TURKEY'S PHARMACEUTICAL SECTOR

Vision 2023 Report

Strategy Document

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AiFD

Araştırmacı İlaç Firmaları Derneği
Association of Research-Based Pharmaceutical Companies

Making Turkey a Global Center for Pharmaceutical R&D and Production

*İlaç gibi gelecek!**

Turkey, a rising star in the region and the world, has ambitious social and economic goals for 2023 - the 100th anniversary of the Republic.

The pharmaceutical industry creates value through innovation. By tapping its potential, the innovative pharmaceutical industry can lead the way in helping Turkey achieve its 2023 goals.

AIFD is ready to do its part to help the Turkish population age healthfully, contribute to national economic growth, and strengthen Turkey's global competitiveness by promoting pharmaceutical innovation, R&D, and capital investment.

AIFD's vision is to help create a pharmaceutical industry in Turkey that can manufacture higher value-added products, attract globally significant R&D investment, and use advanced technologies to export products on a exponentially greater scale, which will in turn help tip the foreign trade balance in Turkey's favor.

Now is the time that all interested parties - both domestic and international must join together with common aims and commit ourselves to achieve these goals through dialogue and collaboration, so that together we shape an industry that will be "good medicine" in helping Turkey achieve its 2023 vision.

* The Pharmaceutical Industry: Good Medicine for Turkey!

AIFD Members

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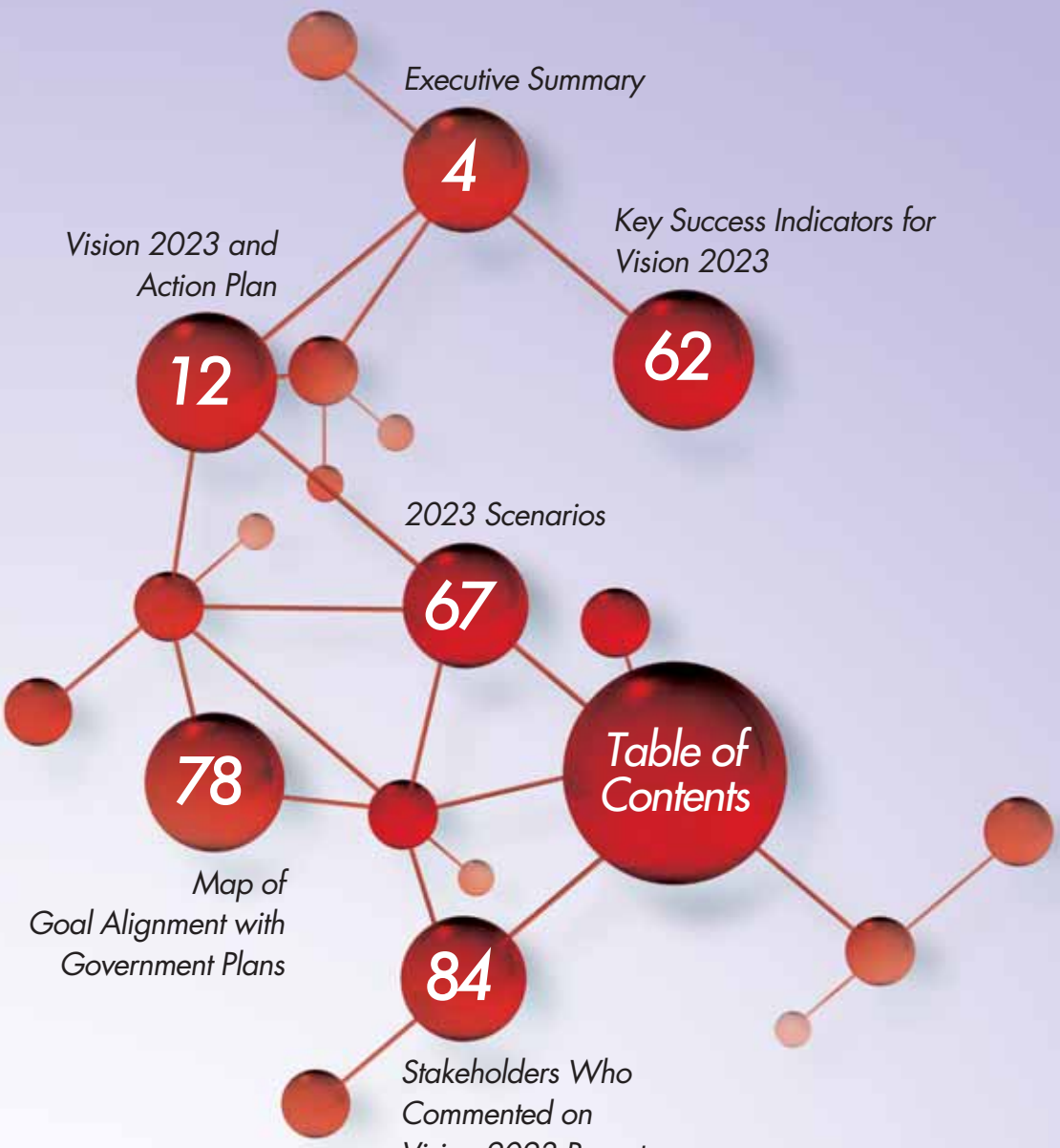

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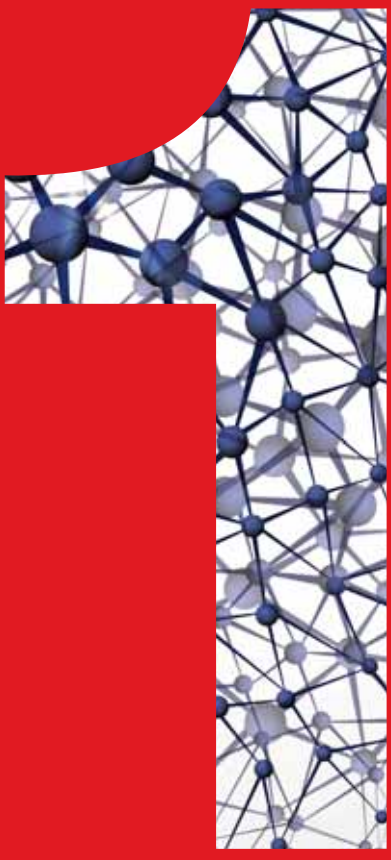
Executive Summary



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Executive Summary

As a result of aging populations, extended life spans, and socioeconomic changes around the world, health services is one of the most important topics of the 21st century. As the average life expectancy increases, the risk of falling ill to chronic diseases and experiencing health concerns in the later stages of life also increases. When we consider these factors, **innovative drugs and new treatments**, which can help prevent diseases and reduce treatment costs, become increasing important over time. Thus both developed and developing countries consider pharmaceutical research and development (R&D) aimed at the discovery of **new treatments and the production of new drugs** a **priority area for investment** and a strategic growth sector.

The Turkish Government aims to make Turkey one of the world's **top ten economies in health services by 2023** by increasing R&D expenditures to 3% of GDP and by increasing exports to **USD 500 billion**. Moreover, according to the Turkish Ministry of Science, Industry, and Technology (AIFD)'s Strategy Report, Turkey should become the Eurasian production base for medium- and high-level technology products. Taking into account Turkey's current macroeconomic conditions, political stability and increasing economic efficiency, AIFD considers these **R&D targets** to be realistic.

Turkey's **"Health Care Transformation Program"** that was implemented in 2004 marked a major development in public access to health services and treatments. Physician consultation per capita increased five times from 1.7% in 1994 to 7.7% in 2011. The average life span in Turkey also increased 24% in the last 30 years and has now reached 74 years. Innovative drugs play an important role in increasing in life expectancy. Based on a study of conducted by Professor Lichtenberg of Columbia University and the National Bureau of Economic Research, innovative drugs accounted for 75% of the increase in life expectancy in the 30 countries surveyed, including Turkey.

Thus if the Turkish government can implement the necessary structural changes and effectively promote innovation in the health care system, **the pharmaceutical industry can be the driving force in helping to achieve the Turkish Government's public health and economic targets.**

However in order to achieve sustainable progress in health services, Turkey must also focus on improving its competitive position. Currently, Turkey lags behind other emerging pharmaceutical companies, now referred to as "pharmerging" countries such as Brazil, Russia, India and China, in global pharmaceutical investment.

- According to the World Economic Forum's Global Competition Index (2011-2012), Turkey is ranked **59 out of 142 countries**, and ranked **71** in the **Innovation Capacity** Index.
- In the Global Competition Index, Brazil is ranked 31, Russia 38, India 35 and China 47.
- While the **Turkish pharmaceutical sector** is ranked **16th** in terms of market value, it is **36th** in terms of the **clinical research** conducted and the volume of pharmaceutical **exports.**

Countries that invest in R&D, develop technology, and effectively convert this technology into products become more competitive. **Innovative drugs** create added value in the pharmaceutical industry and are key to a country's economic advancement. While global investment in innovative drug R&D is USD 120 billion each year, Turkey's share is only **USD 60 million**, representing only a 0.039% of global R&D. Currently, drug production is Turkey is focused around low value-added products, with high value-added products being imported. Moreover, R&D aimed at developing new molecules (core research) has never been done in Turkey. **As production of innovative drugs increases, the added value of the drugs produced will also increase accordingly.**

Turkey's competitors in the health services sector made global pharmaceutical investment a priority in the 1990s and were able to became net pharmaceutical exporters through **strategic governmental planning.** Turkey, which now boasts the strongest and most dynamic economy in the region, can become a formidable player in the pharmaceutical sector. Turkey has the necessary knowledge base, infrastructure, and geostrategic location to attract global pharmaceutical R&D and could become a global player in the pharmaceutical industry. **This report suggests an exports-focused plan of action to develop Turkey's pharmaceutical industry into a global R&D and production center and regional shared service center location.**

The main targets of this plan are:

- **Developing Basic and Clinical Research Competency and Services Exports:** Improving Turkey's R&D competency and increasing national and foreign direct investment; thereby making Turkey's pharmaceutical sector a leader in R&D
- **Developing Production Competency and Product Exports:** Increasing the production capacity of specific high value-added product groups; thereby allowing Turkey to become a regional/global pharmaceutical powerhouse and net exporter
- **Making Turkey a Regional Management and Service Center location** for the pharmaceutical industry

Prerequisites for this action plan are:

- **The formulation and implementation of a long-term policy to support innovation in the field of health sciences** that makes R&D and value- added drug production the highest priority. Additionally, the government will provide grants that support innovation and implement regulations that protect international property rights (IPR).

- **The implementation of a legal and administrative framework that counterbalances the concerns of public health and the pharmaceutical sector,** which should entail:
  - **A current and realistic budget** that can sustain pharmaceutical sector growth. While patient access to health care and pharmaceutical drugs has increased significantly in Turkey, the percentage of Turkey's population with health insurance has also increased rapidly. However, the budget allocation for public pharmaceutical expenditures has decreased since 2009, and pharmaceutical expenditures as a percentage of GDP has dropped to 1.11%. This number is considerably below the OECD average of 1.50%. **These factors should be considered when determining the pharmaceutical budget for 2013 and beyond, as budget expenditures should match the growing healthcare needs of the country. The recommendation is to increase pharmaceutical expenditures as a percentage of GDP to 1.35%.**
  - **An improvement in patient access to pharmaceutical drugs to ensure that Turkish patients can immediately benefit from innovative drugs once on the market.** It is imperative that the government streamline the processes and procedures for pharmaceutical drugs entering the marketplace (via good manufacturing practices (GMP), timely registration, effective pricing, and reimbursements) to ensure that **pharmaceutical drugs become available to patients in a time-frame comparable to other developed countries.** The increased speed to market will in turn, attract new investment in innovative R&D.

If the above is agreed upon with the cooperation and collaboration of all stakeholders, AIFD believes Turkey can achieve the following results by 2023:

- Achieve **local pharmaceutical production of USD 23.3 billion** through the production of innovative and technologically advanced products (as compared to local production of USD 5 billion in 2011)
- Achieve **pharmaceutical exports worth USD 7.3 billion** and **clinical trial services exports worth USD 782 million - totaling USD 8.1 billion** (as compared to total pharmaceutical product and service exports of USD 587 million in 2011)
- **Become a net exporter of pharmaceutical drugs with an export surplus of more than USD 1 billion** (as compared to a 2011 foreign trade deficit of USD 4.1 billion)
- Achieve total **R&D investment of USD 1.7 billion** (R&D investment was USD 60 million in 2010), with **USD 1.1 billion of that investment derived from 3,600 clinical trials** (as compared to 240 clinical trials amounting to USD 40 million in 2011)
- Become a **regional Shared Service Center location** for the pharmaceutical industry that exports management services

The economic development plan outlined in the following **"Turkey's Pharmaceutical Sector Vision 2023 Report", will enable sustainable expansion and improvement in Turkey's health care system while also achieving governmental targets.**

Vision 2023 and Action Plan

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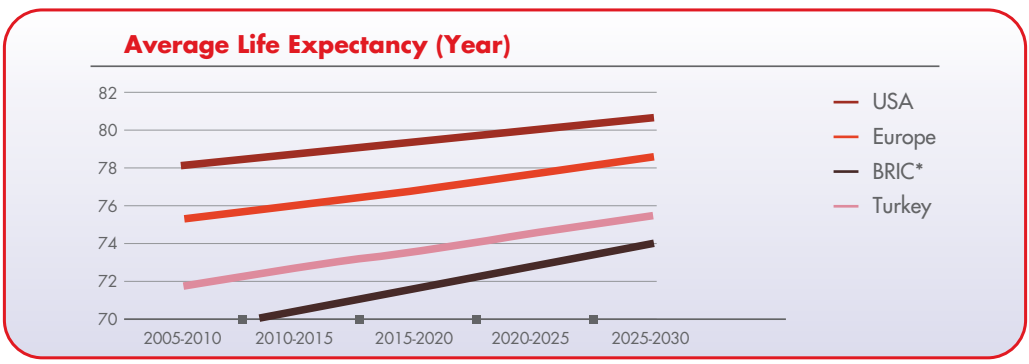
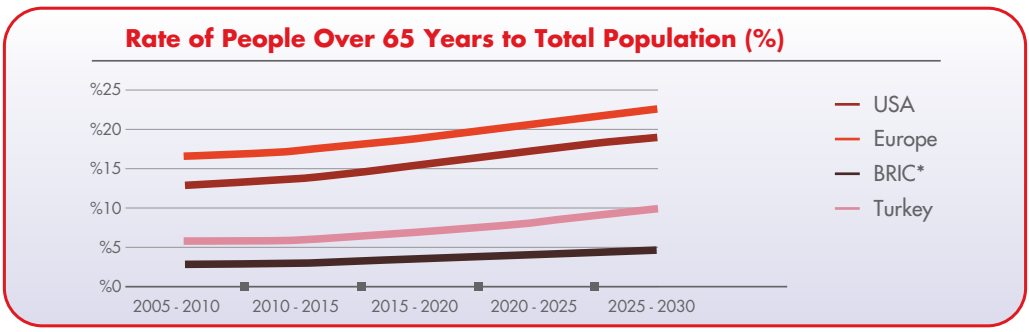
Aging population, extended lifespan, and socioeconomic changes around the world will increase the need for health services in the coming years.

- While **the world population** in 2005 was 6.5 billion, it will reach **7.6 billion** in **2020**, and the share of **people aged 65 years and above in the total population** will reach 9.4% **with an increase of 242 million. 80%** of people over 75 years of age use **at least 1 prescription** drug, while **36%** of those receive **at least 4 prescription drugs**.
- Exposure time of people to chronic diseases will increase with effects of changing nutritional habits, more inactive lifestyle, and extended human life expectancy. **A 17% increase** is expected in deaths caused by chronic diseases in the next **10 years.**
- While **hypertension** is noted in **639 million people** in developing countries as of 2004, this number is anticipated to reach **1 billion** in 2025. Similarly, the number of **patients with diabetes, 366 million people** as of 2011, is expected to reach **552 million** in 2030.
- As in the SARS and bird flu cases, diseases that can be treated are expected to evolve and spread more rapidly due to the increase in **urbanization** and **mobility.**





* BRIC: Brazil, Russia, India and China
Source: PwC Analysis, PhRMA, OECD, Earthtrends, WHO, International Diabetes Federation

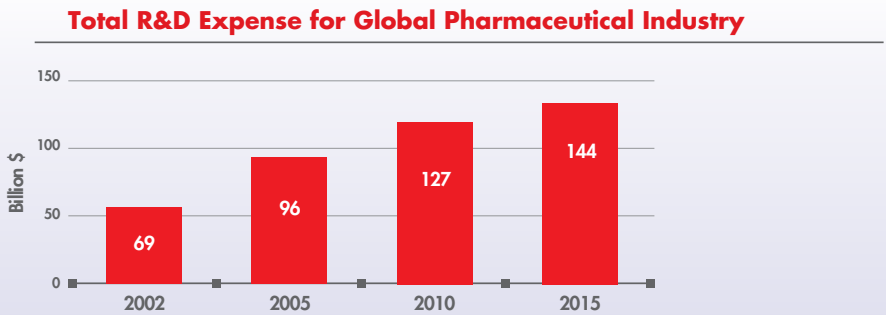
With the increase of need for health services, innovative drugs & treatments will gain importance in the pharmaceutical industry.

Contribution of new treatment methods and innovative drugs to public health will increase.

- **The awareness of patients about the contribution of innovative drugs to public health is increasing, which increases the demand for new treatment methods.**
- **Effects of many chronic diseases have been brought under control by new drugs and treatment methods developed so far:**
  - From 1960 to the present, deaths due to heart attacks have decreased by 50% in developed countries.
  - From 1980 to today, life expectancy of cancer patients in USA has extended by 83%, or approximately 3 years, with the effect of new drugs and treatments.
  - From 1995 until today, as the result of retroviral treatment, death rates due to HIV/AIDS have decreased by more than 75% in the USA.
  - The average life expectancy in the USA between 1900-2000 increased 66% and reached 78 (The contribution of innovative drugs to the improvement in life expectancy was observed to be by 40%).
  - Between 1982-2005, the frequency of disabilities arising from chronic diseases in the USA decreased more than 25%.
- **Studies for developing new drugs and treatment methods** will continue in parallel with changing and increasing health demands:
  - Pharmaceutical companies will specialize in sophisticated fields such as biotechnology, oncology, etc.
  - As biotechnology develops, customized drug treatments will increase (Biotechnology-based innovative treatments cured **350 million patients** so far).
  - The importance of **preventive and protective treatment** will increase. According to studies by the World Health Organization, **80% of diabetes and heart diseases** are preventable.

Source: PhRMA, PwC analysis

Innovative drug investments will increase.

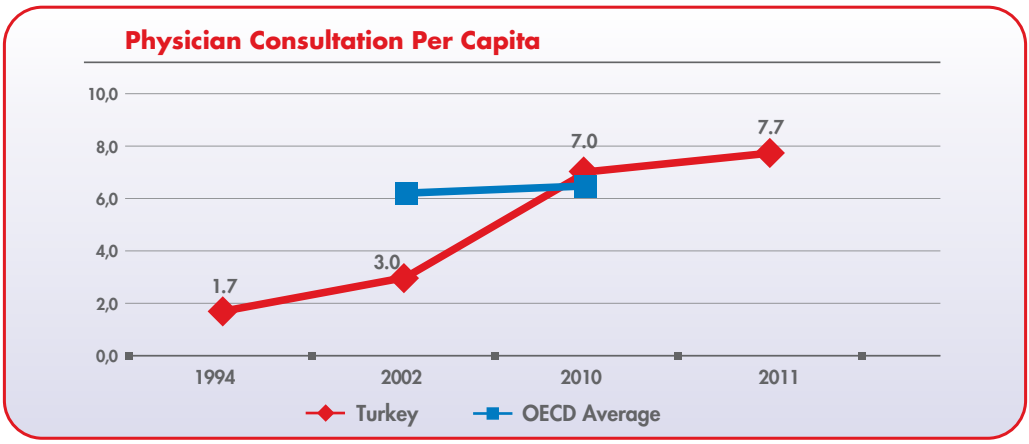


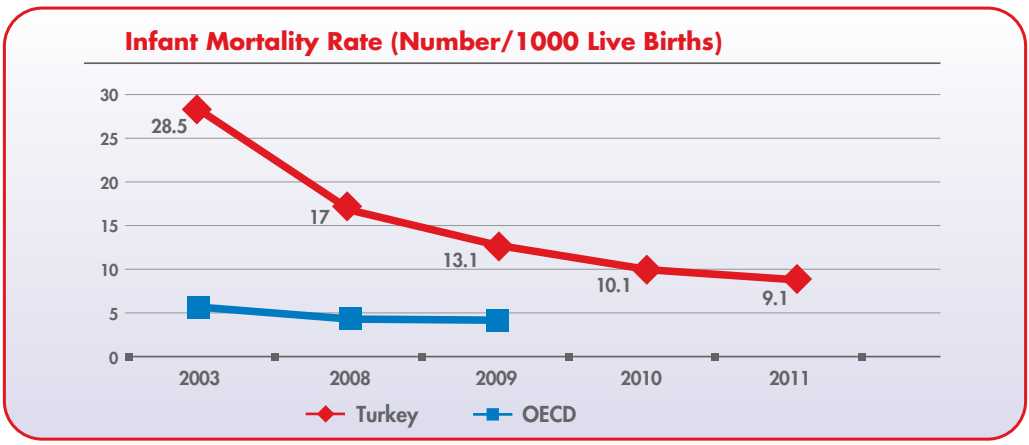
- Convergence of medicine and technology will increase: Computer-aided drug design, customized drugs, genome projects and applications, etc.
- For R&D studies of pharmaceutical companies, R&D collaborations with universities and small-scale R&D companies will increase.

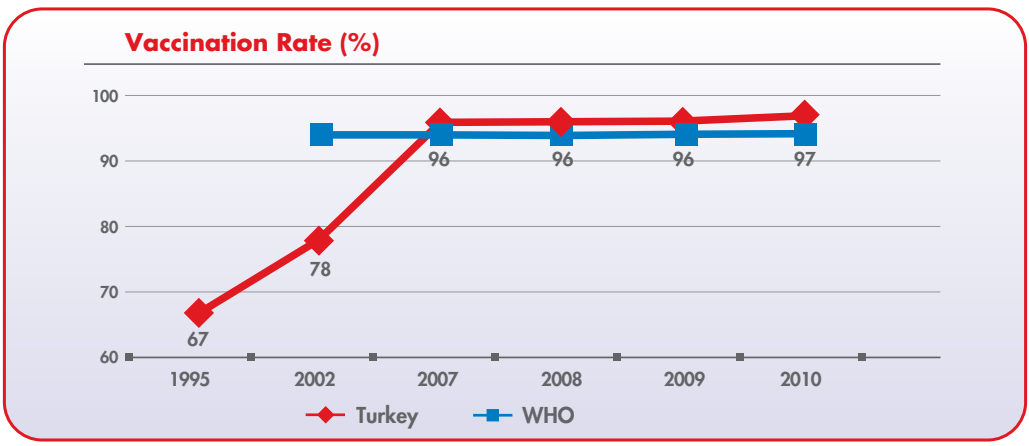
Innovative drugs support disease prevention, increase life expectancy, reduce treatment expenses and enable patients to live more productive, active and happier lives.

Source: EP Vantage, PwC analysis

With the Health Transformation Program, Turkey achieved progress in 8 years that the OECD accomplished in 30 years.







Source: Ministry of Health Yearbook 2011 and 2012 Budget Presentation, WHO, OECD

- Among OECD countries, Turkey shows the most rapid increases with regard to average life expectancy statistics (according to OECD; 1960: 48.3; 2010: 74.3).
- Thanks to the health transformation program, access to many treatment services and drugs in Turkey has been led to a physician consultation per capita increasing 5 times, to 7.7 in 2011 from 1.7 in 1994.
- All kinds of services can be freely offered nationwide through the family health practice and other primary health institutions without requesting any social security certificates.
- **A vaccination rate greater than 95%,** which is the average rate in high-income countries, was attained.
- There was a significant decrease in mortality rates of mothers and children.

Continuation of this success will be possible by following global trends in the healthcare sector and offering the innovative drugs to patients at the same time they are offered to the world.

Many developed and emerging economies compete in order to attract R&D and manufacturing investments in pharmaceutical industry.

Examples of Good Applications

Ireland prioritized its pharma sector in **1970.**

- Manufacturing of **5 of the world's top 12** medicines
- 11% of Ireland's GDP is generated by the pharmaceuticals industry
- Over **50%** of Ireland's exports are from the pharmaceutical sector
- Provided 2 out of every 5 pharmaceutical jobs in Europe in 2008

South Korea started to develop its pharma sector with the "Biotechnology Development Plan" in **1998.**

- The industry revenue increased by **14 times** over period **2001-2005** due to strong state investment and scientific success.
- Invention of **15 new molecules**, placed 7th in international patent competitiveness
- Aim to be among world's top seven biotech players by 2016

Singapore's development in the pharma sector started with the launch of the Biomedical Science Initiative in **2000.**

- Aim to reach USD 17 billion in manufacturing output by 2015
- Within the highly qualified R&D cluster, 50 global companies partnered with around 30 local public-sector academic and research institutes

Source: PwC Benchmark Analysis

Some Recent Investment & Export Facts

- **EUR 7 billion in investment** in last decade
- **USD 31 billion in pharma export** in 2010
- **Received 1/3 of total US investment in EU's** pharma industry

- **USD 550 million** venture capital fund by Novartis available since 2007
- **USD 15 billion** in FDI in 2010

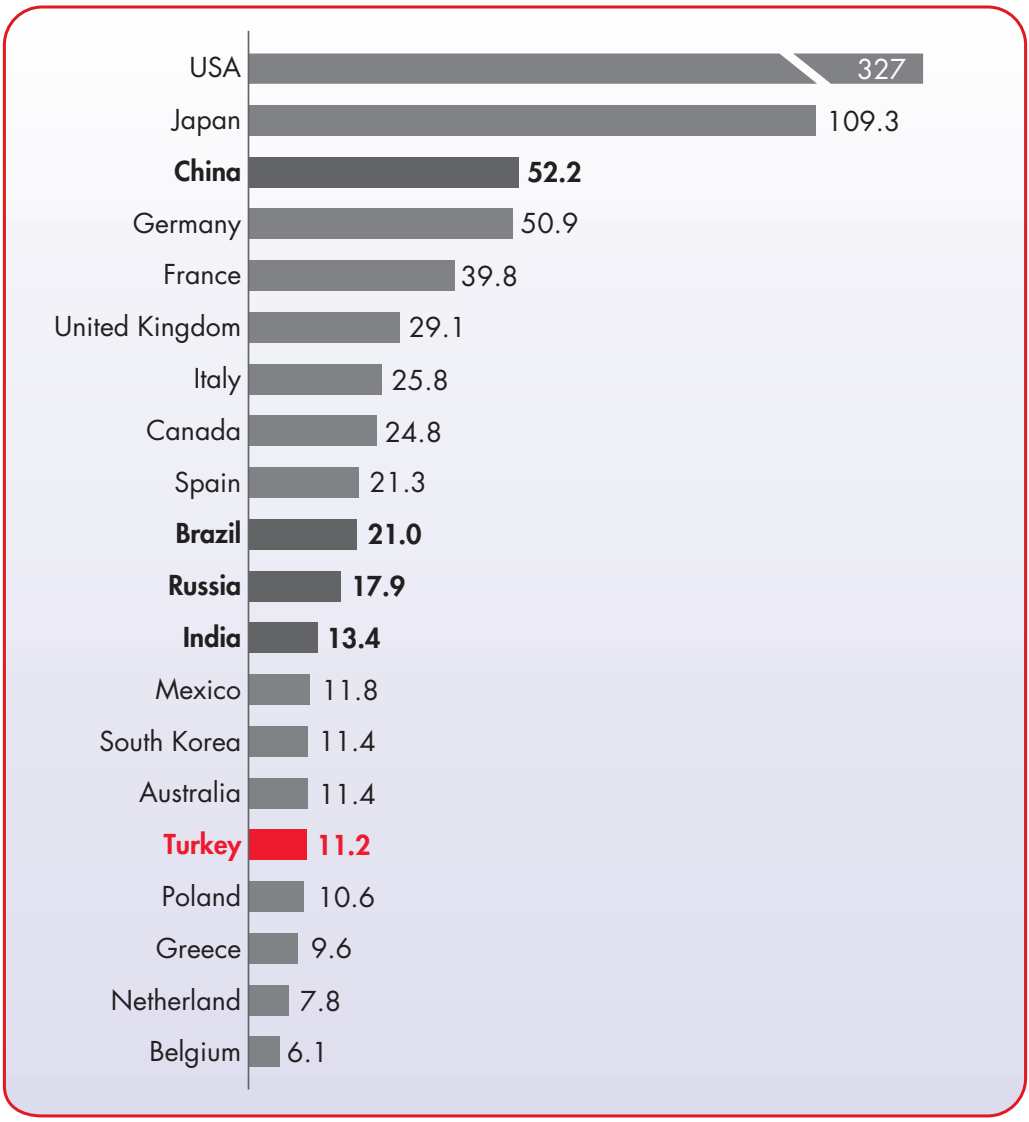
- **USD 500 million** investment in Biopolis cluster
- **USD 2 billion** in investments in last four years, for 6 new plants
- **USD 4.4 billion in exports** in 2010

Many developed and emerging countries focused on the pharma sector over a decade ago and gained substantial investments, in turn creating a competitive and net exporting industry. Turkey needs to develop and implement a government-initiated industry strategy to compete with these countries.

Source: PwC Benchmark Analysis

Turkey risks lagging behind the competition among BRIC countries to attract pharma investments.

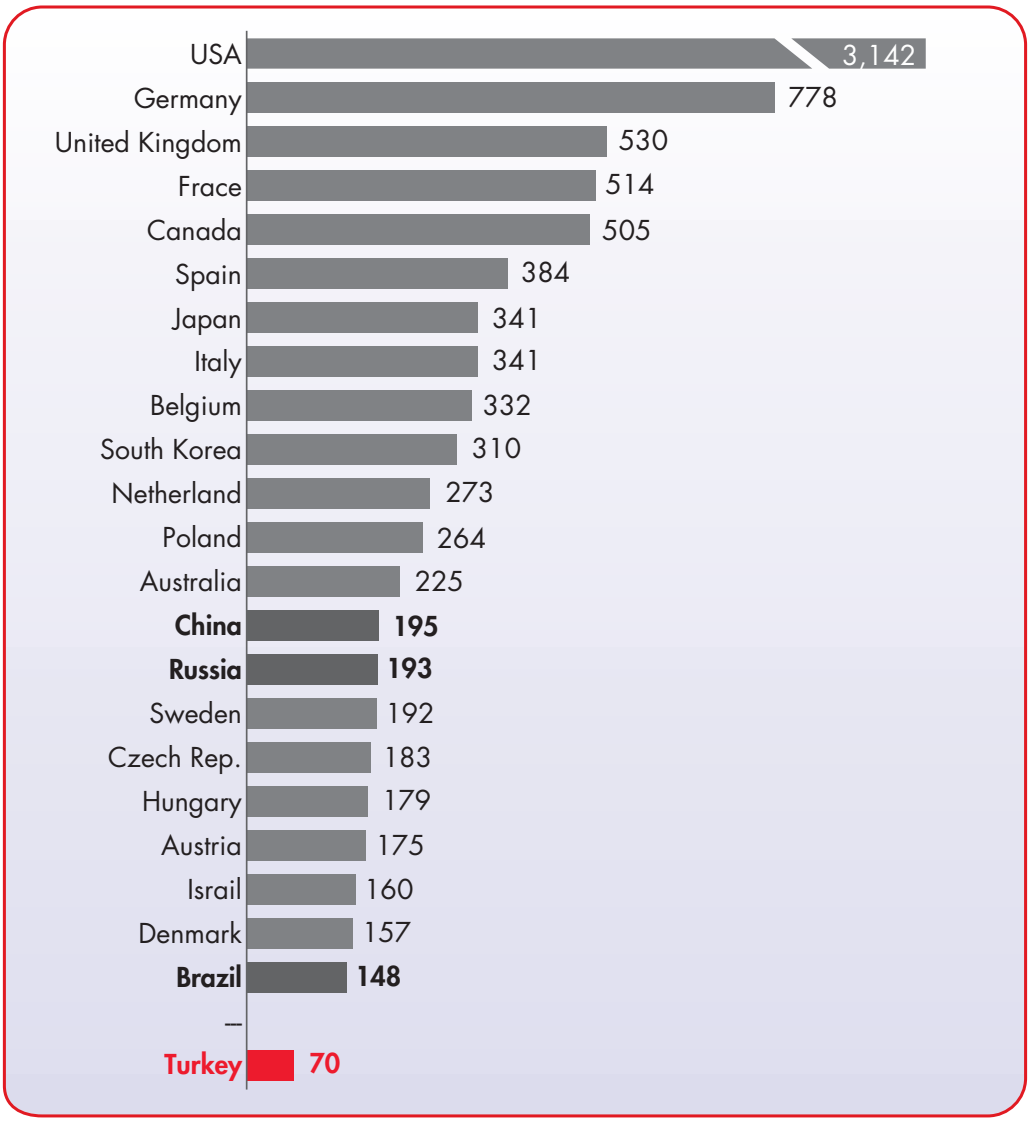
Pharma Market Size (Billion $), 2011



Turkish Pharma industry ranks 16th as market size..

Source: IMS

Number of Clinical Trials (Number)*, 2011

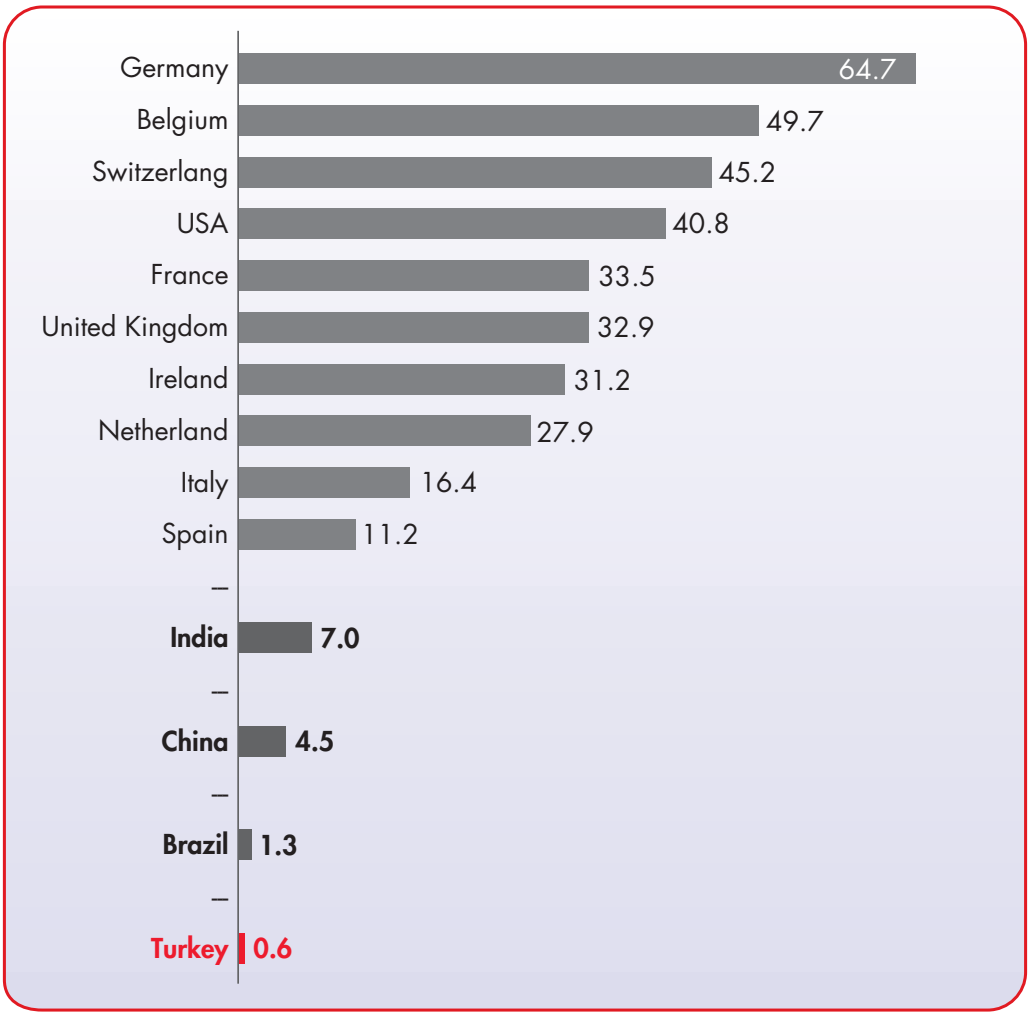


..however ranks 36th in clinical trials..

* Only industry sponsored trials are taken into account
Source: clinicaltrials.gov

Turkey is also behind in export volume and hence in the export/import coverage rate.

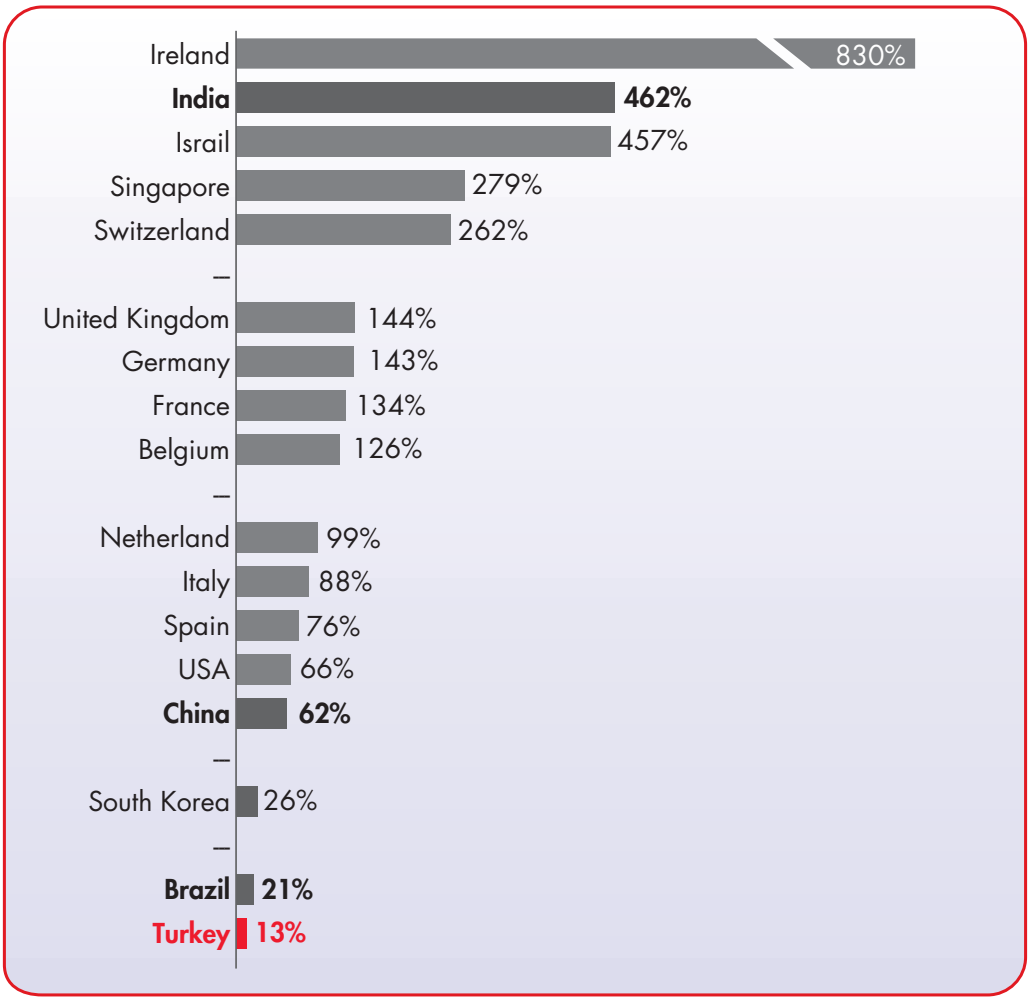
Pharma Export (Billion $), 2011



Turkish pharma industry ranks 36th...

Source: UNCOMTRADE

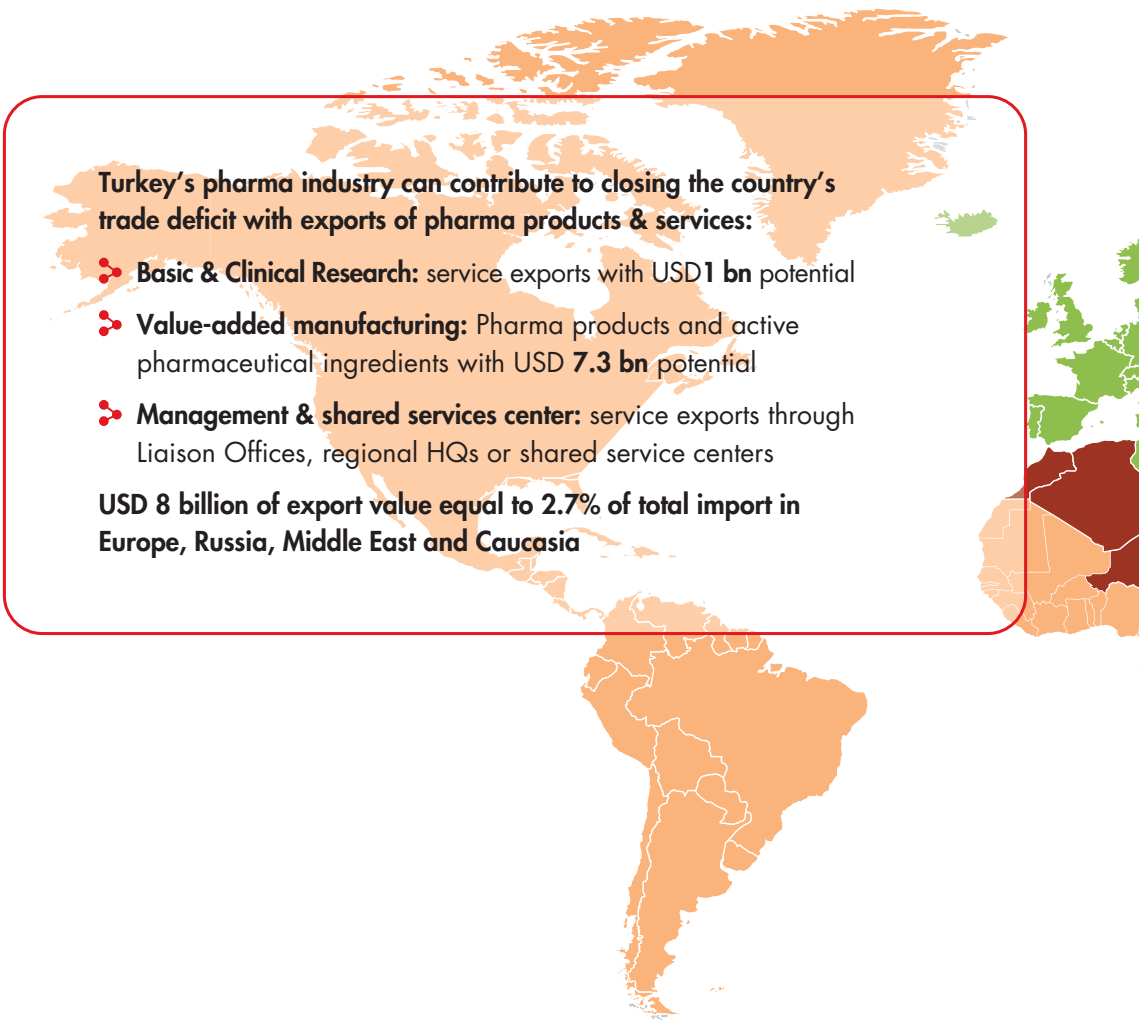
Export / Import Coverage Rate (%), 2010



...and is very behind in terms of its export / import coverage rate.

Source: UNCOMTRADE

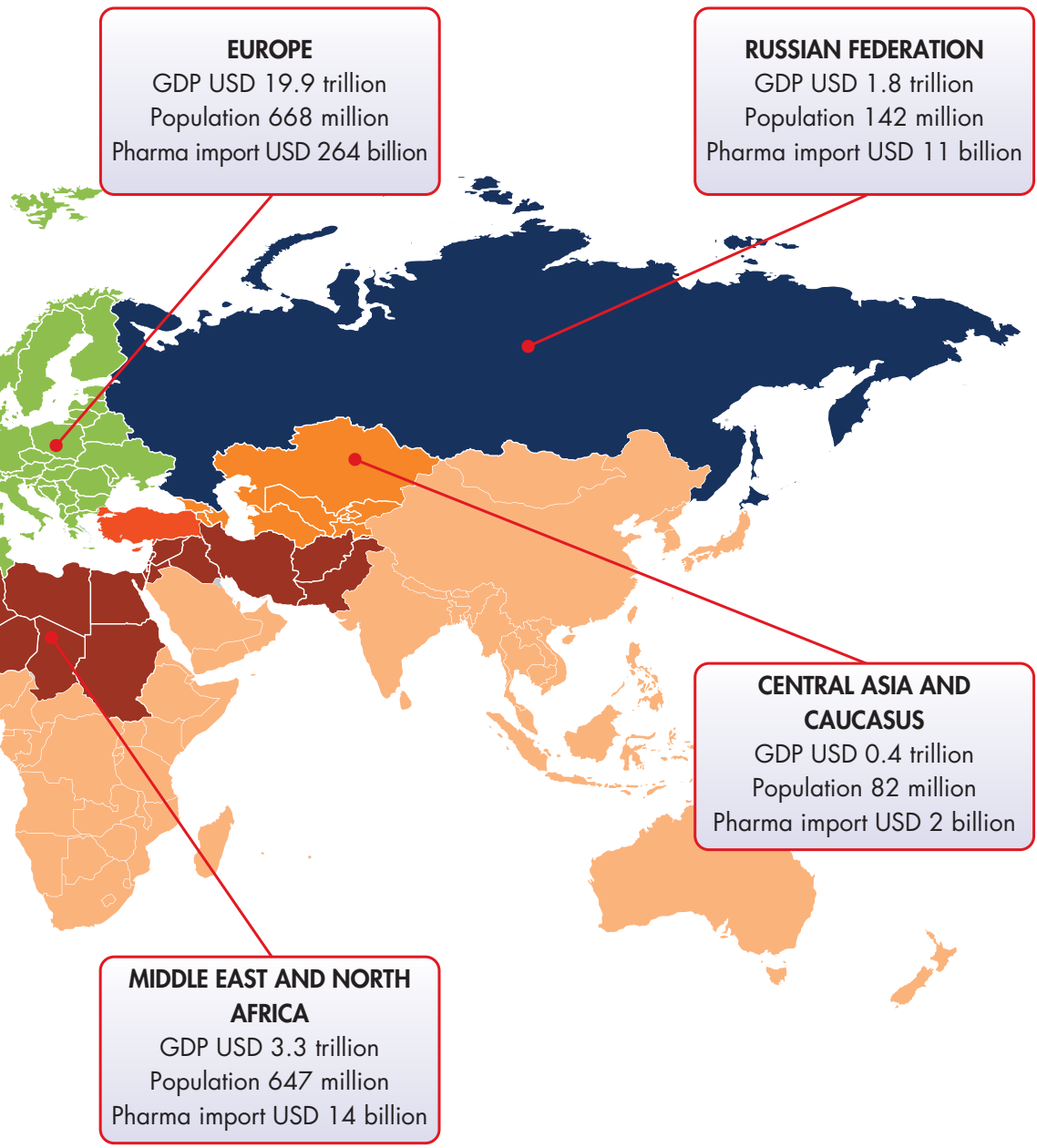
Turkey has a major opportunity to become a key services and pharma products supplier for neighboring regions with its location, with total export potential of USD 8 billion.



Turkey's pharma industry can contribute to closing the country's trade deficit with exports of pharma products & services:

- **Basic & Clinical Research:** service exports with USD**1 bn** potential
- **Value-added manufacturing:** Pharma products and active pharmaceutical ingredients with USD **7.3 bn** potential
- **Management & shared services center:** service exports through Liaison Offices, regional HQs or shared service centers

USD 8 billion of export value equal to 2.7% of total import in Europe, Russia, Middle East and Caucasia



Source: Investment Support and Promotion Agency, UNCOMTRADE

Turkey's pharmaceutical industry has enough infrastructure and potential to realize this vision and become a global player.

Strong features of Turkey's pharmaceutical industry that will support the targets in the "Vision 2023".

The scope of social security services increased with **successful healthcare reform**, as did patient satisfaction, access to services, and **industrial indicators**.

Steady macroeconomic structure and **rapid growth** rates

Modern law system supported by economic and political stability

Turkish pharmaceutical industry ranks **7th in Europe, 16th in the world**

Strong **production facility infrastructure**; 76% of drugs consumed in Turkey on a box basis and 49% on a value basis are locally produced

Industrial employment includes approximately 25.000 people.

Over 300 industrially sponsored or academic **clinical trials** are conducted in 2011

Strong education capacity in **fundamental sciences, medicine and pharmaceutical departments**

Number of **specialist physicians** increased from 18.000 to 31.000 since 2002

Competency in **diagnosis** and **treatment**, and strong development of healthcare tourism

Being regional center due to **strategic geographical location** and high possibility and advantage of export to markets such as the Middle East, Eastern Europe

Investments in health and pharmaceutical industries will improve public health and provide an economic benefit by increasing research, production, exports and employment.

Public Health Goals:

The main objective of the Ministry of Health in the 2010-2014 Strategy Document was defined as **"Improving the health care level of our people"**.

- Supporting R&D studies within the scope of improving health services
- Increasing the quality, effectiveness, and productivity of diagnostic and treatment services
- Improving pharmaceutical and medical device services, and sustaining safe market access
- Making regulations that will encourage the development of new drugs to make progress in the field of pharmaceutical technology, and to carry out scientific studies in collaboration with the public, universities and private sector

Economic and Development Goals:

The long-term vision of the Turkish Industrial Strategy was specified as **"To be the production base in Eurasia by producing medium - and high-level technology products"**.

Strategic Targets:

- Promote and strengthen the position of companies that can develop their competencies and skills in a sustainable manner
- Promote medium- and high-level technology industries in production and exports.
- Switch from low technology industries to high value-added products

Industrial policies include:

- Increasing the share of medium- and high-level technology industries in production and exports and developing a policy for industry clusters

The pharmaceutical industry is important for its potential to support the government's public health and economic targets by increasing R&D, innovation, employment, production and exports.

"Turkish Pharmaceutical Industry Vision" will provide economic and social benefits for our country and increase competitiveness.

It will ensure DEVELOPMENT

- Becoming a **global supplier** of products by meeting a great portion of the requirements of the Local Market through **local production**, and by producing specific products in Turkey
- Decreasing the current account deficit by **increasing pharmaceutical exports**, and becoming a **global supplier** for important products
- Improving pharmaceutical R&D and production competencies, to enable **new local molecule invention** and **long-term interest** by international pharmaceutical companies
- Becoming **a regional management center** in the pharmaceutical sector, and developing other industries that are associated with pharmaceutical production
- Supporting **small and medium-sized enterprises** and integrating them into the pharmaceutical supply chain through clustering
- Expanding Turkey's financial sector by introducing new **venture capital into Turkey**

It will provide SOCIAL benefits

- Ensure the **most effective treatment of diseases** with the introduction of more innovative drugs to the market
- **Discover new molecules and increase domestic patents with the development of R&D**
- **Increase the number of researchers** working in life sciences
- **Gain scientific knowledge** and **experience** participating in global R&D networks
- Increase **employment in the pharmaceutical industry** (currently 25,000)
- Increase indirect employment in the pharmaceutical sector's supply chain

It will increase COMPETITIVENESS

- Increase the global competitiveness of Turkey by developing and producing advanced technology products **through the discovery of new molecules and an increase in number of patents**
- Shift the competitiveness of Turkey from cost advantage to innovation competency **by merging the knowledge of academia with industry**
- **Increase investment** by making Turkey **a regional management center** and creating an investment environment suitable for production and R&D
- Ensure that **domestic pharmaceutical companies** gain the regional and global prominence in R&D and production competency
- Increase **the global competitiveness of universities** with effective industrial collaboration and greater funding


2023

Vizyon 2023

Positioning the Turkish Pharmaceutical Industry, as one of the global R&D and production hubs and a regional management center

Main Objective

Improve the pharma industry's international competitiveness and make the industry a net exporter by improving R&D competency and increasing value-added manufacturing

Pre-Requisite Sustainable Investment Environment

A predictable, transparent, stable and attractive investment environment for the Turkish pharmaceutical industry

Goal

1. **Basic, Clinical Research Competency and Services Export:** Increasing national and foreign direct investments in R&D, training a competent labor force, and becoming the pioneer industry of Turkey in R&D by improving R&D capacity in life sciences
2. **Production Competency and Product Export:** Becoming a regional/global supplier and net exporter by increasing the production capacity of high value-added products in Turkey
3. **Management Center and Service Export:** Contributing to the economic development of Turkey and improving its competitive positioning by becoming a management and/or service center for the global pharmaceutical industry

Regulations

- Government Health and Pharmaceutical Policies

Support Mechanisms

- Incentives
- Finance
- Collaborations

Resources & Infrastructure

- Human Capital
- Education
- Technological and Scientific Development

In order to achieve Vision 2023 goals, the following actions are suggested.

	Regulations	
1. Basic, Clinical Research Competency and Services Export	1. Government adoption of a central research policy on life sciences in alignment with the strategy put forth by the Turkish Pharmaceutical Industry 2. Developing a road map for life science clusters 3. Implementing clinical research regulations in order to improve Turkey's competitive position	
2. Production Competency and Product Export	9. Determining the production plans for priority fields in alignment with Turkish Pharmaceutical Industry's strategy 10. Developing an action plan to increase the volume of exports 11. Providing the necessary support to increase the volume of production in the relevant life sciences cluster	
3. Management Center and Service Export	15. Provide tax incentives to international life sciences executives who provide services abroad	

Sustainable Investment Environment	18. Developing legal and administrative regulations that both align with Turkey's vision for pharmaceutical industry and counterbalance the interests of the pharmaceutical sector and public health authorities

Support Mechanisms	Resources & Infrastructure
4. Increasing the variety of R&D financing resources to encourage & support an increase in life sciences R&D 5. Strengthening collaboration between universities and pharmaceutical industry	6. Developing infrastructure to motivate & improve the level of research of universities and research hospitals, and to enable the integration of this research within global R&D networks 7. Standardizing clinical trials procedures to match international standards 8. Implementing information systems and a judicial framework to support life sciences research
12. Incentivizing the prioritized production areas 13. Incentivizing and facilitating knowledge transfer in high-technology production	14. Developing the competencies & improving the education level of the work force based on industry needs
16. Preparing a communication plan to announce the advantages of locating a company's management and/or a shared service center in Turkey.	17. Improving Turkey's competitive position with regard to human capital & working standards in order to attract more shared service centers & management offices

19. Develop regulations to increase patients' access to innovative healthcare products and enable reliable and rapid market access

20. Developing effective and adequate intellectual property rights (IPR)

Action Plan
Basic and Clinical Research

1. Government adoption of a central research policy on life sciences in alignment with the strategy put forth by the Turkish Pharmaceutical Industry

A Strategic Plan for Life Sciences that focuses on R&D has been recently launched in the UK.

The government in China has developed a strategic plan for science and technology with the aim of becoming an "R&D hub" in 2006 and defined specific goals for life sciences.

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
1.1. Including life sciences in "Prioritized Areas" by the decision of the Supreme Council for Science and Technology (SCST) *(TÜBİTAK has identified energy, food, automotive, information and communication technology and machinery manufacturing technologies as prioritized areas for R&D support in accordance with National Science, Technology and Innovation Strategy (NSTIS) 2011-2016 Document.)*	SCST, MoH, MoSIT, MoD, STRCoT, CoHE, NGO, SI	Implementation of the regulation	2012 - 2013
1.2. Determining essential life science research fields for Turkey based on consideration of trends related to pharmeceutical research globally and synchronizing with government's healthcare policies	MoH, MoSIT, MoD, Univ, PS, SI	Prioritization of R&D goals dedicated to at least 3 fields related with to the pharma sector	2012
1.3. Updating of education, financing and incentive mechanisms to support the Basic Research Policy	MoH, MoD, MoSIT, CoHE, Univ, STRCoT, MoNE, NGO	Implementation of the regulation	2013 - 2015
1.4. Establishment of an organization to coordinate efforts, management and financing for the field of life medical sciences in Turkey	MoH, STRCoT, MoSIT, MoD, MoF, MoE, UoT	Preparation of regulations	2013 - 2014

Action Plan
Basic and Clinical Research

2. Developing a road map for Life Science Clusters

The Biopolis R&D Cluster and Tuas Production Cluster in Singapore attract significant FDI in the life sciences.

USA Massachusetts Cluster has played an important role in commercialization of R&D capabilities of top-ranking universities in the state.

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
2.1. Relevant geographical placement for the formation of life sciences clusters and preparation of the required regulation	MoSIT, MoD, MoE, CoCI, SI	Implementation of the regulation	2013
2.2. Creating the relevant platform for communication and collaboration between university and industry which is required for the clusters	MoSIT, CoCI, MoE, SI	Workshops with universities and representatives of industry	2013
2.3. Developing techno-park regulations (Technology Development Zones Law No. 4691 dated 26.06.2001) to meet the requirements and respond to the demands in pharma industry **a.** Preparation of incentives to facilitate essential investment for new initiatives at techno-parks **b.** Updating of techno park regulations to meet the requirements and pave the way for specializations in the pharmaceutical sector (shared lab and similar resources, support for initial investments of company)	MoH, MoSIT, Univ., MoF, MoD	Inclusion of pharmaceuticals and biotechnology into the techno-park	2013
2.4. Supporting the fundamental research of small and medium research foundations and establishing mechanisms for trading inventions (e.g., incubation centers in every life sciences cluster)	MoSIT, MoE, Univ., CoCI	Implementation of the regulation	2013 - 2014
2.5. Establishment of technology transfer offices,which support academic efforts to transfer into companies and commercialize	MoH, MoSIT, MoE, PC, Univ., SI	Initially at least 1 technology transfer office in each development district	2013 - 2014

Action Plan
Basic and Clinical Research

3. Implementing clinical research regulations in order to improve Turkey's competitive position

Singapore is the leading country in its region in terms of time needed for approval of clinical research (4 weeks for authority, 4-6 weeks for ethical approval).

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
3.1. Evaluate and approve clinical research in time frames set out in regulation **a.** Initiate online filling and approval procedures for Pharmaceuticals and Medical Devices Institution and ethical committee **b.** Decrease the time it takes to initiate clinical research by increasing staff at the relevant ministry **c.** Support acceleration of procedures by adding an organizational performance indicator to MOH clinical research approval procedures	MoH, Univ.	Approval durations of clinical research	2012 - 2013
3.2. Design procedures and processes to reduce the time it takes for evaluation and approval of clinical research	MoH, SI	Execution and implementation of process design	2013 - 2014
3.3. Implement regulations necessary to incentives researchers and promote pharmaceutical research (funds for research grants in addition to research project grants; gradation of funds according to research areas and project types)	MoH, MoF, MoSIT, CoA, SI, STRCoT, CoHE, Univ.	Implementation of the regulation	2013
3.4. Develop a communication plan with stakeholders for improving public awareness of clinical trials	MoH, PC, SI, NGO, Univ, CoA	No. of meetings for communication plan (4 in a year)	2013 - 2015
3.5. Implement online filing, electronic signature, and online approval in Ministry of Health and Ethic Committees	MoH	Level of services given online	2014

Action Plan
Basic and Clinical Research

4. Increasing the variety of R&D financing resources to encourage & support an increase in life sciences R&D

In Massachusetts, USA, along with USD 1 billion of various state funds, researchers and research companies receive support by 30 venture capital funds, amounting to USD 1.1 billion.

In Ireland, postgraduate research programs with R&D projects, R&D infrastructure, education, and advisory services are supported by investment improvement agency funds. USD 1.2 billion of investment has been made in postgraduate programs in order to increase research capacity since 1998.

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
4.1. Promote and provide institutional support to ensure that Turkish pharma research enterprises can benefit from international capital funds	ISPAT, PC, SI, MoE, MoSIT	No. of seminars-meetings/year	2013
4.2. Establish a Turkish Government venture capital fund to support basic research by small and medium research organizations	MoSIT, UoT, MoE, SMEDO	Establishment of venture capital fund	2013 - 2014
4.3. Develop new incentive programs/and revise existing R&D support programs in TÜBİTAK, TTGV and programs like SAN-TEZ in accordance with the R&D objectives of pharma industry and update these periodically **a.** To determine the grant amounts, periods and assessment criteria according to the specific properties of basic and applied sciences **b.** Generating an innovation-based support mechanism by transparently evaluating research projects and researchers according to determined success criteria	MoSIT, STRCoT, MoF	Follow-up of supported projects and tehir overall success rate	2013

Action Plan
Basic and Clinical Research

4. Increasing the variety of R&D financing resources to encourage & support an increase in life sciences R&D (continued)

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
4.4. Develop regulations that allow clinical and translational research to benefit from incentives under the R&D law **a.** Remove the requirement in article 6. 1.d. of the R&D regulation numbered 5746 (Regulation of Implementation and Audit on the support of R&D activities, published on the Official Gazette dated 31.07.2008 , numbered 26953) which mandates that a minimum of two clinical trials (among clinical phases I-III) are obliged to be conducted in Turkey in order to benefit from incentives. **b.** Revise the requirement in article 4.1.b and 15.1.a that an R&D center must employ at least 50 full-time R&D employees so as to decrease the requirement for full-time employment and reduce constraints for pharma basic and clinical research. (If a clinical trial is conducted in the pharmaceutical company's own laboratory or R&D center by personnel employed by the pharmaceutical company, incentives cannot be utilized at present)	MoSIT, MoH, MoF, MoE, SI	Amendment of relevant legislation The number of clinical trials that utilize incentives	2013

Action Plan
Basic and Clinical Research

5. Strengthening collaboration between universities and pharmaceutical industry

The life sciences ability management and biotechnology program aims to train the necessary workforce for the life sciences areas in industry and academia in Massachusetts, USA.

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
5.1. Create and support platforms to facilitate cooperation between university and industry **a.** Initiate large scale and multi-stakeholder (university, public, private sector) research programs through TÜBİTAK and relevant institutions, similar to the Inovita Life Sciences and Technologies Istanbul Cooperation Platform	MoSIT, MoE, STRCoT, Univ, SI, PC, CoCI	Increase in number of cooperations in life sciences	2012 - 2015
5.2. Develop legislation that will allow researchers to work both in techno-parks and in private sector R&D centers with similar benefits	MoH, CoHE, Univ, SI	Amendment of relevant legislation	2013
5.3 Develop legislation that will allow researchers to work in every research center and enable sustainable finance and management of research centers **a.** Improve legislation related to employment of full-time employees/technicians in research centers **b.** Provide governmental financial support until stronger relations with industry are formed **c.** Improve legislation to increase the portion allocated to researchers in research funding	MoH, MoSIT, MoD, CoHE, MoLSS, STRCoT, MoF, Univ, SI	Full-time personnel rate in research centers Rate of non-public income to total income in research centers	2013
5.4. Facilitate private sector guidance and support of academic stuff to increase participation of researchers in international research networks of pharmaceutical companies and institutions **a.** Increase participation in clinical research studies conducted on international platforms	Univ, PC, SI, CoCI	Number of Global Basic and Clinical studies in Turkey that researchers participate in	2012 - 2015

Action Plan
Basic and Clinical Research

6. Developing infrastructure to motivate & improve the level of research of universities and research hospitals, and to enable the integration of this research within global R&D networks

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
6.1. Develop a road map aimed at integrating a qualified labor force in Turkey into global R&D studies **a.** Assess research capabilities & interests of Turkish scientists & Turkish expatriates scientists, and implement mechanism for continuous monitoring **b.** Organize workshops aimed at developing or enhancing collaboration with Turkish scientists in successful R&D centers around the world	SI, PC, NGO, MoSIT, CoHE, Univ.	Taking inventory of scientists and integration of them into a database. Number of workshops organized	2012 -2014
6.2. Establish bachelors, masters and doctorate programs in biomedical and clinical engineering which will be necessary to increase R&D and domestic pharmaceutical production **a.** Enhance interdisciplinary programs for increasing academic capacity in Turkish universities in necessary areas	MoH, CoHE, Univ, MoSIT, SI	Number of departments established	2013 - 2015
6.3. Improve ability of academic staff to transfer knowledge, have simultaneous appointments within the country and abroad, and support collaboration and global integration	CoHE, MoSIT, Univ., NGO, SI, PC	Number of academics appointed	2012 - 2014
6.4. Implement regulations that encourage greater remuneration of academic staff working in basic and clinical research	TGNA, CoHE, MoF, MoH, Univ., ERH, SI	Enforcement of relevant legislation Ratio of net salary of doctors to total clinical research budget	2012
6.5. Develop working hour regulations that allow academics to conduct research for product & service development	MoH, CoHE, Univ.	Enforcement of relevant legislation	2013

Action Plan
Basic and Clinical Research

7. Standardizing clinical trials procedures to match international standards

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
7.1. Provide necessary training of stakeholders so that clinical studies can be conducted in a rapid, ethical and effective way. **a.** Ethical Committee and Ministry of Health audit committee's take necessary training regarding process **b.** Investigators are provided necessary technical education related to clinical studies **c.** In undergraduate study, add technical education about Clinical Research to the syllabus	MoH, SI, PC, MoHE, MoNE, Univ.	Number of people to whom education training is provided throughout the year	2012 - 2013
7.2. Audit all stakeholders conducting clinical trials and research to assure they are meeting necessary Good Clinical Practice (GCP), Good Laboratory Practice (GLP) criterion	MoH, TAA, TSI	Ratio of certified institutions	2013 - 2014
7.3. Improve clinical studies infrastructure at universities and hospitals, and increase capacity for clinical studies	MoH, Univ., ERH, CoHE, PC	Amount of research per clinic center	2013 - 2014

Action Plan
Basic and Clinical Research

8. Implementing information systems and a judicial framework to support life sciences research

England aims to establish a Clinical Research Web Access wherein clinical research information is published by the National Health Service (NHS) which has made it center of innovation.

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
8.1. Standardize and integrate current data systems (family health practices and hospitals)	MoH, SSI	Integration percentage of current systems	2013
8.2. Develop legislation in order to omit personal identifiers and to sort anonymous data into prioritized categories (age/geographic area/illness, etc)	MoH, SSI	Preparing related regulations	2013 - 2014
8.3. Create a legal framework for usage of this data (terms of use, duration, authorization mechanisms and responsibility for criminal sanctions)	MoH, SSI, MoJ, MoSIT	Preparing related regulations	2013 - 2014
8.4. Activate "Saglik.net" (health.net) system	MoH, SSI	Percentage of health.net system that is working	2013 - 2014
8.5. Create a voluntary database based on data-processing infrastructure that researchers doing clinical research can benefit from; transform database into a transparent application that volunteers can use	MoH, Univ., ERH, SI, SSI, NGO	Preparing necessary regulations The ratio of data recorded	2013 - 2016

Action Plan
Production and Export

9. Determining the production plans for priority fields in alignment with Turkish Pharmaceutical Industry's strategy

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
9.1. Map out an Inventory of Turkish pharmaceutical industry (facilities, production capacity and usage rate, actual production, production range, production structure, technological level, etc.)	MoH, MoSIT, MoE, MoD, PC, SI, UCCT	Carrying out a detailed inventory of pharmaceutical industry	2012
9.2. Implement the regulation of the Incentive Package declared in April 2012 (The new incentive system became effective 20 June 2012 by the Notification on State Aid for Investments Decree and Application of the Decree. Only the criteria for strategic investments were defined. The related commission was held responsible for selecting strategic investments. None the less, some biotechnological products, blood products and oncology products are defined as prioritized investment areas in the State Aid for Investments Decree no:2012/3305 , Article 17.1.e, issued 19.06.2012)	MoE, MoH, MoSIT	Enact incentive package	2012
9.3. Include the government's prioritized production areas (oncology, biotechnology, blood products) that were announced by the Incentive Package in April 2012 to the Turkish Pharmaceutical Industry Strategy and, if necessary, determine other prioritized areas and develop an action plan accordingly. In June 2012, some biotech products, blood products and oncology products were defined as prioritized investment areas (the State Aid for Investments Decree no:2012/3305 , Article 17.1.e, issued 19.06.2012	MoH, MoSIT, MoE, MoD, PC	Publish of the action plan Determine of other prioritized production areas considered necessary	2012

Action Plan
Production and Export

10. Developing an action plan to increase the volume of exports

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
10.1. Having determined potential export markets, develop of action plans to improve exports to these countries (bilateral licensing agreements)	BSTB, EB, YDTA, TİM, DEİK, İSF	At least 5 priority countries identified	2013
10.2. Apply to the Pharmaceutical Inspection Concention & Pharmaceutical Inspection Cooperation Scheme (PIC/S), and enter into mutual recognition agreements with countries that are target export markets	SB, EB	No. of countries with which mutual recognition agreements are signed	2013 - 2014
10.3. Apply pricing conditions compatible with global pharmaceutical pricing	BSTB, SB, SGK	Implementation of regulation	2013
10.4. Develop market access regulations that align with global market access conditions	MoH, SSI	Implementation of regulation	2013
10.5. Remove licensing obligations for export production purposes	MoH, MoSIT	Implementation of regulation	2012
10.6. Develop action plan to improve the ecosystem so as to create a competitive environment vis-a-vis other emerging markets that will attract manufacturing investments by which Turkey becomes the global supplier for selected product lines	MoH, MoSIT, MoE, TEA, PC, SI	Implementation of action plan and regulation	2012 - 2013
10.7. Determine of competitive advantages in terms of raw materials, auxiliary materials and package production; complete feasibility studies	MoSIT, MoE	Determination of at least 5 raw materials given global consumption levels	2013

Action Plan
Production and Export

11. Providing the necessary support to increase the volume of production in the relevant life sciences cluster

Biomedical intervention was established in Singapore in 2000 in order to create a biomedical scheme within the government's improvement plan for the biomedical industry. It was carried out by the Research, Innovation and Intervention High Commission and will improve the clustering process in 3 stages: 2000-2005 improvement of infrastructure and collaboration; 2006-2010 improvement of R&D sustainability; 2011-2015 creation of economic output and contribution to growth.

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
11.1. Develop the necessary regulations to ensure the investments in the cluster benefit from the incentives in the Incentive Package launched April 2012 (According to the new incentive system that became effective by the State Aid for Investments Decision no:2012/3305 issued in 19.06.2012 and the Notification on State Aid for Investments and Application of the Decree no:2012/1 issued in 20.06.2012, large scale investments in Organized Industrial Zones (OIZ) and investments covered under regional incentives could benefit from incentives for less developed regions in which they are located. (Regions are divided into 6 classes based on level of development.)	TGNA, MoH, MoSIT, MoE	Implementation of regulation (the decree law on State Aid for Investments and Application of the Decree numbered 28239, No: 2012/1 issued in 20 June 2012)	2012

Action Plan
Production and Export

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
12. Incentivizing the prioritized production areas			
12.1. Ensure incentives for prioritized production fields (oncology, biotechnology, blood products, etc.) identified by incentive system announced in April 2012 are used by investors • The State Aid for Investments Decree no:2012/3305 issued in 19.06.2012 in Official Gazette numbered 28328. • The Notification on State Aid for Investments and Application of the Decree no:2012/1 issued in 20.06.2012 in Official Gazette numbered 28329. By these law and notification the design of the legal infrastructure regarding the new incentive system has been completed	ISPAT, PC, MoH, MoSIT	Number of applications for benefiting incentives Value of incentives which companies utilize Positive/Negative respond rate of applications	2012 - 2013
13. Incentivizing and facilitating knowledge transfer in high-technology production			
13.1. Develop incentives and financing advantages for high-technology investments within the Incentive Package announced to public in April 2012 and/or in the Turkish Pharmaceutical Industry Strategy prepared by MoSIT (In the new incentive system that is based on the State Aid for Investments Decree no:2012/3305 issued in 19.06.2012 and the Notification on State Aid for Investments and Application of the Decree no:2012/1 , 4 types of incentive mechanism were defined; however the investment for high technology is not specified.)	MoSIT, MoE, MoH, MoF, MoCT	Regulation of relevant legislation	2012
13.2. In high technology production, grant temporary employment permits for foreign experts	MoLSS, MoF	Average time to obtain temporary employment permits	2015

Action Plan
Production and Export

14. Developing the competencies & improving the education level of the work force based on industry needs

Ireland prioritized its pharmaceutical industry in 1970 and established industry-specific technical universities and engineering faculties between 1970-80.

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
14.1. Strengthen pharmaceuticals and pharmacology departments (medicine, pharmacy, chemistry, biology etc.) and orient graduates towards the sector, increasing information exchanges of local academics with those abroad	CoHE, MoH, Univ., MoNE, STRCoT	Ratio of employees who graduated from related faculties to total number of graduates	2013 - 2015
14.2. Establish departments that focus on medical engineering and medical production technicians, and establish and strengthen vocational schools related to the medical sector	CoHE, MoH, Univ., MoNE, SI, CoCI	Number of departments established	2013 - 2015

Action Plan
Management Center

15. Provide tax incentives to international life sciences executives who provide services abroad

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
15.1. Eliminate tax disadvantages of international executives/qualified white-collar workforce who work as experts in free-trade zones and R&D centers: For the foreign-owned companies, coordination and management of affiliations and business units in Europe, Asia and the Middle East are allowed to function in Turkey as a Regional Management Center by the Amendment of the Implementation Regulation of Foreign Direct Investment Law issued on 3.7.2012 in Official Gazette numbered 28342,. In this context , wages of employees in a Regional Management Center in Turkey will not be subject to income tax and exempted from stamp tax in accordance with income tax legislation. Tax disadvantages for white-collar employees have been eliminated by this legislation. However a similar legislation should be implemented for R&D personnel	MoLSS, MoF, MoE	Implementation of regulation Tax disadvantages eliminated for white-collar personnel by the Amendment of the Implementation Regulation of Foreign Direct Investment Law issued on 3.7.2012; similar revision is still needed for R&D personnel	2013

Action Plan
Management Center

16. Execute a publicity campaign to highlight the advantages of locating a management and/or a shared services center in Turkey

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
16.1. Participate in domestic and international platforms to explain the advantages to investors about why their management and/or shared services center should be located in Turkey	ISPAT, PC	Number of related meeting / seminars	2013 - 2014

Action Plan
Management Center

17. Improving Turkey's competitive position with regard to human capital & working standards in order to attract more shared service centers & management offices

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
17.1. Provide employment and training of qualified workforce to work in administrative and support units of companies. Initiate training programs so that employees in these companies develop competence and leadership skills according to international norms	MoLSS, CoHE, Univ., PC	Increase number of white-collar workers in the sector	2013 - 2015
17.2. Designate areas in which Turkey could be competitive according to competencies of authorities working within mutual service areas (for example; finance, accounting, audit, etc.). Improve vocational, undergraduate and graduate programs that contribute to the growth of the workforce and increase employment in the sector (Education of Russian, Arabic Language or IFRS and etc)	MoSIT, CoHE, PC, MoF, CoCI	Number of mutual service units of companies	2013 - 2015
17.3. Improve quality of life, security and transportation services in areas where the pharmaceutical sector thrives (e.g. in life science clusters) and seek to address infrastructure needs of medical companies	Related Ministarials, Mun., CoCI	Launching of necessary infrastructure projects	2013 - 2015
17.4. Ease employment restrictions foreign qualified work force in the country **a.** Provide assistance with work permits. **b.** Allow foreign workers to apply for a position in a Turkish company by providing related documents to the Ministry of Labor, without application at a Turkish Consulate **c.** Give decisions about applications in less than 30 days, do not require residence permits and residence documents in addition to work permits, and deliver work permits to applicants or their new companies	MoLSS, MoF, MoE	Performing the regulations	2013

Aciton Plan
Sustainable Investment Environment

18. Developing legal and administrative regulations that both align with Turkey's vision for pharmaceutical industry and counterbalance the interests of the pharmaceutical sector and public health authorities

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
18.1. Provide necessary regulations that are compatible with international standards, mindful of the investor, transparent and predictable (New Turkish Commercial Code which has come into effect as of 1 July 2012 is a good example of transparency)	Related Ministries.	Speed of updating regulation	2013
18.2. Develop legislation in a way that it does not allow for broad interpretation, is clear and based on objective and measurable criteria	Related Ministries.	Speed of updating regulation	2013

Aciton Plan
Sustainable Investment Environment

19. Develop regulations to increase patients' access to innovative healthcare products and enable reliable and rapid market access

In Ireland, reimbursement decisions for new products are based on the Ireland Health Technology Assessment Guide. This guide is prepared according to a collective agreement of the Health High Commission and Ireland Medicine and Health Institution (Reimbursement decisions for "existing products" are made in 60 days or less and "for new products" max. 90 days).

In Ireland, there are 3 types of registration procedures; there is a different procedure for innovative medicines. Sales permission is given to European Medicine Agency (EMA) licensed products.

In Singapore, drug pricing is left to market forces in the private sector, but in the public sector drugs are divided into two categories: 'standard' and 'non-standard'. Standard drugs are subsidized by the government.

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
19.1. Develop a regulatory framework that allows for fast introduction of new and innovative products into the market **a.** Exclude innovative medicines from budgetary control action **b.** Use current exchange rates when setting pharmaceutical prices	MoH, SSI	Implementing the regulation	2013
19.2. Until the mutual recognition is secured: **a.** Review GMP and registration applications concurrently **b.** Ensure transparency in GMP processes and share these with stakeholders, agree on criteria and timetables **c.** Increase number of GMP audit staff at Ministry of Health **d.** Implement risk-based audit approach to GMP audits • Allow for non facility-based GMP audits, independent of the product itself • Allow for paper documentation in place of physical audits in clearly defined cases	MoH	Implementing the regulation	2013

Aciton Plan
Sustainable Investment Environment

19. Develop regulations to increase patients' access to innovative healthcare products and enable reliable and rapid market access (continued)

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
19.3. Accelerate registration of applications **a.** Allow clinical benefits to be sufficient criteria for the registration process **b.** Allow for an accelerated registration process according to the EU and EMA criteria	MoH	Finalization of registration applications within 210 days, which is an AB criteria	2013
19.4. Improve reimbursement and pricing implementation in accordance with legal duration and legislation **a.** Develop and implement of regulations regarding pricing, reference pricing and fixed exchange rate application **b.** Define & implement criteria related to inputs/outputs on reimbursement lists and make them transparent **c.** Implement the current legislation by holding regular meetings of the reimbursement commission (three times a year) and preparing annual action plans	SSI	Application of change in exchange rates frequency of commission meetings; implementing currency changes; placing related regulations in related announcements	2013

Aciton Plan
Sustainable Investment Environment

20. Develop effective and adequate intellectual property rights (IPR) system

Actions	Rel. Stakeholder	Follow-up Ind.	Duration
20.1. Develop regulation to compensate the defficiency arising from the lack of penalties/sanctions as a result of the cancellation of Council of Ministers Decree No. 551	TGNA, MoJ, TPI, MoSIT	Enacting the related law	2012 - 2013
20.2. Adding a supplement support period by taking registration processes into account while evaluating patent rights (Implement legislation similar to EU and TRIPS member countries, which allows for a shortened time for benefitting from an invention while waiting for the license for pharmaceutical inventions)	TGNA, MoJ, TPI, MoSIT	Making the related regulation	2015
20.3. Start data protection after the registration date in Turkey and change duration to "8+2+1 years"	TGNA, MoJ, MoH, M0SIT	Making the related regulation	2014

Abbrevations for stakeholders mentioned in the Action Plan section

Abbrevation	Description
CoA	Courf of Accounts
CoCI	Chamber of Commerce and Industry
CoHE	Commission of Higher Education
MoNE	Ministry of National Education
ERH	Education and Research Hospitals
FERB	Foreign Economic Relations Board
ISPAT	Investment Support and Promotion Agency
MoCT	Ministry of Customs and Trade
MoD	Ministry of Development
MoE	Ministry of Economy
MoF	Ministry of Finance
MoH	Ministry of Health
MoJ	Ministry of Justice
MoLSS	Ministry of Labour and Social Security
MoSIT	Ministry of Science, Industry and Technology
Mun.	Municipalities
NGO	Non Govermental Organizations
PC	Pharma Companies
SCST	Supreme Council for Science and Technology
SI	Sector Institutions (AIFD, IEIS, TISD)
SMEDO	Small and Medium Enterprises Development Organization
SSI	Social Security Institution
STRCOT	Scientific and Technological Research Council of Turkey
TAA	Turkish Accreditation Agency
TEA	Turkish Exporters Assembly
TGNA	Turkish Grand National Assembly
TPI	Turkish Patent Institution
TSI	Turkish Standards Institutions
UCCT	Union of Chambers and Commodity Exchanges of Turkey
Univ	Universities
UoT	Undersecretariat of Treasury

Actions proposed for Turkish Pharmaceutical Industry have yielded results in other countries.

Basic, Clinical Research Competency and Service Export

The South Korean Government started restructuring its pharma sector via the Biotechnology Development Plan in 1994.

Development through 1st plan

- Establishment of Korean Biotechnology Research Institute in 1985
- Biotech venture boom with 500 enterprises
- Government's investment in biotech worth $5.5 bn since 1994
- 9 bio-venture centers supporting venture capitals

1st Framework Plan for Biotechnology Development (1998 - 2007)

Status in 2006

- **Ranked 12th among all countries** for number of science technology papers published.

2nd Framework Plan (2007-2016)

- **Ranked 15th among all countries** for competitiveness in patented technology
- **9,500 R&D manpower** with post-graduate degree
- 15 new molecule inventions since 1999

Target for 2016

Vision 2016

- **Rank 7th among all countries** for number of science technology papers published
- **Rank 7th among all countries** for competitiveness in patented technology
- **17,300** R&D manpower with post-graduate degree
- Industialized market value: **~USD 66 bn**

Key actions that improved R&D competency

- Improved the regulatory and legal infrastructure
- Restructured national biotech initiatives in order to support innovation and research
- Expanded infrastructure for upgrading R&D
- Achieved globalization of bio-industries

Ireland identified its pharma sector as a priority for FDI and improved investment environment for production.

Production Competency and Product Export

In 1970, the Investment Development Agency (IDA) identified the pharma industry as a priority for foreign investment.

Between 1970-80, 9 technical universities, research centers, and engineering faculties were founded for targeted industries.

In 2000, the "Science Foundation Ireland" was founded.

In 2006, the Science, Technology and Inovation Strategy for 2006 - 2013 was launched by the government with promises to invest EUR 3.8 bn.

Incentives

TAX

- 12.5% Corporate Tax Rate
- 25% R&D tax credit
- Intellectual property tax write-offs

LABOR

- Social security contributions are lowest in EU (10.75%)
- Easy access to skilled labor

Key success factors of the pharma sector

- **5 of** the world's **top 12** medicines are manufactured in Ireland.
- Pharmaceutical industry in Ireland created **2 out of every 5** pharmaceutical jobs which came to Europe in 2008.
- **11% of Ireland's GDP** is generated by the pharmaceutical industry.
- Pharma exports worth EUR 31 bn in 2010 and sector generates over 50% of Ireland's total exports.

Source: PwC Benchmark Analysis

Massachusetts, USA became management center for pharma companies by providing financing sources and a qualified workforce.

Management Center And Service Export

Key Facts

Industry

240 pharma & biotech companies: of 83 are listed

Funding

- 30 Venture Capital Firms: USD1.1 bn VC investment for biotech in 2010,
- 24% of all US biotech VC investment, available in Massachusetts,
- NIH funding

University / Medical Center

- 16 medical centers and 5 of the top eight NIH funded hospitals: Harvard, Uni. of MA, Boston, MIT, Tufts)
- 5,997 research facilities covering thousands of square feet

Talent Base

- More than 85,000 high-tech research employees and more than 340,000 medical employees
- **Life Sciences Talent Initiative and Biotech Program:** Study conducted to develop collaborative statewide strategy between business, government and higher education to ensure that the state's talent needs in life sciences are met.

Regulatory Environment

- In 1980, **Massachusetts Biotechnology Council (MBC)** was formed.
- **MA Life Sciences Initiative:** Designed to administer the state's 10-year, USD1 bn life sciences initiative to support the cluster through job growth, economic development.
- State governors also **promoted MA as a location for biotech expansion at all biotech trade shows** and conferences.
- State supported shared services to achieve cost efficiency.

Source: PwC Benchmark Analysis

Several possibilities to ensure steadiness of the market in parallel with increasing the investments in pharmaceutical industry.

Sustainable Investment Environment

- In China, approval processes were sped up under the name **"Green Channel"** for ensuring **the rapid introduction of innovative products to the market.**
- Massachusetts, USA supports existence of favorable regulatory regime for IP protection to support an innovative business environment.
- In Ireland, **product classification and mutual recognition** are performed for **quick authorization.**
- In Ireland, critical decisions such as pricing are under taken through **cooperation by agencies and the government.**
- In Singapore, drug pricing is left to market forces in the private sector, but in the public sector drugs are divided into two categories: 'standard' and 'non-standard'. Standard drugs are subsidized by the government.

Source: PwC Benchmark Analysis

Key Success Indicators for Vision 2023

pwc

AiFD


250ml
±0,15 ISO
In 20°C

Basic Indicators of Success

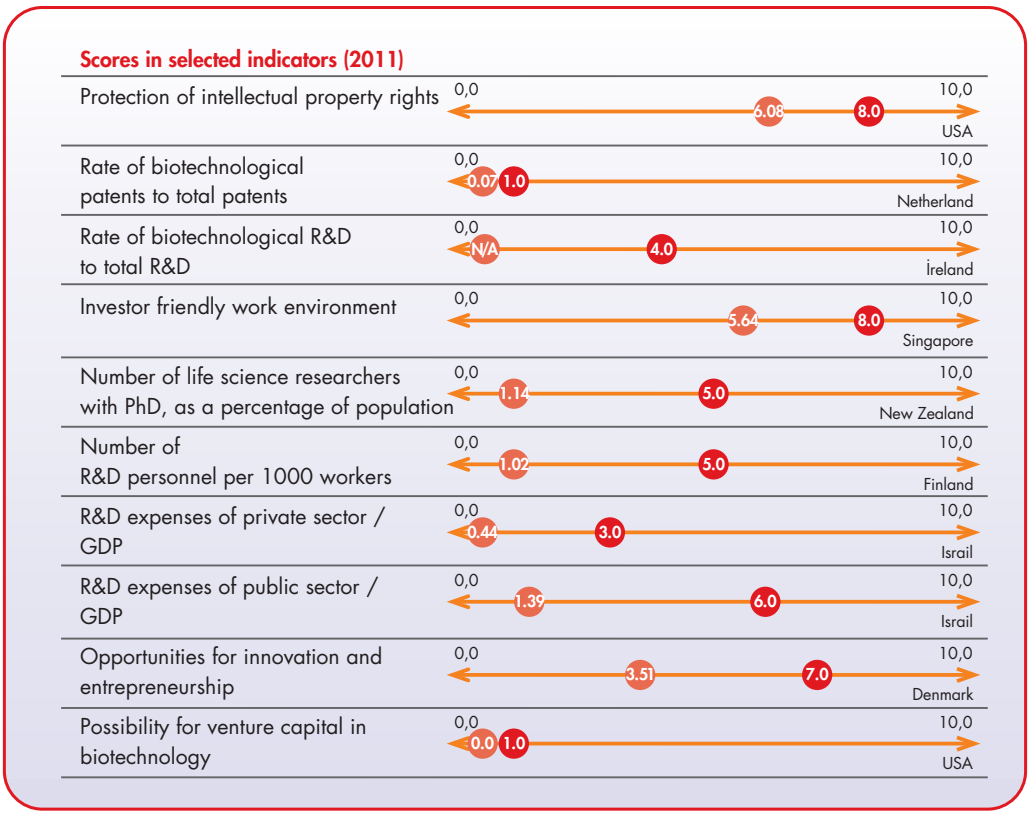
Key Success Indicators	Current Status	Vision 2023
1. Basic and Clinical Research		
World Economic Forum Index of Global Competency, out of 142 countries (2011-2012)		
Innovation capacity *Brazil (31.), Russia (38.), India (35.), China (23.)*	71.	Top 20
The quality of scientific research centers *Brazil (42.), Russia (60.), India (34.), China (38.)*	89.	Top 30
Cooperation beetween university-industry in R&D *Brazil (38.), Russia (75.), India (50.), China (29.)*	74.	Top 20
Quality of education system *Brazil (115.), Russia (82.), India(38.), China (54.)*	94.	Top 40
Quality of Life Sciences and Mathematics education *Brazil (127.), Russia(50.), India (32.), China (31.)*	103.	Top 40
Availability of venture capital *Brazil (52.), Russia (88.), India (27.), China (22.)*	82.	Top 20
Retaining scientists and engineers *Brazil (91.), Russia (72.), India (21.), China (33.)*	35.	Top 20
Global Innovation Index, out of 141 countries (2011)		
Global Innovation *Brazil(58.), Russia (51.), India (125.), China (34.)*	74.	Top 30
Instituitions (political-regulatory and business environment) *Brazil (84.), Russia (93.), India (64.), China (121.)*	86.	Top 50
Innovation linkages (university collaboration, cluster development, etc.) *Brazil (57.), Russia (118.), India (59.), China (73.)*	130.	Top 55
Human Capital and Research *Brazil (83.), Russia (43.), India (131.), China (84.)*	82.	Top 40
Number of new local molecules	0	At least 1
Pharmaceutical R&D expenditures/GDP (2010)[1]	0.008%	0.1%
Pharmaceutical R&D expenditures/total R&D expenditures (2010)[1]	0.7%	3.6%
Rate of domestic patents to total drug patents registered in Turkey in the last 5 years (2008)[2]	6%	11%
Number of medical researchers per 1000 people (2009)[3]	0.14	1.2
Number of clinical trials conducted throughout a year (2011)[4]	240	~3,600
Share of total industrial clinical trials in the world (2011)[4]	0.6%	3.7%
Number of clinical centers per 1 million people (2010)[5]	3	15

Source: 1. TURKSTAT, **2.** Turkish Patent Institute, **3.** UNESCO, World Bank, **4.** clinicaltrials.gov, **5.** Clinical Trial Magnifier

Key Success Indicators	Current Status	Vision 2023
2. Production and Export		
Pharmaceutical exports as a percentage of pharmaceutical imports (2010)[1]	10%	107%
Share of total global pharmaceutical exports (2010)[1]	0.1%	1%
Pharma's share of Turkey's total exports (2011)[2]	0.4%	1.1%
3. Management Center		
Number of multinational pharmaceutical companies, that have established regional management centers in Turkey (2011)[3]	3	20
Sustainable Investment Environment		
World Economic Forum Global Competitiveness Index, ranking of 142 countries (2011-2012)		
Global Competitiveness *Brazil (53.), Russia (66.), India (56.), China (26.)*	59.	Top 25
Rights for intellectual property *Brazil (59.), Russia (130.), India (69.), Çhina (41.)*	72.	Top 30
Protection of rights for intellectual property *Brazil (84.), Russia (126.), India (68.), China (47.)*	108.	Top 50
Transperancy in government policy making *Brazil (78.), Russia (115.), India (58.), China (41.)*	54.	Top 30
Importance of government legislations *Brazil (142.), Russia (132.), India (96.), China (21.)*	93.	Top 40
World Bank Doing Business 2011 Index Raking of 183 countries		
Ease of doing business *Brazil (127.), Russia (123.), India (134.), China (79.)*	65.	Top 35
Protection of Investors *Brazil (74.), Russia (93.), India (44.), China (93.)*	59.	Top 25
Number of drugs authorized in Turkey in the last 5 years / number of drugs authorized according to FDA and EMA in total[4]	29%	80%
Rate of 20-year drugs to the total domestic market (on volumebasis) (2011)[5]	69%	40%
Duration of GMP certification- (parallel registration) (2011)[6]	410 days	Less than 210 days
Average registration duration (2011)[6]	752 days	Less than 210 days

Source: 1. UNCOMTRADE, **2.** TURKSTAT, **3.** PwC Analysis, **4.** FDA, **5.** IMS, **6.** AİFD (Association of Research-Based Pharmaceutical Companies)

Turkey ranks **42th** among 50 countries and aims to rank in the **top 25**, based on Vision 2023.



Refers to the current score of Turkey.

Refers to the desired score of Turkey within the scope of "Vision 2023".

* Methodology of Scientific American Worldview Scorecard: The country acquired the best result in the evaluation of scorecards was given 10 points and other countries were placed on a scale down to 0; Desired scores of Turkey within the scope of "Vision 2023" were determined taking the current scores of countries compared in terms of indicators as a basis.

2023 Scenarios

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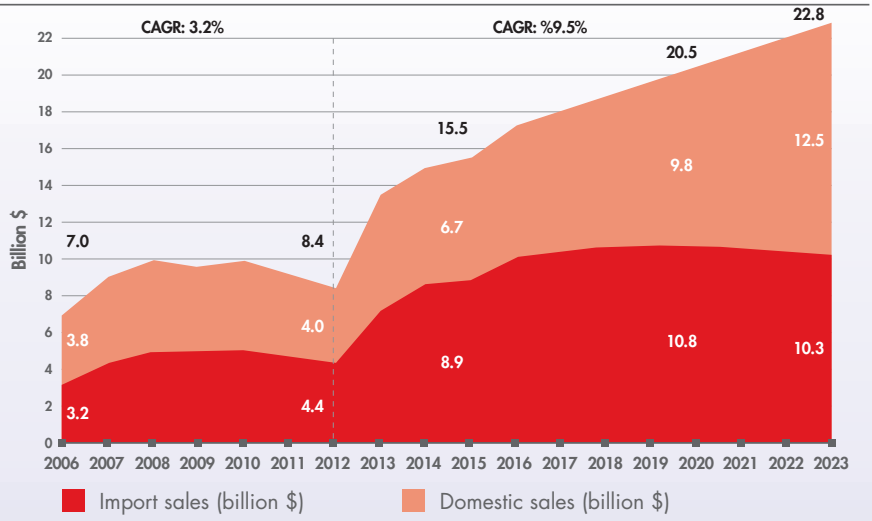
Under current budget framework, Turkey's pharma industry will reach USD 23 billion by 2023; imported products will maintain their share and account for half the market.

Turkish Pharmaceutical Industry "Current Status" Projection, 2006 - 2023



CAGR

	2006 - 12	2012 - 23
Total Market	**3.2%**	**9.5%**
Sales from domestic production	1.1%	10.9%
Sales from imported production	5.4%	8.1%

Market Distribution

	2012	2015	2020	2023
Sales from domestic production	48%	43%	48%	55%
Sales from imported production	52%	57%	52%	45%

Market Estimation:

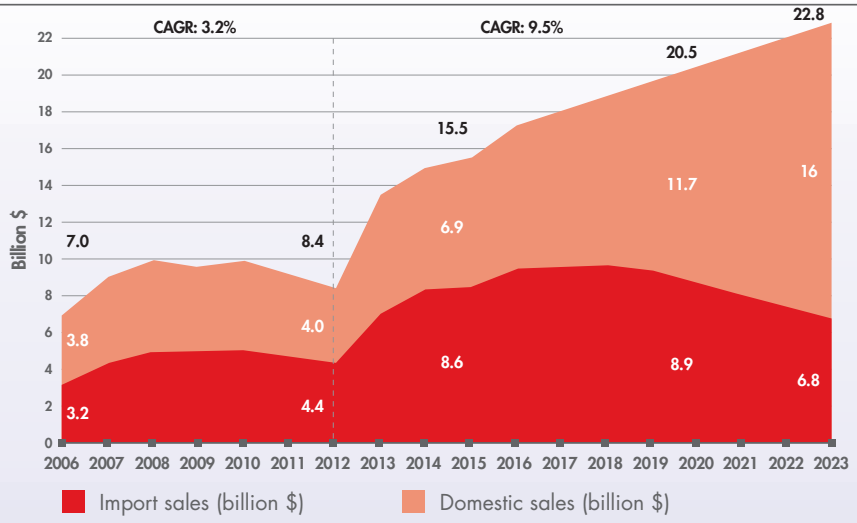
- Market growth:
  - Between 2012-15 IMS Budget Scenario is used.
  - Between 2015-23 [GDP growth rate + Inf(%)].
- Market is estimated as TL and converted to US$. In TL currency, the market is predicted to reach **TR 45.6** billion in 2023.

Estimated Market Dynamics:

- Increase in Turkey's domestic investments in areas specified by the government
- Majority of innovative products will continue to be imported
- No significant change in supply composition in areas specified by the government

In "Vision 2023" scenario for Turkey's pharmaceutical industry, the ratio of locally manufactured products to market size will increase and reach USD 16 billion by 2023.

Turkish Pharmaceutical Industry "Vision 2023" Projection, 2006 - 2023



	CAGR	
	2006 - 12	2012 - 23
Total Market	**3.2%**	**9.5%**
Sales from domestic production	1.1%	13.3%
Sales from imported production	5.4%	4.2%

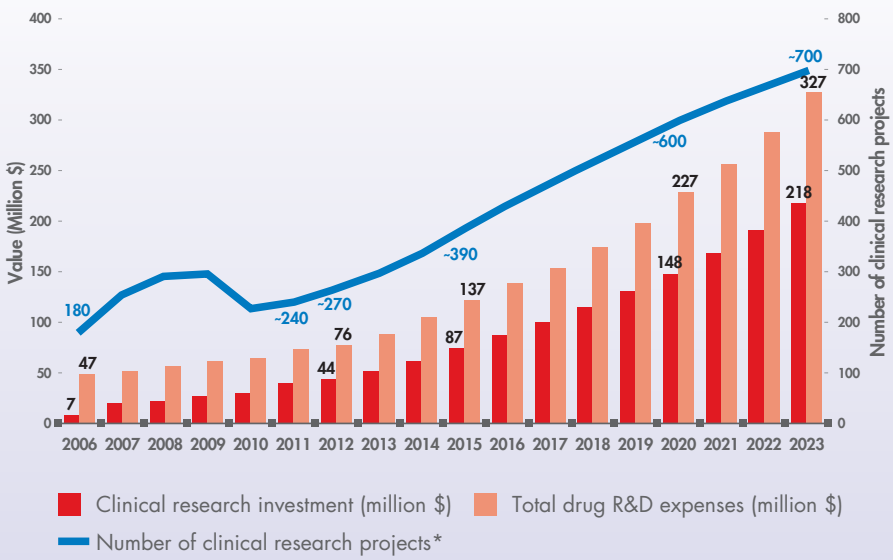
	Market Distribution			
	2012	2015	2020	2023
Sales from domestic production	48%	45%	57%	70%
Sales from imported production	52%	55%	43%	30%

Market dynamics estimated in "Vision 2023" scenario:

- Announcement of the "Pharmaceutical Industry Strategy" by the government and implementation of governmental and judicial legislation that creates a consistent, transparent and competitive investment environment
- Making legislative regulations in terms of infrastructure and incentives
- Implementation of recommendations in 2023 scenario
- Increasing local production in the government-specified areas and/or high-tech innovative products
- Continuation of import of innovative medicines and medicines with small volume in the market

In "Current Status" scenario, clinical research is expected to attract investment of USD 218 million, which is the current investment that Poland attracts.

Turkish Pharmaceutical R&D "Current Status" Projection, 2006 - 2023



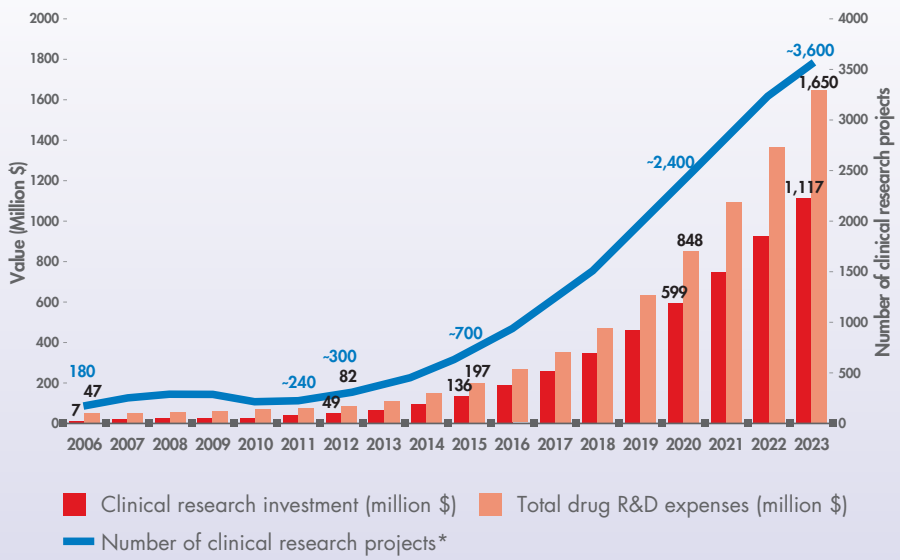
Estimated R&D dynamics in "Current Status" scenario

- Positive effects of new clinical research legislation are expected to be seen as of 2012; however, it is assumed that the problems in the researcher payment system won't be resolved in 2012.
- The lack of collaboration among scientists and industry, as well as the shortage of opportunities to encourage the private sector to invest in basic research, are likely to continue. It is estimated that basic research investments will have a 20% share in total R&D spending if the current status continues.

* The number of clinical research projects conducted throughout a year and initiated within the year are taken as a basis.

In "Vision 2023" scenario, clinical research investments are expected to reach USD 1.1 billion and total R&D investment by pharmaceutical industry is expected to reach USD 1.7 billion.

Turkish Pharmaceutical R&D "Vision 2023" Projection, 2006 - 2023



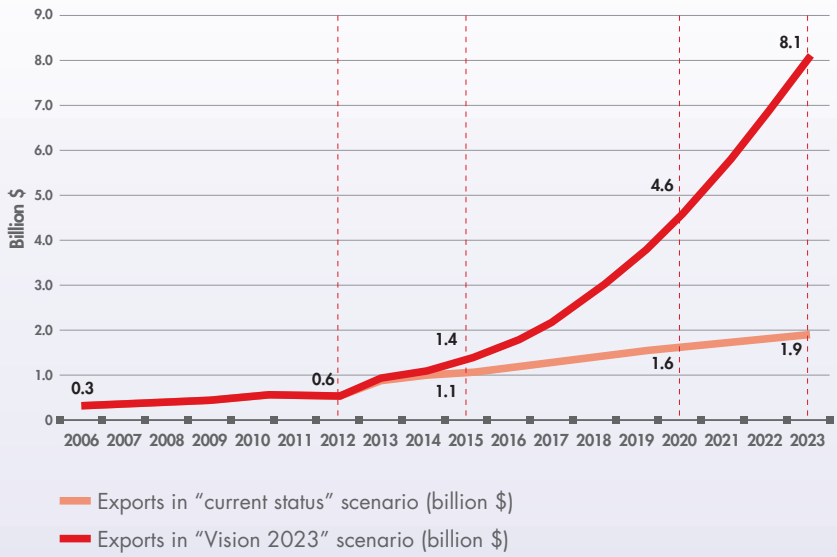
Estimated R&D dynamics in "Vision 2023" scenario

- It is anticipated that basic research will be supported more and investments that are made in basic research will grow after prioritizing the life sciences area in basic research by 2012, changing the education system by 2013 (multidisciplinary programs), and by using the incentive mechanisms (regulating techno-park legislation, incubation and technology transfer offices).
- Positive effects of new clinical research legislation will begin to be realized as of the second half of 2012, problems regarding payments made to researchers will be resolved in 2013, a fast and fair payment system will be implemented after ameliorating the approval process, which will increase investments.
- After 2015, industrial clustering is expected to form and increase R&D investments. While R&D included only clinical research and domestic industrial studies in 2012, the share of basic research that allows for the discovery of new molecules, will rise to 30% by 2023.

* The number of clinical research projects conducted throughout a year and initiated within the year are taken as a basis.

Turkey's pharma export rate is expected to remain stable under current policies, but it could reach USD 8.1 billion as a result of increased production and clinical trial capacity in the "Vision 2023" scenario.

Turkish Pharmaceutical Industry Export* Projection, 2006 - 2023



	CAGR	
	2006 - 12	2012 - 23
Current Status	10.2%	11.8%
Vision 2023	10.8%	26.9%

	Share of exports in total market			
	2012	2015	2020	2023
Current Status	7%	%7	%8	8%
Vision 2023	7%	%10	%22	36%

* Total pharmaceutical exports and clinical research service exports were considered, half of the clinical research investments were regarded as service exports.

Estimated export dynamics in “Current Status” scenario

It is expected to show growth greater than that of the local market; basic dynamics:

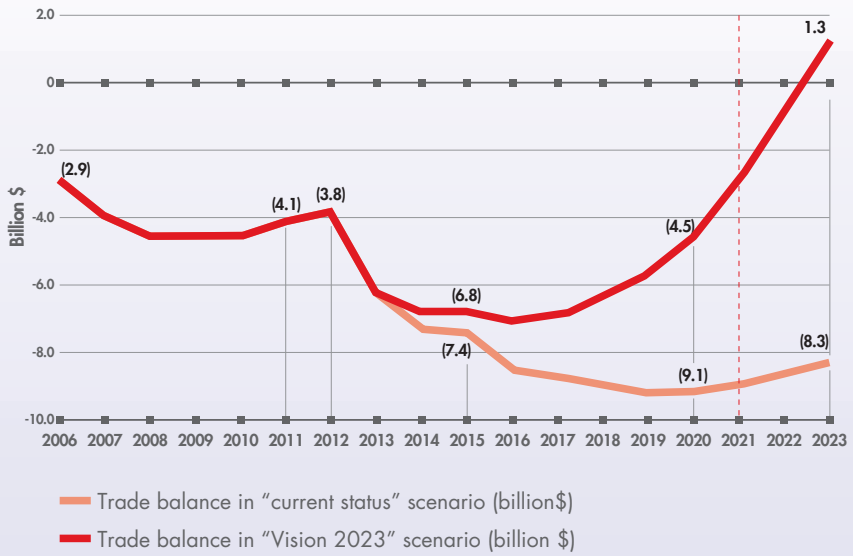
- Increase in production capacity of generic products.
- Policy for getting Turkish generic products into international markets
- More partnerships with international companies
- Realize 50% of the total clinical research investment as service export

Estimated export dynamics in "Vision 2023” scenario

- Turkey being a production hub in fields that are prioritized by the government or for some specific products and becoming a regional/global supplier
- Reaching the position of an exporter of some active ingredients especially by increasing the production of raw materials
- Increase in the ratio of clinical research investment as service export to total clinical research investment from 50% in 2012 to 70% in 2023

In "Vision 2023" scenario, Turkey's pharmaceutical indusry will help decrease the trade deficit by increasing domestic production and exports. Turkey will position itself as a net exporter by 2023.

Turkish Pharmaceutical Industry Foreign Trade Balance*
Projection, 2006 - 2023



	CAGR	
	2006 - 12	**2012 - 23**
Current Status	%5	%7.4
Vision 2023	%5	N/A

* Total pharmaceutical imports and exports and clinical research service exports were considered.

Foreign trade balance estimations for the pharma industry under the "Current Status" scenario

- Increasing local production capacity at a limited rate as the result of market growth in Turkey
- Increased manufacturing capacity for generic products
- Continuing exports of innovative products
- Clinical research service exports will be USD110 million which is 50% of the total clinical research investment

Foreign trade balance estimations for the pharma industry under the "Vision 2023" scenario

- Decreasing the import of value added and innovative products as a result of the increase in new investments for such products through incentives
- Identification of new export markets; rapid increase in exports, especially in the investment period
- Increase especially in the production of raw materials that constitute 25% of imports
- Clinical research service exports will be USD800 million which is 70% of total clinical research investment and contribution to exports

Map of Goal Alignment with Government Plans

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"Vision 2023" scenario and suggestions that will support the "Turkish Pharmaceutical Industry Strategy Report" comply with the targets below, which are included in the government's strategic documents.

1. **Vision 2023**
   Turkey's Strategic Vision 2023 Report.

2. **Industrial Strategy Document**
   T.R. Ministry of Science, Industry and Commerce, Turkey's Industrial Strategy Document 2011-2014.

3. **9th Development Plan**
   State Planning Organization, 9th Development Plan 2007-2013.

4. **Ministry of Health Strategic Plan Document**
   Ministry of Health, 2010-2014 Strategy Document.

5. **TÜBİTAK SCST Vision 2023**
   TÜBİTAK, Supreme Council for Science and Technology 2023 Project.

6. **TİM 2023 Strategy Report**
   Turkish Exporters Assembly, Execution Plan of Turkey's Export Strategy for 2023 and Sectoral Strategy Report.

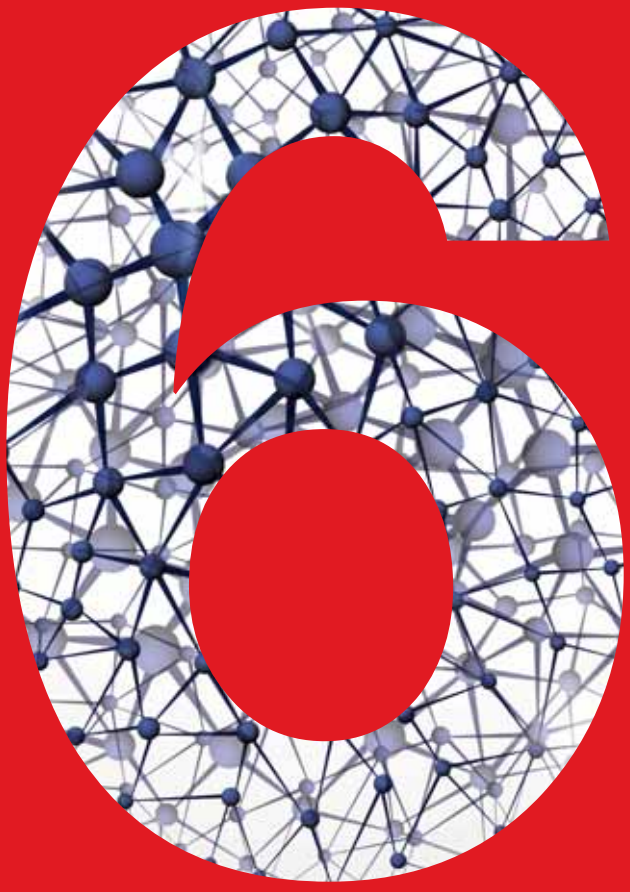
Goal Alignment with Government Plans

Goals	Related Gov't Document	Reference
Government adoption of a cuetral research policy on life sciences in alignment with the strategy put forth by the Turkish pharmaceutical industry	4	Science and R&D, article 1 Industrial Approaches, article 1 Economic and Financial Policies, article 2
	5	Annex-11, Annex-12 and Annex-16
	2	Industrial policies, article p
Developing infrastructure to motivate & improve the level of research of universities and research hospitals and to enable the integration of this research within global R&D networks	4	Investment Policies, article 1
	6	Chemical Products Sector, Product Development, articles 2 & 3
Developing a road map for Life Science Clustering	1	Cooperation of University - Industry for Scientific and Technological Development Targets
	5	Annex - 12
	6	Chemical Products Sector, production, article 2
Strengthening collaboration between universities and pharmaceutical industry	3	Improving the Work Environment, article 383 R&D and Development of Innovativeness, article 476
	6	Chemical Products Sector, inter-institutional relations, article 1
Increasing the variety of R&D financing resources to encourage & Support an increase in life sciences R&D	3	Development of R&D and Innovativeness, article 475
	4	Foreign Trade Policies, article 103
	6	Chemical Products Sector, Regulation, article 2
Implementing clinical research regulations in order to improve Turkey's competitive position	2	Investment and Work Environment, article a

Goals	Related Gov't Document	Reference
Standardicing clinical trials procedures to match international standards	1	Fundamental Problems of Higher Education in Turkey
Determining the production plans for priority fields in alignment with Turkish pharmaceutical industry's strategy	1	Cooperation of University-Industry for Scientific and Technological Development Targets
	5	Annex - 12, Annex - 14 and Annex - 16
Incentivizing the prioritized production areas	2	Industrialization, article 6
	5	Annex - 16
Developing the competencies & improving the education level of the work force based on industry needs	2	Skills and Human Resource, article g
	6	Chemical Products Sector, Human Capital, article 1
Incentivizing and facilitating knowledge transfer in high-technology production	3	Improving the Educational System, article 248
	5	Annex - 12 and Annex - 16
Developing an action plan to increase the volume of exports	2	Strategic Targets, article b Industrial Policies, article ö
	4	Institutional Policies and Legal Regulations, article 2
	6	Main goal
Developing regulations to increase patients' access to innovative healthcare products and ensure enable reliable and rapid market access	2	Strategic Targets, article b Industrial Policies, article ö
	3	Improving the Work Environment, article 384

1 Vision 2023
2 Industrial Strategy Document
3 9th Development Plan
4 Ministry of Health Strategic Plan Document
5 TÜBİTAK SCST Vision 2023
6 TİM 2023 Strategy Report

Stakeholders Who Commented on Vision 2023 Report



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Stakeholder Who Commented on Vision 2023 Report

Public Instituition

1. Republic of Turkey Ministry of Science, Industry and Technology
2. Republic of Turkey Ministry of Development
3. Republic of Turkey Ministry of Health
4. Republic of Turkey Prime Ministry Investment Support and Promotion Agency
5. The Scientific and Technological Research Council of Turkey (TÜBİTAK)

Industry Instituitions

6. Association of Research-Based Pharmaceutical Companies
7. Pharmaceutical Manufacturers Association of Turkey

Universities

8. Acıbadem University Department of Clinical Microbiology and Infection
9. Bilkent University Department of Molecular Biology and Genetics
10. Bilkent University Computer Engineering - Computational Genom
11. Boğaziçi University Department of Chemistry and INOVITA Sciences and Technologies İstanbul Cooperation Platform
12. University of Boğaziçi Department of Molecular Biology and Genetics
13. Ege University Pharmaceuticals Development & Pharmacokinetic Research and Application Center (ARGEFAR)
14. Gazi University Department of Medicine Endocrinology
15. Hacettepe University Technopark Technology Transfer Office
16. İstanbul University Department of Medicine Pharmacology and Clinical Pharmacology
17. İstanbul University Department of Medicine Department of Internal Diseases
18. Erciyes University Clinical and Experimental Research Center (DEKAM)
19. Koç University Department of Chemistry and Biology Engineering and Institute of Health Sciences

Pharmaceutical Companies

20. AIFD Members
21. Abdi İbrahim
22. Bilim İlaç
23. Mustafa Nevzat

Other Stakeholders

24. Paragon Consulting - Intellectual Property & Trademark

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Serkan Tarmur
Pharmaceutical Industry, PwC Advisory Services Partner
Phone: 00 90 212 376 5304
serkan.tarmur@tr.pwc.com