

Turkey Market Report

Research conducted by GBR*

Analysing Pharma Industry trends and techniques

CPhI Pharma Insights reports: CPhI, the world's leading pharmaceutical networking event, with over 100,000 attendees globally—is now using its collective resources to create Pharma Insight reports, analysing individual parts of the pharma industry as well as creating the well respected and eagerly anticipated Annual Report featuring a global panel of experts (now in its second year). The vision is to harness the power of CPhI's independent position within the industry so that it can produce unbiased analysis of the global pharmaceutical industry and help to see emerging trends and bring different perspectives together. The Annual Report utilises expert in-depth essays, looking at future contingencies, whilst the Pharma Insights series takes perspectives from CPhI exhibitors and the wider industry.

To get more information on how CPhI events can drive forward growth and new business opportunities for the pharma community, please visit www.cphi.com

*About GBR: Headquartered in Singapore and with offices in Istanbul, Global Business Reports (GBR) was established in 2001 in order to provide up to date and first hand information for global business decision makers. In an age where cross boundary trade and investment and the globalization process are the driving factors for businesses, information is crucial. Precise sectorial reports help companies understand and expand their markets, improve their sourcing chain, target their investments and discover the trends affecting their industry around the world. GBR provides in depth surveys and up to date information and data covering all aspects of the hydrocarbon, Chemical, Pharmaceutical, Energy, Minerals, Mining and the Metallurgical industries around the world.

For previously published reports visit www.gbreports.com

NUMBER OF PHARMACEUTICALS ON THE MARKET

>7,000

Including alternative posologies

>3,000

Excluding alternative posologies



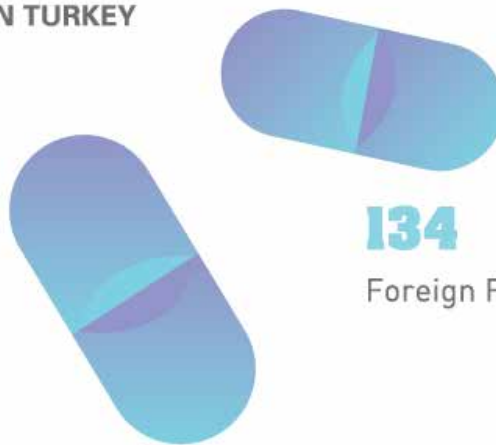
NUMBER OF PHARMACEUTICAL ENTITIES OPERATING IN TURKEY

≈166

Local Firms

134

Foreign Firms



VALUE OF TURKISH PHARMACEUTICAL EXPORTS (US\$)

2013

\$754,894,000

2012

\$661,783,000

2011

\$566,797,000

2010

\$558,172,000



EMPLOYMENT IN THE TURKISH PHARMACEUTICAL INDUSTRY

≈25,000
Total Employment



≈12,500
o/w university educated



MAJOR EXPORT MARKETS FOR TURKISH PHARMACEUTICALS



The Turkish pharmaceutical market is expected to reach

**\$22.8 bn**

by end 2015.

Introduction

This report is designed to evaluate the overall position of manufacturers and foreign pharmaceutical companies working with the Turkish pharmaceutical market and has been commissioned to mark the launch of CPhI Istanbul-

a new event in the CPhI portfolio. At the show a more detailed report, co-authored with research partner Global Business Reports (GBR), providing full interview transcripts and data will be available.

Methodology

Research partner GBR has undertaken in-depth executive interviews with Turkey's largest pharmaceutical manufacturers, working across the country to provide a holistic view of the short-term conditions and macro-economic analysis of how the market is set to develop.

CPhI would like to thank our research partners GBR and the Pharmaceutical Manufacturers Association of Turkey (IEIS), as well as the executives involved in providing raw data to produce this report. These insights have been an invaluable asset in evaluating the overall picture of the market, and have enabled the production of a value-added document

that provides strategic input to anybody seeking to do business within the region. Our contributors included:

<i>Pharmaceuticals Manufacturers Association of Turkey (IEIS)</i>	<i>Ekin Kimya</i>
<i>Abdi İbrahim</i>	<i>ERA Pharma</i>
<i>Ali Raif</i>	<i>Farkim</i>
<i>Berko Pharmaceuticals</i>	<i>Koç University</i>
<i>Biofarma</i>	<i>Onko Koçsel</i>
<i>Centurion</i>	<i>Pharma Vision</i>
<i>Deva Holding</i>	<i>Pharmactive</i>
<i>Ejder Kimya</i>	<i>YükselKarkınKüçük</i>
	<i>Mustafa Nevzat</i>

Background to Turkish healthcare environment

Turkey is a changing and dynamic economy and GDP per capita has more than tripled in the last 10 years, with disposable income rising. As a healthcare economy, the country is seeing tremendous changes thanks in part to an aging population, and a social security system that covers 97% of the population. With rising economic prosperity and an aging population, the government has been systematically increasing healthcare infrastructure. However, the country is now entering a new phase of growth whereby the government has targeted reducing its overall healthcare trade deficit- encouraging local industry and a greater proportion of domestically produced drugs.

"Today, Turkey at this point has an advanced pharmaceutical industry in terms of installed capacity, a production standards and technology. The industry consists of 300 pharmaceutical companies, produces around 8000 drugs and employs around 30K people. This volume and 7 bl USD turnover makes Turkish phama market world's 16th

and Europe's 7th largest market" Inci Ayyildiz, International Commercial Operations Director Mustafa Nevzat Pharmaceuticals

Growth at major Turkish manufacturers:
In 2012, the Turkish pharmaceutical grew at 6.5%. Individual growth at some Turkish manufacturers was much higher. Onko Koçsel, who has taken an aggressive position in the still nascent market for oncological products through the development of a €70 million manufacturing facility, grew by 11.5% last year. The company predicts growth at a staggering rate of 38% in 2014.

Abdi İbrahim, the market leader in the Turkish pharmaceuticals industry with revenue of over 870 million TL and a Turkish capital company, will seek high levels of growth driven by the development of their biologicals division and position within export markets: particularly North Africa and the CIS. To this end, the company will

begin production through a new facility in Kazakhstan at year end, which will support their current operations (acquired through partial acquisition in 2012) in the country.

Nobel Pharmaceuticals, who posted revenue of 300 million TL in 2013, also expects high growth in coming years driven by the company's position within export markets. The company accrued over \$100 million in sales to foreign markets last year.

One of the most aggressive forays to be made into pharmaceutical manufacturing recently, though, was by a name outside of manufacturing. Established by the co-founder of Hedef Alliance, Turkey's largest pharmaceutical

wholesaler, Pharmactive entered into the market through a \$120 million investment. Through their facility, which began manufacturing in 2013, Pharmactive hopes to stake out a position as one of Turkey's five largest generic pharmaceutical manufacturers in the next five years.

Smaller, local players within the industry who have sought to strengthen their position through fortifying their manufacturing capabilities include Berko Pharmaceuticals and Centurion. Berko Pharmaceuticals is now developing its third production site as demand for production currently exceeds capacity, a dynamic that the €60 million investment will, no doubt, help correct. Centurion will invest €20 million in the development of its own facilities.

Rise of R&D

Turkey has traditionally focused heavily on generics manufacturing, with profits on the whole being generated from a typically brand-oriented generics business. "The true strength of Turkey's pharmaceutical industry at the moment is production. There are a lot of high-tech modern production facilities, approved by both the EMEA and the FDA", commented Sirin Deha, General Manager, ERA Pharma.

The true strength of Turkey's pharmaceutical industry at the moment is production

More recently, however, the industry has shifted from standard contract manufacturing to focus more intensively on research and development. Deva Holding, which dates to 1958 and ranked as the sixth largest pharmaceutical manufacturer by revenue in 2013, has pursued vertical integration to support new product development. Philipp D. Haas, Chairman and CEO of Deva Holding, explains "we created the first generic for Imatinib available in the Turkish market. We have also developed an API for it, vertically integrating our supply chain. It is a rarity to find vertical integration in Turkey's pharmaceutical industry."

The delayed uptake in research efforts has been attributed to a number of factors: "A lack of qualified people to conduct research has prohibited the industry from focusing more on molecule generation, as has the hesitance of companies to challenge what has been their usual business model. During profitable years, Turkish pharmaceutical manufacturers were earning so much money from selling generics that they did not spend time on research.

Beyond anything else, the major obstacle to the development of a more research-focused industry has been time. Real drug research – from beginning to end – takes ten years research and is deemed unnecessary and too risky; only one out of a hundred would succeed", remarked Professor Burak Erman, Department of Chemical and Biological Engineering, Koç University.

The formation of collaborations and partnerships will be a key driver of Turkey's R&D sector, and international companies are showing an increased interest to break into the Turkish market through partnerships. Big pharmaceuticals such as Sanofi are already present in Turkey, and Astra Zeneca, as cited by Professor Erman, has noted its eagerness to bring research to Turkey.

IP Protection

A key objective for any pharmaceutical manufacturer when outsourcing to a contract manufacturer is ensuring the security of their intellectual property. The impressions of Turkey's IP laws are seemingly negative, with many asserting that laws do not offer sufficient protection.

Turkey's system of intellectual property law is closely aligned with European standards

Throughout our research, however, Turkish pharmaceutical companies have re-iterated the fact that these sentiments are largely unjustified. "Although certain negative impressions exist, Turkey's system of intellectual property law is closely aligned with European standards. There is a satisfactory level of IP protection in Turkey; this is evidenced in the activities of the industry's generic pharmaceutical manufacturers, which have begun to patent many of their own productions: a reflection on their growing trust in Turkey's system for IP protection", highlighted Mr Gökhan Gökçe, YükselKarkinKüçük.

Fatma Taman, General Manager, PharmaVision shared the same views, citing that the negative impression stems from past events in which some contract manufacturers produced a client's product as a generic. Many contract manufacturers now have systems in place to protect against such issues arising, ensuring the trust required by pharmaceutical manufacturers, with PharmaVision holding an ISO/IEC 27001 Information Security certification.

Taman notes, "We sustain our Information Safety Management System by involving our complete workforce, protecting the continuous workflow, preserving the business continuity and increasing the collective awareness through intercompany seminars, risk management studies and internal audits. By means of this internationally auditable certification, we are proud to provide our business partners with high confidentiality commitment that substantiates how much we value our customers.

In fact, in the recent International IP Report published in January 2014 by The Global Intellectual Property Center (GIPC) under the US Chamber of Commerce, Turkey ranked 10th out of 25 countries in terms of patents, related rights, and limitations.

Government incentives

A key driver in emerging domestic pharma economies is government support and it is vital in order to grow, flourish and create an environment for investment. As Professor Burak Erman, Koç University notes, "Only ten years ago, Ireland, South Korea and Singapore embarked on the development of pharma industries. The governments gave great support to pharma companies, which attracted the attention of Western companies, and a lot of money was poured into projects. These companies are now leading the world in production, especially in South Korea. This began with tax incentives."

According to ERA Pharma, government support of the generics industry favours local manufacturing of finished formulations in Turkey. Berko Pharmaceuticals stated that the government currently covers over 80% of total medical expenses. However, in order to minimize the impact this has on the public budget, Kemal Yildiz, General Manager of Berko Pharmaceuticals indicated that it has thus been difficult for

pharmaceutical manufacturers to produce anything other than generics- leading to a regional industry struggling to remain profitable. As a consequence, some companies have moved into niche areas of the market, including Over-The-Counter drugs and oncology.

As an example of this emerging trend, currently around 93% of oncology pharmaceuticals in Turkey are imported. Mustafa Nevzat is one example of an established domestic manufacturer, with 10 molecules in production at its oncology plant and a commitment to invest further in this field.

Moreover, the government has prioritised domestic production of oncology drugs. This has backed the decision of several companies to invest in the field, including Onco Koçsel, which has recently established one of the industry's largest manufacturing plants for these products. "This will be a unique investment for the country since it will be the

sole pharmaceutical plant to produce such a broad array of oncological products”, notes Tugçe Koç, General Coordinator, Onko Koçsel. This new production facility could take Turkey into the realms of leading the global oncological drug field through the 184 different products that it seeks to develop in its portfolio.

To support and incentivise such a project, the government offers corporate tax relief, access to institutions including Tubitak, and R&D expenditure support, which for accredited R&D centres the government covers 60% of staff expenditures.

If the government is to successfully fulfil its desire for domestic pharmaceutical manufacturers to develop super

generics and biosimilars – a goal well within the capabilities of Turkey’s pharma industry – further support will be pivotal. The Pharmaceuticals Manufacturers Association of Turkey (İEİS) intensively lobbied for government incentives and as such, the domestic pharma sector now enjoys one of the most comprehensive incentive schemes.

Secretary General of İEİS, Turgut Tokgöz remarked, “Despite such improvements, the government continues to suppress the industry’s prices. The government has been severely restricting reimbursement prices of pharmaceutical products. So although we receive some valuable support, this is hugely undermined by existing pricing policies.”

Price referencing and conversion rates

A considerable challenge within the Turkish pharmaceutical industry is the government’s price referencing system and fixed euro-lira conversion rates. The price referencing has been deemed a highly negative aspect of the industry by 100% of companies surveyed during this countrywide review, clearly highlighting the significant impact this has on the market. These factors, “alongside regulatory change, are the sources for the decline in industry profitability”, notes Yüksel Karkin Küçük.

As part of the price referencing system, the government compares costs of production ex-factory prices in other countries (currently Portugal, Spain, Italy, Greece and France). The lowest price is set as Turkey’s reference price and a percentage of that is determined as a ceiling price, which according to the İEİS, means Turkish prices are “well below their European counterparts and that puts enormous pressure on profitability”.

After the initial price-referencing obstacle, Turkish pharma manufacturers are met with much larger issue in the shape of the euro-lira exchange rate used in the price calculation. The government has fixed the price of the euro to approximately 1,95 lira, despite it being worth approximately three liras, meaning further discounts and resulting in an industry that may struggle to remain profitable. Professor Erman of Koç University added that

due to this “even the industry’s largest players are in survival mode. They need to maintain their profitability”. Larger profits will pave the way for the domestic industry to invest in both technology and R&D, which the İEİS notes will add to Turkish pharma’s capacity to “introduce value-added products for the global market”.

Turkey’s system of price referencing is one of the biggest obstacles that Turkish companies

The implications as a result of the price referencing have been far reaching, with even multinational companies reluctant to manufacture new medication in Turkey- as it is no longer economically viable for certain products to be produced domestically. Ersin M. Erfa, General Manager at Centurion added, “Turkey’s system of price referencing is one of the biggest obstacles that Turkish companies face in developing innovative product lines: especially if one considers developing new molecules and biosimilar products. We invested significantly in these areas. Some of our projects failed due to the price-referencing system.”

Dr. Alper Menegi, Vice General Manager at Centurion agreed but also added that the system has encouraged manufacturers to become more globally competitive.

“There is a greater interest in R&D-intensive niche products and Turkish pharmaceutical manufacturers are now more interested in entering foreign markets”.

A further consequence, although somewhat unintended, has been the move to develop products outside of the price-referencing system. Like Centurion, Kemal Yildiz, Berko Pharmaceuticals argued that this has influenced Turkish pharmaceutical manufacturers to strengthen their research and development

departments. Turkish manufacturers are bringing value added products through their pipeline, but domestic sales are hindered by the current price referencing system- with combination products only reimbursed if they are below the level of the individual component products. As Turgut Tokgöz comments, this does not recognise the value created in the new product and “ironically, most of these products have been developed under TÜBİTAK grants, so they have R&D support from the state.”

Is Turkey moving towards an export driven market?

With the domestic market suffering reduced margins and profitability, manufacturers are expanding their horizons and are looking at new opportunities for growth, particularly turning their attentions towards exports. This approach is also well supported by the Government, as it will help to reduce the Country’s trade deficit. Currently, Turkey exports to 150 different countries but overall the export numbers are low considering the market potential.

Having recognized these significant growth opportunities the Pharmaceuticals Manufacturers Association of Turkey (İEİS) has taken the initiative to set up a Turkish Pharmaceutical Exporters Platform with the specific aim of raising international competitiveness. With a high standard of pharmaceutical regulation and manufacturing standards comparable with the West, alongside a geographic position ideal for distribution across the Eurasian region Turkey is well placed to supply the MENA region.

One company, Mustafa Nevzat is currently exporting to over 30 countries with \$44 million in international sales, and is predicted to increase these numbers to 40 countries and over \$50 million in the coming years.

However, due to an absence of EU membership it is more difficult for manufacturers to make inroads into the profitable European and US markets, as often a second release of products is required, and many manufacturers are choosing to take a partnership approach within Europe.

“We are targeting the CIS, the Gulf States, Africa, Russia and Europe. The European market is a huge challenge and that is why we are meeting with a number of companies that are already operating in the continent. We are about to sign a few toll manufacturing agreements to enter Europe with the help of our partners.

– Tugba Koç, Board Member Marketing and Sales, Onko Koçsel

Within the next 10 years we would like to have 80% of our sales generated through foreign market activity

However, the advantages of price competitive pharmaceuticals, produced to a comparable standard should see this market expand- with India seen as the main competitor nation. Already we are witnessing some companies’ shift their product development focus towards exports as the drivers of future growth.

“Turkey stands as our main market, but within the next 10 years we would like to have 80% of our sales generated through foreign market activity. We have designed our product portfolio with this in mind. Since making this decision, our sales volume has experienced double-digit growth... Turkish pharmaceutical manufacturers are quality-oriented. This sets us apart from our competitors. We do face stiff competition from Indian companies,

but our clients can perceive the difference between our products and those of Indian manufacturers and therefore perceive greater value in what we have to offer as a Turkish pharmaceutical manufacturer”

– Ersin M. Erfa, General Manager, Centurion

Turkey is now well placed to act as a regional hub to supply finished formulations across the Eurasian continent covering CIS and MENA regions.

Foreign direct investment in Turkey

Already Turkey has witnessed investment with multinational players like Sandoz and Novartis, having nurtured significant operations in the region. The market overall has seen several major acquisitions over the last year and the country remains attractive because of the reimbursement system, with the government buying the vast majority of pharmaceuticals produced.

we know of several large global companies that are looking to make buy-ins to the Turkish market

Vefik Koral, Owner of Farkim, a leading importer of excipients and APIs into Turkey since the early 1970's has seen the industry within the country change rapidly over the last few years and sees multinational investment growing. “During Ozal period, with the introduction of the GNP regulations the illegal pharma companies slowly disappeared. The legal companies have improved themselves strongly. However in the last couple of years, we have seen a decrease in the Turkish companies in the market. The foreign/multinational companies now dominate with the larger Turkish firms

acquired. There only a few large-scale Turkish companies left in the market”

However, there is now a wider acceptance that market entry needs to be based on more than just acquisitions and generics as margins in this part of the market continue to decline. “The future of the industry is found in niche products. Unless MNCs can develop these products, they will struggle locally.” – Kemal Yildiz, General Manager, Berko Pharmaceuticals.

Recently we have also seen a rise in the number of partnerships between international firms and rising domestic stars. For example, Mustafa Nevzat is partnering with Amgen to increase its work in biotechnology.

An additional pull factor for international investment is the importance placed upon domestic drug production by the government with attractive incentive schemes now in place. “Even contract manufacturing is looked upon favourably by the state. For these reasons, in the coming five years we will continue to see multinational corporations invest into the Turkish market... At present, we know of several large global companies that are looking to make buy-ins to the Turkish market.” – Mr. Gökhan Gökçe, Partner, YükselKarkınKüçük

Conclusion

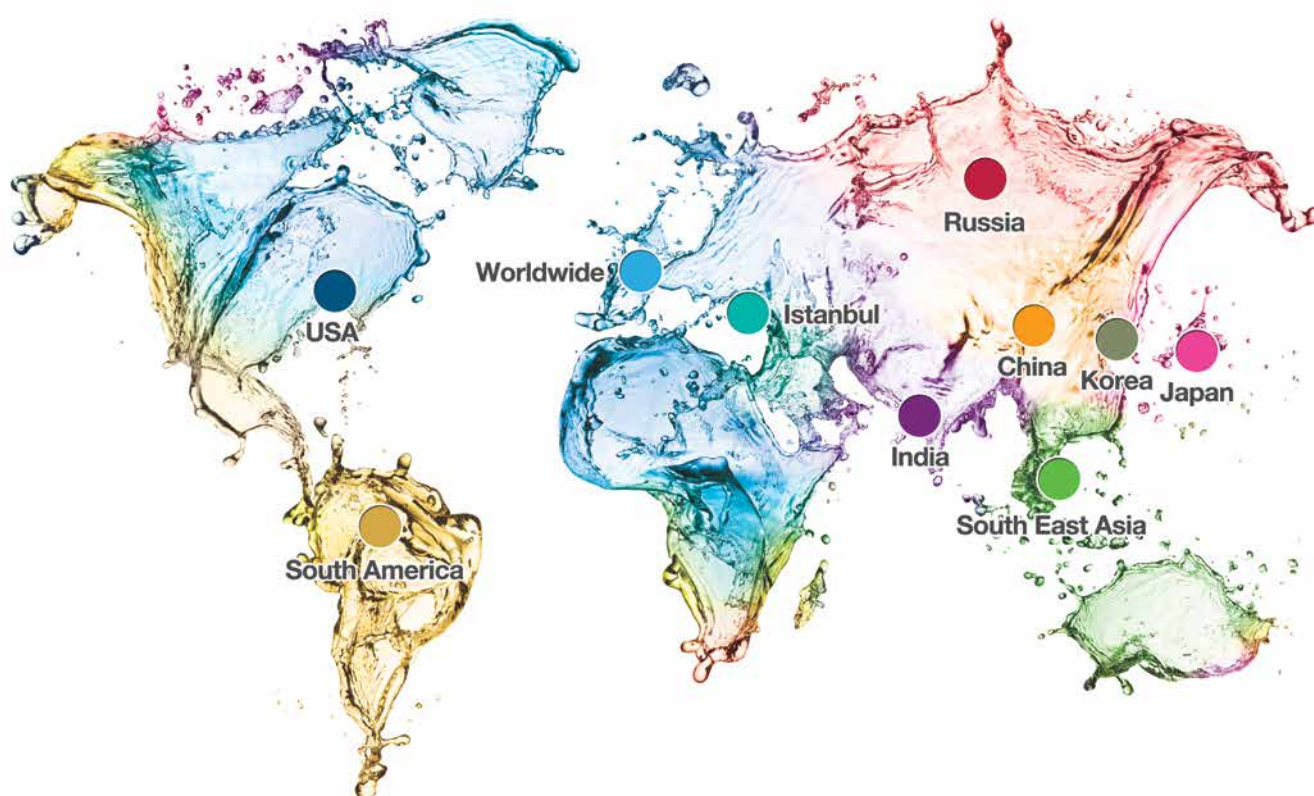
Although it is clear considerable difficulties are present for those companies looking to supply drugs domestically with Turkey this has had the knock-on effect of increasing the dynamism in the market and improving overall competitiveness of the sector. As a result, the country now boasts a highly price efficient manufacturing industry (far cheaper than those in the West) coupled with comparable regulatory standards. If price conditions ease this should provide the right environment for a burgeoning industry.

However, beyond the domestic market niche products and export lead growth also offer significant avenue for greater revenues for companies operating within Turkey. What we will witness in the next few years should firmly establish Turkey as the definitive player and supply of drugs across the MENA and CIS regions, with growth even as far reaching as the Baltic states. Ultimately, the country will be aiming, like its larger Indian competitor, to begin supplying directly into Europe and even the USA.

About CPhI

CPhI drives growth and innovation at every step of the global pharmaceutical supply chain from drug discovery to finished dosage. Through exhibitions, conferences and online communities, CPhI brings together more than 100,000 pharmaceutical professionals each year to network, identify business opportunities and expand the global market. CPhI hosts events in Europe, China, India, Japan, Southeast Asia, Russia, Istanbul, Korea and South America co-located with ICSE for contract services, P-MEC for machinery, equipment & technology, InnoPack for pharmaceutical packaging and BioPh for biopharma. CPhI provides an online buyer & supplier directory at CPhI-Online.com.

For more information visit: www.cphi.com



CPhI Global Events

CPhI Istanbul	4 - 6 June 2014
CPhI and P-MEC China	26 - 28 June 2014
CPhI South America	5 - 7 August 2014
CPhI Korea	2 - 3 September 2014
CPhI Worldwide	7 - 9 October 2014
CPhI and P-MEC India	2 - 4 December 2014
informEx	3 - 6 February 2015
CPhI Japan	22 - 24 April 2015
CPhI Russia	27 - 29 April 2015
CPhI Southeast Asia	26 - 28 May 2015
CPhI Conferences	year round

Addendum

The statements and figures contained within this release were collected at an early stage of GBR's research. As such, it may not reflect final conclusions on market trends. GBR is finalising its research this May and will be presenting its conclusive findings at the opening conference of CPhI Istanbul 2014