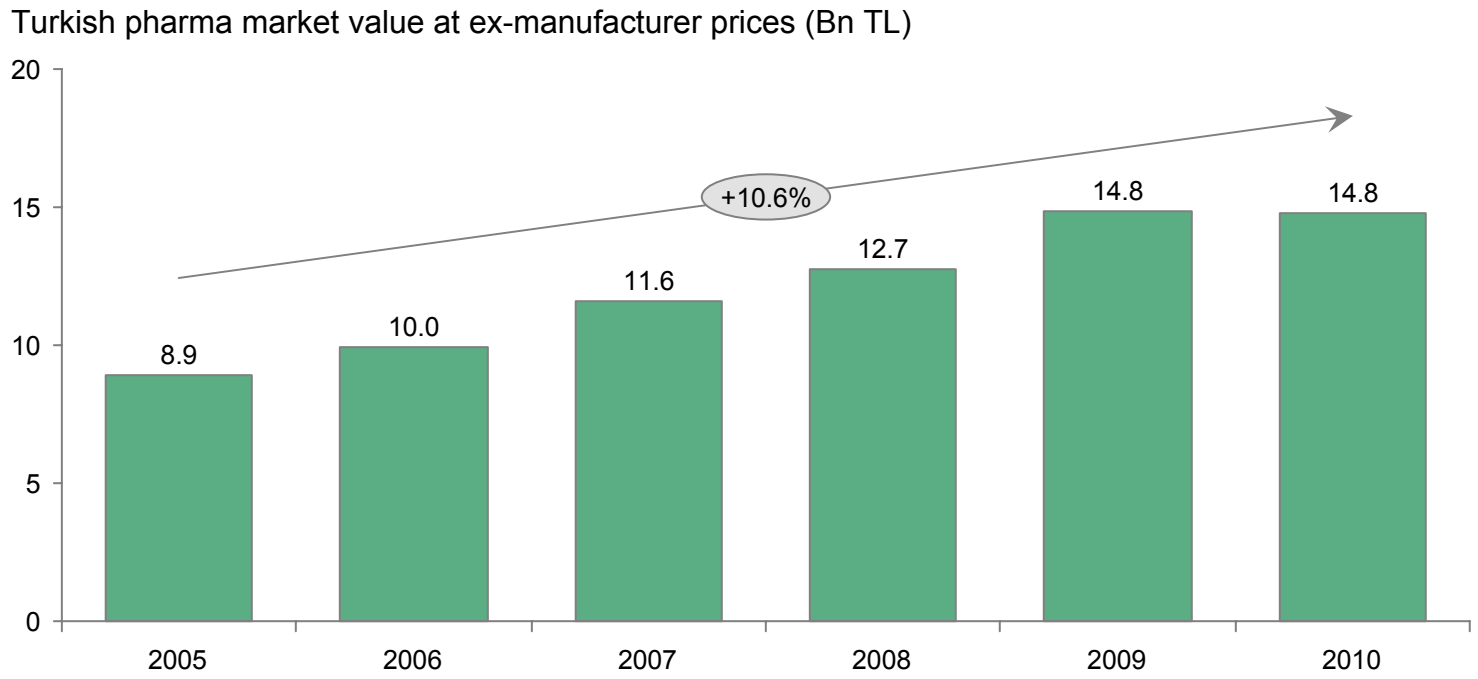


GDP per capita ($)

1. TUIK projection 2. EIU forecasts
Source: TUIK, MoH statistics, Economist Intelligence Unit (EIU)

As a result, pharma spending in Turkey has been increasing at a rapid pace over the last years

Turkey pharma market (ex-manufacturer prices)

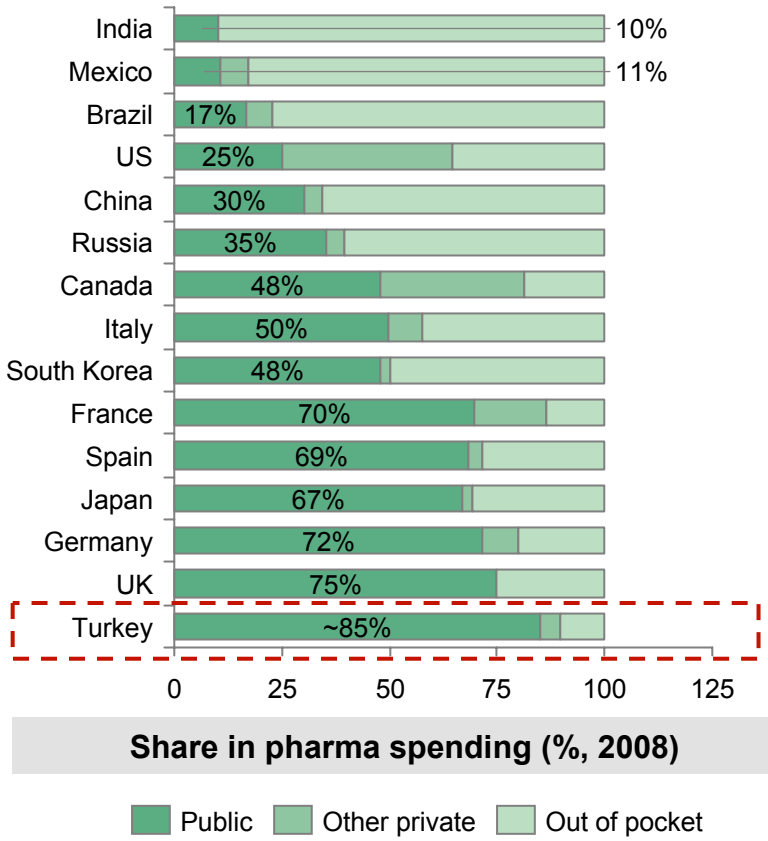


Changes in socioeconomic indicators and public policy has resulted in the growth of the Turkish pharma market

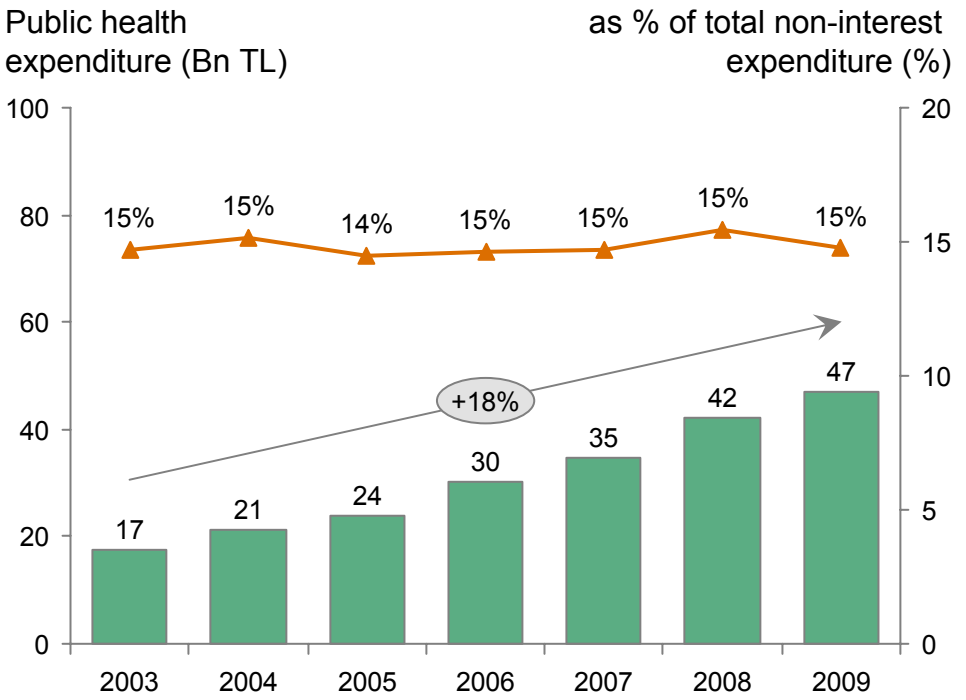
Source: IMS, IEIS, BCG analysis

Government managed to contain public budget impact of pharma demand growth

Government spends for ~85% of pharma spending in Turkey



Public health expenditures constantly amounted to ~15% of total Government non-interest expenditures



Source: IMS, Ministry of Health statistics

Price cuts and discounts were two main levers to control the public budget

Two main policies to counter pharma expense impact

1 Price cuts

- 2004 – Prices were indexed to the lowest prices in 5 different European countries. Reference drugs could take 100% of the reference price while generic drugs could take 80% of the reference price
- 2009 – Move to pharma budget[1]. Price ceiling was set at 66% of reference price for reference drugs with generics available and generic drugs
- 2009 – Drugs priced according to 1.9595 TL per € fixed exchange rate
- 2011- Price ceiling was set at 60% of reference price for reference drugs with generics available and generic drugs

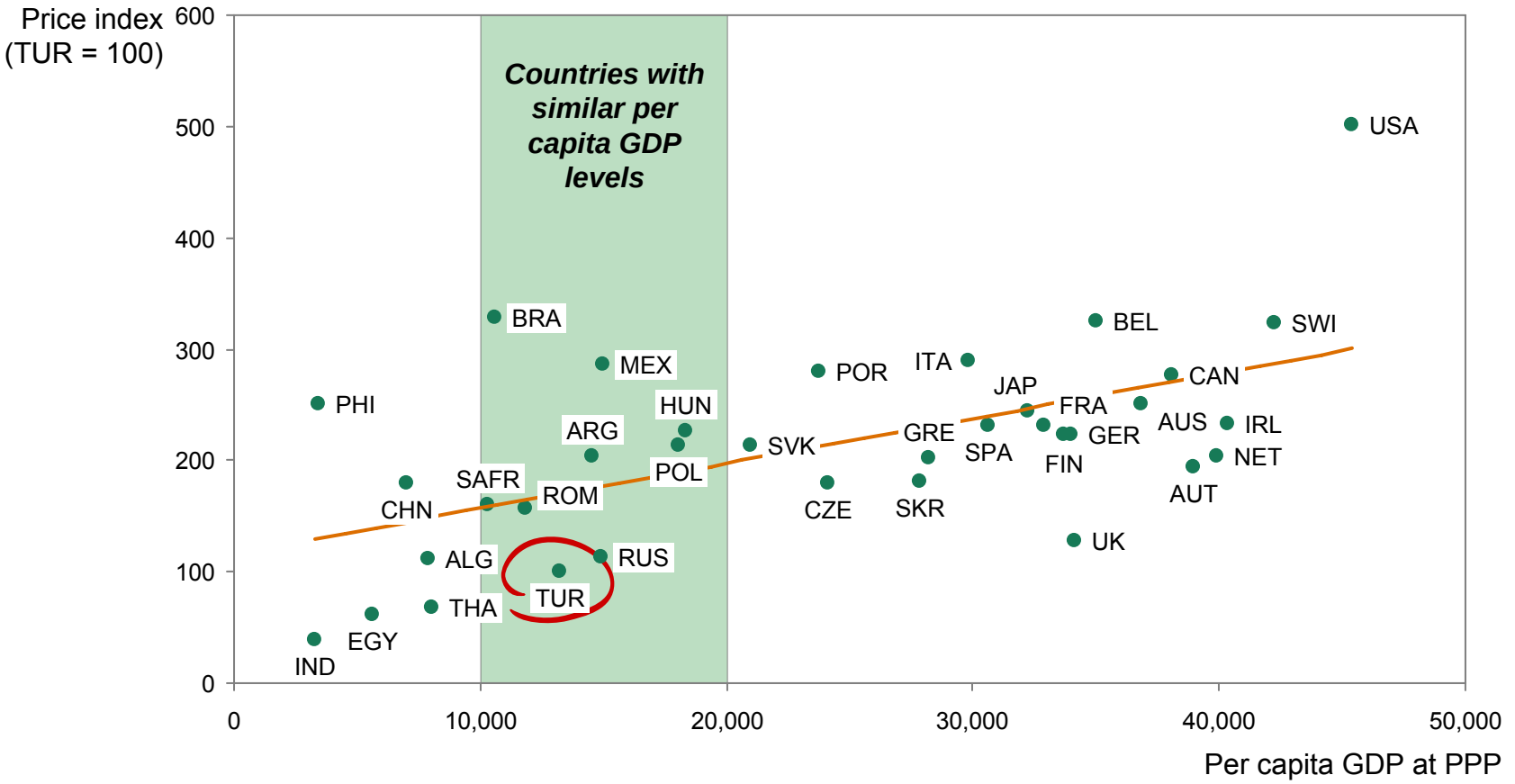
2 Discount rates

- 2005 – Upon the start of discounts, all generic drugs and reference drugs older than 6 years were given a discount of 11% while all other drugs were given a discount of 4%
- 2008 – Shift to 11% discount for all drugs
- 2009 – In scope of the pharma budget practice, reference drugs without generics were given an additional 12% discount (11%+12%)
- 2010 – 9.5% extra discount was given to all products to avoid overrunning pharma budget. Therefore, discounts on reference drugs without generics reached 32.5% and 20.5% on generics
- 2011- Discounts on reference drugs without generics reached 41% and 28% on generics.

1. Pharma Budget practice started as part of the Government's Medium Term Programme. Pharma expenditure caps for 2011, 2012 and 2013 were set at 14.6, 15.6 and 16.7 Bn TL respectively.
Source: IMS, press research, IEIS, BCG analysis

Policies have reduced pharma prices in Turkey below those in many other countries

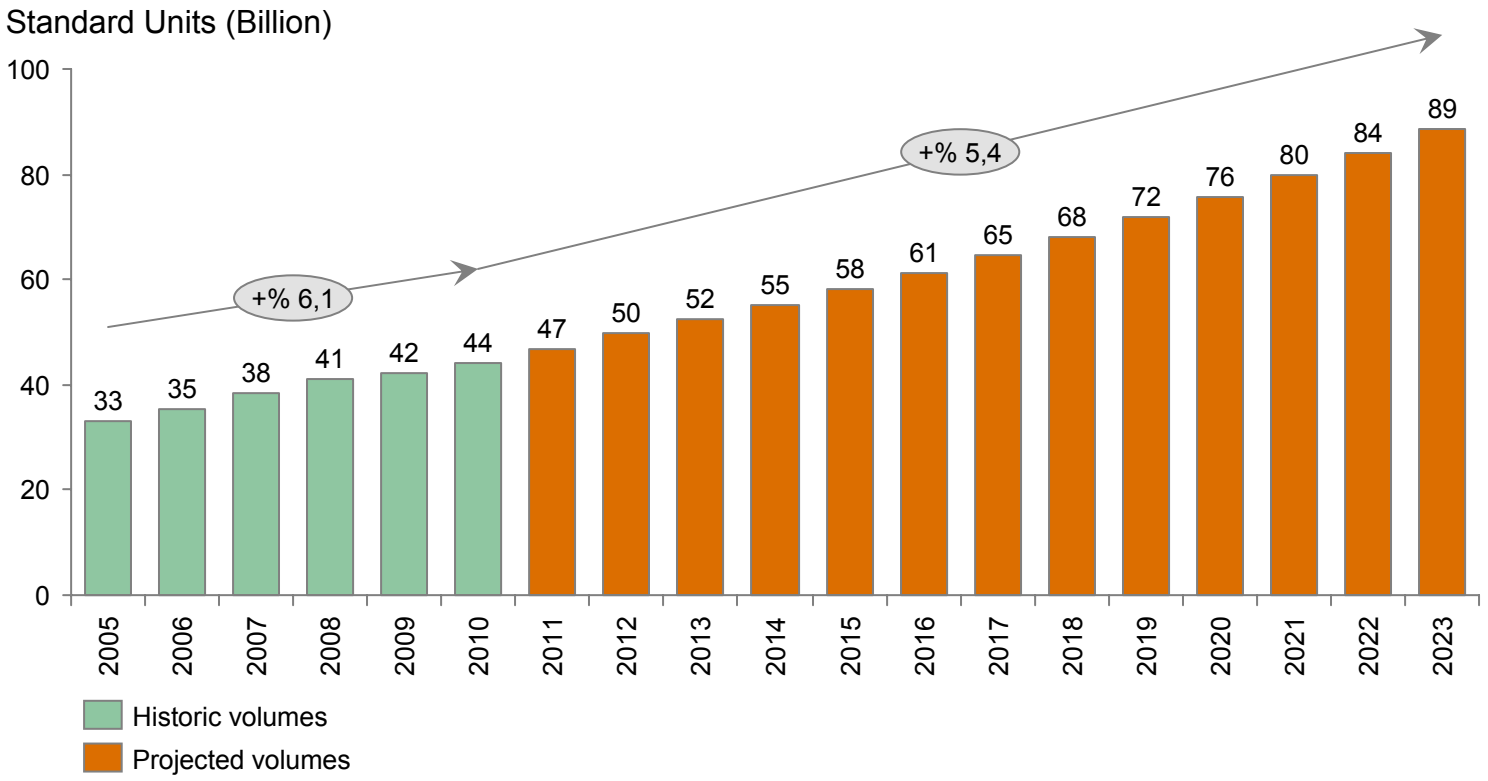
Comparison of prices among countries in 15 highest selling (by volume) ATC3 classes in Turkey



Note: 2010 data used for Turkey, 2009 data used for other countries. Chosen ATC3 classes: A10J, A2A, A2B, B1C, C7A, J1C, M1A, M2A, N2B, N6A, R1A, R3A, R5A, S1A, S1K
Source: IMS statistics, EIU

Future growth in pharma market will be driven by increasing demand and consumption

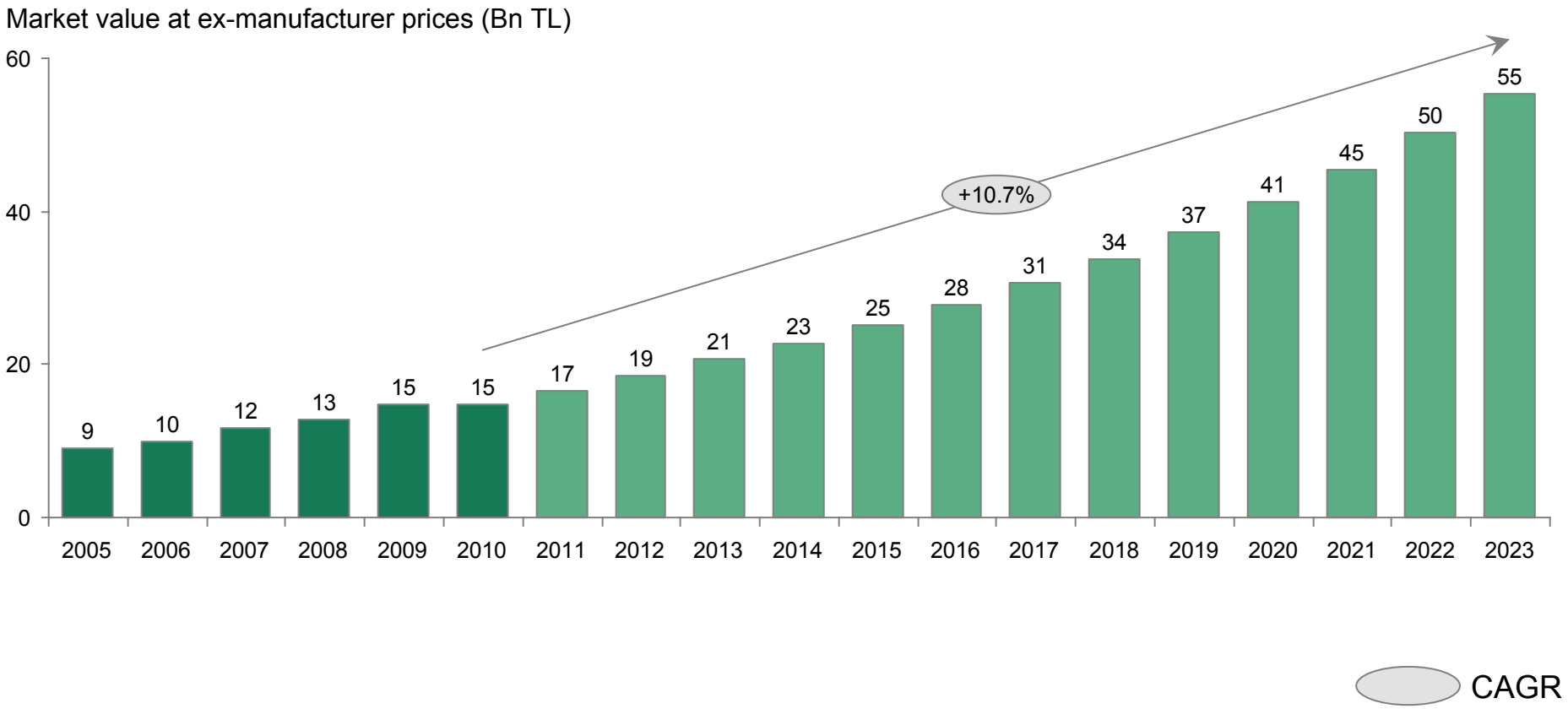
Turkish pharma market volume growth expectations



Source: İEİS, IMS, BCG analysis

Total pharma market is expected to reach 55 Mn TL by 2023 with the forecasted growth in volumes

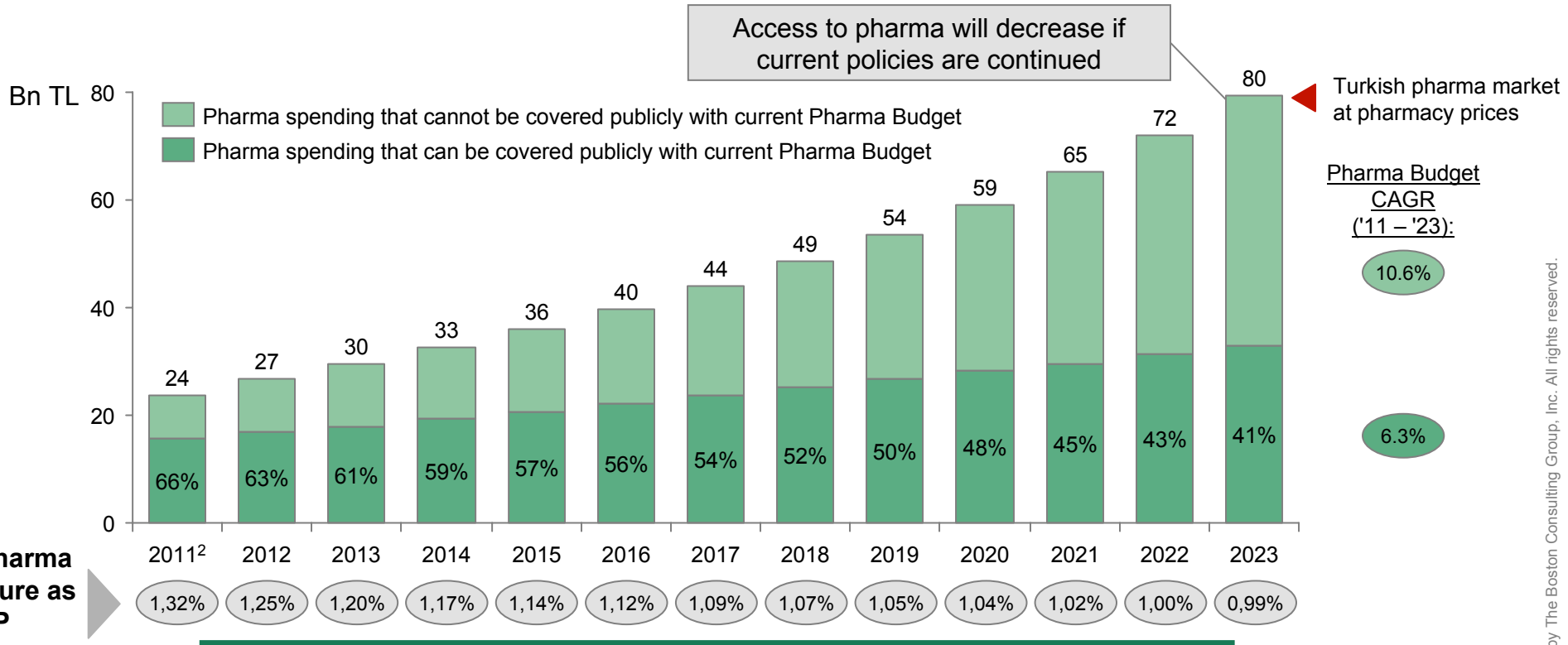
Turkish pharma market projection at ex-manufacturer prices



Note: Based on IMS market definition
Source: İEİS, BCG analysis

Public pharma spending will amount to 41% of total pharma spending in 2023 with current pharma budget methodology

Turkish pharma market projection at pharmacy prices[1]



Gov't either has to increase its own contribution or consider external options to cover the spending gap

1. 8% warehouse margin, 8% VAT, 23% average pharmacy margin added to ex-manufacturer prices
2. Gov't curently covers 80-83% of pharma expenditure, but at pharmacy prices the same this corresponds to 66%

Source: EIU, State Planning Organization, BCG analysis

Among all possible options, Government should choose the ones that would create win-win situations for all stakeholders

Options	Comments
Continued price cuts	• Further price cuts will endanger the sustainability of the market while making it difficult to reach the various targets (e.g. exports, employment) set by the industry
Promotion of rational drug use	• Increased usage of treatment guidelines will act as volume control in drug prescriptions
Increased private insurance penetration	• Increased penetration of private insurance will reduce the load on social security system
Increased co-payment / Flexible co-payment scheme	• Revision of the current co-payment scheme to increase the contributions of the insured people will reduce the load on the Gov't budget
Revision of pharma budget calculation methodology	• New methodology allowing Gov't pharma budget to grow as much as the economy will help the industry to reach its goals

Source: BCG analysis

Further reducing drug prices would endanger sustainability of Turkish pharma market

Frequent changes in pricing may have serious implications for the market ...

De-prioritization of Turkish market by global pharma players
- Low price realization and other regulatory challenges reducing the relative attractiveness of Turkish Pharma market

Cutbacks in future investments by local & global pharma players in Turkey
- Concerns on sustainability and unpredictability of pricing system discourages companies for new investments

Consolidation of local manufacturers
- Price discounts depress profit margins of small size local pharma

... while also hindering the future economic contributions of pharma

Reduced trade deficit
- $17 Bn export target by 2023

Self-sufficient local industry
- Increasing share of locally produced drugs

Increased contribution to GDP
- Focus on high value-added products

High-skilled job creation
- Increased production, intensified R&D activity

Increased economic activity
- New investments on production facilities, R&D

Increased income generation for government
- Tax generation with increased business volume

Very difficult for pharma industry to reach 2023 targets if price cuts are continued

Recommended actions

In this context, four main actions are recommended to sustain domestic market

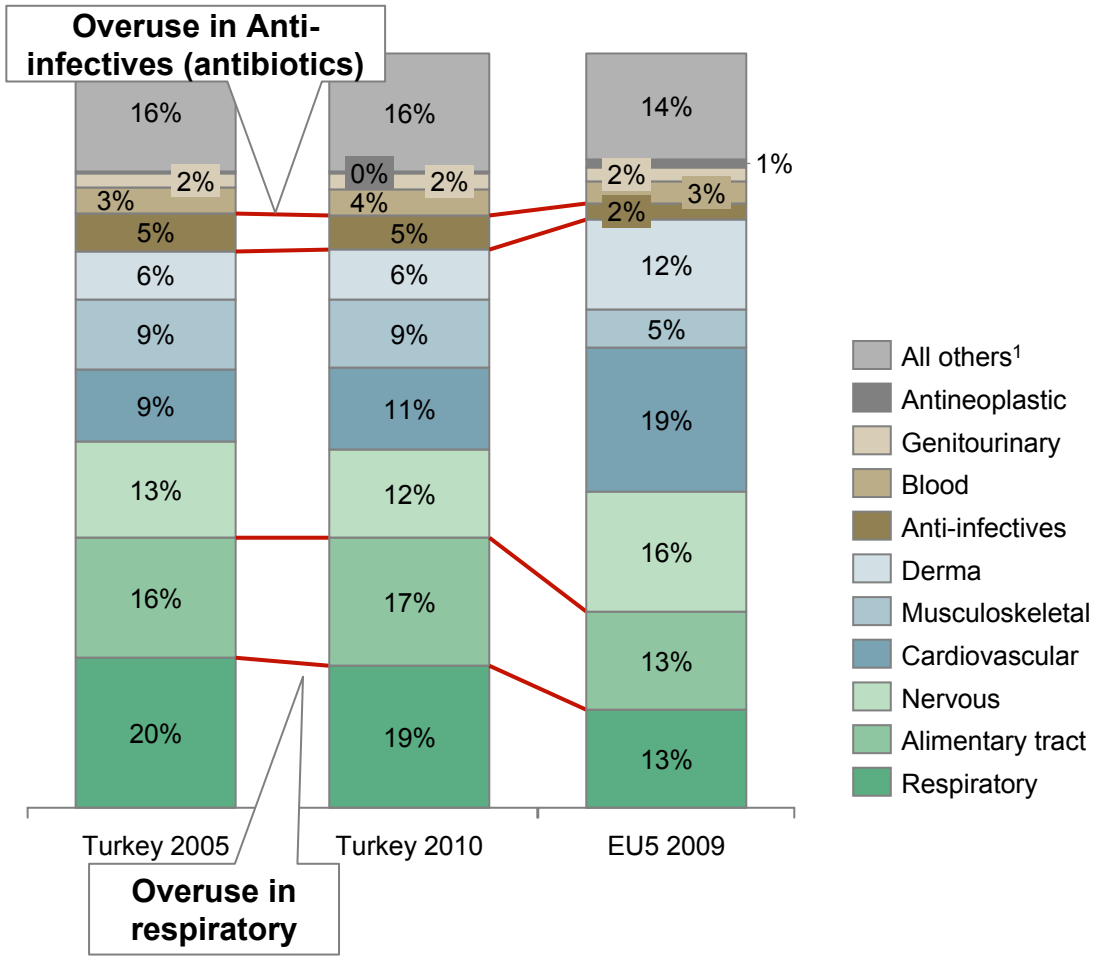
Lever	Action	Responsible
Promote rational drug usage	D1 Promote rational use of drugs via treatment guidelines	Ministry of Health
Revised budget capping methodology	D2 Budgets should be set in line with the natural growth of the sector	Ministry of Health & Social Security Institution
Increase private contribution to HC and pharma financing	D3 Redistribution of the public pharma spending to a broader base via the revision of co-payment scheme and OTC regulations	Social Security Institution
	D4 Investigate ways to increase private medical insurance penetration	Undersecretariat of Treasury

Priority actions detailed in the following pages

Source: Interviews, BCG analysis

Overuse in certain TAs justifies implementation of rational drug use guidelines

Consumption Volume by Therapeutic Area (SU)



1. Includes S, V, H, T, P, K
Source: IMS; Interviews, BCG analysis

Implications

Overuse seen in certain therapeutic areas; can be prevented by rational drug usage

- Anti-infectives (5% of Turkish market vs. 2% of EU5 countries)
- Respiratory (17% of Turkish market vs. 13% of EU5 countries)

Growth in cardiovascular expected

- Various factors linked to heart disease (e.g. obesity) increasing in Turkey

Early diagnosis of chronic diseases (e.g., hypertension, diabetes) can increase by more focus on primary and preventive HC

Rational use of drugs is a strategic target for the Ministry of Health

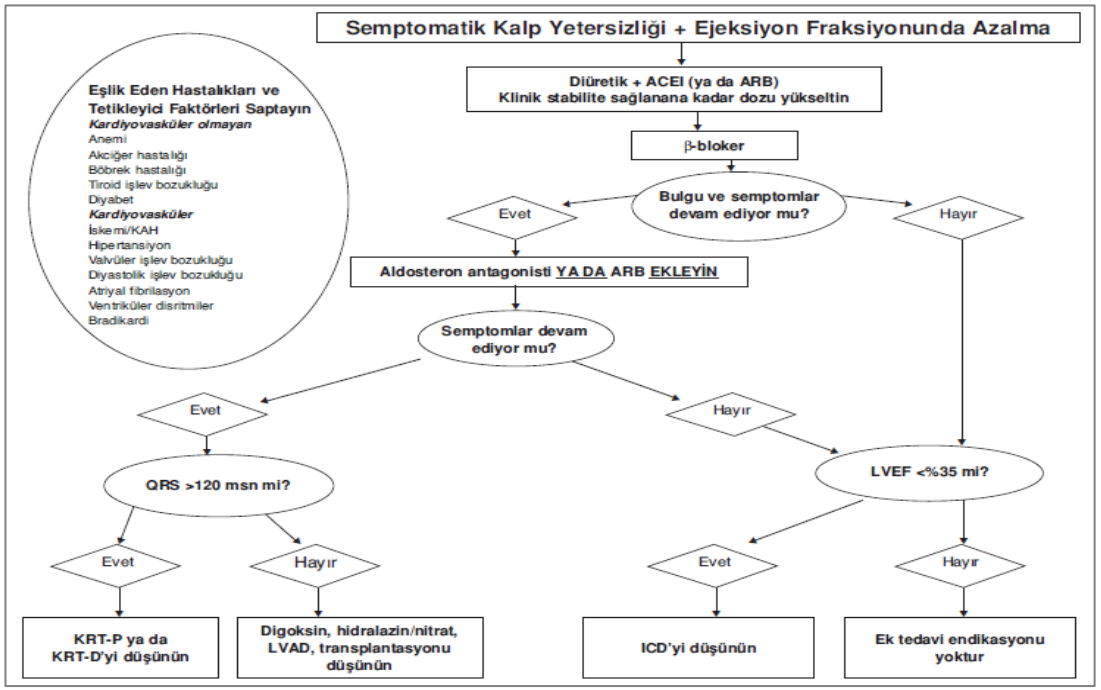
MoH Strategic Plan, 2010 - 2014

Targets	Strategies
Target 2.2.1: • To ensure that at least 95% of all doctors have the skills to diagnose and treat illnesses according to evidence-based procedures by the end of 2014	**Strategies for Target 2.2.1:** • International clinical guidelines will be adapted to Turkey and tracked via field research • Instruction on evidence-based diagnosis and treatment procedures will be included in the curricula of medical schools • Use of "Diagnostic and Treatment Guidebooks[3]" will be expanded
Target 2.6.1: • To implement rational drug use and Turkish Phama Policy[1] by the end of 2011	**Strategies for Target 2.6.1:** • Drug Tracking System[2] will be developed • Instruction on rational drug use will be included in the curricula of medical schools • A new system to incentivize and track rational drug use will be created

1. Türkiye İlaç Politikası 2. İlaç Takip Sistemi 3. Tanı ve Tedavi Rehberleri
Source: Turkish Ministry of Health Strategic Plan, 2010 - 2014

Gov't should develop and implement therapeutic guidelines across Turkey to ensure more efficient drug prescription

Illustrative example: Chronic cardiac failure treatment algorithm



- Approved by European Society of Cardiology, prepared by Turkish Society of Cardiology
- Recommend for use, but definitely not mandatory and not enforced

Current efforts

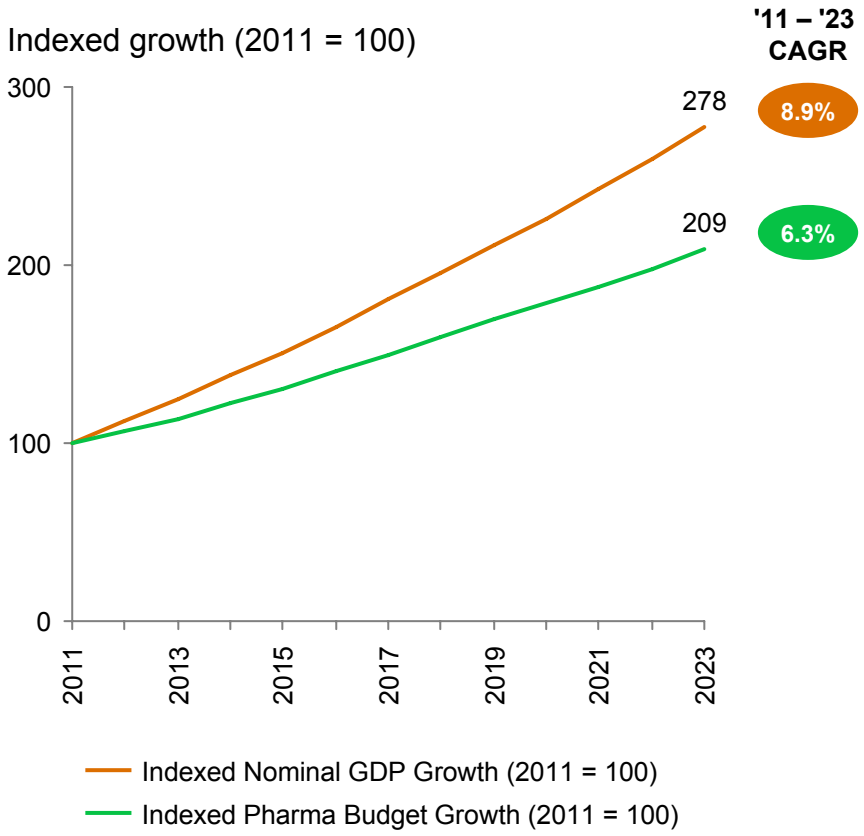
- Limited but growing number of treatment guidelines available for chronic diseases and other diseases that require public awareness, e.g.,:
  - Diabetes,
  - Chronic kidney disease
  - Chronic pains
  - Mental illnesses
- Guidelines compiled and/or prepared mainly by specialty associations and professors at leading universities

Gov't expected to be more involved in Therapeutic guideline development and application

Source: Turkish Cardiology Association, interviews, BCG research

Revision of the Pharma Budget calculation methodology should be taken into consideration to improve access to drugs and service quality

Pharma Budget vs. Nominal GDP Growth



Source: EIU, BCG analysis

Implications for the Turkish pharma sector

$$\text{Pharma Budget}_t = \text{Pharma Budget}_{t-1} * (1+ \text{GDP Deflator}_t) * (1+ \text{Real GDP Growth}_t / 2)$$

Full effect of price increases

Half effect of output (quantity) increases

Gov't budget for pharma spending lags behind GDP growth with current methodology

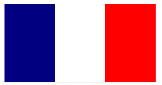
Pharma market depends heavily on Gov't spending, currently ~85% of pharma spending at ex-manufacturer prices (66% at pharmacy retail prices) covered by Gov't

Current methodology will not allow the Gov't budget to grow in line with the expected pharma demand

- With the current methodology, Pharma Budget is expected to cover 45-55% at ex-manufacturer prices (41% at pharmacy retail prices) of projected Turkish pharma market size in 2023

Revised co-payment scheme

Mature countries leverage on non-Rx products and co-payments as additional sources for healthcare spend

					
Non-RX products	**Availability**	yes	yes (217 drugs currently)[1]	yes	yes[3]
	Pricing	Free pricing	Free pricing	Free pricing	Free pricing Reimbursed for children under 12
Co-payments	**Availability**	yes	yes	yes	yes
	Details	Charge of 6.50 GBP per prescription but many exemptions	Co-payments ~30% usually covered by PMI[1] , many exemptions	Small co-payments, Income-based payments in discussion	Prescription charge 5€-10€ but several exemptions

1. Many drugs are in direct competition with reimbursed drugs and therefore market doesn't evolve very quick 2. Only very small share distributed in drugstores 3. Main self medication groups are cough and cold, analgesics, digestives, skin treatment, vitamins and minerals 4. Approval needed beforehand
Source: AESGP; IMS health; BAH; BCG analysis

Co-payment practice can be broadened via introduction of variable co-payment, decreasing the burden on Gov't budget

Co-payment currently in place for outpatient prescriptions

Co-payment applied at different rates to different groups of insured

- 10% co-payment requested from pensioners and dependents
- 20% co-payment requested from all other groups of insured

Co-payment is not requested from drugs on the "Co-payment Exempt Drugs List"

Payment of co-payments are conducted in the format of

- Deductions from payments made by SSI to pensioners and dependents
- Collection by pharmacies for all other groups

Variable Co-payment system can be implemented to differentiate acute & chronic drugs

Aim of setting different co-payment rates to different patient groups

Indicative

	Acute drugs	Chronic drugs
Retired	15%	10%
Working	30%	20%
Exempt	0%	0%

Exemptions to be defined according to social needs

- Green Card holders
- Pregnant women (dependent or insured)
- People with mental diseases
- Dependent children <=12 years old

Annual maximum cap of 330 TL[1] per insured can be set for co-payments

1. Half of current net monthly minimum wage
Source: " Sosyal Güvenlik Kurumu Sağlık Uygulama Tebliği"

Revision of non-Rx products regulations should also be implemented to ease the burden on Gov't budget

Improvement of non-Rx drug regulations seems key to free resources

Revision of current regulations on self medication and **the list of relevant drugs seem relevant**

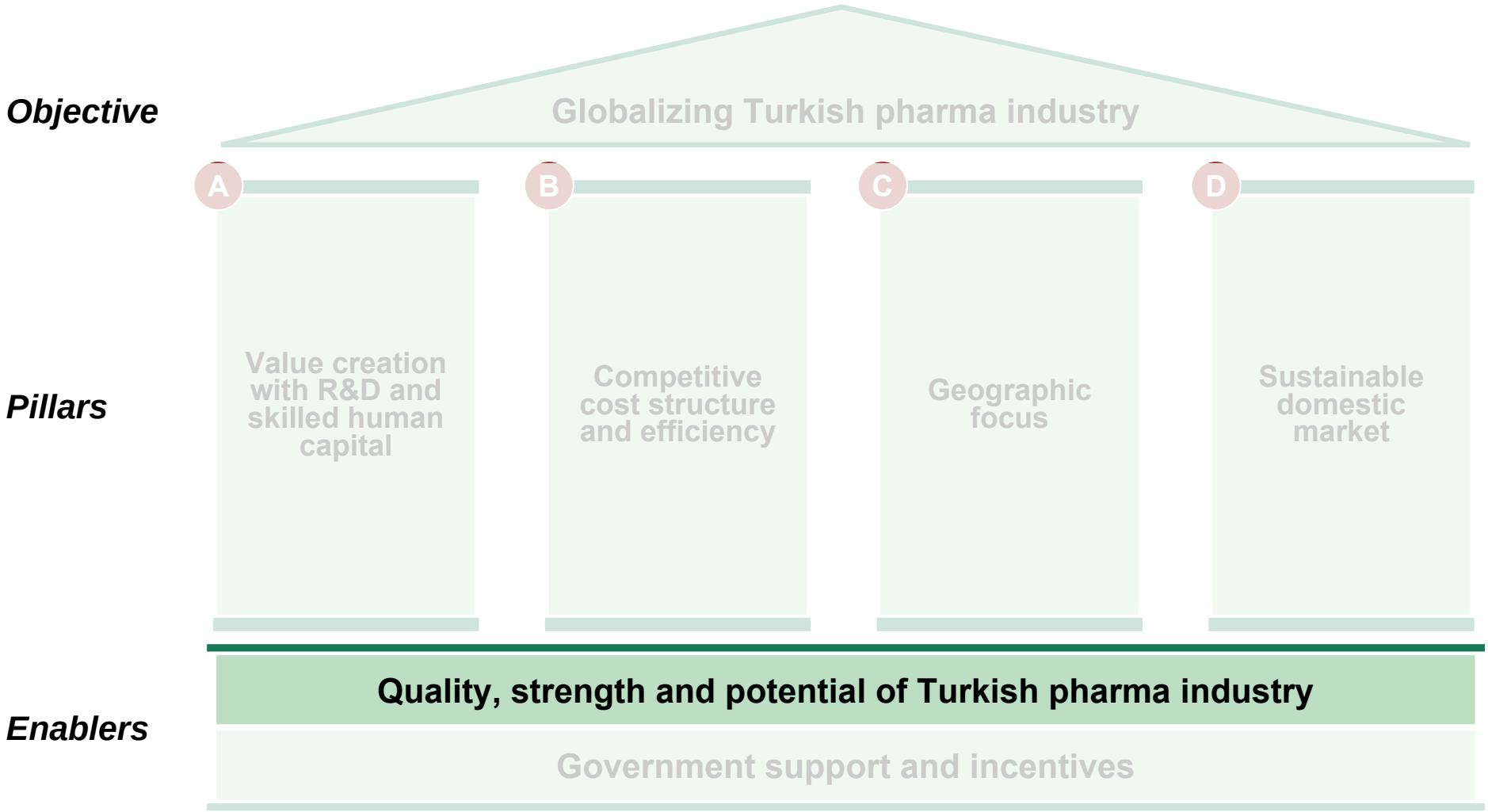
For drugs specified as self medication relevant following points are proposed:

- The **pricing should be free**
- **Advertising should be allowed** to public with appropriate control by authorities
- **Distribution** of self medication drugs **should remain in the pharmacies**

Impact of co-payment would increase with the tightening of the Green Card rules in 2012

Source: BCG analysis

Reaching globalization target dependent on implementation of 4 key pillars with industry efforts and Government support



Source: BCG analysis

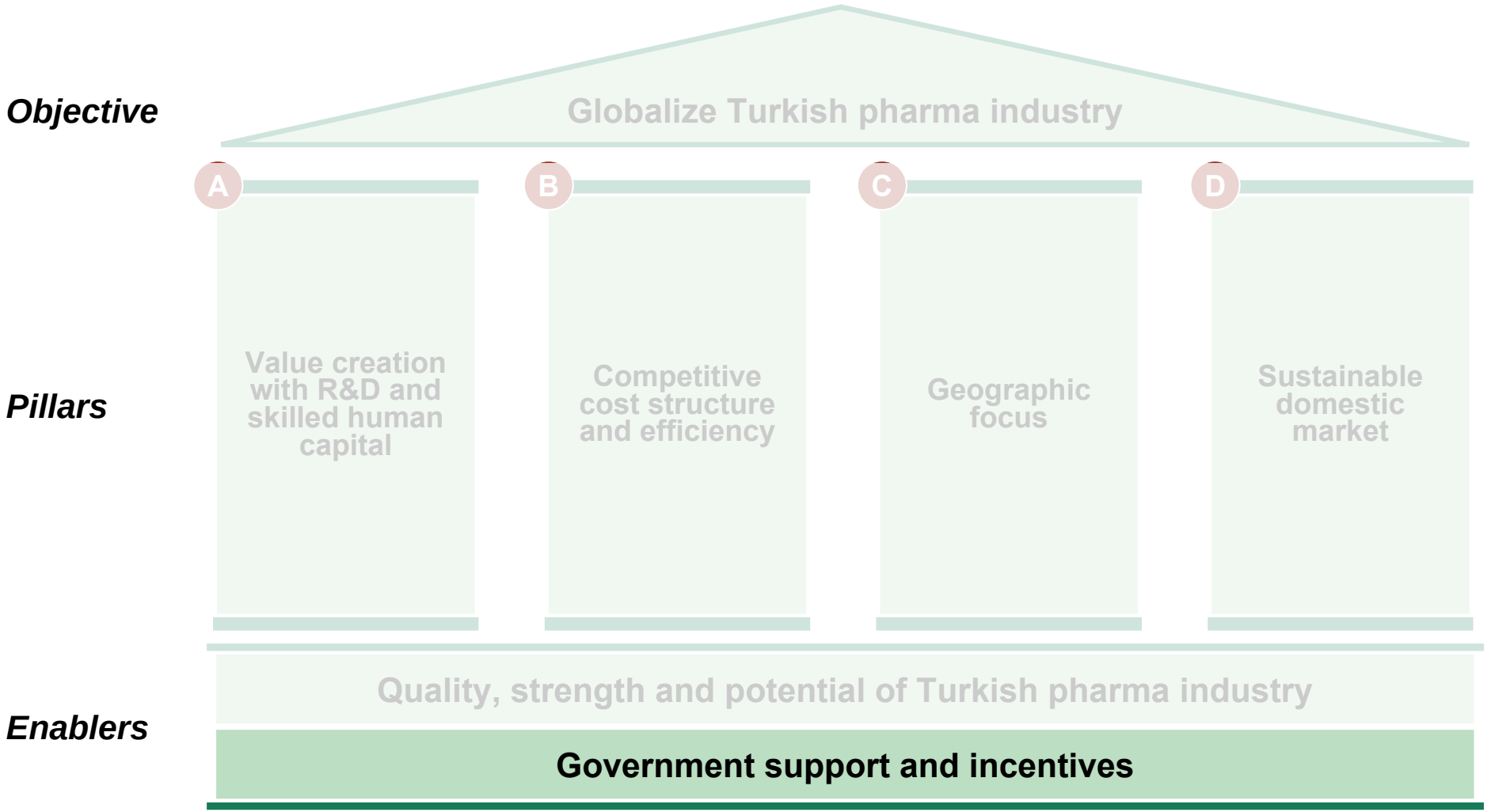
Summary of actions for the pharma industry (I/II)

Pillar	Lever	Action	Owner
R&D	Shift focus to value-added R&D	Focus efforts to improve capabilities in "development" (e.g., formulation and process development) and clinical trials	Pharma industry
R&D	Increased collaboration with universities, R&D companies/ organizations	Increase collaboration with research entities linked to universities or to techno-centers via pharma industry funded projects	Pharma industry
R&D	Other R&D incentives (e.g. low-interest loans)	Form a workgroup to provide support services to member companies regarding the utilization of R&D incentives provided by public institutions	Pharma industry
Cost structure	Pharma-specific manufacturing and export incentives	Form a workgroup to provide support services to companies regarding the usage of current incentives	Pharma industry
Cost structure	Purchasing alliance	Investigate possibility of building alliance for purchasing of pharma ingredients and utilities (e.g., electricity, gas)	Pharma industry
Cost structure	Backward integration	Investigate investment opportunities for pharma ingredient manufacturing to decrease production costs (e.g., acquisition of foreign API manufacturers)	Pharma industry

Summary of actions for the pharma industry (II/II)

Pillar	Lever	Action	Owner
Geographic focus	Improvement of export and foreign trade capabilities	Improve organizational capabilities of local pharma producers in order to increase their competitiveness in international markets (e.g. setting up representative offices in target markets or strengthening of HR structures)	Pharma industry

Reaching the globalization target dependent on implementation of 4 key pillars with industry efforts and Government support



Source: BCG analysis

Suggested action items for the Government (I/III)

Pillar	Lever	Action	Owner
R&D	Modify legislations to accommodate R&D needs	Revise current R&D legislation (Law #5746) to reduce 50 R&D employee threshold to receive R&D center license to 10 R&D employees	Ministry of Science, Industry & Tech
R&D	Modify legislations to accommodate R&D needs	Ease legislation to grant "R&D visa" or work permits to international pharma R&D staff	Ministry of Labour
R&D	Increased collaboration with universities, R&D companies/ organizations	Develop pharma manufacturing and R&D oriented curriculum in pharmacy faculties	Council of Higher Education
R&D	Increased collaboration with universities, R&D companies/ organizations	Establish a dedicated institution for higher education and advanced research in pharmaceutical sciences with support of the industry	Council of Higher Education
Cost structure	Pharma-specific manufacturing and export incentives	Introduce new measures to incentivize local manufacturing and exports in line with international agreements (e.g., WTO, EU)	Economic Coordination Committee
Cost structure	VAT rates for imported inputs	Remove discrepancies in VAT system causing uneven competition for local pharma manufacturing	Deputy Prime Minister

Suggested action items for the Government (II/III)

Pillar	Lever	Action	Owner
Cost structure	Special economic zones for pharma	Develop pharma specialized industry zones enabling clustering with solid infrastructure and access to ports and inland transportation	Ministry of Science, Industry and Technology
Geographic focus	Ease marketing authorization in target regions	Ease marketing authorization and technical inspection processes in target regions/ countries (i.e. mutual recognition, harmonization, participation in PIC/S)	Ministry of Health
Geographic focus	Promote Turkish pharma industry in international markets	Establish pharma export promotion agency	Ministry of Economy
Geographic focus	Promote Turkish pharma industry in international markets	Organize roadshows to target regions to promote Turkish pharma industry and overcome challenges	Ministry of Economy
Geographic focus	Promote Turkish pharma industry in international markets	Leverage off-set trade negotiations for energy imports to increase pharma export (i.e., include export of pharma goods to negotiations for energy import from CIS and MENA countries)	Ministry of Economy

Suggested action items for the Government (III/III)

Pillar	Lever	Action	Owner
Domestic market	Promote rational drug usage	Promote rational use of drugs via treatment guidelines	Ministry of Health
Domestic market	Revised Pharma Budget methodology	Setting of pharma budget application on a more sustainable basis while also keeping the natural growth of the sector in perspective	Ministry of Health & Social Security Institution
Domestic market	Increase private contribution to HC and pharma financing	Redistribution of the public pharma expenses to a broader base via the revision of co-payment scheme and OTC regulations	Social Security Institution
Domestic market	Increase private contribution to HC and pharma financing	Investigate ways to increase private medical insurance penetration	Undersecretariat of Tresury

Agenda

Current state of Turkish pharma industry

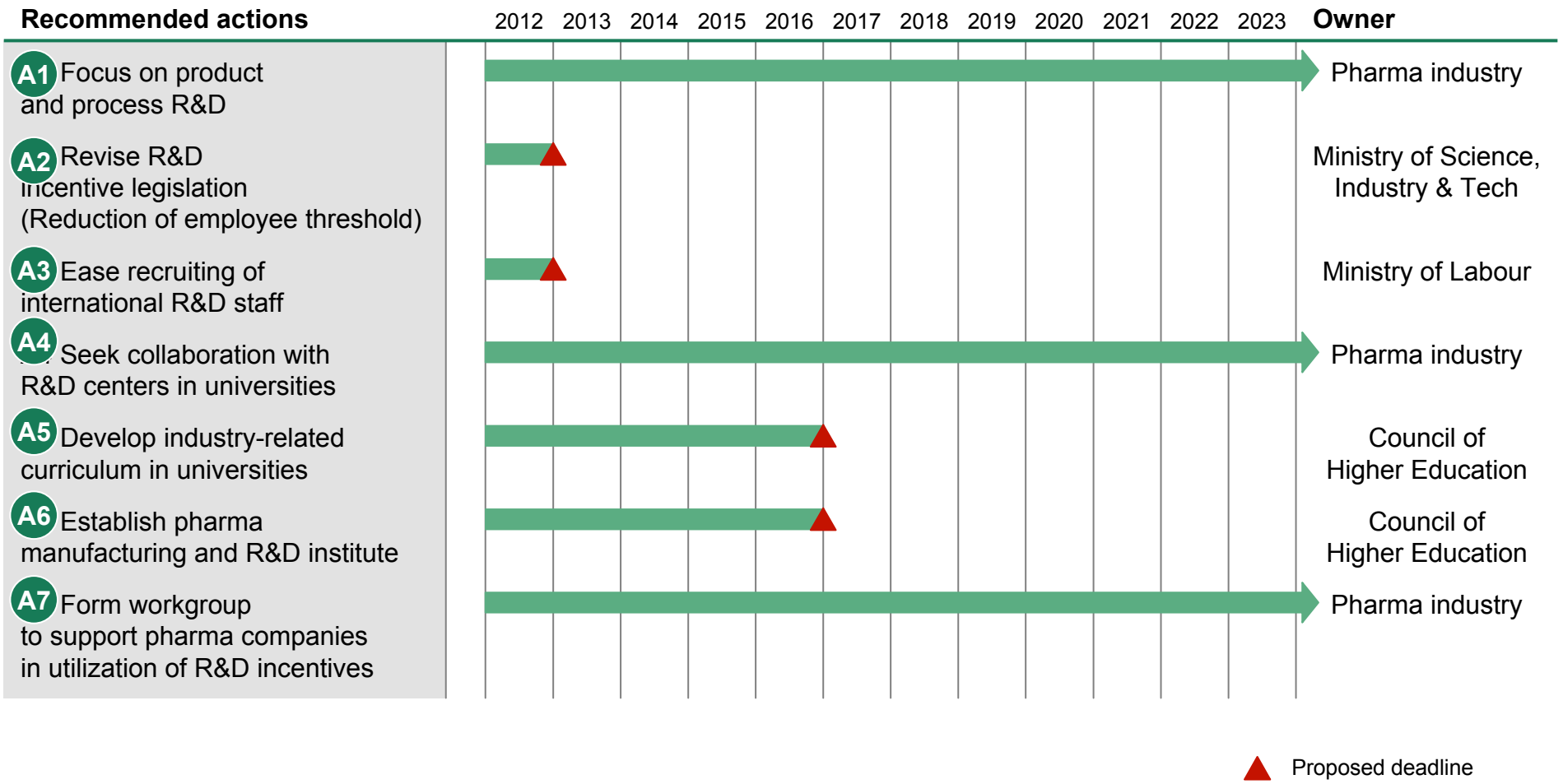
Objectives and targets of Turkish pharma industry

Proposed industry strategy and actions

Action plan

Timeline for recommended actions

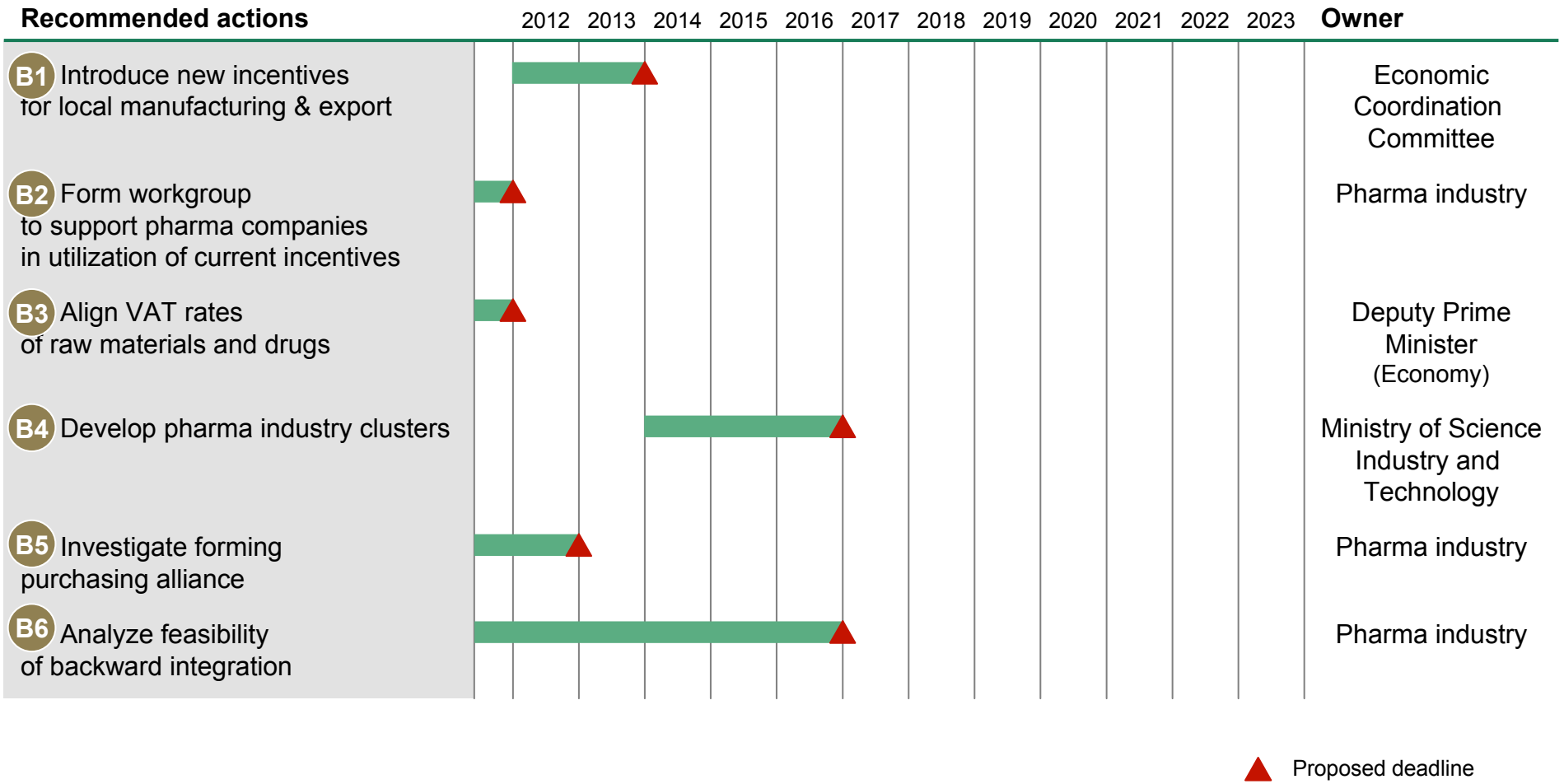
Pillar A: Value creation with R&D and human capital



Source: BCG

Timeline for recommended actions

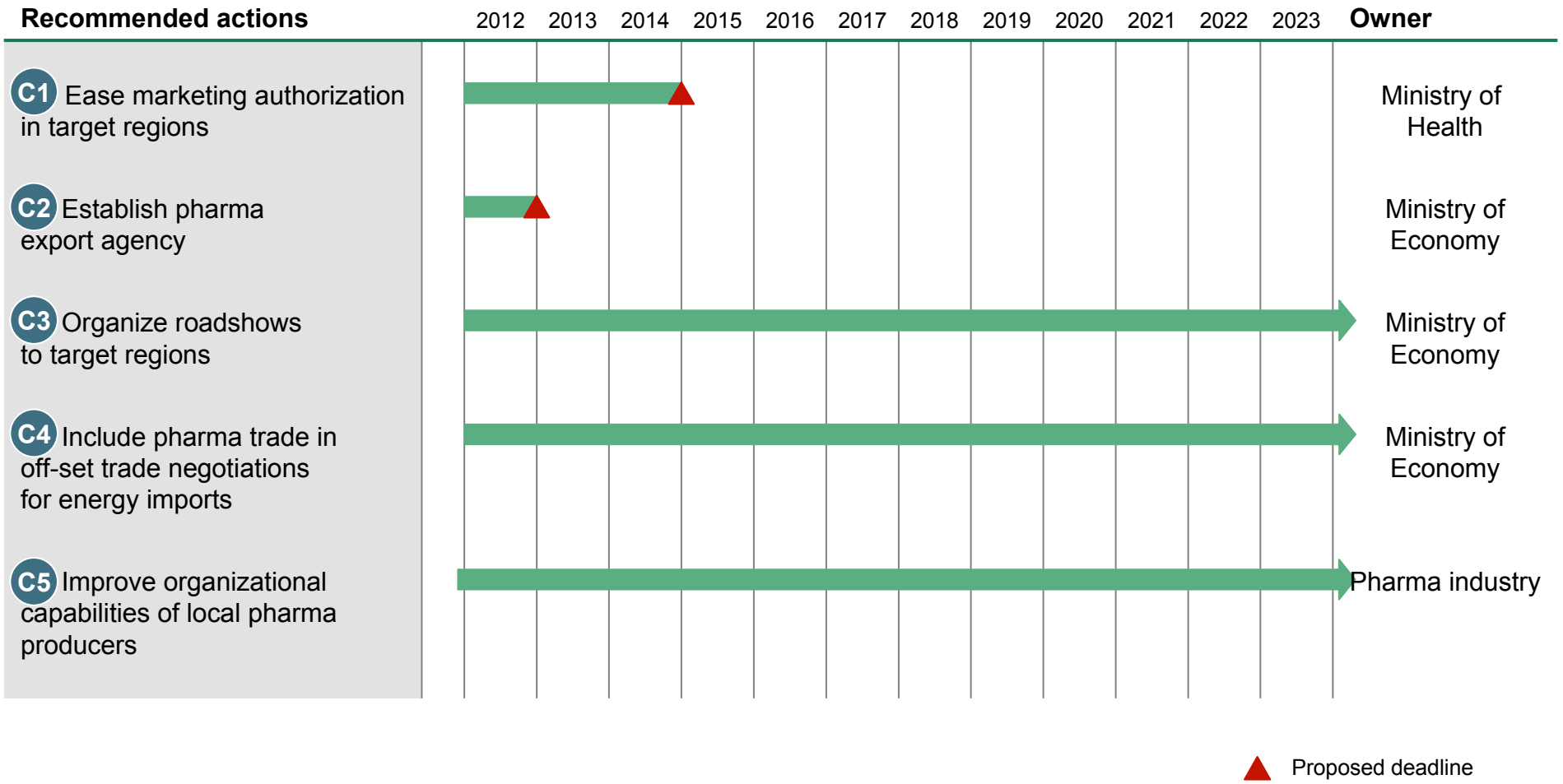
Pillar B: Competitive cost structure and efficiency



Source: BCG

Timeline for recommended actions

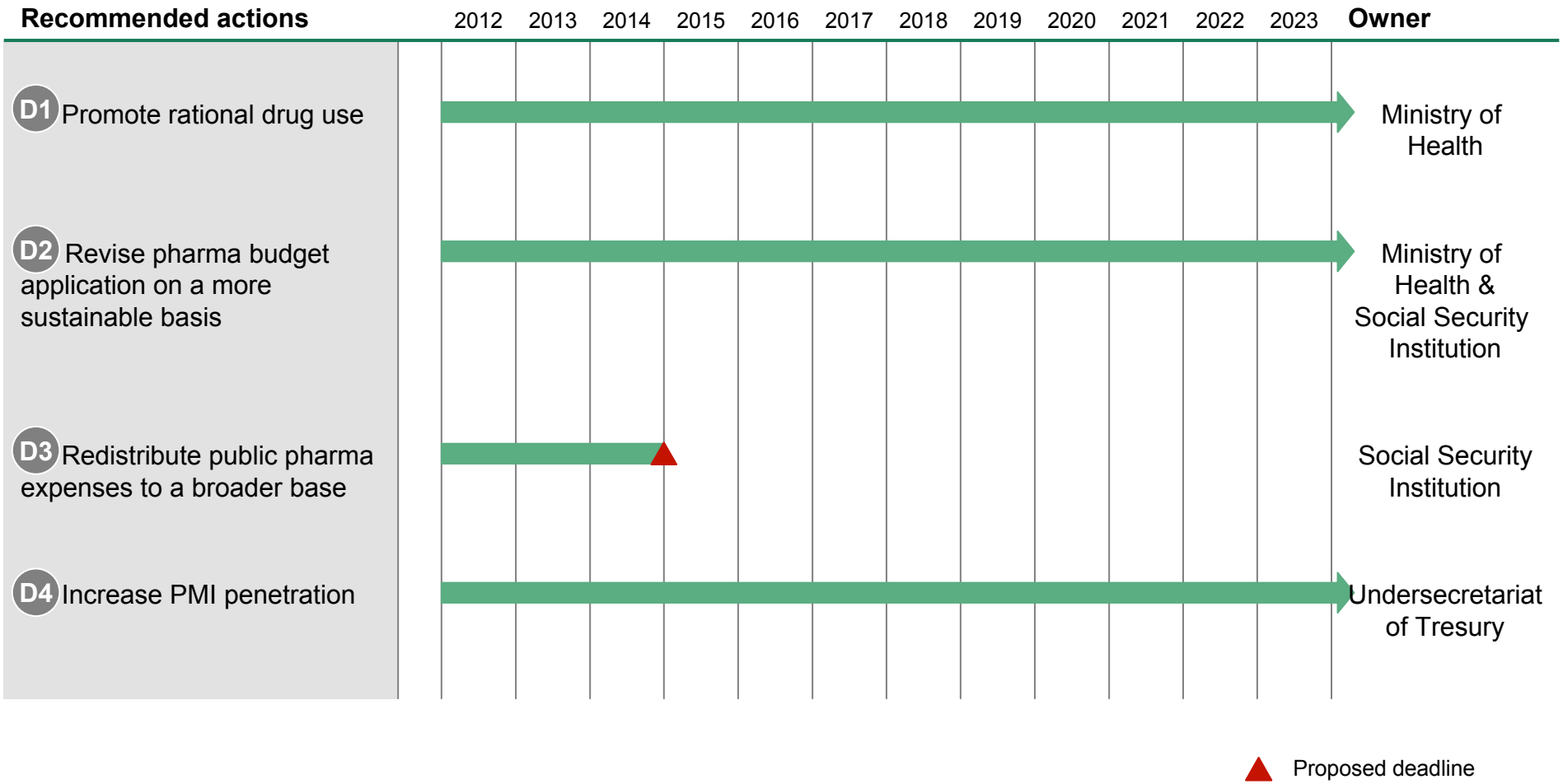
Pillar C: Geographic focus



Source: BCG

Timeline for recommended actions

Pillar D: Sustainable domestic market



Source: BCG

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