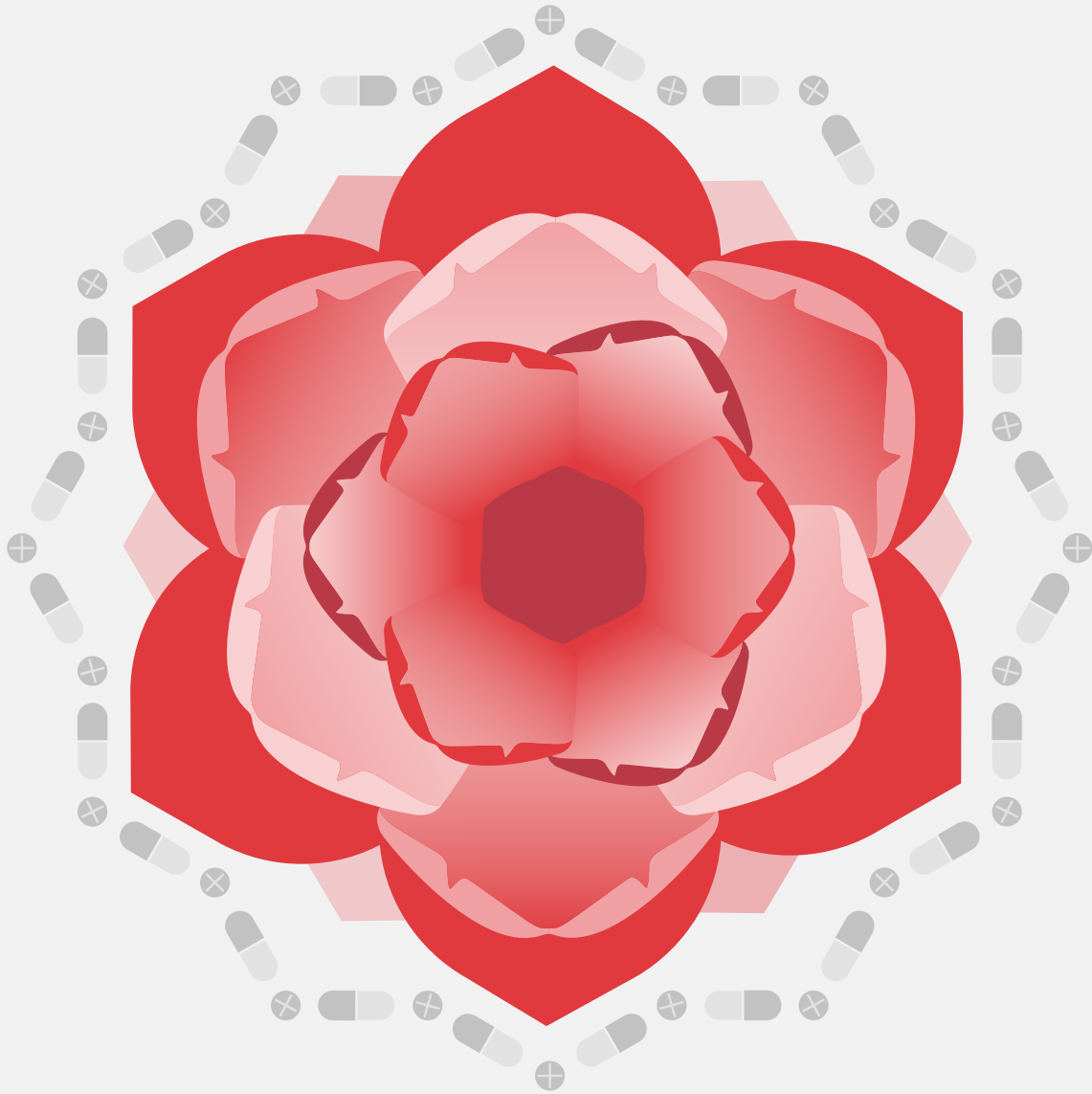




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June 3, 2015

Dear readers,

.....

It is with great pleasure that I write to you again in this comprehensive report prepared by Global Business Reports, in partnership with the Pharmaceutical Manufacturers Association of Turkey (IEIS) and CPhI. "Turkey Pharmaceuticals 2015" is a work of seminal importance both in the insight it provides as to the many benefits of pharmaceutical manufacturing within Turkey and the context it grants to the development of Turkey's manufacturing sector, but, moreover, for its symbolic significance.

This is the second such report that Global Business Reports has released on the Turkish pharmaceutical sector. Launched at CPhI in Istanbul in 2014, the first publication sought to place the development of the Turkish pharmaceutical manufacturing and the dynamics underscoring the industry in front of the backdrop of successful healthcare transformation in Turkey, which began in 2003. On this point, much has been accomplished.

"Turkey Pharmaceuticals 2015" seeks to build on this platform through portraying several of the ways in which the Turkish pharmaceutical manufacturers have responded to long-term and structural changes both within the industry itself as well as the country's business environment that have occurred over the course of the past several years. Great emphasis is placed on research and development. Export-led growth is now an integral part of the industry's framework. "Turkey Pharmaceuticals 2015" is both a product of these changes, providing thoughtful reflection on the importance of each of these areas to the Turkish pharmaceutical manufacturing today, but also a blue-print, providing guidance as to how the industry might better leverage its current strengths for continued growth.

In the past year, the Turkish Ministry of Health has closely followed the development of the country's pharmaceutical manufacturing industry, working with many of the bodies that have come together for this publication in crafting a better industry. Our government has identified pharmaceutical manufacturing as a strategic priority. With respect to this, I am pleased to say that we have made significant strides in raising awareness of this issue in both the public and private sectors.

We hope that this report will serve as the national voice of Turkey's pharmaceutical industry and provide readers with an understanding of what we, collectively, are striving to build today: a manufacturing base, but additionally a health care system, that is second to none.

My best regards,

Dr. Mehmet Müezzinoğlu,
Minister of Health



June 3, 2015

Dear readers,

.....

It is my great pleasure to communicate with you through this detailed report. Pharmaceutical manufacturing, especially in Turkey, is not an industry whose relevance, or significance, can be confined to its implications on public health. Pharmaceuticals, and the importance of their production, extend beyond this, representing a high-tech industry of strategic importance in a country that is firmly committed to a fundamental industrial transformation towards the production of higher value-added products.

As the Ministry of Science, Industry and Technology, our goal is to ensure that Turkey produces higher technology products and emerges as a production base, with the end goal of supplying such products to the global markets. Our domestic pharmaceutical manufacturing capability stands as one of the most important levers for our goal of becoming one of the top ten economies in the world, as stated in our 2023 vision.

To this end, we, as an extension of the Turkish government, have made important commitments to the development and production of value-added pharmaceuticals within Turkey. Our research and development incentive program for the development of biopharmaceutical products has resulted in the generation of wide-spread interest among the country's pharmaceutical manufacturers. It has also triggered greater levels of cooperation between academia and industry. This is but one example of the types of collaboration that we will mark the nature of Turkish industry moving forward.

This publication, developed by Global Business Reports in partnership with the Turkish Pharmaceutical Manufacturers Association (IEIS) and CPhI, stands as a testament both to that which the Turkish pharmaceutical manufacturer has accomplished already and the future of Turkish industry. I do hope that you, as I have, will enjoy this considerable publication.

My best regards,

Fikri Işık,
**Minister of Science,
Industry and Technology**



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This research has been conducted by Alice Pascoletti and JP Stevenson.

Edited by John V. Bowlus
Graphic design by Gonzalo Da Cunha

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Exclusive Interviews

Leading industry and government figures from Turkey's pharmaceuticals industry discuss market trends and opportunities, as well as pitfalls and current business strategies.

**18, 21, 29, 33,
37, 41, 47,
and many more**



Editorial Content

Global Business Reports' journalists provide unique insights into all aspects of the pharmaceuticals value chain by working on the ground for weeks and meeting face to face with industry leaders.

10, 68, 76, 86



Market Analysis

Pharmaceutical Manufacturer's Association of Turkey (IEIS) provides an in-depth analysis of Turkey's pharmaceuticals industry, focusing on developments in from 2009 to 2014.

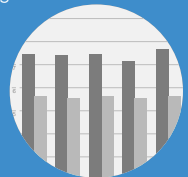
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Company Profiles

Turkey's top-five pharmaceuticals manufacturers outline the reasons for their success and discuss trajectories for near-, medium-, and long-term growth.

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Future Outlook

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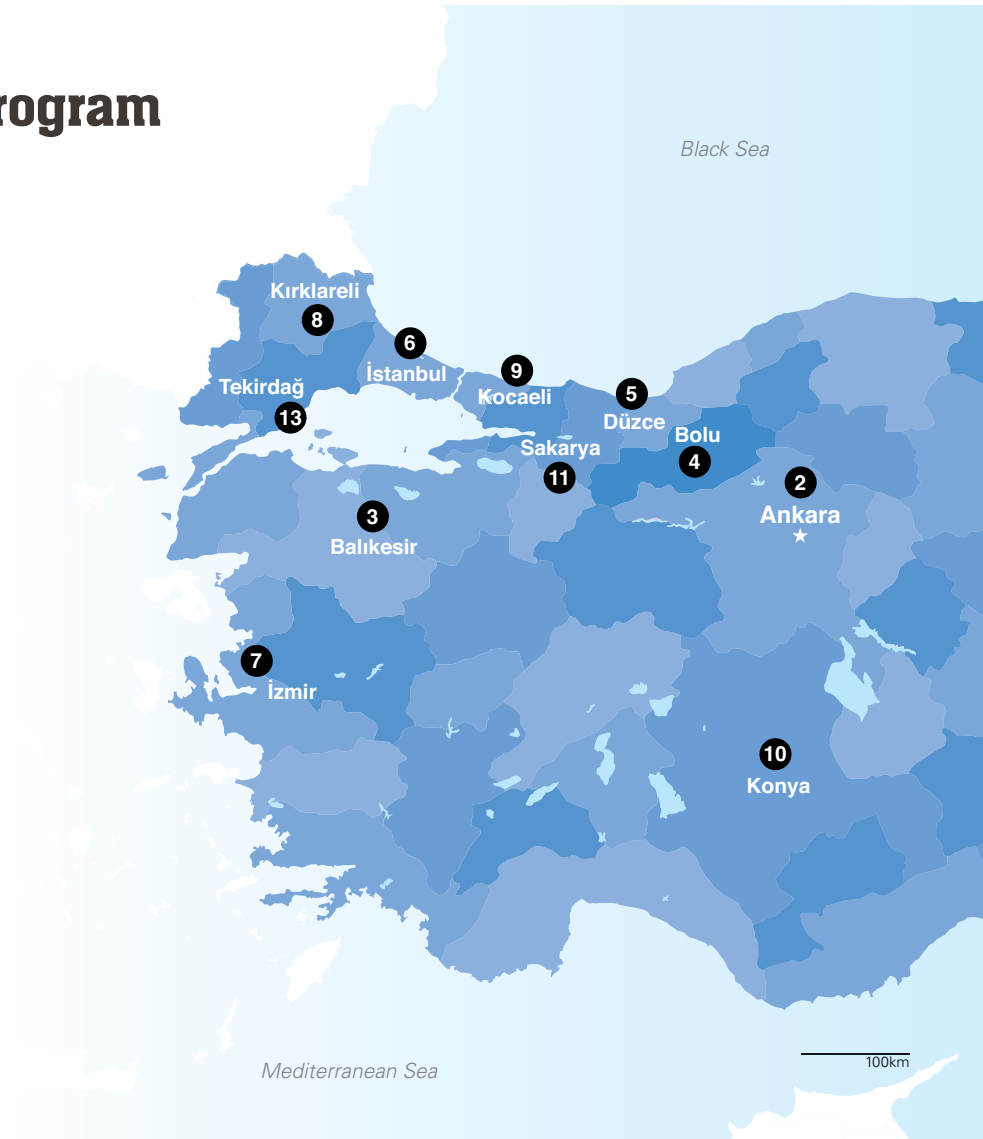
Introducing Turkey and its Pharmaceuticals Industry

"Price volatility and its impact on the domestic market have often been discussed. Yet there is no volatility observed in either the depreciation of the Turkish lira nor the current pharmaceutical pricing environment. There has only been continuous depreciation and market contraction, both of which have followed a predictable, and stable, pattern. There has been no relief."

- Hasan Ulusoy, Chairman,
Nobel Pharmaceuticals

Turkey's Health Transformation Program Ten Years On

Opportunities and Pitfalls



Value of Pharmaceutical Industry (in real terms)

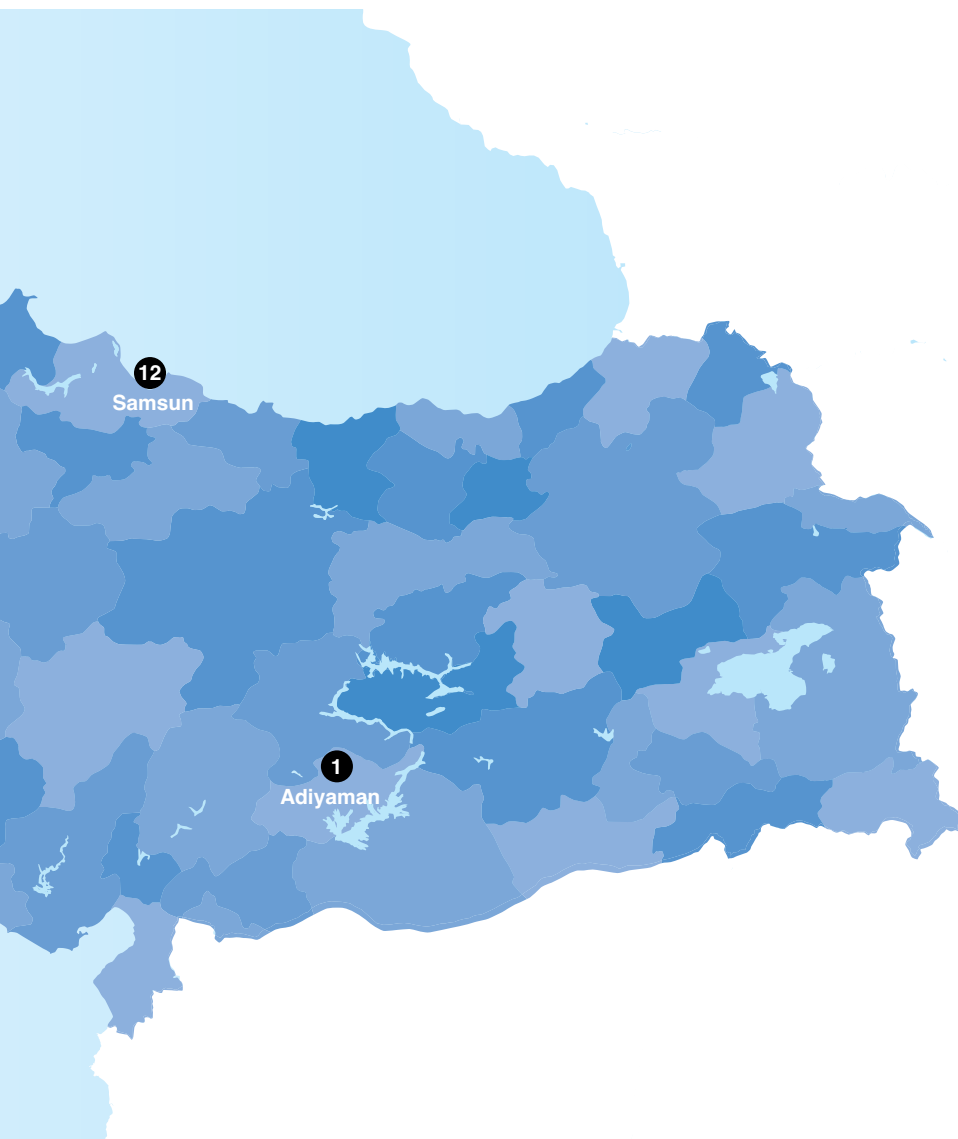
\$8.5
billion in 2009

\$6.7
billion in 2014

Far less profitable yet far more innovative than its predecessor of ten years ago, the Turkish pharmaceuticals manufacturing industry and its outlook have changed rapidly as a result of policy reforms enacted in 2004. Executed by the Turkish Ministry of Health under the Health Transformation Program, these reforms were, true to the name that encompasses them, transformative. They restructured healthcare financing, broadly increased medical access within the poorest regions of Turkey, and consolidated Turkey's three systems of social security under one umbrella, the SGK; 99% of Turkey's population now has medical coverage. Over the last decade, consumer satisfaction with the country's health care system rose, per capita doctor visits increased, and rates

of child and infant mortality fell. Yet, this expansion of the medical system brought an expansion in public medical expenses, and with it, the creation of a system of cost controls to prevent these expenses from encumbering the public budget. Cost controls have taken two forms: first, a series of direct discounts imposed on domestic manufacturers in accordance with the originator status of their product and the availability of comparable products within the market; and second, the introduction of a system of drug-price referencing that sets the price at which the Turkish pharmaceutical manufacturer can sell a product in the domestic market, linking it to the lowest price at which a comparable pharmaceutical product is sold within a basket of Euro-

pean markets. Turkey is not alone in establishing a price-referencing system – France and Ireland both employ similar schemes – but the mechanics of Turkey's system have undermined the development of its pharmaceutical industry. Since April 2009, the Turkish government has frozen the conversion rate for the reference price at which a pharmaceutical product is sold within its country of origin – denominated in euros – at 1.9595 Turkish lira, in effect discounting the price at which Turkish pharmaceutical manufacturers can sell their products by as much as 30%. In the past year, the negative effect on profitability has been exacerbated by currency volatility and the appreciation of the U.S. dollar, the currency in



MANUFACTURING COMPANIES

- 1 VETAL SERUM
- 2 DİNÇSA
- 2 DROGSAN
- 2 MSB ORDU
- 2 TÜRK TIPSAN
- 2 YENİŞEHİR
- 3 KURTSAN
- 4 ÇETİNKAYA
- 5 NOBEL PHARMACEUTICALS
- 6 ABDİ İBRAHİM
- 6 ALİ RAİF
- 6 ATABAY
- 6 AVIS
- 6 BAYER TÜRK
- 6 BERKO
- 6 BİKAR
- 6 BİOFARMA
- 6 CAN
- 6 DENTORAL MEDIFARMA
- 6 ECZACIBAŞI BAXTER
- 6 FARMAMAG
- 6 GRİPİN
- 6 İBRAHİM ETHEM
- 6 İDOL
- 6 KANSUK
- 6 MEFAR
- 6 MERKEZ LABORATUARI
- 6 MÜNİR SAHİN
- 6 MUSTAFA NEVZAT
- 6 MY FARMA
- 6 NOVARTIS
- 6 OSEL
- 6 PARO
- 6 PFIZER
- 6 PHARMAVISION
- 6 RECORDATI
- 6 SANOVEL
- 6 SANTA FARMA
- 6 TUM EKİP
- 6 VEFA
- 6 WORLD MEDICINE
- 7 ORVA
- 7 ŞANLI
- 8 ARİMED
- 8 ZENTİVA
- 9 ATABAY
- 9 BİLİM
- 9 DEVA HOLDİNG
- 9 ECZACIBAŞI MONROL
- 9 MOLTEK
- 9 ONKO KOÇSEL
- 9 SANDOZ
- 10 İLKO
- 11 NEUTEC
- 11 TOPRAK
- 12 ADEKA
- 12 İMARETÇİOĞLU
- 13 AROMA
- 13 BİLİM
- 13 DEVA HOLDİNG
- 13 EMBİL
- 13 KOÇAK FARMA
- 13 LAURUS
- 13 PHARMACTIVE
- 13 POLİFARMA
- 13 VEM

which most raw materials used for domestic pharmaceutical production are denominated, drastically escalating the cost structure of Turkish pharmaceutical manufacturers. For some, such as Deva Holding, a pharmaceutical manufacturer that has been active in Turkey since 1958 and stands among Turkey's largest, this has resulted in a steep decline in their gross margin. In 2014, profitability stood at one-third of what it did the previous year. Philipp Haas, CEO of Deva Holding, explains: "DEVA's decline in profitability was a product of the current macroeconomic environment in Turkey: specifically, depreciation of the Turkish lira. This directly lowered our gross margin, which of course translates into lower profits."

The collective effect of price controls

and currency volatility has been a contraction of the Turkish pharmaceutical market. While the value of the pharmaceutical industry stood at \$8.5 billion in 2009, over the course of the past five years this figure has declined by 21.6% in real terms to \$6.7 billion in 2014.

This, of course, has not occurred without a response from the domestic industry. In late 2014, the Pharmaceutical Manufacturers Association of Turkey (İEİS) sought redress of this frozen exchange rate, which has culminated in a court-level rejection of 1.9595 and its attendant implications and given hope to some that there might soon be a readjustment.

To believe that this would revert the Turkish pharmaceutical industry to its former state would be to ignore the

fact that the Healthcare Transformation Program has changed irreversibly the course of the Turkish pharmaceutical manufacturer's development. Most immediately, this is seen in declining profitability over the past half decade, but, on a strategic level, two dynamics have emerged that will shape the industry's further development.

The first is that the industry now emphasizes export-led growth. Muzaffer Bal, general manager of Ali Raif, a Turkish pharmaceutical manufacturer that was first founded in 1928 as a tobacco company but today has developed a portfolio of generic products that it manufactures through in-licensing agreements, said: "Taken collectively, the Turkish pharmaceutical manufacturer had been lazy, until recently, in pursuing export



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markets. Previously, few companies saw a need to export outside of Turkey; the internal market was appealing and this drove their growth." Far be it from the case today.

This has not been caused by demographic factors; in fact, Turkey's demography is highly attractive for pharmaceutical production. A population of over 70 million characterized by the seemingly contradictory term of 'young, but aging', Turkey offers the youngest populace in Europe, with 50% of its citizens below the age of 30. At the same time, the population of those over 65 is growing at three times the rate of the general population. Aside from this, Turkey's Healthcare Transformation Program created one centralized buyer, the SGK, to access these consumers.

Yet, as the profitability of the domestic market has eroded, so has the Turkish pharmaceutical manufacturer ventured further afield, seeking greener pastures. Bal continued: "Today, we have seen much greater weight put on the importance of export-led growth by the industry. This, most commonly, has resulted in the Turkish pharmaceutical manufacturer pursuing near markets, such as the Balkans or Common Wealth of Independent States (CIS)."

The contraction of the Turkish market has also tilted the playing field tilted to the advantage of the multinational and driven out the Turkish manufacturer for several reasons. Most obviously, as multinationals draw upon a global operational presence and diversified activities over a number of markets, they

can more easily take a longer-term view on the Turkish market's development, taking a loss today in the hope that later profitability might return. In addition, dropping a product line in the Turkish market has hurt these companies far less than domestic manufacturers. Still able to monetize their initial investments into research and development (R&D), multinationals, through their presence in many markets, can recoup their cost of product development more easily than the domestic manufacturer, which remains, at present, still focused on Turkey's internal medical market.

The net outcome of these changes in the industry's competitive landscape has been a rise in unmet medical needs. Tuğba Koç, board member at Onko Koçsel, a leader in the field of on-



cology that has recently begun to produce non-cytotoxic products through its newly commissioned oncology plant, an investment of €70 million, explained: "Certain medical products have become increasingly unavailable in the Turkish market. The rise of unmet medical needs has been in direct correlation with the fall of profitability for Turkish pharmaceutical manufacturing. Many, including the government, have portrayed the Turkish pharmaceutical manufacturer as capable of supplying these products but unwilling. In truth, unmet medical needs have resulted from the lack of profitability for certain business lines."

Tuğçe Koç, general manager of Onko & Koçsel, said: "As a pharmaceutical manufacturer we cannot be expected

to bring these products into the Turkish market to our own detriment. Now, especially in several critical therapeutic areas such as oncology, we have seen many patients go unserved because of these declines. An expectation should not exist that it is the private sector's responsibility to correct this: this is clearly a regulatory failure."

This, however, is also symptomatic of a larger issue. Though acknowledged as a strategically important industry for correcting Turkey's trade deficit – the pharmaceuticals industry was the third largest contributor to the country's trade deficit in 2014 at 4.6%, representing 4.6% of, behind only the energy and defense industries – domestic pharmaceutical manufacturers have been unable to reduce this deficit because of the rise in pharmaceutical imports, an unintended consequence of regulatory structures, as cost reduction measures have encouraged the foreign manufacturer to distribute products directly into the Turkish market. These imports are subject to a separate system of regulation governed by the Turkish Pharmacists' Association and are exempt from price discounts. Additionally, the price at which these products can be sold in the domestic market is subject to the current rate at which the euro is converted to the lira. Given the relative profitability of employing this model, unsurprisingly, pharmaceutical imports have risen 13% by value and 47% by volume in the past five years.

The rise of multinationals has encouraged Turkish manufacturers to move to foreign markets. Elvan Sevi Firat, partner at Firat & Izgi, a Turkish law firm that covers the pharmaceutical and life sciences industry through their work as consultants and litigators for multinational corporations related to intellectual property issues in Turkey, said: "Many have now turned to product exports and the development over-the-counter (OTC) pharmaceutical products as part of their product portfolio as a mechanism for maintaining their levels of profitability. This is both a product of globalization and internal market regulation. Previously, the Turkish pharmaceutical manufacturer was complacent with their profits realized from the country's medical market. Greater levels of

competition, especially on the part of multinationals, have furthered domestic interest in expanding abroad and as a result, we are now seeing unprecedented levels of interest in accessing international markets."

A second dynamic is the emphasis that local producers now place on R&D within their portfolio strategy. This is a product of both market development and domestic market circumstance.

Cem Baydar, senior principal and head of Turkey and the Middle East for IMS Consulting, a subsidiary of IMS Health that focuses on the provision of management and strategy consultancy services to the domestic market related to the pharmaceuticals industry, explained: "Whereas previously, five years ago, primary care may have driven market growth, continued growth will depend upon specialization. The consequence of this has been that the Turkish pharmaceutical manufacturer has had to alter its portfolio strategy through focusing on one of these specialized areas through the development of generic or in-licensed products."

Stemming from this, in 2014, oncology and antidiabetic products realized the highest rates of growth in market share if measured by therapeutic area, standing at 11.2% and 6.2%. Some argue that this portends a larger shift that we will see in the portfolio strategies of the Turkish pharmaceutical manufacturer. Baydar continued: "Reflecting the maturation of the Turkish pharmaceutical industry from a market focused on primary care to one focused on specialty care, we believe that we will see growth within the former segment of 13%, whereas we expect the latter to grow by just 5%. Five years from now, in 2020, Turkey, as a pharmaceutical market, will be entirely driven by specialty care."

The second and third drivers behind these alternations within the portfolio strategies of the Turkish pharmaceutical manufacturer have been a desire to expand into product areas that are less constrained by Turkey's internal regulatory environment and, as market segments, are less saturated by competition. In the case of the former, this has resulted in some expanding into areas such as the OTC market, which are not

300
market
participants

66
production
facilities

300,000
employees

necessarily subject to Turkey's system of cross-price referencing.

The push of the manufacturer into areas less saturated with competition has helped to introduce new pharmaceutical products to the Turkish market. Deniz Demir, general manager of Dem Pharmaceuticals, which, established in 1992, was the first Turkish pharmaceutical manufacturer to receive a license to produce these products. Entering into a manufacturing agreement with a pharmaceutical company in the Far East, Dem Pharmaceuticals has since launched three biosimilar products in the Turkish market. Expanding into this product area, however, did not come easily. Demir recalls: "When Dem Pharmaceuticals first entered into the marketing of biotechnological products, no other company in Turkey had begun to consider them as part of their portfolio strategy. The immediate challenge was that Dem Pharmaceuticals had to single-handedly introduce both the Turkish consumer and government to their potential efficacy, and in doing so, help create the regulatory structures that to this day govern the product development of these products."

Since Dem Pharmaceuticals first pioneered the development of this field within Turkey, partnerships such as the one that Dem Pharmaceuticals forged with an Asian manufacturer have become near commonplace. Among those to do so include Ilko Pharmaceuticals, which today operates ILKOGEN, their partnership with South Korean Genexine for the development of biotechnological products. Even those whose businesses have been built on the back of the production of generic pharmaceutical manufacturing and today stand as the largest manufacturers within the industry because of it are, if not presently involved in the development of these

products, actively seeking out partnerships so as to enter this market.

Yet the success of the Turkish manufacturer in expanding into foreign markets and value-added pharmaceuticals will, like so much else related to the industry's future, be shaped by regulation. The government has responded to the push of Turkish manufacturers into biotechnology and has offered various incentives, but Turkey is not the only country seeking to enter into the production of these products. Ismail Yormaz, vice president and regional director of Recordati, the Italian pharmaceutical manufacturer that recently expanded its presence in Turkey through the development of a new \$50-million

50%
of Turkey's Citizens
are Below Age of 30

manufacturing plant, explained: "Access to capital will, in part, define the ability of this Turkish manufacturer to expand. R&D is an extremely expensive process, often bearing no commercial product. Government incentives are a prerequisite, but they do not guarantee success."

In undertaking the self-evaluation required to build a better industry, the Turkish government must scrutinize its internal pricing policies, and whether the tradeoffs they offer through minimizing public medical expenses outweigh what could be lost in developing an industry that now, finally, has come to be viewed as strategic.

The June parliamentary elections could usher in a change in the regulatory

regime, but the country's ruling party since 2002, the Justice and Development Party (AKP), is widely anticipated to continue to hold its majority. More immediate relief could be forthcoming, as Turkey's courts have rejected the conversion ratio used in Turkey's system of cross-price referencing, leading to a slight readjustment in pricing controls by the end of the second quarter of 2015. At the same time, the Turkish government appears to have shifted its attitude towards the domestic industry. Dr. Erhan Baş, general manager of Bilim Pharmaceuticals, one of Turkey's largest manufacturers and a leader within the domestic market for both foreign market sales and the development of R&D intensive products, in particular within the field of diabetes, said: "We will see the Turkish government play a more supportive role in developing the industry. The matter of the public budget and the priority that medical expenses should take within it is perhaps one of the most complex macroeconomic issues that the government faces. But the government has shown that it supports R&D activities that develop the sector and will seek to resolve issues that hinder the sector's growth. This is reflected in the incentive structures that it implemented for the expansion of the pharmaceutical manufacturer into R&D-intensive fields, which have resulted in 10 new R&D centers, and export-led growth through such as 'Turquality', which allows for manufacturers to recoup expenses associated with foreign market development." This readjustment, although slight, is therefore most important as a symbolic victory: an acknowledgement of the role that Turkish pharmaceuticals could play in moving the Turkish economy, and the global pharmaceutical industry, forward. •

Message from Investment Support and Promotion Agency of Turkey (ISPAT)

Dear Distinguished Representatives of the Pharmaceutical Industry and Readers,

I would like to extend my sincere thanks to Global Business Reports (GBR) and Pharmaceutical Manufacturers Association of Turkey (IEIS) for preparing this report, an essential source of information for the Turkish pharmaceutical industry. This study presents in-depth interviews with industry executives, market analyses, valuable insights, as well as facts and figures which offer industry professionals, public officials and investors a substantial opportunity to better understand the actual and future potential of the industry.

Turkey has not only been experiencing a remarkable economic performance over the last 13 years but has also been improving human health by expanding medical access with offering a high-quality health care system. The introduction of the Health Transformation Program and public private partnership (PPP) healthcare projects enabled this improvement and will ensure the sustainability of high-quality healthcare service. It is no doubt that pharmaceutical industry has been and will be one of the key stakeholders and supporters of this accomplishment.

In addition, as Turkey realizes its goals of Vision 2023, the pharmaceutical industry stands out as one of the strong candidates for being a driving force of the Turkish economy; since it is research and development (R&D)-intensive, it has the potential to boost Turkey's exports and contribute to human development. For these very reasons, the Turkish government has identified the pharmaceutical industry

as a strategic sector and included it in the "Structural Reform Program," which aims to increase the domestic production of pharmaceutical products, to improve R&D infrastructure and incentivize R&D operations in the industry, and increase the number of clinical research activities.

As the targets are ambitious and we are dedicated to achieve them, foreign direct investment (FDI) in the pharmaceutical industry has a pivotal role in providing Turkey with not only "tangible" capital but also "intangible" capital in terms of know-how and R&D capability. In other words, the transfer of knowledge and intellectual capabilities through FDI activities in the pharmaceutical industry is as important and vital as the transfer of physical inputs.

Turkey has some unique characteristics, which make it an attractive investment destination: a stable political and economic landscape, fiscal discipline and effective governance, a growing economy with a dynamic population, and favorable geographic position. Moreover, the Turkish government supports FDI, particularly in the pharmaceutical industry, by offering strong and lucrative incentive mechanisms to encourage international investors to transfer the knowledge, technology, and R&D capabilities that can develop an eco-system of innovation. All efforts of the government are aiming at discovering and proposing a win-win strategy for the country and international investors, which will in turn make Turkish pharmaceutical industry capable of designing, developing, manufacturing, and selling high value-added products on the global markets.

Thanks to these efforts, the stock value of FDI in Turkish pharmaceutical industry reached \$2.5 billion as of 2012, while Turkey managed to attract more than \$1.3 billion of FDI in the last three years. Greenfield investments as well as cross-border merger and acquisition activities in pharmaceutical business made it possible for international investors to benefit from a favorable investment environment, growing domestic and proximate markets, and a highly-skilled, Turkish labor force.

I would like to extend my appreciation once again to all who have contributed to preparing this report. I would also like to take this opportunity to invite international investors to take their part in growing Turkey's pharmaceutical industry and be a member of this developing eco-system, since I firmly believe that the Turkish pharmaceutical industry has untapped potential for further progress. Industry professionals, government officials, international investors and all other stakeholders should exert their best effort to realize this potential.



Arda Ermut
President

The Republic of Turkey Prime Ministry
Investment Support and Promotion
Agency

Prof. Dr. Özkan Ünal

President
**TURKISH MEDICINES AND
 MEDICAL DEVICES AGENCY
 (TITCK)**



Established in March 2012, the Turkish Medicines and Medical Devices Agency (TITCK) functions as Turkey's regulatory body charged with the development and execution of regulatory policies governing Turkey's pharmaceutical, medical device and cosmetic industries. The pharmaceutical industry in Turkey is one of the country's five most important industries for economic development, with the objective of growing local manufacturing so as to counter balance Turkey's trade deficit.

TITCK seeks to encourage the pharmaceutical and medical devices industries to develop innovative and value-added products. For this purpose, industries, universities, TUBITAK, and other non-governmental organizations are encouraged to cooperate more on specific projects, such as blood-derivatives, biotechnological products, and oncology products that can be locally manufactured. In addition to this, according to the legal amendment in the New Investment Incentive Scheme of the Ministry of Economy (MOE), all pharmaceuticals and active pharmaceutical ingredients are considered as part of high technological industrial products, as defined by the OECD technological intensity classification and included in the scope of "Priority Investment Subjects." Recently appointed as President of TITCK, Professor Özkan Ünal provides insight into the direction that he seeks to take both the organization and, through its work, the Turkish pharmaceutical industry.

As TITCK's new President, what legacy do you seek to create through the work of your organization with the Turkish pharmaceutical manufacturing industry?

It is a fact that the increase in the demand for pharmaceutical products and medical devices inflicts oppression on the social security expenditures and current deficit because of the growing and aging population, increase in the average

life expectancy, improvements in the health services and access to medicine, augmenting level of welfare, and awareness in our country. Our basic approach to the pharmaceuticals industry, one of the five top significant industries of Turkey in terms of economic development, is to increase domestic production and export.

In this scope, the main elements that are included in the 10th Improvement Plan and should be reached by Turkey's pharmaceuticals sector are as follows:

1. Fulfillment of the domestic need for medical devices and pharmaceutical materials through 20% domestic production in terms of value;
2. Fulfillment of the domestic need for medicines through 60% domestic production in terms of value;
3. Improvement of the basic research infrastructure of pharmaceuticals for the purpose of discovery of at least one molecule and/or repositioning of two current molecules with different indications in 2023;
4. Increase of the share Turkey receives from the global clinic research investments and of the number of the conducted clinical researches by 25% based on years.

Accordingly, we will altogether experience in the forthcoming period the licensing policies of our country in the Middle East and Eurasia concerning medicines and its realization of implementations that stand out for the purpose of taking place in such markets.

Turkey, in seeking to expand its global market share in specialized product areas such as biopharmaceuticals, stands among many other regions because it offers attractive incentives for the local production of these products. From a regulatory perspective, what unique advantages does Turkey offer to those that are evaluating investing in these areas that set it apart from countries such as like Algeria or member nations of the

GCC that also seek to attract investment capital for these fields?

It is important that Turkey becomes a global research and development (R&D) production center of pharmaceuticals and reaches a competitive position in terms of pharmaceuticals and medical devices. The objective has been set to shift to a production structure that can manufacture products with high added value, is able to provide services and products to the global markets, and can fulfill a substantial part of domestic medicine and medical device requirements.

In this sense, the targets of the Tenth Development Plan will be carried into effect through Action Plans. As stated in the Tenth Development Plan:

The production axis and the center of gravity in the global economy are being shifted from the developed Western countries to the developing Asian countries. With the policies of the developing countries to transform their population and natural resource advantages into technological production and competitive advantage and their investments, high ratios stand out as the determinative factors. Our country has had an advantageous position compared with the other countries during the last ten years by means of covering significant distance in terms of regulation, audit, supervision, and creation of the legal infrastructure of the financial markets. There have been significant progresses in Turkey during the recent period in terms of compliance with the international rules and strengthening the administrative capacity and the level of institutionalization. Turkey is one of the rare countries that might make use of the demographical window of opportunity in terms of the workforce potential by 2030. Our country will be able to constitute the conditions of being an international center of attraction by strengthening its regional role through the new breakthroughs that it will make. One of the biggest resources that might be provided to our country by the gradual

increase of the interests of investors in emerging markets might be the attraction of the capital in the Gulf Region to our country.

Following actions were included in the Action Plan for the Structural Transformation Program in Health Industries of the Tenth Development Plan for the encouragement of investments for the increase of high technology production in our country.

- Arrangements and implementations required for the evaluation with priority of the medicines and medical devices produced in Turkey in the reimbursement and pricing policies as well as licensing processes will be carried out.

- R&D and manufacturing of the advanced medical treatment products within the scope of the advanced treatments will be promoted.

- The products manufactured as a result of the R&D activities realized having been planned in line with the requirements of our country would be supported in terms of price and repayment practices.

- Supports regarding the encouragement of the investments on the pharmaceuticals and medical devices that are not manufactured or insufficiently produced in Turkey will be activated.

- It will be ensured that the support mechanism for ensuring Turkey to become a regional administration and joint service center in the pharmaceuticals and medical devices sector will be constituted.

- It will be ensured that the firms of the pharmaceuticals and medical devices sector will utilize the export supports efficiently.

In addition, the investments for the production of the products that are within the high technology industry class are included in the scope of strategic investments in the Resolution on the State Aids in Investments, issued by the MOE. The pharmaceuticals industry is also evaluated in this class, and all investors, whether they are foreign or

domestic, can make use of the strategic investments in terms of manufacture of medicines thanks to these arrangements.

TITCK has named the development of blood derivatives as a strategic area of investment for pharmaceutical manufacturing and actively seeks to develop these products within Turkey. Yet barriers to the development of these products, such as the position of the Turkish Red Crescent, which holds monopoly control of Turkey's blood supply, and several examples of failed tenders for manufacturing facilities, have made investors skeptical of Turkey's ability to realize these ambitions. How do you address these concerns?

Issues regarding the collection and procurement of blood and blood products are regulated by the Health Services Directorate General of the Ministry of Health (MOH) and implemented by the Turkish Red Crescent.

However, the issue regarding the production of blood products was highlighted in the Action Plan for the Structural Transformation Program in Health Industries of the Tenth Development Plan. Accordingly, domestic production of the plasma products and vaccines will be ensured within the framework of the cooperation model that will be developed.

It is stipulated that the plasma products to be ascertained by the MOH will be produced domestically by the private sector in return for the guarantee of their purchase for a particular period. Domestic production of these products will be carried out under the control and supervision of the public sector and within the framework of the model that would yield know-how to the country.

Public purchase programs will be conducted in order to ensure the production of some particular vaccines in Turkey by the private sector. Purchase guarantee will be designated through special protocols. •

Nezih Barut

Chairman

PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF TURKEY (IEIS)



As the Chairman of the Pharmaceutical Manufacturers Association of Turkey, I am pleased to reach out to you through this special and comprehensive report. As the leading organization for the Turkish pharmaceutical industry, we strongly believe in the importance and impact of CPhI Istanbul in informing the global pharmaceutical audience on latest industry trends and changing market dynamics of Turkish industry. CPhI Istanbul is an important medium for this, and it is because of this that we are happy to again act as the official partner of the event. We are certain that CPhI Istanbul will play an important role as a platform for furthering collaboration between local and foreign pharmaceutical manufacturers and in promoting domestic industry.

Turkey stands as a leader for its region, both acting as a point of nexus for many of the world's fastest growing and most dynamic pharmaceutical

markets and possessing highly attractive demography for the further development of the country's internal medical market. Over the coming years, average income levels are poised to grow within the country. In meeting the challenges posed by this, and an attendant expansion of medical needs, Turkey has developed a pharmaceutical industry firmly committed to the provision of quality healthcare: built through the country's long-standing culture of production and strong infrastructure and supported by its high standards for the production of technology intensive products and wealth of technically adept personnel. It is because of this that today, the Turkish pharmaceutical industry boasts 300 market participants and 66 production facilities, which collectively employ 30,000 and produce approximately 11,500 products.

Turkey has long been dedicated to the

development and provision of high quality pharmaceutical products, having adopted Good Manufacturing Practices over thirty years ago, in 1984. These quality standards have led domestic manufacturers to be accredited by both the Turkish Ministry of Health and many other international authorities. Increasingly, this has led the Turkish pharmaceutical manufacturer to be acknowledged internationally within developed markets for not just satisfying, but exceeding, international quality standards.

As the perception of the Turkish pharmaceutical manufacturer has evolved internationally, so too has the interest of domestic manufacturers in the foreign market. Turkey has begun to position itself as a leader abroad. Today, export-led growth stands as a priority of the domestic manufacturer. In the coming years, we anticipate that we will see Turkey's relative market share of the global pharmaceutical industry grow, driven by the outward expansion of domestic manufacturers – in near markets, certainly, but also within many of the world's most mature medical markets. This, again, is a reflection on the quality standards of domestic industry and a process that will be aided by the commitments that the Turkish pharmaceutical manufacturer is now making to further expand the value of their products.

The transformation of domestic industry into one that is both a leader in the foreign market and the development of value-added pharmaceuticals are two of the IEIS' most important goals. We believe that, in realizing these ambitions, it is paramount that the domestic pharmaceutical manufacturing industry work in close collaboration with stakeholders both in and outside of the sector – be they governmental agencies such as those you will find featured in this book; non-governmental organizations; or foreign regulators. Our success will depend upon a collaborative approach being taken to the industry's further development.

It is my great hope that this report, as a reflection of the larger state of domestic industry, will allow you, the reader, to better understand the strengths of our industry. •



Turgut Tokgöz

Secretary General

PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF TURKEY (IEIS)



Through your work with the Turkish Pharmaceutical Exporters Platform, an initiative undertaken by IEIS to further the presence of local manufacturers in foreign markets, what success has the industry had in exporting?

The Turkish pharmaceutical industry has a century-old culture of production, state-of-the-art technology and infrastructure, qualified human resources, and large production capacity. In its modern and technologically advanced facilities, the Turkish pharmaceutical industry easily meets the requirements of developed markets. Our products are exported to 170 countries, largely to European Union (EU), MENA and CIS countries.

Despite such an impressive and comprehensive reach, Turkish pharmaceutical exports are still quite low and far from their true potential. However, thanks to increasing awareness at the company level and the strategic efforts of government agencies together with NGOs like ourselves, we have been observing an encouraging improvement lately.

We established the Turkish Pharmaceutical Exporters Platform at the beginning of 2012, which currently has 30 members, with the specific purpose of increasing the export capacity and the competitiveness of the Turkish pharmaceutical industry. Following the establishment of this platform, there has been a considerable acceleration in the export of pharmaceutical products. Total exports amounting to \$474 million in 2009, reached \$856 million in 2014, registering an increase of 80% in five years.

This performance brought down the pharmaceuticals industry's share in the country's trade deficit to 4.6% in 2014, from 10.2% in 2009.

Much has been said about the importance of academic institutions to enabling the movement of the pharmaceutical manufacturer into more research- and risk-intensive product areas. What advances have we seen in these types of collaboration within Turkey and how might the intellectual resources of Turkey be better leveraged?

Pharmaceutical companies in Turkey have considerably increased their financial allocations to research and development (R&D) in recent years. The number of large-scale R&D centers accredited by the Science, Technology and Industry Ministry currently stands at 10, while many small-scale centers operate within techno-parks.

With the strategic R&D support provided by academia and the government, the capacity for innovation in the Turkish pharmaceutical industry will increase. The industry will be able to produce higher value-added products and biosimilars, not only for the domestic market but also for export markets.

Within this framework, our association plays a leading role in R&D as well. We show intensive effort to enhance cooperation between academia and industry. Towards this end, we signed R&D cooperation protocols with two leading universities, Hacettepe and Gazi University, which will increase the cooperation and scope of working areas between IEIS members and these institutions. Moreover,

we organized a R&D conference last year titled "Pharma R&D: Importance of State-University-Industry Collaboration." At this event, we brought together more than 350 participants from public authorities, universities, industry and other related stakeholders to improve the ongoing communication and cooperation between them.

To the future: what might the Turkish pharmaceutical industry look like in five years? In addition, as Secretary General of IEIS, what legacy do you seek to create?

The Turkish economy needs to move out from the middle-income trap, which necessitates producing and exporting higher value-added products and services. To this end, the government has an industrial transformation program and needless to say, pharmaceuticals is one of the few industries that has the potential to deliver results in line with this program.

The Turkish pharmaceutical industry is eager to contribute to this transformation and become a global player in its field. However, the industry is struggling under the existing price regulation, which does not permit adequate capital accumulation to compete with its global peers.

Public authorities are aware of the value that this industry can bring to the economy and therefore have placed special emphasis to our industry within their incentive schemes of all sorts. However, existing pricing policies are totally in contrast with such supportive industrial programs, so our biggest challenge in the next five years is to align government policies from its current contradictory state.

As the Secretary General of IEIS, my primary mission will be to establish this alignment within public policies as well as continuing to work towards enhancing the R&D and export capabilities of the industry. If such an alignment can be achieved, the Turkish pharma industry will be a serious global player in the coming years. •

Cem Baydar

Senior Principal,
Head of Turkey and the Middle East
IMS CONSULTING



Industry profitability, as an aggregate, has fallen in the past because of currency volatility and Turkey's system of cross price referencing. In what ways has this caused the strategies of the Turkish pharmaceutical manufacturer to evolve?

Currency volatility has cut heavily into the profit margin of the local pharmaceutical manufacturer. Though taken collectively the Turkish pharmaceutical market grew by 10% over the course of the past year, as the Turkish lira has depreciated by over 25%, the expansion of the country's pharmaceutical market has not balanced out the declines in profitability that have been driven by exchange fluctuations.

Still, the Turkish market has attractive growth prospects. Growth in the domestic pharmaceutical market in the past year has been driven by activity within several segments: among them, the hospital channel, which accounted for 20% to 22% of the growth in the past year, and specialty care, specifically in areas such as oncology and blood products. Whereas previously, five years ago, primary care may have driven market growth, as the Turkish market has matured, like many other global pharma-

ceutical markets, continued growth will depend upon specialization. The Turkish pharmaceutical manufacturer has had to alter its portfolio strategy by focusing on one of these areas through the development of generic or in-licensed products. Those that have chosen to focus on the latter strategy have found their ability to in-license complicated by the currency environment. Multinationals that are not already present in Turkey now show greater reluctance to enter the country. Coupled with fallen levels of internal profitability and the lack of recourse that this creates, this could result in market consolidation.

On the subject of consolidation, what might the profile of those that choose to buy-in to the industry look like?

At present, it is difficult to speculate on what form industry consolidation might take. If we are to compare 2015 and the past year against previous years, we are surprised at how slow acquisitions have been to materialize, compared to years when there were high levels of activity within the market, such as in 2012, when Amgen acquired Mustafa Nevzat. Following the June elections, this will change. There is interest in the Turkish pharmaceutical industry, evident in the private equity houses that have expressed interest in entering areas such as consumer health and to use Turkey as a springboard for accessing regional markets.

Which projects, by historical standards, have driven the activities of IMS Consulting in 2015?

Five years previously IMS Consulting was heavily involved in assisting the Turkish pharmaceutical industry on tactical projects: areas such as sales force optimization and structuring. Now there is far greater focus on portfolio strategy. IMS Consulting is now occupied with projects in fields such as public-private partnerships and due-diligence on in-licensed products: areas, in which, at least previously the Turkish pharmaceutical manufacturer was less involved. The former area has been driven by government interest, a product of the Turkish government's experience in successfully developing partnerships in the defense industry. Now, in managing the development

of the Turkish pharmaceutical industry, they seek to emulate this success. Specifically, IMS Consulting is working closely to examine the best practices of other markets, such as Korea, Latin America, and the United Kingdom, applying them to Turkey, and presenting the government with our findings. Equally, there is now far greater focus on market access. The Turkish manufacturer, now more than ever, seeks to generate a large proportion of his growth through export market sales. IMS Consulting currently assists many domestic players in developing these companies' market access strategies.

Which therapeutic areas are being over- and under-served within Turkey?

Many within the industry have continued to release cephalosporins, in spite of the market for these products shrinking last year by 18%. Specialty care products are still relatively underpopulated. Especially as Turkey matures as a healthcare market, and grows as a market for oncology products, we expect that clinical nutrition will grow as well.

How will the Turkish pharmaceutical market will evolve over the next five years?

Again, reflecting the maturation of the Turkish pharmaceutical industry from a market focused on primary care to one focused on specialty care, we believe that we will see growth within the former segment of 13%, whereas we expect the latter to grow by just 5%. Five years from now, in 2020, Turkey, as a pharmaceutical market, will be entirely driven by specialty care. In realizing this trajectory, a large proportion of growth will be driven by the hospital channel: we expect that, relatively, growth driven through primary care will slow.

IMS Consulting expects a second transition within the Turkish pharmaceutical market. As a market, Turkey will not continue to grow through larger sales volumes: growth by volume will, comparatively, be far less than what we have seen over the course of the past five years. In place, higher value pharmaceutical markets will drive industry expansion. It is for these reasons that IMS Consulting is bullish on the future of the Turkish pharmaceutical industry. •

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Start of the
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plant
construction

JUN'13
GMP
certification
by the
Turkish MoH

AUG'13
Delta Vital
acquisition

SEP'13
Product launch
in Turkey

SEP'14
Turkey's
9th accredited
pharma
R&D centre
status.

DEC'14
32nd
in the Turkish
market with 40
products.

FEB'15
EU-GMP
certification by
Germany
BfArM

GMP

32nd

9th

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SAYA
GRUP





The Times They Are a Changin': Turkish Pharmaceuticals Manufacturing

"All pharmaceutical companies, both those that originate from Turkey and the multinational alike, have seen their profitability constrained in the past year by volatility exhibited by the Turkish Lira and appreciation of the U.S. dollar... This has hit at the greatest irony of our current business environment. Though Turkey employs a system of price-referencing that links the price at which the Turkish pharmaceutical companies can sell their products domestically and though the value of the Euro has depreciated sharply in the past years, having fallen by as much as 40% from its historical high, since 2011, we have been left with market price for pharmaceuticals that does not bear this into account and, because of the lira's decline, a thickened cost structure. This discrepancy between the cost/price at which we manufacture/purchase our products and the price at which we sell our products has struck the industry hard."

- Süha Taşpolatoğlu, CEO,
Abdi İbrahim

Preface to Market Analysis by Pharmaceutical Manufacturer's Association of Turkey (IEIS)

Global Business Reports, in conjunction with the Pharmaceutical Manufacturer's Association of Turkey (IEIS), presents the following overview of the key changes observed within the Turkish pharmaceutical market over the last five years.

The key finding of the report is that while the value of the Turkish pharmaceutical market has expanded by 10.6% in nominal terms, the market has, in fact, contracted by 23.1% in real terms, when accounting for depreciation of the Turkish lira (TL). There have been two catalysts behind this change: a decline in the internal profitability of the Turkish pharmaceutical market and currency volatility, which has wreaked havoc on net profitability, particularly over the last year. Market growth denominated in the U.S. dollar and the Turkish lira illustrates this de-

velopment. Over the last five years, the market grew only by TL1.4 billion, despite the fact that, when measured by unit volumes, the Turkish pharmaceutical market grew from 1.49 billion boxes in 2009 to 1.82 billion boxes in 2014.

The fall in average unit pricing from TL 8.84 to TL 8.01 over the last five years is indicative of the decline in average pharmaceutical pricing. This decline has been spurred by the strong intervention of the government on medicine prices. Though standing in contrast to the efforts of the pharmaceutical manufacturer to move into research and development-intensive products, which would command a higher price point in the local market, the market share of products priced between TL 0 and TL 10 in the retail market grew from 16% in 2009 to 42% in 2014. A tighter

public budget, it seems, has meant a cheaper pharmaceutical market.

These events have occurred alongside a shift in the profile of the Turkish pharmaceutical manufacturer. Turkey's pharmaceutical manufacturing industry boasts many domestic businesses that trace their roots to the early 20th century, but the local pharmaceutical manufacturer has seen competition stiffen, as the presence of multinationals has expanded. The number of foreign multinational corporations operating in Turkey rose to 106 companies in 2014, an increase of 33 over the past five years. Today, these companies control 67% of the Turkish pharmaceutical market.

Most telling has been the link that this report establishes between the growth of the Turkish pharmaceutical market and public expenditures on pharmaceuticals, which, mirroring one another, grew by 6.1% in the past five years while declining by 26.2% in real terms. This suggests that Turkey's regulatory policies have a direct impact on the pharmaceuticals market. Only a political solution can improve market conditions. •

International Turkish brand in pharma

Since 1964, Nobel İlaç's high quality products have been at the service of human health in over 50 countries on three continents through its 20 international subsidiaries.

Nobel, the pharma group, open to Turkey, to the world, to novelties and partnerships.





Turkish Pharmaceuticals, Market Analysis, 2009-2014

By Pharmaceutical Manufacturer's Association of Turkey (IEIS)

Pharmaceutical manufacturing, with its direct implications on the quality of human life and its technologically-rich manufacturing requirements, has been named an industry of strategic importance for Turkey for both its social and economic impacts. Growing in tandem with the expansion of the country's medical needs, the landscape of the Turkish pharmaceutical industry has changed quickly over the course of the past ten years, following the reform of the country's healthcare sector under the Turkish Ministry of Health's "Health Transformation Program" which began a decade ago. The operational experience of the Turkish pharmaceutical manufacturer includes decades of history which has given way to an industry strongly committed to upholding international quality standards. On par with products produced in developed markets, owing to the quality of the country's

human capital and state-of-the-art technology, the footprint of Turkish pharmaceuticals now extends to 170 countries, among which include member nations of the European Union (EU), the Commonwealth of Independent States (CIS), North Africa and the Middle East.

Established in 1964, the Pharmaceutical Manufacturers Association of Turkey (IEIS) is committed to improving the business conditions of its members and contributing to the development of healthcare policies within Turkey. Though the core of IEIS's 60 members, which include national and multinational companies alike, consists of pharmaceutical producers, the IEIS closely follows the interests of all segments of the pharmaceutical industry in seeking to realize the organization's larger goal of furthering the global presence of an industry that is strongly focused on both export-led

growth and the production of value-added products through its R&D activities.

In this report prepared by IEIS, the changes observed in the Turkish pharmaceutical industry over the course of the past five years are analyzed in detail. Market construction includes both prescription and non-prescription medicines licensed by the Ministry of Health, as well as medical devices that take the form of pharmaceuticals, infant medical formulas, and food supplements approved by the Ministry of Food, Agriculture and Livestock.

A. Turkish Pharmaceutical Market

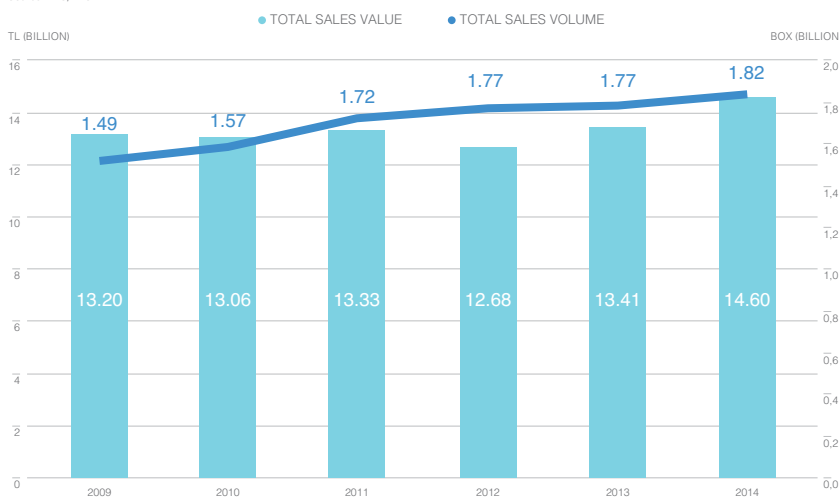
The Turkish market for pharmaceuticals reached a size of 14.6 billion Turkish lira in 2014, growing by 8.8% from the previous year. Unit sales rose by 2.7% over this same period, reaching a value of 1.82 billion units. The price of newly-introduced products which stood higher than the average price of pharmaceuticals currently on the market was the main contributor to growth.

When compared against preceding years, the market growth in 2014 is phenomenal, since the total growth has remained only at 10.6% over a five year period. In 2009, the Turkish pharmaceutical market stood 1.4 billion Turkish liras smaller than that of today. If weighed against wholesale inflation over this five year period, the Turkish market for pharmaceuticals declined by 23.1%, in real terms.

Touching on what is perhaps the defining characteristic of the Turkish market of today, and highlighting the impact that the country's Health Transforma-

TURKISH PHARMACEUTICAL MARKET

Source: IMS, IEIS



Abdi Ibrahim

For more than 100 years, Turkey's most established pharmaceutical company, Abdi Ibrahim, has continued to improve public health with resolute, innovative approaches. With its strong vision, a dynamic structure, and an up-to-date approach, it has been the leader of the Turkish pharmaceutical industry since 2003.

FOUNDER

1912-1926: Pharmacist Abdi Ibrahim Barut
1939-1961: Pharmacist Ibrahim Hayri Barut
1981-Present: Pharmacist Nezh Barut

LEADERSHIP

Nezh Barut, Chairman
Dr. Süha Taşpolatoğlu, CEO

In 1981, the third generation took over, and the era of the siblings Pharm. Nezh Barut and Nesrin Esirtgen began. Pharm. Nezh Barut prioritized the increase of the number of preparations and international collaboration with other companies, reaching the number of 150 products; today, it is 350. Seeing the trend towards globalization, Pharm. Nezh Barut set up a new production facility with the most advanced technology, which broke ground in Istanbul's Esenyurt district was in 1994 and began production in 1997. With the opening of world markets in 1999, the first overseas establishment was in Algeria. Today, Abdi Ibrahim is active in 50 countries.

In order to develop medical products with international standards, in 2008 Abdi Ibrahim opened the first R&D center, accredited by the Ministry for Science, Industry, and Technology. In 2010, the Abdi Ibrahim Logistics Center started operating in Esenyurt.

On the 100th anniversary of its foundation, Abdi signed a partnership agreement with one of the biggest pharmaceutical companies in Kazakhstan, Global Pharm, to invest in a production facility satisfying good manufacturing practices (GMP) standards. Also in 2012, Abdi Ibrahim founded the Abdi Ibrahim Otsuka Company to produce original products from one of the biggest Japanese drug companies, Otsuka Pharmaceutical, in Abdi Ibrahim's facilities and market them in Turkey and neighboring countries.

In 2014, Abdi Ibrahim partnered with the prominent Algerian drug company Remede Pharmaceuticals, to produce in Algeria, investing in production facilities conforming to GMP standards. In 2015, the Abdi Ibrahim Biyoteknoloji Ürünleri Sanayi ve Ticaret A.Ş. was founded.

REVENUE AND GROWTH

During the financial year of 2014, Abdi Ibrahim exhibited a growth rate of 45%, with revenue of 1.176 billion TL on a consolidated basis. The revenue in the domestic market increased by 53% and reached 991 million TL, rising from the 2013 level of 647 million TL.

INTERNATIONAL MARKETS

Total sales in international markets almost doubled for the last three years and reached \$52 million by 2014. Abdi Ibrahim has manufacturing sites not only in Turkey but also in Kazakhstan and now also one under construction in Algeria. The total number of employees in the international markets reached almost 400 while export countries reached 50. Abdi Ibrahim is representing many companies outside Turkey, in addition to selling its own products; furthermore, the joint venture with Otsuka Pharmaceuticals is now extended to Algeria and Tunisia.

R&D FOCUS AND APPROVALS

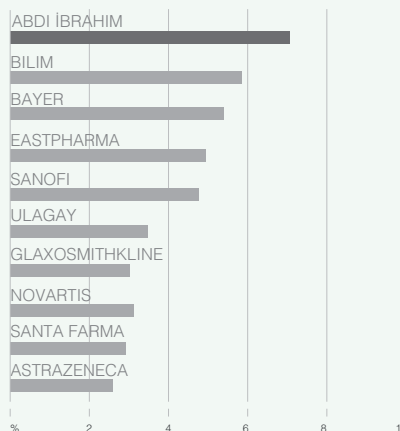
Adapting new technology platforms and developing value-added products has created a competitive product portfolio. Abdi Ibrahim supports its partners through licensing of blockbusters where only a few competitors are able to penetrate due to the complexity of project. Our development program and regulatory dossiers are in line with European regulations and additional work is completed swiftly to comply with regulatory requirements of other major markets like Canada, Brazil, Australia, and GCC.

UPCOMING PRODUCTS

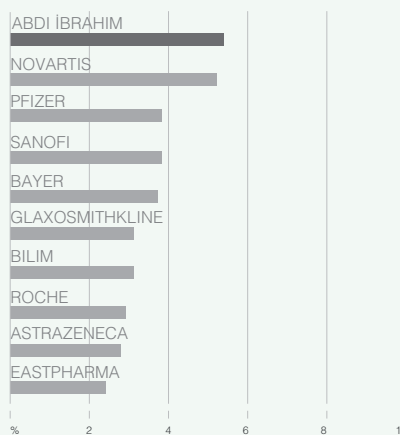
Abdi Ibrahim is consistently investing in new products. Recent novelties cover new dry powder inhalation products and nanotechnology. Our development activities are focused on new technologies, drug delivery systems and biosimilars. Biotechnology-related infrastructure and biosimilars development are also prioritized investment areas. Our GMP manufacturing plant for biotech products is planned to be operational by the end of 2016. Supported by the governmental incentives, development of biosimilars will be the first step and the cradle for future innovation of biotechnological drugs.

MARKET SHARE AND PRODUCT GROWTH

MARKET SHARE - UNITS (2014)



MARKET SHARE - \$ TURNOVER (2014)



CORPORATE SOCIAL RESPONSIBILITY

Out of a sense of institutional social responsibility, Abdi Ibrahim has been active in the fields of education, culture and arts, public health, and protection of the environment, with institutions and activities such as the Abdi Ibrahim Primary School, Belma Barut Primary School, the "Iron Turkey" health project, the "Reasonable Drug Use" project, and the digital Van Gogh exhibition.

In 2015, Abdi Ibrahim renovated the health museum in the Dar al-Shifa', focusing on Ottoman medicine from the 15th to the 18th century, making the treasures of our medical history accessible to the public. Applying modern and effective presentation techniques, it has been turned into a state-of-the-art museum.

In returning to the Turkish pharmaceutical industry in 2015, the largest change has been a decline in profitability for Turkish pharmaceutical companies as a result of currency volatility. As Turkey's largest pharmaceutical company, what has this meant for Abdi Ibrahim?

All pharmaceutical companies, both those that originate in Turkey and multi-nationals, have seen their profitability constrained in the past year by volatility in the Turkish lira and appreciation in the U.S. dollar. Turkey is still import-dependent, both in API and finished products, the cost of which grow sharply in conjunction with these currency movements.

This has hit at the greatest irony of our current business environment. Though Turkey employs a system of price-referencing that links the price at which the Turkish pharmaceutical companies can sell their products domestically and though the value of the euro has depreciated sharply in the past years, having fallen as much as 40% from its historical high since 2011, we have been left with a market price for pharmaceuticals that does not bear this into account. Moreover, we have a thickened cost structure because of the lira's decline. This discrepancy between the cost/price at which we manufacture/purchase our products, and the price at which we sell our products has struck the industry hard.

We want to be optimistic that we will see a solution; otherwise, investors would not make long-term investments in Turkey. A frozen exchange rate directly undermines this.

The only way in which the Turkish pharmaceutical companies can grapple with these constraints is through close scrutiny of its cost structure. One of the social ramifications associated with this pricing system is that the employees in the sector have been losing their jobs. In the last four to five years, the pharmaceutical sector has lost almost 15,000 employees and is expected to lose more in 2015.

Abdi Ibrahim identifies three avenues in its strategic action plan for continued growth of the company. Could you provide an overview of these initiatives?

First of all, we are determined to maintain our strength in the Turkish pharmaceuti-

Süha Taşpolatoğlu

CEO
ABDI İBRAHİM



cal sector as the market leader, as has been the case for the last 12 years, and to focus on rapidly growing therapeutic areas like diabetes and respiratory.

Other than this, Abdi Ibrahim will enact three corporate strategic initiatives in the coming five years in order to continue to drive profitability. We are currently investing heavily in the development of biological pharmaceuticals. This year we will inaugurate a new facility dedicated to the production of bio-technological products. We expect that biological pharmaceuticals will soon represent 20% of total global pharmaceutical production. It is because of this that Abdi Ibrahim views the development of drugs that fall within these product areas to be critical in expanding its global footprint.

Our second goal stems from this: we strive to grow the proportion of our turnover that is generated through foreign market sales. To this end we will soon open a manufacturing facility in Kazakhstan, which will serve both internal and near markets. This facility will begin to operate in the fourth quarter of 2015. This comprises one component of Abdi Ibrahim's global strategy. In addition, we seek to grow our foreign market presence both through out-licensing to foreign pharmaceutical companies

and the distribution of branded products through a network of strategic partners.

A third area in which Abdi Ibrahim seeks to expand in the near-term is in the over-the-counter market, which is both less constrained by the country's system of cross-price referencing and more approachable with regard to its competitive landscape.

The Kazakh market is one in which several other Turkish pharmaceutical companies, including Nobel Pharmaceuticals, have included in their export market strategy. What made Kazakhstan desirable for Abdi Ibrahim to enter on a regulatory level?

The Kazakh market is attractive both for its internal dynamics and the country's regulatory environment. In growing its pharmaceutical sector, the Kazakh government was smart: it mandated that all producers, even those already manufacturing within the country, have facilities that are GMP-compliant and, as an incentive for doing so and investing in the country, offered certain companies guarantees of exclusivity for certain products. This attracted Abdi Ibrahim. We have since secured these contract structures for 50 of our products, for which our off-take will be guaranteed for the next seven years.

What has underscored Abdi Ibrahim's investment in Algeria?

Abdi Ibrahim will soon also establish a manufacturing facility in Algeria, which has, like Kazakhstan, strategically incentivized the development of local manufacturing. Those that operate within the market without a local manufacturing facility are prohibited from exporting. The dynamic that this creates for the local manufacturer, whereby one can use Algeria as a point of entry for other regional markets, offered a strong fit with Abdi Ibrahim's foreign market strategy.

Do you have a final message for our readers?

Abdi Ibrahim has a commitment not only to our immediate stakeholders, but also to the customers who we serve. We are dedicated both to sustainability and product quality and to representing the Turkish market as a leader, as it expands its footprint outward. •

OVERALL MARKET SUB DISTRIBUTIONS

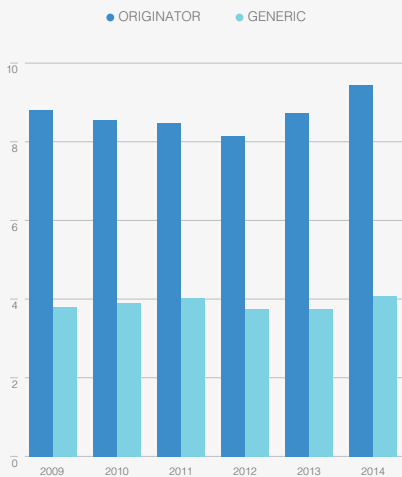
Source: IMS, IEIS

	UNIT		TL	
	2009	2014	2009	2014
Overall Market	100%	100%	100%	100%
Prescription Drugs	90.2%	88.1%	93.5%	89.2%
Prescription Reimbursed	88.7%	86%	91.6%	85.6%
Prescription Non- reimbursed	1.5%	2%	1.8%	3.6%
Non-prescription Drugs	2.3%	2%	0.8%	0.9%
Non-prescription Reimbursed	2.3%	1.7%	0.8%	0.7%
Non-prescription Non- reimbursed	0.04%	0.36%	0.01%	0.2%
Other*	7.5%	10%	5.7%	10%
Other Reimbursed	3.8%	6%	2.2%	3.7%
Other Non- reimbursed	3.7%	3.9%	3.5%	6.2%

*Other products: Medical baby formulas and some medical devices in pharmaceutical form, and food supplements approved by the Ministry of Food, Agriculture and Livestock.

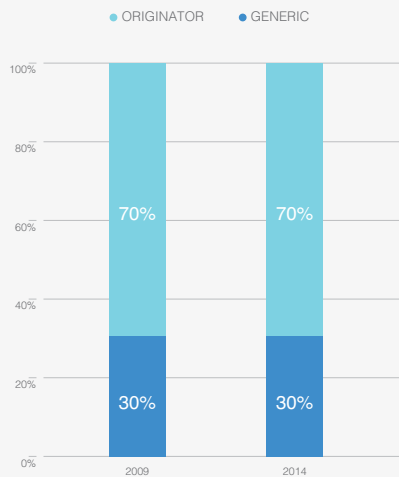
ORIGINATOR - GENERIC PRODUCTS (VALUE)

Source: IMS, IEIS



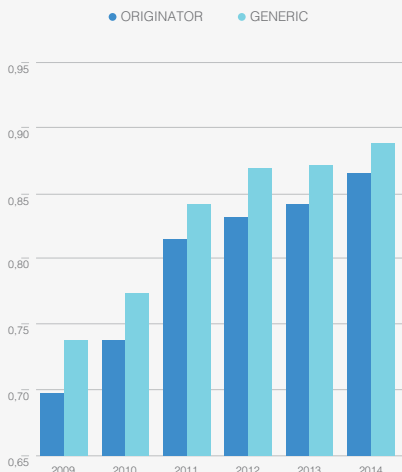
MARKET SHARE OF ORIGINATOR - GENERIC PRODUCTS (VALUE)

Source: IMS, IEIS



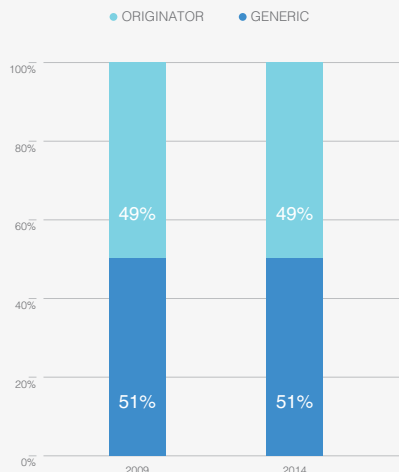
ORIGINATOR - GENERIC PRODUCTS (VOLUME)

Source: IMS, IEIS



MARKET SHARE OF ORIGINATOR - GENERIC PRODUCTS (VOLUME)

Source: IMS, IEIS



tion Program has had on public health, pharmaceutical sales as measured by volume grew by 22.1% from 2009 until 2014. Chiefly spurred by improved medical access and growth in annual doctor visits per capita, public consumption of pharmaceuticals grew rapidly over this period. Yet the Turkish government has actively sought to counter balance the impact that this unit growth has had on its pharmaceutical budget through strict price controls.

This is observed most acutely in the declines that have been seen in the average price levels of pharmaceuticals which regressed from 2009 until 2014, falling from 8.84 TL to 8TL – a decline of nearly 9.4% in nominal terms.

Over this same five-year period, the profile of the Turkish market for pharmaceuticals underwent restructuring, observed across two events. First, the presence of the multinational pharmaceutical companies expanded rapidly. 33 multinational pharmaceutical companies entered the Turkish market over the course of the past five years, bringing the total number of foreign entities within the domestic market to 106. Collectively, these 106 companies constitute 67% of total domestic market share. Second, market concentration intensified. While in 2009 45 companies made up 90% of the total market for pharmaceuticals, five years later, 60 companies now control this same proportion, 70% of which are multinationals.

Combined, the effect of lower levels of prices has been to reshape the portfolio dynamics of Turkish pharmaceutical manufacturers: in 2014, the value of the prescription drug market shrank to below 90% of total market value, of which, reimbursed prescriptions accounted for just 85.6%, a decline from 91.6% in 2009.

a. Originator vs. Generic Products

The originator drug market, which stood at a value of 8.8 billion TL in 2013, reached 9.65 billion TL in 2014. An increase of 9.7% from the previous year, this growth was primarily spurred by increased sales of imported originator products, which in itself grew

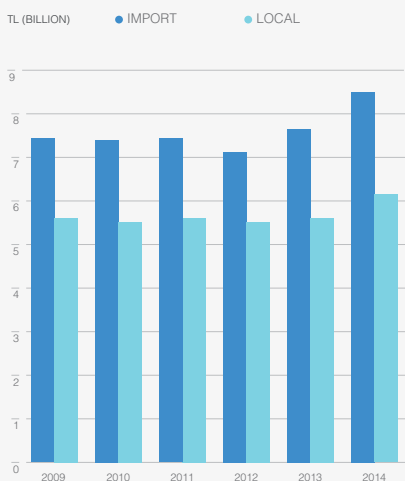
SUB DISTRIBUTIONS OF ORIGINATOR-GENERIC PRODUCTS

Source: IMS, IEIS

	ORIGINATOR DRUGS				GENERIC DRUGS			
	2009		2014		2009		2014	
	Import	Local	Import	Local	Import	Local	Import	Local
Box (mn)	37%	63%	48%	52%	6%	94%	3%	97%
	258	439	412	452	46	692	27	866
TL (mn)	75%	25%	78%	22%	12%	88%	6%	94%
	6,644	2,220	7,555	2,097	472	3,371	228	3,873

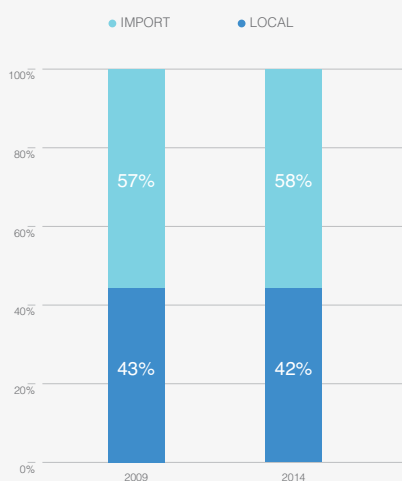
IMPORT - LOCAL PRODUCTS (VALUE)

Source: IMS, IEIS



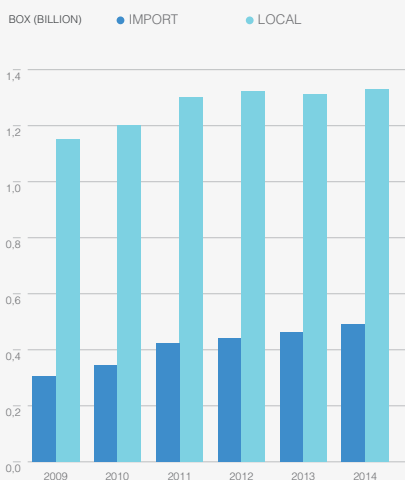
MARKET SHARE OF IMPORT - LOCAL PRODUCTS (VALUE)

Fuente: IMS, IEIS



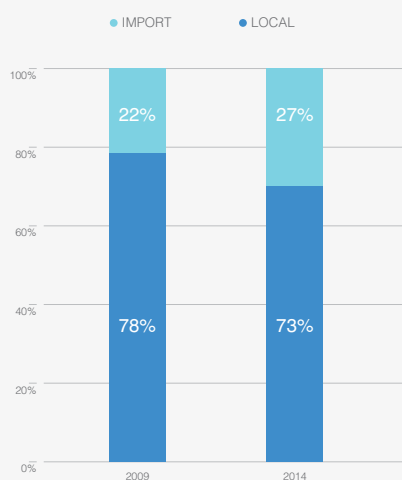
IMPORT - LOCAL PRODUCTS (VOLUME)

Source: IMS, IEIS



MARKET SHARE OF IMPORT - LOCAL PRODUCTS (VOLUME)

Fuente: IMS, IEIS



by 10.3%. Turkey's generic market grew by 6.4% from the previous year, reaching a size of 4.1 billion TL in 2014, predominately led by an increase in domestically produced generic products, which rose by 7.3% over the previous year. Volume growth for both of these product categories stood less; originator and generic products increased by 2.7% and 2.5%, respectively, in 2014. To assume that growth in both of these product categories typified annualized growth patterns would be far from the case. Between 2009 and 2014, the value of the market for originator drugs, which declined during the first three years of this period, increased only in 2013 and 2014, allowing for collective market growth to reach 8.9% over the course of the past five years. The market for generic drugs, on the other hand, grew by only 6.7% from 2009 until 2014. Taken as an aggregate, for neither product category was market growth rapid enough to outpace inflation, which led to a collective real decline of 24.3% and 25.8% for originator and generic products, respectively.

This was reflected in growth of product volumes, which, although increasing by 24% for originator and 21% for generics over this five year period, did little to alleviate the impact of these decreases in market value: again, a product of the decreases in drug prices experienced by the industry.

The market share of generic and originator drugs did not change over the course of the past five year period. Originator drugs received 49% of the total market share, but comprised 70% of total market value.

A divide exists between sources of production for pharmaceuticals in Turkey. Originator products show a tendency towards importation. Typically, generic products are produced domestically.

b. Import vs. Local Products

Over the course of the past five years, the Turkish pharmaceutical market has favored the importation of foreign pharmaceutical products over those manufactured domestically. Though initially, following the enforcement of

Nobel Pharmaceuticals

FOUNDER

In 1964, Nobel İlaç has been established in Istanbul. The company has been run by the owner Ulusoy family for more than fifty years.

LEADERSHIP

Mr. Hasan Ulusoy is leading the group, as the Chairman. Also, board of directors and executive board made up of four members are present.

REVENUE AND GROWTH

In 2014, a level of \$150 million in domestic sales and \$60 million in exports has been achieved. The level of foreign sales is \$120 million. This year's budget has been created with an increase of 20%.

EXPORTS

The trade deficit of the pharma sector in Turkey is a vicious matter. Each year the trade deficit is around \$4 billion. For the past three years, Nobel İlaç is the only company that doesn't participate in the deficit. For example, last year the import levels were at \$35 million whereas the export levels were at \$60 million. We are very proud that the majority of the export is finished products with our own brands. In more than twenty countries, we are carrying out marketing activities with our own teams. We have over 1,100 employees in a wide geography from Mongolia to Albania besides Turkey.

R&D FOCUS AND APPROVALS

Research and development (R&D) is a priority in our pharmaceuticals sector. We have an R&D center at our facilities in Düzce. In 2014, we qualified for the R&D center certificate issued by Ministry of Science, Industry and Technology. We are allocating 5% of our net sales to R&D and we will maintain this level in the upcoming years. The value of our budget allocation to R&D would be better regarded when compared with the national ratio of R&D allocation to national income is considered as 1% approximately.

Furthermore, this past year we experienced the honor of being the only company selected among the 28 applicants for the program of "Production and Development of Indigenous Biosimilar Drugs." We have begun working on the project and we are looking forward to sharing substantial results in a few years.

MARKET SHARE AND PRODUCT GROWTH

Our market share in Turkey is 2%, according to IMS reports. There are countries in which we have reached 4%. We aim to expand the market share with the newly developed products and by entering new markets in the near future.

UPCOMING PRODUCTS

Currently, we have a wide range of products almost in all therapeutic areas. Development studies of different forms for

the products with high potential molecules in these areas are on-going. Moreover, we have a growth target in the area of non-prescription products.

CORPORATE SOCIAL RESPONSIBILITY

Nobel Medicus, a scientific publication, a refereed journal for more than 10 years is our remarkable social responsibility project. Nobel Medicus, is indexed in SCI-E, accepted in a large number of national and international indexes and libraries including the British Library, is published three times a year in editions of 13.000, and distributed free of charge to health care professionals. It has an independent editorial structure and publishes original articles that are not previously presented in any documentation. Besides, we are supporting several social projects in different manners.



Industry profitability fell sharply in 2014, part of a larger trend that we have seen over the last five years. Though collectively the pharmaceutical industry has grown by just over 10%, in real terms, market value declined by as much as 26%. On a strategic level, what has this meant for Nobel Pharmaceuticals?

Nobel Pharmaceutical stands among the largest domestic pharmaceutical manufacturers and enjoys a strong portfolio of export markets. During the past few years, we have relied primarily on foreign market sales in order to offset the losses associated with the state of the domestic market. This, however, is not a healthy solution. We find it increasingly more difficult to absorb the declines in profitability at home through our operations abroad.

We have tried to communicate this adverse and possibly unsustainable trend on every platform possible to Turkey's regulatory authorities.

Our operations in Turkey must be profitable, otherwise we find ourselves unable to reinvest either at home or abroad. In building a global market presence, our experience shows that it takes time for investments abroad to translate into net profit. Notwithstanding initial losses, a company needs to persevere in order to establish a sustainable global business. Yet declining levels of profitability that come with the current state of the domestic market make it increasingly difficult for us to hedge against the losses that we expect when growing our global presence.

What impact has price volatility had on the ability of Nobel Pharmaceuticals to minimize its cost structure, in particular with regard to its contracts for raw materials?

Price volatility and its impact on the domestic market have often been discussed. Yet there is no volatility observed in either the depreciation of the Turkish lira nor the current pharmaceutical pricing environment. There has only been continuous depreciation and market contraction, both of which have followed a predictable, and stable, pattern. There has been no relief.

As a reaction to this, Nobel Pharmaceuticals has tried to apply pressure to its

Hasan Uluoy

Chairman
**NOBEL
PHARMACEUTICALS**



suppliers where possible. This, again, cannot be done sustainably – our suppliers have their own limits. The end result has been that we have had to internalize these losses and respond by increasing our product volumes: a strategy that is effective only if one does not have capacity constraints. Higher production volumes necessitate further expansion and in this current market environment, only a few can afford to do so.

Is it realistic to expect to see a reevaluation of the public budget for Turkey's next political cycle?

Nobel Pharmaceuticals would like to believe that we could see a reevaluation of the public budget. It is an important expectation to have. However, the Turkish government has shown no sign of responding to such an expectation, which is based on quantitative evidence from the market. Those complaints that we have levied over the past five years have led us to wonder why now they might.

What strides has Nobel Pharmaceuticals made in expanding into the production of value-added pharmaceuticals?

In the past three years, Nobel Phar-

maceuticals was able to work collaboratively with the Turkish government in creating an attractive environment for the production of biopharmaceuticals. This involved taking several of Turkey's ministers with us in attending global biopharmaceutical conferences and building in them an understanding that, while there may be promise in this field, Turkey, as of yet, has only a very small position within it. The product of our work was the development of an incentive scheme that is now in place to encourage the development of biopharmaceuticals within the country. 28 projects applied for government funding for these products. Of these, only Nobel Pharmaceuticals was successful in its application. Over the course of the next years, as a part of this program, Nobel Pharmaceuticals will work in collaboration with TÜBİTAK, the research arm of the Turkish government, in the development of a biosimilar product. We hope that within the next four years we will be able to take this product through Phase I. Eight years from now, we hope to produce the first fully Turkish biosimilar product.

In working with the government to expand into the production of biopharmaceuticals in Turkey, what lessons can be learned from foreign markets about creating an attractive environment for their production domestically?

Nobel Pharmaceutical believes that underscoring the success of many of the regions that now lead in the production of biopharmaceuticals – India, China, South Korea – has been a system of regulation that has enabled manufacturers to develop these products in accordance with the resources possessed by an individual market. Each region has its own regulation. Yet Turkey, in creating its regulatory framework, borrowed many of its regulatory statutes from Europe. With this has come a substantially higher requisite investment cost, which could limit the development of these products domestically. In seeking to expand the production of biopharmaceutical products within the country, Turkey must develop its own regulatory framework, one that does not impose such stringent requirements in areas of excessive clinical trials. •

SUB DISTRIBUTIONS OF IMPORT-LOCAL PRODUCTS

Source: IMS, IEIS

	IMPORT DRUGS				LOCAL DRUGS			
	2009		2014		2009		2014	
	ORI.	GEN.	ORI.	GEN.	ORI.	GEN.	ORI.	GEN.
Box (mn)	85%	15%	94%	6%	39%	61%	34%	66%
	258	46	412	27	439	692	452	866
TL (mn)	93%	7%	97%	3%	40%	60%	35%	65%
	6,644	472	7,555	228	2,220	3,371	2,097	3,873

price-control methods in 2009, foreign pharmaceutical imports stagnated, over the course of the past two years, these products have expanded their presence within Turkey – first by 8.7% in 2013 and then by 10% in 2014, exhibiting collective growth of 13% over this five year period. Over this same period, domestic production grew by a paltry 6.8%. This discrepancy in growth between foreign and local product sales held true in examining volume growth. Though foreign drug imports grew by 47%, local production grew only by 15%.

Regardless of examining the size by either value or volume, the relative market share of imported drugs has risen strongly against those produced domestically since 2009.

While the presence of originator prod-

QUANTITATIVE DISTRIBUTION OF THE PRODUCTS IN MARKET

Source: IEIS

	2014
Market Total	11,229
Entries	736
Licensed Drugs	464
Originator	125
Generic	332
Import	136
Local	328
Other	272
Withdrawals	753
Reimbursement List	8,344
Entries	424
Originator	112
Generic	312
Import	119
Local	305
Withdrawals	1,229

ucts, which are largely imported, has increased if measured by both value and volume, that proportion of these products which has been manufactured domestically has fallen over the course of the past five years. In 2014, 65% of the drugs manufactured in Turkey were generic pharmaceuticals.

c. New Product Entries to the Market

In 2014, the Turkish pharmaceutical industry grew across a diverse array of product areas. While 753 products were withdrawn from the market, 736 new products were launched, of which 464 were licensed products and 272 were non-pharmaceutical products such as food supplements. Of the 464 new pharmaceutical products to reach the Turkish market, 125, or 27%, of these products were originator products and 332 were generic pharmaceuticals. Of equal interest, 136, or 29%, of these products were imported from foreign markets. The remaining 328 products were produced locally.

Of the 736 products that were added to the market in 2014, 424 were included on the Turkish government's reimbursement list. Bearing in mind alterations to this list, such as the removal of 1,229 products from the reimbursement system, the total number of products eligible for reimbursement stood at 8,344 at the end of 2014. 26% of these new products eligible for reimbursement in 2014 were originator products, with the remaining 74% represented by generic products. 28% of these products were imported from foreign markets, with the remaining 72% represented by those produced locally.

d. Pharma Pricing Regulation

Turkey's system of price referencing was first introduced in 2004, with the intent of checking governmental healthcare expenditures through linking the price of pharmaceuticals to the lowest price at which a similar pharmaceutical product is produced within a basket of five European nations (France, Greece, Italy, Portugal and Spain). Whichever region produces a specified pharmaceutical at the lowest price so will that price becomes the reference price for producer prices in Turkey.

Once a reference price has been set, then official prices of products in different categories are established based on a fraction of the reference price. For example, while an originator product with no generic competitor may have the right to receive 100% of the reference price, an originator and generic product that compete against one another are subject to 60% of the reference price. In effect, the result of this is that as soon as a generic drug that competes against an originator product is introduced in the domestic market, the price of the originator product falls by 40%.

Of additional importance, in interpreting the rate at which the reference price is applied to the Turkish market, as the rate of origin is denominated in the Euro, an exchange rate is employed in converting this rate to the Turkish lira. In spite of the variance in the currency level, this conversion rate has remained frozen at 1.9595 TL since April 2009.

Once a producer price is established by the Ministry of Health, discount rates are applied by the Social Security Institution (SSI) for granting reimbursement status. The following table shows discount rates applied for different product groups as they have evolved over the course of the past five years.

e. Retail Price Ranges

Reflecting a movement towards lower priced pharmaceuticals, the market share of products eligible for reim-

REFERENCE PRICE RATIOS

Source: TITCK (Ministry of Health, Medicines and Medical Devices Agency of Turkey)

		2009	2010	2011	2012	2013	2014
Originator	Retail price 5.22 TL and below	100	100	100	100	100	100
	Retail price between 5.23 and 9.97 TL	100	100	100	100	100	100
	Retail price between 9.98 and 14.97 TL	100	100	100	100	100	100
	Retail price 14.98 TL and over	100	100	100	100	100	100
Originator with a Generic Product and the Generic Product	Retail price 5.22 TL and below	100	100	100	100	100	100
	Retail price between 5.23 and 9.97 TL	80	66	66	60	60	60
	Retail price between 9.98 and 14.97 TL	80	66	66	60	60	60
	Retail price 14.98 TL and over	80	66	66	60	60	60
Twenty Years	Retail price 5.22 TL and below	100	100	100	100	100	100
	Retail price between 5.23 and 9.97 TL	100	100	100	100	100	100
	Retail price between 9.98 and 14.97 TL	100	100	100	80	80	80
	Retail price 14.98 TL and over	100	100	100	80	80	80

DISCOUNT RATES

Source: SSI Communiqué on Healthcare Practices

			2009	2010	2011	2012	2013	2014	
Originator	Retail price 5.22 TL and below	No Generic Product	4	4	4	4	0	0	
	PSF between 5.23 and 9.97 TL		24	23	32.5	41	20	20	
	Retail price between 9.98 and 14.97 TL		24	23	32.5	41	41	41	
	Retail price 14.98 TL and over		24	23	32.5	41	41	41	
Originator with a Generic Product and the Generic Product	Retail price 5.22 TL and below		4	4	4	4	0	0	
	Retail price between 5.23 and 9.97 TL		11	11	20.5	28	20	20	
	Retail price between 9.98 and 14.97 TL		11	11	20.5	28	28	28	
	Retail price 14.98 TL and over		11	11	20.5	28	28	28	
Twenty Years	Retail price 5.22 TL and below		4	4	4	4	0	0	
	Retail price between 5.23 and 9.97 TL		11	11	11	11	7	7	
	Retail price between 9.98 and 14.97 TL		Local	-	-	-	28	20	20
			Reference price available	11	11	20.5	28	20	20
			No reference price	24	23	32.5	40	20	20
	Retail price 14.98 TL and over		Local	-	-	-	28	28	28
			Reference price available	11	11	20.5	28	28	28
			No reference price	24	23	32.5	40	40	40

bursment in the 0-10 TL price range increased compared against 2009, whereas the market share of products with a value of over 100 TL fell. Today, 42% of all products available domestically are priced within the 0-10 TL price range.

This movement towards lower value products is disproportionately observed amongst generic drugs with the 0-10 TL price range. While just 17% of all generics were priced within the 0-10 TL range in 2009, today, nearly half of all generics are priced within this range: a movement of

nearly threefold.

This trend held true for originator products, which, with a retail value closely correlated to those of generic products, saw their share of products priced in the 0-10 TL range grow by 18 percentage points (pp) since 2009. Interestingly, those originator products priced at over 250 TL grew strongly over this period, as well, reaching 14%.

This trend has also been observed for imported pharmaceuticals: unsurprising, given that originator products constitute a large proportion of total

pharmaceutical imports. In 2014, the largest share of these products was priced in the 0-10 TL range, 21%, followed by those priced in 10-25 TL range, 20%. Compared against 2009, the greatest change over the past five years was observed in the movement of product prices in the 0-10 TL range, which saw an increase of 13 pp. Extending from the second dynamic observed in the price of originator drugs, the second largest movement over this period was seen in those products priced at over 250 TL, which grew by 8 pp from 2009 to 2014. → 38

Bilim Pharmaceuticals

LEADERSHIP

Leadership is the responsibility of all of us for sustainable success and a stronger company. Our leaders use various tools to review and improve the effectiveness of own behaviors and take necessary actions in accordance with improvement and future leadership needs receiving feedback through various meeting carried out in line with Communication Plans & Performance Assessment System & 360° Competency Assessment System. In order to reach our vision by realizing our mission, we attach great importance to the maximum use of our leadership capability. We have implemented the Bilim Pharmaceuticals Leadership Model (BI'L Model) for a stronger leadership strategy and to make sure that all of our leaders act with a common leadership understanding and approach

This strong practice called the "BI'L Leadership Model" aims to:

- Reveal a visionary, inspiring and holistic leadership model;
- Further support our employees' leadership skills; and
- Discover and develop the leaders among us.

EXPORT

Bilim Pharmaceuticals is a strong player not only in the domestic market but also in foreign markets, currently exporting its products to more than 50 countries. It has representative offices in Moldova, Bosnia Herzegovina and Albania. Total export turnover has reached to \$50 million at the end of 2014. According to figures prepared by the Exporters' Association, Bilim's export share in total product exports was 6.4% in 2014. The foreign trade deficit, which has a considerable bearing on the Turkish economy, is also important in our sector. The exports/imports ratio in our industry is around 18%. At Bilim, this ratio reached 55% in 2014, having improved every year.

R&D FOCUS AND APPROVALS

The underlying factors behind our rising sales targets are our concentration on technologically based, R&D activities and the steadily increasing budget allocated for them. Our Research and Development Center has been equipped with more than 220 high-tech machinery units, apparatus and equipment. Our R&D budget, which has been growing incrementally for many years, was even raised from 2009 to 2012, when economic measures had to be taken by pushing through significant cuts in drug sale prices. The budget was maintained at 5% of our net sales.

With its building expenses as high as €120 million, our Research and Development Center is the largest R&D center of the Turkish pharmaceutical industry with a total of 4,500 square meters of laboratory space. An investment of \$15 million was made in our R&D center located within our Bilim Gebze plant, which is the biggest drug manufacturing plant in the Turkish pharmaceutical industry. We continue to invest an average of an ad-

ditional \$5 million every year. This R&D budget has increased by approximately 320% in the last four years.

CORPORATE SOCIAL RESPONSIBILITY

As Bilim Pharmaceuticals, we aim at being recognized as a "model company" on sustainability, not only in the pharmaceuticals industry, but in all sectors.

Bilim Pharmaceuticals Community Volunteers (BPCV) was established in 2005 by voluntary employees in order "to be a part of the solution" in social problems. It is based on the fundamental idea that volunteering is one of the most important ways to develop and grow the community. As Bilim Pharmaceuticals employees, we know that social responsibility transforms into a corporate living value only if it becomes a part of the corporate culture and is kept alive in collaborations and by all stakeholders. Such transformation is possible only if our employees improve their social sensitivity on a platform of volunteering and popularize volunteering among the community.



Bilim Pharmaceuticals is one of Turkey's most active pharmaceutical manufacturers in foreign markets. What foreign markets are most attractive in 2015?

Bilim Pharmaceuticals currently exports to 58 countries, a number which grew by six since last year. Today, we are present in regions ranging from South America to Far Asia. Annually, we have consistently realized double-digit growth for our foreign market sales.

For expanding our global footprint, Bilim Pharmaceuticals targets two markets in particular in the near-term: Russia and Vietnam. These markets will see the strongest growth globally. Our entry into them is part of a larger, global strategic plan that Bilim Pharmaceuticals has developed which entails both market entry for several regions and, annually, the addition of 20 products to our portfolio. These products will then become part of our foreign market portfolio.

Bilim Pharmaceuticals sees great opportunity for the Turkish pharmaceutical manufacturer within near markets, for example, MENA, CIS, and Iraq. These countries have been complicated by regional conflict, which has resulted in constraints on public medical expenses not dissimilar to those imposed in Turkey. Yet, as a whole, Turkey is fortunate in that regional medical markets, by and large, lack a domestic pharmaceutical manufacturing base. Turkey can fill this role.

Aside from a heavier focus on the foreign market, what are two other initiatives that Bilim Pharmaceutical will enact over the next five years to grow further?

First, we seek to grow our capacity utilization for contract-manufacturing activities by working closely with multinationals. There are only 50 production sites in Turkey, though 300 companies operate in the domestic market. Contract-manufacturing is a strategic business, and one poised for growth, especially if the Turkish government implements local content requirements.

Second, Bilim Pharmaceuticals, a leader in diabetes, has emphasized the development of biosimilars related to these products. We have a network of businesses in many countries that we are working with in their development. The foreign market will play a role in monetizing these efforts, but these efforts have been com-

Dr. Erhan Baş

General Manager
BILIM PHARMACEUTICALS



licated by the nascence of international regulations related to biosimilars. It is still unclear how equivalency for biosimilars can be established. According to the developments, Bilim Pharmaceuticals has keen interest to enter into producing biosimilars.

Turkey has placed emphasis on research and development (R&D) in pharmaceuticals and many other sectors of the economy. On a cultural level, what must change if Turkey is to successfully develop value-added products?

Turkey should develop R&D-intensive products internally. In India and South Korea, regions that lead in the development of technologically advanced products, R&D is part of each country's social fabric: their educational systems place strong emphasis on it and government provide incentives. Turkey is behind in creating this environment. Five years ago, universities expressed little interest in collaborating with domestic industry, but this is changing. Now, there are many incentives given for R&D. We could see many universities within Turkey, such as Hacettepe University, Ankara University, Boğaziçi University and Istanbul University play a larger role, which is paramount to cultivating the development of value-added products.

In the past year, we have seen industry profitability continue to fall, driven by Turkey's system of cross-price referencing, but also currency volatility. On a strategic level, what has this meant for Bilim Pharmaceuticals as one of Turkey's largest pharmaceutical manufactures?

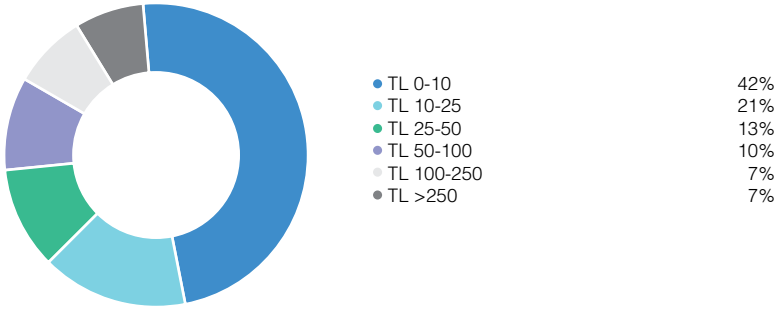
Currency volatility, driven by fluctuations in the value of the euro and lira and the appreciation of the dollar, has impacted Bilim Pharmaceuticals in two ways. First, currency volatility has cut sharply into profitability. Bilim Pharmaceuticals, if compared against many other operating within the Turkish market, is fortunate because it has established a strong position in exports, which has hedged against the declines in profitability. This is not so for many others: only 18% of those products that the Turkish pharmaceutical manufacturer imports are recouped by pharmaceutical exports. For Bilim Pharmaceuticals, this ratio stands at 55%. So, while our presence in export markets has enabled us to protect ourselves from currency volatility, this is far from typical for the industry. Second, currency volatility has impacted supply chain dynamics. Bilim Pharmaceuticals employs many manufacturers for sourcing its APIs and excipients, both of which are priced in the foreign currency.

Many contend that any change in the rate at which the euro is converted to the lira will be inconsequential, unless Turkey's public budget is also readjusted. Is this a realistic expectation?

We will see the Turkish government play a more supportive role in developing the industry. The matter of the public budget and the priority that medical expenses should take within it is perhaps one of the most complex macroeconomic issues that the government faces. But the government has shown that it supports R&D activities that develop the sector and will seek to resolve issues that hinder the sector's growth. This is reflected in the incentive structures that it implemented for the expansion of the pharmaceutical manufacturer into R&D-intensive fields, which have resulted in 10 new R&D centers, and export-led growth through such as 'Turquality', which allows for manufacturers to recoup expenses associated with foreign market development. •

RETAIL PRICE DISTRIBUTION

Source: TITCK, IEIS



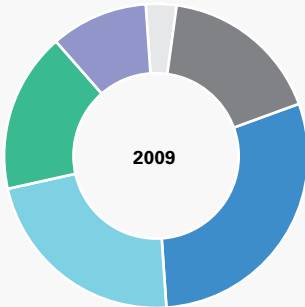
Tied to the market for generic pharmaceuticals, the largest change observed in the market for locally manufactured products occurred in the 0-10TL price bracket. A remarkable 52% of all locally produced products were priced within this range in 2014, an increase of 33 pp from 2009.

f. Average Prices

The average price of prescription drugs fell from 9.2 TL in 2009 to 8.11 TL in

PRICE DISTRIBUTION OF GENERIC PRODUCTS

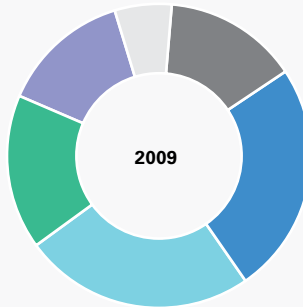
Source: TITCK, IEIS



- TL 0-10
- TL 10-25
- TL 25-50
- TL 50-100
- TL 100-250
- TL >250

PRICE DISTRIBUTION OF ORIGINATOR PRODUCTS

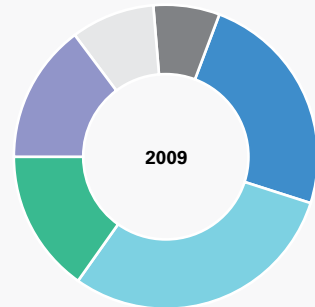
Source: TITCK, IEIS



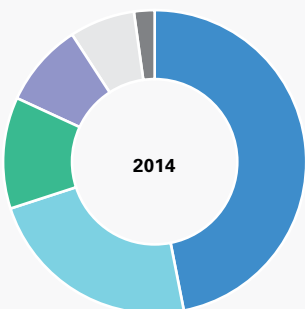
- TL 0-10
- TL 10-25
- TL 25-50
- TL 50-100
- TL 100-250
- TL >250

PRICE DISTRIBUTION OF IMPORT PRODUCTS

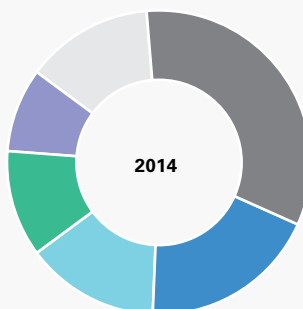
Source: TITCK, IEIS



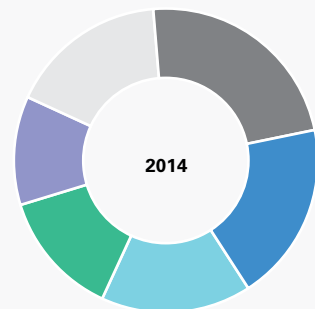
- TL 0-10
- TL 10-25
- TL 25-50
- TL 50-100
- TL 100-250
- TL >250



- TL 0-10
- TL 10-25
- TL 25-50
- TL 50-100
- TL 100-250
- TL >250



- TL 0-10
- TL 10-25
- TL 25-50
- TL 50-100
- TL 100-250
- TL >250



- TL 0-10
- TL 10-25
- TL 25-50
- TL 50-100
- TL 100-250
- TL >250

2014, a decrease of 11%. If examined by product origin and type, imported pharmaceuticals posted the largest decline in average price, falling by 23% over the last five years.

From 2013 to 2014, a 5.9% increase is observed in the overall price of prescription drugs. If analyzed by product type, the most notable increase occurred among originator products, which saw their pricing, grow by 7%. Both imported and local products saw their average prices grow by 5%.

g. Therapeutic Groups

In 2014, the market share of oncology products, as measured by value, retained its position as the fastest growing segment of the Turkish pharmaceutical market as categorized by therapeutic area. Last year, oncology products accounted for 11.2% of the total pharmaceutical market. Other quickly changing therapeutic areas included antidiabetics, which reached a total market share equivalent to that

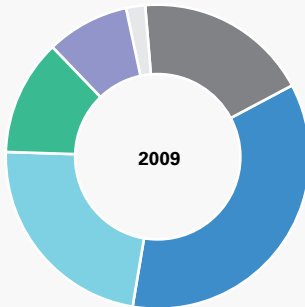
of antirheumatics in 2014, standing at 6.2%.

The market share of antibiotics continued to fall from 11.5% to 8.5% in 4 years. Cardiovascular products saw their market share fall as well, from 7.6% to 5.8%

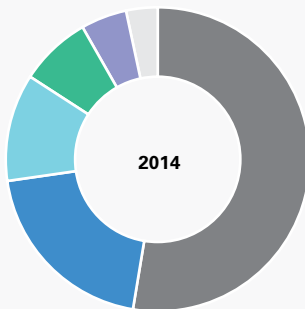
If changes in market values as measured by volume are analyzed, several of these trends are upheld. Antibiotics continued to lose its share of the market, decreasing to 10.9% of the total drug volume in 2014. Using this line of

PRICE DISTRIBUTION OF LOCAL PRODUCTS

Source: TITCK, IEIS



Price Range (TL)	Percentage
TL 0-10	19%
TL 10-25	32%
TL 25-50	24%
TL 50-100	14%
TL 100-250	9%
TL >250	1%



Price Range (TL)	Percentage
TL 0-10	52%
TL 10-25	22%
TL 25-50	11%
TL 50-100	8%
TL 100-250	5%
TL >250	2%

AVERAGE PRICE DISTRIBUTION (TL)

Source: IMS, IEIS

	OVERALL MARKET	PRESCRIPTION	REIMBURSED	IMPORT	LOCAL	ORIGINATOR	GENERIC
2009	8.84	9.16	8.83	22.74	4.91	12.71	5.21
2010	8.33	8.55	8.27	20.36	4.67	11.70	5.02
2011	7.75	7.90	7.59	17.84	4.48	10.58	4.81
2012	7.17	7.24	6.92	16.13	4.20	9.76	4.42
2013	7.56	7.66	7.29	16.66	4.34	10.47	4.42
2014	8.01	8.11	7.64	17.57	4.56	11.18	4.59

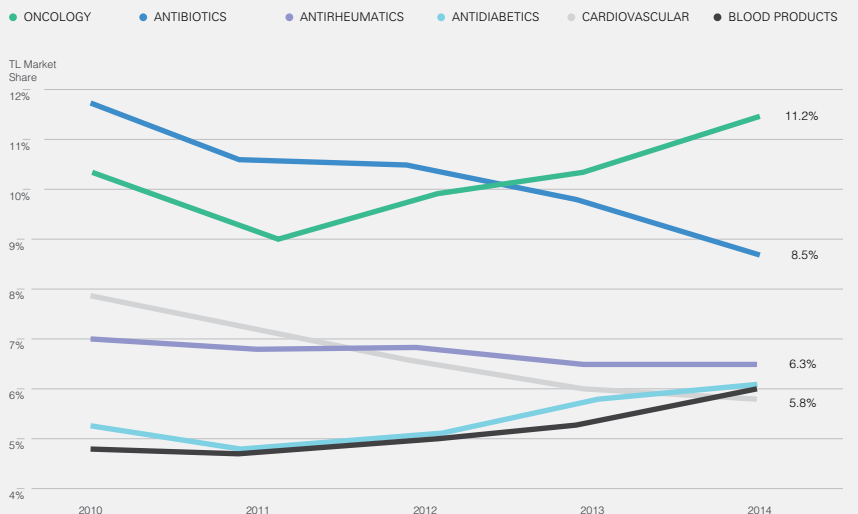
AVERAGE PRICE CHANGE

Source: IMS, IEIS

	OVERALL MARKET	PRESCRIPTION	REIMBURSED	IMPORT	LOCAL	ORIGINATOR	GENERIC
13-14 Change	6.0%	5.9%	4.9%	5.4%	5.2%	6.8%	3.9%
09-14 Change	-9.4%	-11.4%	-13.4%	-22.7%	-7.1%	-12.1%	-11.8%

TREATMENT GROUPS (VALUE)

Source: IMS, IEIS



Sandoz

FOUNDER

Sandoz' history dates back over 120 years, during which time it has transformed itself from a small diversified chemical company to the world's second largest producer of high-quality generic pharmaceuticals and global leader in biosimilars and differentiated products. Sandoz in its current form has existed since 2003, when Novartis united its generics businesses under the single global brand, Sandoz.

LEADERSHIP

Sandoz is led by a team of individuals who not only share in its vision of a healthier world with global access to affordable, high-quality medicines, but also bring passion and care to everything they do. Through product development and production to quality assurance and marketing, our management team works hard to maintain Sandoz' standing as a world leader in high-quality, affordable medicines. Division Head of Sandoz is Richard Francis.

REVENUE AND GROWTH

In 2014, Sandoz achieved consolidated net sales of \$9.6 billion. Sandoz employs more than 26,000 people worldwide and supplies a broad range of affordable, primarily off-patent products to patients and customers around the globe. Sandoz holds the global #1 position in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines. In addition, Sandoz holds leading global positions in key therapeutic areas ranging from generic injectables, dermatology and respiratory to cardiovascular, metabolism, central nervous system, pain and gastrointestinal.

R&D FOCUS AND APPROVALS

Sandoz stands out from the competition through its ability to develop and produce complex differentiated products, which

by value already comprise well over one third of its portfolio. This differentiated portfolio, which goes well beyond standard generics, is the result of clearly focusing on and understanding our customers – but also even more importantly, anticipating their evolving needs. These value-added products predominantly focus on the biosimilar, oncology injectable and respiratory fields, three key pillars to our strategy of differentiation, where we already have or aspire to a global leadership position. Sandoz's expertise in these complex products is based on decades of experience, particularly in producing intermediates for third parties, with early successes including the first-ever oral penicillin in 1951 and one of the first recombinant proteins, an interferon, in 1980.

Leading the way in the development and production of differentiated generics, Sandoz was also the first company to develop and market follow-on versions of highly complex biopharmaceuticals, becoming a true pioneer and global leader in the field of biosimilars. By offering these complex medicines, we are helping to make quality healthcare affordable for all patients and to slow the increase in escalating global healthcare costs.

Major R&D Sites: Holzkirchen, Germany; Kundl and Schafstau, Austria; Ljubljana and Menges, Slovenia; Rudolstadt, Germany

RECENTLY LAUNCHED PRODUCTS

Sandoz launched a number of important products in various countries in 2014, including: – Valsartan (Diovan) – Cyclophosphamide injection, USP – AirFluSal Forspiro – Kerydin (tavaborole) topical solution, 5% – Vitaros (alprostadil) – Dexmethylphenidate ER (Focalin XR) – Tobramycin inhalation solution, USP (TOBI) – Calcipotriene and betamethasone dipropionate ointment, (Leo Pharma's Taclonex®) – Adapalene

gel (Galderma Laboratories' Differin®) – Lansoprazole capsules, amoxicillin capsules, USP; and clarithromycin tablets, USP (Takeda Pharmaceuticals' PREVPAC®) – Decitabine (Eisai's Dacogen®) – Escitalopram (Lundbeck's Cipralex®) – Mometasone (Merck Sharp & Dohme's Nasonex®) Disclaimer These materials contain forward-looking statements that can be identified by words such as "potential," "expected," "will," "planned," or similar terms, or by express or implied discussions regarding potential new products

CORPORATE SOCIAL RESPONSIBILITY

At Sandoz, we believe financial success and social commitment go hand in hand. Our corporate responsibility program is a strategic priority for our business, focusing on increasing access to affordable medicines, and being a responsible and ethical employer, community member and business leader.

Our main aim is to increase access to affordable medicines, healthcare services and education. Sandoz focus on:

- **Fighting Tuberculosis (TB):** Fighting TB is one of Sandoz's leading corporate responsibility initiatives. To help increase awareness of the global TB health problem and provide resources to those who are interested in joining the fight, Sandoz provides a dedicated TB website, tbdots.com. Partnerships with local health authorities support community engagement programs to raise awareness, provide preventive solutions and counter many myths surrounding tuberculosis.
- **Supporting Maternal & Child Health:** Sandoz is committed to supporting the achievement of these goals by increasing access to high-quality, affordable medicines, as well as health care services and education for mothers and children around the world.

Sandoz has an ambition to become one of the country's ten largest pharmaceutical manufacturers. As the new country manager in Turkey, how will you advance the company toward realizing this goal?

Sandoz still has much to accomplish before realizing its goal, as today we are ranked 29th. Sandoz has operated within Turkey since 1959. Today, through our three factories and the factory of our parent company, Novartis, we export almost one-fourth of Turkey's total pharmaceuticals that are present in foreign markets. We therefore have a strong base to expand our position.

Immediately, we expect to accomplish this through launching differentiated generic products within Turkey, which will be predominantly developed through our research and development (R&D) department. This is in addition to our broad portfolio of clinical forms of existing products that have lost patent protection. We, as an organization, strive to add value to the generics that we produce.

In applying our internal capabilities, which enable Sandoz, in part through its relationship with Novartis, to improve

Altan Demirdere

Cluster Head,
Turkey & CIS
SANDOZ



upon difficult-to-make product areas, in Turkey, Sandoz will focus heavily on therapeutic areas such as anti-asthmatics, antibiotics and cardiovascular prod-

ucts, which pose additional difficulties for most pharmaceutical manufacturers because of their development and registration processes. Biosimilars, an area in which Sandoz is a pioneer and a global leader, is another market in which our organization, because of its resources, has been able to carve out significant global market share. Though there are many Turkish businesses that have now focused on these products, I believe few will be able to realize their ambitions because they might lack these resources that Sandoz possesses.

What, with regard to R&D, do you believe to be the strengths of the Turkish pharmaceutical manufacturer?

The local Turkish pharmaceutical industry cannot be underestimated for its capabilities in development. The products that the Turkish pharmaceutical manufacturers can develop often surprise multinationals. It is not easy to develop a globally competitive, local pharmaceutical manufacturing base. It takes time and requires know-how. For example, in the late 1990s, the Russian government prioritized the development of the national pharmaceutical industry, naming



We produce for the whole World at Sandoz Turkey!

We are proud that at Sandoz Turkey, at our **3 factories**, **85% of our production is exported and curing patients all over the world.**





it an industry of strategic importance. Many firms poured money into developing pharmaceutical products that they hoped would lead to globally competitive product portfolios, but very little materialized, and Russia today struggles to cultivate such a pharmaceutical industry. There are numerous cases of other regions that have undertaken the same goal, employing a similar strategy. But the culture of operations and the intellectual resources of a country are by far the greatest determinants of whether a country can develop globally competitive products. For this, Turkey is unique in its strength. Our government should be required to protect local pharmaceutical manufacturing, which also help encourage greater levels of foreign direct investment and expand the country's production base.

As the former chair of AIFD, you worked closely with the Turkish government as an advisor on the potential implications of the enforcement of Turkey's system of cross-price referencing. How has this system impacted the development of the Turkish pharmaceutical manufacturer?

The government instituted cross-price referencing ten years ago, since which the pharmaceutical market has grown. Turkey – and this must be emphasized – is not the sole country to employ such a system, but Turkey's path veered from other countries that use a cross-price referencing system when the government froze the euro/lira exchange rate. The frozen conversion rate allows for the government to save on the country's medical expenses and decreases the burden on the public. The negative consequences, however, are significant. For example, there are many unmet medical needs because the Turkish pharmaceutical manufacturer cannot profitably operate certain business lines. There is also a lack of innovative products because the Turkish manufacturer cannot afford to invest in R&D.

Private companies are not foundations. They of course have to operate profitably so as to re-invest in themselves, allowing for the industry to further develop. Turkey now faces a choice: either structural reform that would allow for the Turkish pharmaceutical industry to be profitable, or a new strategic di-

rection where the whole pharma industry and pharmaceutical development will be government owned. A combination will not suffice, and historically, the latter has consistently failed.

It is a question of the public budget and which industries will be prioritized. Pharmaceuticals must be viewed as a strategic investment area. Manufacturing of pharmaceutical products within Turkey, and the attendant ramifications of a decline in industry profitability, must be realized. The industry cannot continue to be under-valued.

Where might Sandoz in five years?

We seek to be placed among the top ten pharmaceutical manufacturers within Turkey. We have done this already with Novartis in Turkey. We have done this in Russia. We can now do this in Turkey. To accomplish this, we must closely scrutinize our long-term strategy and identify which areas of investment will lead the country forward. Among these fields, we must prioritize human resources because people carry an organization forward. Human resources cannot be viewed as secondary to sales: they are strongly correlated. •

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01

South Korea's generic market is projected to grow on average 5% per year between 2013 – 2018 to a staggering \$23.84 Bln.

02

South Korea closely ranks after China and India as the third “best outsourcing destination” in Asia.¹

03

Korea Drug Development Fund (KDDF) will promote the development of the Korean biotechnology sector in the Asia Pacific region aiming to produce 10 new treatments by 2019.

04

Investment in R&D and related facilities is very active and establishment of plants according to the international standards is increasing.

¹The changing dynamics of pharma outsourcing in Asia, PwC.



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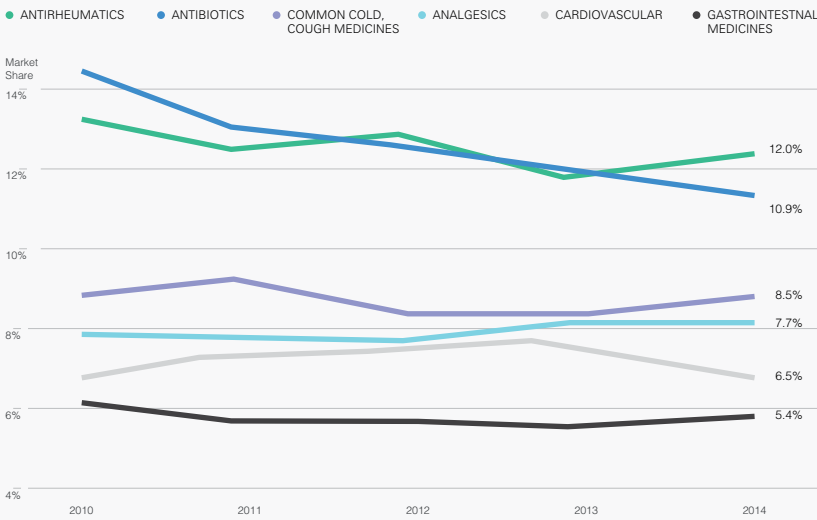
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Organised by



TREATMENT GROUPS (VOLUME)

Source: IMS, IEIS



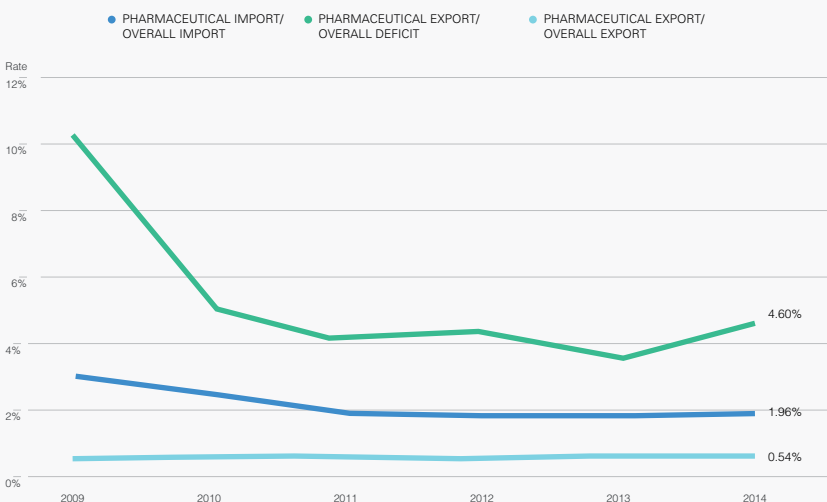
IMPORT AND EXPORT OF PHARMACEUTICAL PRODUCTS (MILLION USD)

Source: TUIK (Turkish Statistical Institute) (In accordance with HS4 Classification-Code:2936-2939, 2941,3001-3006)

YEAR	EXPORT	CHANGE (%)	IMPORT	CHANGE (%)	FOREIGN TRADE DEFICIT	CHANGE (%)	EXPORT / IMPORT
2009	474	0.9%	4,427.5	-6.7%	3.95	-7.5%	10.7%
2010	612	29.1%	4,786.7	8.1%	4.17	5.6%	12.8%
2011	620.4	1.4%	5,093	6.4%	4.47	7.1%	12.2%
2012	720.1	16.1%	4,353.5	-14.5%	3.63	-18.8%	16.5%
2013	817.7	13.6%	4,498	3.3%	3.68	1.3%	18.2%
2014	856.2	4.7%	4,743.4	5.5%	3.89	5.6%	18%

PHARMACEUTICAL INDUSTRY WITHIN TURKISH FOREIGN TRADE

Source: TUIK (In accordance with HS4 Classification-Code: 2936-2939, 2941,3001-3006)



analysis, antirheumatics represented the largest proportion of total market volume in 2014, accounting for 12%. By volume, common cold and cough medicines, analgesics, cardiovascular and gastrointestinal medicines retained their positions.

B. Foreign Trade

Foreign trade values reflected a movement on the part of the Turkish pharmaceutical manufacturer to expand their proportion of sales derived through foreign market activity. Aggregate pharmaceutical exports, which stood at \$474 million in 2009, have since grown by 80% over the past five years, standing at \$856 million in 2014. Driven largely by double-digit growth realized in foreign market sales in 2012 and 2013, growth in exports stagnated last year, standing at 4.7%.

The effect that this held on Turkey's current account balance for pharmaceuticals was exacerbated by an increase in pharmaceutical imports in 2014. Although pharmaceutical imports did not grow significantly over the past five years, in 2014, they gained momentum, exceeding \$4.7 billion – a growth rate of 5.5% from the previous year. The impact of this was to increase Turkey's foreign trade deficit, which rose to \$3.89 billion, and to decrease the country's export-import coverage ratio, which fell from 18.2% to 18%.

The Turkish government's system of drug pricing stood among the largest determinants of both the decline in pharmaceutical exports and increase in pharmaceutical imports observed in 2014. Running contrary to the commonly held belief that lower product prices will result in an increase in the regional competitiveness of a pharmaceutical and therefore will result in higher product exports and lower product imports, this paradox is explained by the absence of free-market forces that would normally determine product pricing and the restrictions imposed on free trade.

Specifically, this is in part attributable to the broader implications of Turkey's system of drug-pricing: Turkey's system of price-setting has established

a baseline for pharmaceutical pricing within the foreign market. Foreign healthcare authorities have come to demand that the prices for pharmaceuticals in Turkey are used in establishing the price which the Turkish pharmaceutical manufacturer will receive in establishing licensing and supply agreements. One consequence of this attendant decline in profit margins has been that Turkish pharmaceutical manufacturers cannot effectively promote their products within the foreign market. Equally, many have moved to contract manufacturing within a target market so as to command a higher price for their products. Regardless, the result of this has been a decline in potential exports.

The consequence of both the decrease in pharmaceutical exports and rise in pharmaceutical imports has been that pharmaceuticals, albeit at a much lower rate, continue to be a net contributor to Turkey's foreign trade deficit.

Today, the markets to which Turkish pharmaceutical manufacturers export are widely dispersed, spread across 170 countries. Chief among these markets is South Korea, Switzerland, Germany, Iraq, Iran, the Russian Federation, the USA and Azerbaijan, which represent, by size, Turkey's largest export markets for pharmaceuticals. In 2014, Turkey imported pharmaceuticals from 94 countries. These regions, in order of significance, included Germany, the USA, France, Switzerland, Italy, the United Kingdom, and Ireland.

C. Conclusion and Assessment

The five year period between 2009 and 2014 was a period marked by significant losses for Turkey's pharmaceutical industry. Although the market as measured by value realized nominal growth of 10.6%, in real terms this translated into a decline of 23.1%.

The budget cap that was established to control public expenditures on pharmaceuticals in the wake of the implementation of Turkey's Health Transformation Program was built on principals that did not allow for the program to be scalable. The result of this is observed in a series of cost reduction policies, including escalating discount rates and

IMPORT ON BASIS OF COUNTRIES

Source: TUIK (Turkish Statistical Institute) (In accordance with HS4 Classification-Code:2936-2939, 2941,3001-3006)

	NAME OF THE COUNTRY	2013	2014	2013-2014 (%)
1	Germany	861,844,570	885,792,983	2.8%
2	U.S.	508,661,290	601,228,376	18.2%
3	France	438,992,901	450,518,407	2.6%
4	Switzerland	433,798,726	429,004,860	-1.1%
5	Italy	401,205,402	328,205,603	-18.2%
6	England	228,613,179	299,634,407	31.1%
7	Ireland	246,214,262	280,780,582	14.0%
8	Belgium	219,869,710	167,908,254	-23.6%
9	Denmark	127,517,994	160,341,447	25.7%
10	China	134,251,500	147,260,981	9.7%

EXPORT ON BASIS OF COUNTRIES

Source: TUIK (Turkish Statistical Institute) (In accordance with HS4 Classification-Code:2936-2939, 2941,3001-3006)

	NAME OF THE COUNTRY	2013	2014	2013-2014 (%)
1	South Korea	30,609,999	110,255,312	260.2%
2	Switzerland	63,346,200	59,939,304	-5.4%
3	Germany	64,191,414	56,746,527	-11.6%
4	Iraq	74,653,667	50,915,905	-31.8%
5	Iran	87,334,339	45,019,621	-48.5%
6	Russian Federation	17,895,792	32,346,831	80.8%
7	U.S.	32,810,627	31,651,642	-3.5%
8	Azerbaijan	30,400,510	30,794,163	1.3%
9	TRNC	30,013,986	29,083,154	-3.1%
10	England	18,225,855	20,445,998	12.2%

a frozen euro-lira convertibility ratio within the country's drug price referencing system, which have, in effect, checked the public burden of the country's medical expenses at the cost of the pharmaceutical industry.

As a consequence of this, public expenditures on pharmaceutical have directly mirrored market growth, increasing nominally by 6.1% over this five year period but declining by 26.2% in real terms. → 48

DEVA Holding

FOUNDER

DEVA was founded by 27 shareholders including physicians and pharmacists in 1958.

LEADERSHIP

Philipp Daniel Haas, Chairman & CEO

REVENUE AND GROWTH

DEVA's Capital Markets Board results showed revenue in 2014 was TL\$467.9 million, up 11.8% from the same period in 2013 (TL\$418.4 million).

DEVA's sales increase was mainly due to increased volumes in DEVA's human pharma and veterinary products business revenue. From 2013 to 2014, human pharma revenue increased by 8.5% (TL\$398.9 million to TL\$432.7 million), and veterinary business revenue increased by 128.7% (from TL\$12.34 million to TL\$28.22 million)

EXPORTS

DEVA, whose regional growth operations and export activities are increasing, have around 300 licences in many countries including Switzerland and EU countries such as Germany, the Netherlands, and UK. The company exports drugs and drug raw materials to more than 25 countries including New Zealand.

DEVA's international operations include the following business models

- Distributorship
- Out-licence and Supply
- API Export
- Contract Manufacturing
- Co-Development
- DEVA Branded Sales

R&D FOCUS AND APPROVALS

Within the scope of R&D work, we are developing innovative new forms and products of high added value with our laboratories and production sites equipped with state-of-the-art technology. In keeping with this, in 2014 we allocated approximately 9% of our turnover to R&D. Consisting of the pre-formulation and pilot production area, synthesis and scaleup laboratories, stability area, analytical development laboratories, biotechnology laboratories, oncolytic and hormone production area, pilot production area, weighing area, raw material packaging material, finished product storehouse, analysis laboratories and CMC documentation archives, DevaArge covers an area of 7.000 square meters.

MARKET SHARE AND PRODUCT GROWTH

According to free market and tender data of IMS Health, sale of drugs of 2.1 billion boxes valued at TL\$16.3 billion took

place in Turkish Pharmaceutical Industry in 2014.(*). The market achieved growth at the rate of 3.7% in terms of boxes and at the rate of 10.1% in TL compared to the previous year.

UPCOMING PRODUCTS

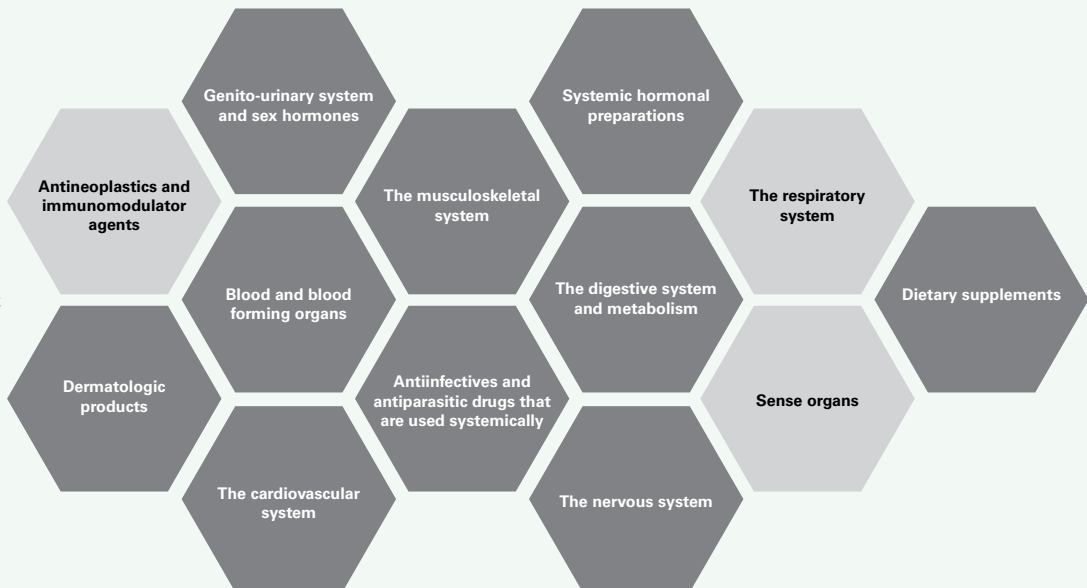
See attached schematic for a list of therapeutic areas.

CORPORATE SOCIAL RESPONSIBILITY

For a healthier future and sustainable development, social responsibility activities are an integral part of DEVA's operations. DEVA develops and implements social responsibility activities especially on education, public health and the environment.

- DEVA sponsored National Sportsperson Şahika Ercümen, who suffered from allergic asthma in her childhood, but overcame her condition and became a world record-holder in free diving.
- DEVA provides free scholarships to successful students of medicine.
- DEVA donates drugs according to need in cooperation with public corporations and nongovernmental organisations.

OUR THERAPEUTIC AREAS



In 2014, profitability for DEVA Holding fell to a third of what it had been in 2013. What underscored this change?

DEVA's decline in profitability was a product of the current macroeconomic environment in Turkey, specifically the depreciation of the Turkish lira, which lowered our gross margin and profits. DEVA imports most of its raw materials. Irrespective of their origin, these products are denominated in either euros or, mostly, U.S. dollars. This will continue in 2015. The Turkish lira, at least in the first quarter of the year, has continued to weaken against the dollar.

On an organizational level, how has DEVA grown since we met in 2014?

DEVA has progressed significantly. If we were in an environment with a more stable currency, this progress would be reflected in our results. In terms of market share, DEVA Holding has ranked second, with a 6.1% share in unit sales in Turkey according to IMS data for 2014. DEVA has advanced in several therapeutic areas and launched products in fields like ophthalmology, where it only entered the market in the past year but now has a large market share. This shows that DEVA's strength is not only as a manufacturing unit, but also in marketing. This also shows DEVA's reputation among the company's key stakeholders, which include doctors, pharmacists and veterinarians. We are trusted. Our excellence in product quality is understood, as are our manufacturing standards. Our facilities, which are approved by the German Ministry of Health and are EU-GMP certified, operate at a higher standard than most European manufacturers. The market understands this, which has enabled us to easily penetrate new market segments such as ophthalmology.

DEVA is committed to research and development (R&D) through DEVA Research, the group's research and development unit. What therapeutic areas will DEVA Holding focus on in 2015?

DEVA has approximately 400 products in 13 diversified therapeutic areas. R&D is one of our key priorities. In 2014, we allocated 9% of our turnover to R&D. DEVA will continue to invest into R&D

Philipp Haas

CEO
DEVA HOLDING



in three therapeutic areas: respiratory, oncological, and ophthalmological products. Last year, DEVA established a separate research facility for generic inhalation products. Through this facility, we have offered the Turkish consumer not only first-generic products, but also several products that were first in market, predating entrance of the originator's product in Turkey. We have a strong pipeline for these products.

DEVA also considers oncology to be an important area, especially for tablets, capsules, and liquids. We have already made significant investments into this field. In addition, DEVA will continue to develop its line of ophthalmological products. None of these areas has been pursued to the exclusion of our core business. We are still involved in the production of antibiotics and cardiovascular products, but these new areas offer prospects for continued growth.

By 2023, DEVA Holding aspires to have foreign market activity constitute 50% of total sales volume. With just 5% in total sales at present, how will DEVA grow its export markets?

Exports to emerging or underdeveloped markets, such as the CIS or GCC

countries, are quicker to realize but come with risks. Exports to developed markets come with less risk, but require more substantial investments in both quality standards and market entry. DEVA has invested substantially in ensuring that its facilities are of a high standard. The approval of our facility by the German Ministry of Health marked an important milestone and signaled that we have now built a platform from which we can begin to export. We will see sales begin in the second half of 2015 to the European market. Though small in the beginning, it will quickly escalate. The more products that one registers in a market, the easier it will become to authorize additional products. As of December 2014, we obtained license approvals for over 200 products in several countries including developed and EU countries. This will be further facilitated by the partnerships that we now have in place with European distributors.

On a strategic level, how will DEVA evolve over the remainder of 2015?

DEVA has now consolidated its strategic initiatives to better evaluate opportunities in new sectors such as biotechnology and vaccines. Our strategy diverges from many others in the Turkish market because we seek to enter into both of these areas without a strategic partner, but instead through bringing in outside talent. Partnerships can bind a business; additionally, they can become costly quite quickly. We seek to avoid these pitfalls.

How has the regulatory framework around the Turkish pharmaceutical industry changed since the release of the industry's sector strategy document last year?

Obviously, there is an effort for a change in policy, and concrete solutions are required. Regulators have become more sensitive to our issues. Even the development of a strategy document signifies a supportive change in attitude. Pharmaceuticals are not just another cost to the public but could play a strategic role in correcting larger macroeconomic issues, such as the country's current account deficit. •

This, invariably, had a negative impact on the financial performance of the Turkish pharmaceutical manufacturer. According to data published by the Ministry of Science, Industry and Technology in 2014 as part of their "Entrepreneur Information System," operating profitability of the pharmaceutical industry decreased significantly from 2009 to 2013, marked by a steep decline in net sales and asset generation.

These declines have been unique to the pharmaceutical industry, standing in contrast to other manufacturing industries that are less technologically intensive. If compared against the manufacturing industry and chemical industry, this becomes obvious. While net pharmaceutical sales declined by 32% in real terms from 2009 to 2013, net sales in manufacturing and the chemical industry grew by 40% and 44% respectively.

These declines are also observed in operating profitability. While the operating profitability of both the manufacturing and chemical industries increased from 2009 to 2013, over this same period, it fell by half for the pharmaceutical manufacturer.

Yet far worse were the declines observed in net profitability. Again, while the manufacturing and chemical industries were able to realize greater levels of net profitability between 2009 and 2013, the pharmaceutical industry saw its net profitability fall from 10.8% to -2.4% as measured as a proportion of equity.

As a consequence of the adversities that the Turkish pharmaceutical manufacturer has faced, the asset base, and the ability of the Turkish pharmaceutical manufacturer to generate new assets, has eroded. Setting aside the implications that this has had on the national business environment for the production of pharmaceuticals, these changes have made it harder for the industry to keep pace with technological developments in the medium term, and from allocating sufficient resources to R&D that would allow for the Turkish pharmaceutical manufacturer to expand its presence in the foreign market.

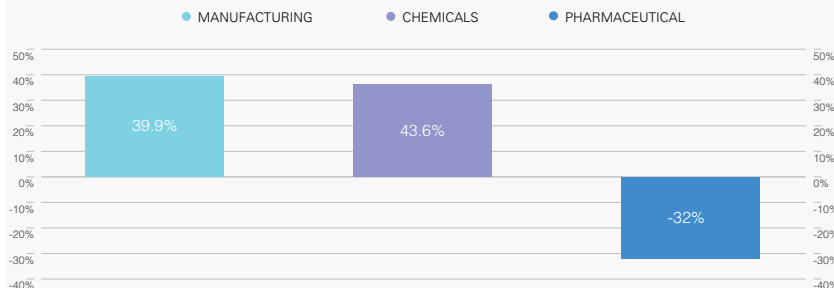
OVERALL MARKET SUB DISTRIBUTIONS

Source: TITCK (Ministry of Health, Medicines and Medical Devices Agency of Turkey)

	2009	2010	2011	2012	2013	2014
Public Pharmaceutical Expenditures (mn TL)	16,068	15,347	15,868	14,484	15,728	17,049
Number of Prescriptions (000)	327,495	308,530	339,225	336,106	338,021	337,403
Cost per Prescription (TL)	49.1	49.7	46.8	43.1	46.5	50.5

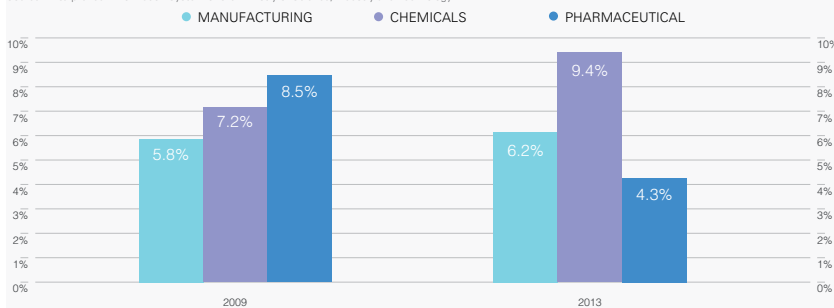
REAL CHANGE IN NET SALES, 2009-2013

Source: Entrepreneur Information System of the Ministry of Science, Industry and Technology



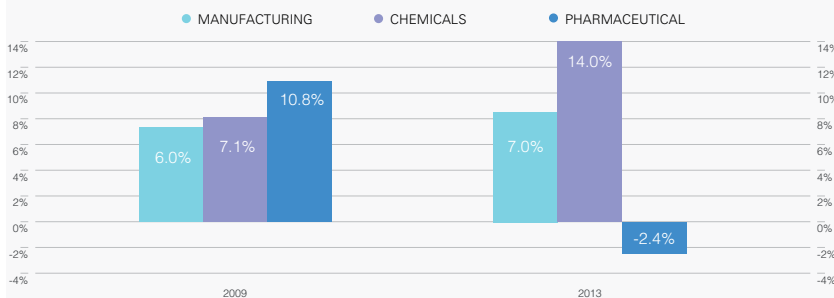
OPERATING PROFITABILITY / NET SALES, 2009-2013

Source: Entrepreneur Information System of the Ministry of Science, Industry and Technology



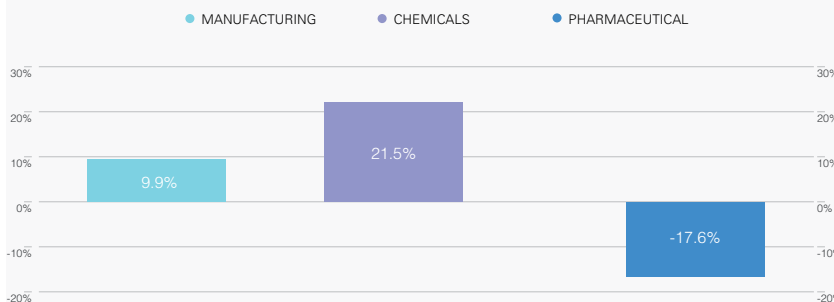
NET PROFITABILITY / EQUITY, 2009 - 2013

Source: Entrepreneur Information System of the Ministry of Science, Industry and Technology



REAL CHANGE IN EQUITY, 2009-2013

Source: Entrepreneur Information System of the Ministry of Science, Industry and Technology



Sedat Birol & Kadir Dabak

SB: Executive Vice President,
Healthcare Division
KD: Business Development Director
ECZACIBAŞI



SB

In 2014, Eczacıbaşı undertook three strategic initiatives related to its pharmaceutical business: expansion of its global nuclear medicine business, development of biological products, and entrance into the market for over-the-counter (OTC) pharmaceuticals. In undertaking each of these endeavors, how has Eczacıbaşı progressed?

Sedat Birol (SB): The growth trajectory of Eczacıbaşı's nuclear medicine division met all targets established in 2014. We have entered into Romania. In February 2015 we entered into Poland. Next month, we will begin production through our facility in Bulgaria. Furthermore, we have expanded our operations within the United States through our subsidiary, Capintec, which we acquired in 2012. We have sought to develop a presence in biopharmaceuticals through partnership agreements. Eczacıbaşı is now in the final stages of structuring several of these agreements.

Kadir Dabak (KD): Regionally, there has been heavy emphasis on the development of biopharmaceuticals. Entry into this field is not easy, as the development of these products requires significant resources, both on a technical and finan-

cial level. As a result, we have sought to work with those that already have established a track record for their success and competency within this field.

SB: The OTC market still possesses many challenges. Rules and regulations that are imposed in the United States for these products do not exist in Turkey. From a regulatory standpoint, these products are subject to the same processes as prescription pharmaceuticals. This should not be the case. Despite this, Eczacıbaşı has made strong headway into establishing an OTC business. Last year, we signed an agreement with Procter & Gamble, which has allowed for us to distribute and market all of their consumer products to pharmacies in Turkey. Through a sales force of 50 personnel, we have extended their presence to 4,000 pharmacies. We anticipate the scope of this agreement expanding in the coming years as Procter & Gamble has established a joint-venture with Teva, which will also grant us access to the OTC products of this company.

In what way has the regulatory environment surrounding biopharmaceuticals impacted the desirability of entering into the production of these products?

SB: For the first time we have seen the Turkish government announce very clearly their intentions for the pharmaceutical industry. A strong desire now exists to expand into the production of biopharmaceutical products. High-level incentives have been announced.

KD: However, uncertainties in several areas remain: how the product registration process might occur and how equivalency might be established. In spite of this, as a result of the pricing advantages offered by these products, which include exemption from the system of discounts employed by the Turkish government, these products remain attractive to many, including Eczacıbaşı.

Industry profitability continued to fall in 2014, shaped by the impact of Turkey's system of cross-price referencing system and currency volatility. Has this affected Eczacıbaşı's Healthcare Division, as a diversified manufacturer that has moved beyond the generic pharmaceuticals business?

SB: Eczacıbaşı has been partially isolated

from the impact that Turkey's system of cross-price referencing has had on the pharmaceutical industry. In 2004, when Turkey first began to introduce new regulation for the healthcare industry as part of the Ministry of Health's Health Transformation Program, Eczacıbaşı anticipated that the domestic pharmaceutical industry would never be the same. At the time we speculated that the movement away from a cost-plus system to a reference-pricing system would result in the Turkish government having too many levers for controlling the direction of the domestic industry. These later appeared in the form of cost controls, including forced discounts and the convertibility ratio now used in translating reference prices into the Turkish lira. We saw the future of Eczacıbaşı outside of the generic pharmaceutical market in niche product areas such as nuclear medicine, where we have since established a strong regional presence.

What strategic initiatives will Eczacıbaşı execute in the next five years to grow further?

SB: Eczacıbaşı's growth strategy will focus on one overriding theme: the movement away from industries in which the government exerts significant control. For our nuclear medicine division, we will place greater emphasis on the foreign market, especially markets that are less desirable because of their size, to global players such as Siemens and GE. These markets may include the Balkans.

SB: We will also seek to extend our partnership with Baxter into the domestic production of blood products. Baxter, as the leading global supplier of blood products, operates three manufacturing facilities globally. They are considering entering into production through a fourth factory, which would be located in Turkey. The current incentive structure offered by the government is attractive for this, but we are concerned about both the sustainability of profitability in the domestic market for these products and the impact that Turkey's forthcoming election may have on the structure of domestic policies. If there is a change of party, we hope that it will not change the government's treatment of the pharmaceutical industry, particularly in the positive developments that we have seen, such as incentives. •

Ali Arpacioğlu

President & CEO
ADEKA



Adeka was founded in 1956. Next year, the company will celebrate 60 years of history. What vision was the firm established upon?

Adeka was established as the first pharmaceutical manufacturing company within Anatolia. At the time, several other businesses had begun to manufacture pharmaceuticals in Turkey. These companies, however, were based in Istanbul. Adeka saw a need for the regional production of these products; as a result, we chose to establish ourselves in 1956 in Samsun located on the Black Sea coast roughly 700 kilometers from Istanbul. Though this has changed in the past 60 years and today there are companies that operate in other areas of Turkey such as Ankara, Adana, Konya and Izmir, we remain the most diversified manufacturer operating outside of Istanbul for the product forms that we produce, holding true to the vision upon which we were established.

Adeka today stands among the largest pharmaceutical manufacturers in Turkey. What strategic vision do you have in seeking to expand the footprint of the company and what has this meant in terms of the initiatives that you are currently enacting?

Adeka's growth has been limited by our existing capacity. To rectify this, we are in the process of designing and constructing two new manufacturing facilities: one in Istanbul and the other in Samsun. These factories will be dedicated to those product lines in which we already operate, allowing us to increase production volumes, as currently we are at full capacity utilization for our existing facilities. Beyond this though, and more importantly, these new manufacturing facilities will play an important role in creating the foundation for the third-generation to build on. We plan to commission these facilities next year on our 60th anniversary.

What has led Adeka, in spite of the current industry operating environment, to invest so heavily in the development of a new manufacturing facility?

Adeka has operated within the Turkish pharmaceutical industry for a number of years. Within the past five years, the profitability of the Turkish pharmaceutical industry has deteriorated. This has been driven by several events: the depreciation of the Turkish lira, and, most critically, our domestic policy environment. Be this as it may, Adeka, as one of Turkey's oldest manufacturers, has seen this happen before. We have seen industry profitability fall. We have seen turbulence in the domestic market. This, however, does not detract from the underlying principles of the Turkish pharmaceutical market, which are attractive. Turkey has the youngest population in Europe, yet a portion of this population is aging rapidly. Turkey offers rising income levels. Turkey offers a population larger than the entire Southeastern Europe. All of these factors make the Turkish medical market one of the most attractive in the world. Our ability, as a pharmaceutical manufacturer operating within the country, to continue to expand our footprint – to position ourselves for the future – will be determined by those investments that we make now.

What impact, on an operational level, has currency volatility had on the dynamics of Adeka's supply chain?

Adeka has been impacted by currency volatility in so far that the appreciation of the U.S. dollar has thickened the cost structure of some of our products, as often raw materials are priced in U.S. dollars. In responding to this, the optimization of our supply chain has been difficult to achieve, complicated by in-licensing agreements which bind us from whom we can source our raw materials. This said, for those products

which do not bear this constraint, we have more closely scrutinized our suppliers.

In what way has the current internal regulatory environment – the Turkish government’s system of cross-price referencing – impacted the way in which research and development (R&D) is and will continue to be conducted within the country?

In response to the Turkish government’s regulatory policies, the focus of R&D centers in the Turkish pharmaceutical industry has been mainly characterized by a strong emphasis on development. Turkish pharmaceutical manufacturers have sought to reposition products that are innovated outside of the country through this focus on development. On the other hand, low margins in pharmaceuticals leaves little prospect for the Turkish pharmaceutical industry to invest in research. For Adeka, the consequence of this has been that many of the products that we develop and seek to launch – countless, in fact – cannot be brought to the market because as soon as we do so, we take a loss due to the ongoing low prices. Under these circum-

stances, the industry focuses more on the development of value-added generics.

What over-arching dynamic do you think will underscore the growth of the Turkish pharmaceutical industry over the course of the next ten years?

Adeka believes that, in line with the strategic development plan that has been released by the Turkish govern-

ment, we will see the Turkish pharmaceutical industry be defined by a push for localized production. This has induced our investment in our new manufacturing plant, as it has the investments of many others. As a result, we expect to see a rise in partnerships between multinationals and domestic manufacturers in accessing the domestic market, a dynamic that we hope will help profitability. •





 **ADEKA**

LOOKING INTO THE FUTURE

Being the first pharmaceutical manufacturing company within Anatolia, Adeka thrives upon 60 years of experience. We are proud to announce that we are in the process of designing and constructing two new manufacturing facilities. One in Istanbul and the other in Samsun, these factories will be dedicated to those product lines in which we already operate, allowing us to increase production volumes, as currently we are at full capacity utilization for our existing facilities. Beyond this though, and more importantly, these new manufacturing facilities will play an important role in creating the foundation for the third-generation to build on. We plan to commission these facilities on our 60th anniversary, next year.

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Muzaffer Bal

General Manager
ALI RAIF



Since we last met in 2014, profitability has fallen in the industry. What has this meant for Turkish pharmaceutical manufacturing and Ali Raif?

We had hoped to see a higher exchange rate used in product pricing, but new generics companies entering the market and the unchanged rate of 1.9595 for converting the euro into Turkish lira have caused product prices to continue to decline.

In 2014, the Turkish pharmaceutical market grew 8% to 9%, but falling profitability has slowed volume growth to 2% to 3%. Based on the first quarter of 2015, this trend is likely to continue, with slightly higher growth in market value, as the industry began releasing higher-priced pharmaceuticals. If the Minister of Health corrects its policy, the market could expand more rapidly, given the strong fundamentals of Turkey's pharmaceutical market, including an aging population and population growth of 1,000,000 per year.

In 2014, Ali Raif performed contrary to the market, as it was the first satisfactory year for the company in the last five years. Due to the strategic initiatives that we enacted in 2013, which included consolidation of both our labor force and product line, we have stabilized our profitability.

We have just completed the first quarter of 2015. What do you expect for the coming three quarters?

We anticipate that we will have more stable levels of profitability than in previous years. This will be par for the market, as the industry as a whole has adapted to current market circumstances.

One of the most perceptible consequences of declines in domestic profitability has been the expansion of the Turkish manufacturer abroad. What has this meant for Ali Raif?

Taken collectively, the Turkish pharmaceutical manufacturer had been lazy, until recently, in pursuing export markets. Previously, few companies saw a need to export outside of Turkey: the internal market was appealing and this drove their growth. Ali Raif's focus in the past decade has been on building up its product portfolio through in-licensing. Today, we have seen much greater weight put on the importance of export-led growth by the industry. This, most commonly, has resulted in the Turkish pharmaceutical manufacturer pursuing near markets, such as the Balkans or Common Wealth of Independent States (CIS). Ali Raif seeks to grow its presence in foreign markets to 10% of total sales volume.

Beyond this, one of the most direct consequences of lower profitability has been in research and development (R&D). For both Ali Raif and the industry, we have not been able to invest heavily in R&D because we lack the margins required to fund product development. Previously Ali Raif launched as many as four products per year. This year, however, like last year, we will launch only two products. Though we will continue to invest what we can in the development of slow-release and combination products, until profitability for the industry returns, our initiatives related to R&D will be constrained, as will the country's ability to expand into value-added pharmaceuticals. This is a larger goal of the Turkish government, as evidenced by the government's implementation of an incentive structure for several of these product categories.

Is the incentive structure that the Turkish government created to develop biotechnological products sufficient?

The incentive structure is still inadequate, in part because we have sought to emulate foreign models for development rather than finding a strategy that harnesses the distinct characteristics of the Turkish market. The government must develop its own standards.

Do you have a final message?

Dialogue with the industry must continue. The government has become more attentive in the past year, but only policy reform will allow the Turkish manufacturer and the government to accomplish their shared goals. •

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The headquarters and production facilities are located in Istanbul.
Ali Raif has nearly 200 pharmaceuticals with their forms in therapeutic fields such as cardiovascular, diabetics, gastrointestinal, analgesic, anti-inflammatory, anti-flu, antihistaminic and central nervous system.

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Köksal Ülgen

General Manager
PHARMACTIVE



Pharmactive recently entered the market, having been established in 2010. Please provide an overview of the company's vision?

Pharmactive is owned by the co-founder of Hedef, which today is known as Hedef Alliance and is one of the largest pharmaceutical wholesalers in the Turkish market. Following our owner resigning from his active management position, he, in conjunction with his brothers, established Saya Group, which is a diversified business group that operates in varied fields: from construction to electric motors. The owners of Pharmactive wanted to utilize their experience and resources to enter the manufacturing and sales and marketing side of the business.

In February 2011, we began constructing our \$200-million manufacturing facility, through which plan to aggressively expand into the local and international markets. Pharmactive wants to be among the top five generic companies in the Turkish market by 2019. The success story of Hedef, which gained 42% market share in six years of its establishment shows that Pharmactive's ambitious vision is achievable with the

experience of the owners and its management team. In the course of 21 months, Pharmactive has completed the construction of what will be one of the industry's largest manufacturing facilities, has received GMP approval from the Turkish Ministry of Health, and has submitted numerous molecules for approval. We have manufacturing capacity to produce 330 million boxes per year, in three shifts.

What rationale backed Pharmactive's decision to enter the market with such a substantial investment?

The Turkish pharmaceutical manufacturing market is a mature industry, so it would be futile to attempt to penetrate it as a small operator. Gaining substantial market share quickly required a large investment, so that we could minimize operating expenses, as the company grows in scale.

What led Pharmactive to decide to pursue such a heavy focus on contract manufacturing?

The introduction of Turkish GMP standards in 2010 changed the market. European countries had asked that Turkish manufacturers distributing products in Europe undergo plant approvals to ensure compliance with European GMP standards. In response, the Turkish government issued a degree mandating that foreign manufacturers selling their products in Turkey comply with Turkish GMP standards, which closed the market to many pure distributors.

Why did Pharmactive recently invest in a 3,200 square meter research and development (R&D) center, when two-fifths of its revenue comes from contract manufacturing?

Pharmactive's R&D center is an additional facet of our aggressive growth strategy. It will be integral to the development of our product lines and to providing value to our clients beyond contract manufacturing. Services will include R&D related to product formulation; analytical method development; preparing CTD dossiers for regulated and less regulated markets; and line extensions for multinational corporations.

Pharmactive has a strong focus on

export markets. What is most important in entering them?

At present, few Turkish pharmaceutical manufacturers have a strong presence in foreign markets. It is important to establish a long-term presence rather than be opportunistic. We will look to establish ourselves in well-established markets first, as developing markets often come with a unique set of challenges and protect their local manufacturers. Our strategy is to establish Pharmactive in the United States, the Balkans, the GCC and MENA, on account of their positive rapport with Turkish countries, as well as in European nations through out-licensing and contract manufacturing, so as to surmount their many barriers associated with product registration. Later, we will enter Southeast Asia, CIS countries, and others.

In evaluating other successful pharmaceutical manufacturing countries, what lessons could the government learn?

Three agents account for the success of South Korea's pharmaceutical industry: the country's entrepreneurs; the incentive structure developed by the South Korean government; and the country's universities. Turkey must forge links between the country's intellectual resources and the pharmaceutical industry, which can decrease the burden and risk for all parties.

What is can you tell us about Pharmactive's current position?

In 2014, its first commercial year, Pharmactive had sales of 115 million TL and 16.5 million boxes. We have 35 molecules on the market, for some of which we are among the top three companies. We have an S&M team of 400 people and ranked 30th at IMS in 2014.

Today, we are collaborating with 14 companies, having been audited and approved by them, either to market their products with our own team or provide CMO services.

In February 2015, we were audited by German Health Authority and got the BfArM approval. Now, we can sell our products in EU countries and in countries where this approval is accepted. In the coming years, we are targeting U.S. FDA approval to have our own S&M structure in the United States. •

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Rovshan Tagiyev

Founder & Chairman
WORLD MEDICINE



Since we last met with World Medicine, in 2014, the company has continued to aggressively expand its footprint in Turkish and foreign markets. Could you provide us with an overview of the key projects that World Medicine has undertaken over the course of the past year?

For the past year, we have put significant effort into expanding our business in the Turkish pharmaceutical market and in global pharmaceutical markets. We have been continuously working towards the development, registration and market launch of new medicines in Turkey. In order to expand our business into foreign markets during this period, we have formed strategic alliances with Pharma Ival Company in Algeria and Polymedic Company in Morocco to build new factories in these countries. Also, we have concluded many distributorship agreements to make our products available to markets in Asia, Africa and the Middle East. We have intensified our efforts in registering our products in European Union (EU), which resulted in the successful registration of nine of World Medicine's products in Greece. We expect to get marketing authorizations for six to eight medicines in Great Britain by the end of this year. In addition, our medicines are under registration today in Portugal, Bulgaria, Romania, and Poland. These developments will yield the desired outcomes for our business expansion.

What external factors have affected your activity in foreign markets?

Currency devaluation in the foreign markets has again impacted World Medicine, as the company is active in several markets that have exhibited macroeconomic volatility over the past year. We are active in Commonwealth of Independent States (CIS) countries, where sharp movements in the currency exchange rates have occurred. On top of that, the company has felt the impact of the war in Ukraine.

Economic turbulence has cut the purchasing power of our target markets. In addition, owing to individual market regulation, we are unable to change the price at which we supply them. As a result, we have operated at a loss on occasion. Be this as it may, the diversification of foreign markets has provided us

with the opportunity to grapple with the twists and turns of the global economy more easily than many others.

While the complicated situation in the markets of Russia and Ukraine has resulted in decreased sales volume of World Medicine in these countries, our activity within other markets has increased.

Which foreign markets are most appealing to World Medicine?

In 2015, World Medicine seeks to focus more heavily on our activity in the EU. We aim to see our products in pharmaceutical markets in Romania, Bulgaria, and even Spain. To this end, we began the market authorization process for the European Union last year. Operating within the European market requires GMP certification. Although the Turkish and European GMP requirements coincide in many respects, we were required to undergo an additional certification process to enter the European market, and naturally, we have undertaken this. Today, the manufacturing facilities of World Medicine have GMP-compliance certification for the EU, which is crucial for the execution of our strategy.

In the past year, we have seen the profitability of pharmaceutical manufacturing in Turkey decline rapidly, impacted by both the country's system of cross-reference pricing and currency volatility. What has this meant for World Medicine?

In 2014, World Medicine launched 15 new products on the market. Of course, World Medicine has been impacted by these two macroeconomic events, the country's system of cross-reference pricing and currency volatility, but the larger impact that these two events have had on the industry is observed in the creation of unmet medical needs within the domestic market, a result of the Turkish pharmaceutical manufacturer's inability to profitably develop new products or continue existing product lines. World Medicine and many others within the Turkish market are fully aware that there is a need for certain types of pharmaceutical products to be developed and launched. The possibilities of the manufacturers to do so are quite limited, and the immediate consequence of this

has been that World Medicine, like many others in the contemporary pharmaceutical environment, is now more heavily focused on the development of export markets.

World Medicine has a strong commitment to research and development (R&D), evidenced in the partnerships that it has forged with Turkish academic community. Can you please provide us with an overview of your R&D strategy in 2015?

In 2015, World Medicine has been engaged in developing two new products through our R&D strategy and is in close collaboration with two Turkish universities.

Beyond this, World Medicine has also commissioned the development of a biotechnological laboratory, which we will complete in 2016. Again, the development of these facilities and relevant laboratory studies will be performed in collaboration with Turkish universities. To guide our R&D strategy, we have also contracted several reputable foreign scientists from Canada, South Korea and Argentina, countries where the governments have already promoted biotech-

nology as a priority of research and engineering policy.

We have now completed the first quarter of 2015. What strategic initiatives will World Medicine enact over the remainder of the year to ensure the further growth of the company?

World Medicine is currently heavily focused on completing the market authorization process, the essential part of our product launching within emerging pharmaceutical markets in Southeast Asia, as well as to East African markets. In fact, we have already begun to export to these two regions; however, we now seek to expand our product offering in them. The markets of Southeast Asia and Africa show great promise for their underlying potential. In the future, they will become quite economically profitable.

What has the Turkish government's treatment of the regulatory framework governing the pharmaceutical sector meant for World Medicine's confidence as a manufacturer in Turkey?

Turkey has prioritized the development of its pharmaceutical sector. We have

felt this at every stage: in developing new products within the country, as well as while using the country as a base for extending our presence within the foreign markets. It is because of the confidence that we have in the Turkish government that this year World Medicine will develop two new factories for pharmaceutical manufacturing, for which we have just acquired land and begun the project development process.

These two factories will have different production lines: one will be dedicated to sterile and lyophilized products, and the other will be dedicated to additional manufacturing for anti-asthmatic products. We hope that the factory opening ceremonies will be performed by 2016.

Where might we see World Medicine in five years?

Over the next five years, World Medicine will become more global than ever before. We are currently establishing a factory in Belarus. We will soon develop a factory project in Algeria. We seek to enter the EU, and many of the world's most quickly growing, emerging medical markets. We see great promise in these regions. •



Image: World Medicine

Ismail Yormaz

Vice President & Regional Director,
South East,

RECORDATI



Since we last met in 2014, what do you feel have been the most important developments in the Turkish pharmaceuticals sector?

While over the course of the past year the Turkish pharmaceuticals industry has not evolved rapidly, there have been several important advances that have been made. We have seen a greater emphasis placed on the importance of the development of value-added pharmaceuticals on the part of the Turkish government, an acknowledgement that, as manufacturers, our operations help strengthen and diversify the industry in Turkey. We are happy to see this change reflected in the strategic policy initiatives that we have seen developed for value-added pharmaceuticals.

What will constrain the ability of the Turkish pharmaceutical manufacturer to enter into the production of value-added pharmaceuticals?

There are several links that must be forged for the Turkish pharmaceutical manufacturer and the government to expand into these types of research-intensive products. Partnerships between manufacturers and academicians must be developed. Risk must be spread across several sectors. Furthermore, access to capital will, in part, define the ability of this Turkish manufacturer to expand. Research and development (R&D) is an extremely expensive process, often bearing no commercial product. Government incentives are a prerequisite, but do not guarantee success.

Declines in profitability also negatively impact the ability of a company to spend on R&D. What impacts on R&D in Turkey have you observed over the course of the past two to three years?

I do seriously wonder about the ability of the Turkish pharmaceutical manufacturer to spend on R&D. The cur-

rency depreciation and second the conversion ratio used for the Turkish government's cross price referencing policy have placed the Turkish manufacturer in a two-fold bind, but these two issues have not had a direct impact on Recordati Turkey's R&D strategy, as our R&D facilities are located in Italy. However, given these conditions, it is very unlikely that we will execute any larger investment in R&D in the country, even though, as an organization, we are highly focused globally on developing innovative products in fields such as orphan drugs.

Recordati, however, has invested heavily in the development of its manufacturing presence in Turkey. Aside from what Turkey might lack as a center for innovation, what benefits does the country offer those that establish a manufacturing presence?

Turkey offers the foreign investor in local manufacturing several unparalleled benefits, chief among which is the country's location. Having a manufacturing presence in Turkey grants one easy access to the Commonwealth of Independent States, the Gulf Cooperation Council (GCC) states, and Russia. At most, any of these regions are two and a half hours away by plane. Turkey also is in closer proximity to two of the pharmaceutical industries most important supply hubs, India and China. These advantages, supplemented with the attractiveness of the fundamentals of Turkey's internal medical market, are what make the country so attractive as a center for manufacturing.

In the past year, we have seen the Turkish pharmaceuticals manufacturer place greater emphasis on the importance of export markets to their total sales volume on account of limitations on their profit margins in the domestic market. What has this

meant for Recordati, a manufacturer that, at least when we met last year, was nearly exclusively focused on internal market sales?

Recordati Turkey has now begun to more actively target the foreign market. We have entered Azerbaijan and Georgia, and within the next year may also enter Moldova and the GCC states. Our ability to enter these markets, however, will be checked by the product authorization process of each market. Pharmaceuticals are considered by many countries to be a strategic product: with this categorization comes many regulatory barriers. Furthermore, there is little nuance in this categorization: oncological products are treated the same as over-the-

counter products. This can hinder the trade of products.

2015 is an election year. What might this mean for the Turkish pharmaceuticals industry?

Election years are always important, but in the lead up to an election, rarely does one observe any large-scale policy change. This may come after the election, when there could be a movement in a positive direction in terms of Turkey's system of drug price referencing. We have seen the current exchange rate of 1.9595, which is still used by Ministry of Health, rejected by the court in favor of the pharmaceuticals industry. How the SGK may respond to this is unclear, but after

July we could begin to see a resolution emerge.

Do you have a final message for the regulators reading this report?

Turkey's regulators must build their confidence in Turkey's pharmaceutical manufacturers. The period from 2009 to 2015 has been a dark one for the country's pharmaceutical manufacturing base, marked by mistrust and poor communication. If pharmaceutical manufacturing is to play a strategic role in the country's future – a goal expressed by the Turkish government – the relationship between regulators and the domestic industry must improve. •



Recordati, established in 1926, is an international pharmaceutical group, with a total staff of over 4,000, dedicated to the research, development, manufacturing and marketing of innovative pharmaceuticals in many therapeutic areas, including a specialized line dedicated to treatments for rare diseases, that improve quality of life and help people to enjoy longer, healthier and more productive lives. Recordati has operations in the main European countries, in Russia, in other Central and Eastern European countries, in Turkey, in North Africa and in the United States of America. Recordati is present in Turkey since 2008 and today Recordati İlaç is the group's fourth largest subsidiary.



Ersan Küçük

General Manager
DROGSAN



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Since we last met with Drogosan, in 2014, how has your organization evolved?

There have been several changes in the Turkish market, including the depreciating currency, which in turn has affected our profit margins. A significant amount of our income is in U.S. dollars, and 30% devaluation in the currency has compromised our budgets. We made a budget at the beginning of the year and were compelled to revise it after two months. After the upcoming election, we hope that the new government will work towards strengthening the currency. Our export business used to account for 8% to 10% of our turnover. In 2014, we increased this business to 13%. Syria significantly contributes to this growth. Our business in Iraq and Iran is growing as well.

Which foreign markets would you like to penetrate?

We aim to enter Macedonia, the Balkans, Ukraine, Belarus, Georgia and Azerbaijan. We have agents who are handling entry to some of these markets. We are compelled to use a distrib-

utor, as we lack knowledge of the regulations in these individual countries and how their markets operate.

What are the tradeoffs of hiring distributors versus having your own marketing and sales force?

Distributors have a higher success rate due to their know-how and reach within specific markets.

How has your strategy for sourcing changed with rising costs of raw materials and other imports?

With a 13% turnover from exports, our increase in import costs is recovered. After the Turkish Lira depreciated, we revised our budget and realized that the currency increased our exports business by 6%. It is a highly profitable aspect of our business.

Would revising the budget for pharmaceuticals be a beneficial step by the Turkish government?

The authorities had a meeting this week, as this is a topic of importance. The budget will increase by approximately 10%, and the government will handle pricing issues. We are attempting to enter markets that are not price controlled for this reason. The profitability is higher for these products, and we will hence be able to increase our exports and contract manufacturing business.

How is Drogosan's contact manufacturing business faring?

There are not many manufacturers in Turkey for spray forms of products. If a company approaches us with a need, we are happy to manufacture for them. What are Drogosan's strategic initiatives for growth in the next three years? We have been improving our research and development facility. We plan to hire new employees and create niche products. We will also work with other companies in the techno-park where our facility is located to increase our business. We will be consolidating our product line to increase profitability.

What is your view on biosimilars with regard to Drogosan's role and Turkey's regulatory framework?

We launched our first biosimilar product this year. We cannot invest in biosim-

ilar production sites in Turkey due to the heavy investment needed, but we would consider a partnership with companies that are already in this business and have experience.

What is your final message to the readers of this publication, including investors and government representatives?

All Turkish companies require consolidation, as decreasing profitability is an issue. Given that it is a valid concern in this economy, the companies need investors and financial backers. Although some Turkish companies can afford to buy out others, domestic and foreign investors will help quicken the process of consolidation. With patent regulations, we cannot manufacture many generics in Turkey. There are several such problems in the Turkish pharmaceutical market, and companies need to focus on tackling these issues and controlling costs. Investors are needed in order to consolidate and help increase profitability. There are several pharmaceutical companies that want to enter the Turkish market, and Drogosan is a mutually beneficial target for partnership because of our niche line of products and our know how of the industry. The European pharmaceutical market is saturated, and each company needs to seek investments and growth opportunities outside the European market and to diversify their portfolio of products and exports. •

Ersin Erfa

General Manager
CENTURION



In the past year, profitability has fallen across the industry. How have these developments impacted Centurion?

In recent years, many new players have entered Turkey's generics market, despite the continued low levels of profitability. Currency volatility has caused us to price the majority of our APIs and excipients, regardless of their point of origin, in U.S. dollars, but our end products are sold either in euros or Turkish liras, which has cut deeply into our profitability. Today, U.S. dollar-euro volatility is the largest handicap, but we expect better conditions in the future. Interestingly enough, the import product market has actually grown. Centurion aims to expand its business while profitability is low, and to reach its local manufacturing and export targets in the next five years. The basic fundamentals of the Turkish pharmaceuticals market are strong. The country has a young population and a high birth rate, both of which strongly contribute to its long-term potential.

In 2014, Centurion invested 20 million euros in a new manufacturing facility. How has this investment advanced?

Since 2014, Centurion has expanded its investments in manufacturing. We have now invested 33 million euros in the development of our facility, including research and development (R&D) activities. This facility will be dedicated to developing generics and biosimilars and will begin producing at the end of 2016. It will be important in light of the injectables, orphan drugs and biosimilars to be manufactured in Turkey.

In seeking to expand your presence in biosimilars, you have partnered with foreign businesses to aid in R&D. Could you provide us with an overview of this partnership?

Centurion holds significant market share in Turkey for plasma products, but also has a global agreement with Sanquin for exporting to roughly 25 countries. Centurion has also signed an important agreement with Amega for the local production of biotech products, as well as global branding and global marketing. R&D activities in Turkey have already started.

Amega Biotech has a strong global footprint, especially in South America and the Middle East. They have a successful facility in Iran. Our work together represents both Centurion and Amega Biotech's second investment in biosimilar and bio-better products. This partnership will develop these products for the benefit of Turkey, and for Centurion's regional markets, such as the European Union.

Centurion is active in over 20 markets globally and is working to expand. What markets will drive Centurion's growth in the mid-term?

Until now, Centurion's actions have been for plasma products. In the future, injectables, orphan drugs, and biosimilars will be exported.

Due to the limited supply of raw materials for plasma products, Centurion has developed its exports to countries within its strategic growth fields, including the Balkans and several Western European nations, such as Poland. For these markets, the product registration process continues, distribution agreements are being finalized, and IP studies are ongoing. We have also started to approach India and the GCC, including South Arabia and Yemen. •

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www.centurion.com.tr



Deniz Demir

General Manager
DEM PHARMACEUTICALS



Dem Pharmaceuticals was established in 1992. Can you provide a historical perspective on the organization's development?

Dem Pharmaceuticals was established by my father, a pharmacist, and began as a pharmacy, a business that we continue to operate at its original location in Kadikoy. We have since expanded into the production and wholesale of pharmaceuticals, which we operate through this business unit, Dem Pharmaceuticals.

Originally, our strength was our expertise in marketing and distribution of niche pharmaceutical products, such as blood derivatives and orphan drugs. Since its inception, Dem Pharmaceuticals has led the Turkish market in blood derivatives, but later, we developed a reputation in hematology, oncology, and cardiology, which we established through licensing agreements with a global network of partners. Annually we seek to expand our portfolio by at least one such product. We were the first Turkish pharmaceutical manufacturer to hold a license to market biosimilars, which we do through a facility in South Korea, and have launched three biosimilar products to date.

What obstacles did Dem Pharmaceuticals encounter in pioneering biosimilars in Turkey?

The immediate challenge was to single-handedly introduce both the Turkish consumer and government to their potential efficacy, and in doing so, help create the regulatory structures that to this day govern the development process of these products. This involved convincing the Ministry of Health (MoH) of the necessity of biosimilar products, and of the high standards that Dem Pharmaceuticals would employ in their production.

Is it realistic to expect that the government will successfully tender the development of facilities to manufacture blood derivatives?

The government controls many variables, especially in the plasma market. There is an interest, but regulatory measure may block their development. As many as three different regulatory bodies – the MoH, Turkish Red Crescent, the SGK – would be involved, which are not harmonized and lack transparency. The government should help establish the structure of a tender, but beyond this, its place should be limited.

Is the market large enough in Turkey to justify their establishment?

The Turkish market is still too small to justify their establishment. A collaborative effort must be undertaken to establish an export market, or an off-take agreement – at least for the first ten years – to help secure project financing for such an undertaking.

What strategic initiatives will guide Dem Pharmaceuticals future growth?

Today, we are focused on several fields, including oncology and multiple sclerosis, for which we will launch several projects in the third quarter of 2015. In the medium-term, we want to grow our exports through foreign licensing agreements and partnerships with distributors within the GCC, North Africa and Eastern Europe. We recently closed three agreements and have since dispatched ten product dossiers. We plan to send out ten more soon. However, our main objective is to develop our own products. We are heavily invested in biosimilars and seek to construct a biopharmaceutical production facility. In five years, we hope to have one to two biosimilars that we can produce. •

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Dr. O. Mutlu Topal

Managing Director
KEYMEN PHARMACEUTICALS



Can you tell us about Keymen's progress in the last year to become one of Turkey's top-40 pharmaceutical manufacturers?

With the constantly changing economic conditions, Keymen has revised its targets and expectations. With the depreciation of the Turkish lira and the rising costs of raw materials and production, we are in the process of downsizing our company, and have decided to focus our attention on selected markets only and our core business of vaccines. Given the current margins in pharmaceuticals, it is impossible to be everywhere. We have maintained our sales prices and absorbed the increases in cost. Pharmaceutical manufacturing is an industry where, without investment, there is no development; therefore, we need to use our monetary sources wisely.

Which areas are you specifically focusing on?

We are concentrating on our core business of vaccines and will be producing vaccines in the future based on the requirements of the Turkish Ministry of Health. We are performing continuous

studies, and are in a partnership with Hacettepe University to establish a vaccine research and development center. We have completed the laboratory design and are in the process of renovating. Once the center is complete, we will use the laboratory to develop vaccines and thereafter produce them. We will first start supplying to the local market, and then move onto exporting to neighboring countries.

What strategic initiatives has Keymen employed in the past year?

We have decided to grow in specific fields of pharmaceuticals, such as women's health and pediatrics. The market is currently very competitive, which has led to small, regional companies moving their businesses out of Turkey.

How have the changes in the competitive landscape affected your sales volumes and profit?

All the raw materials for pharmaceuticals are imported, so the exchange rate directly affects our profits. With increasing costs and constant sales prices, our profit margin is being further compromised. Keymen is not the only company downsizing; in 2014, over 5,000 workers in the pharmaceutical industry lost their jobs. Companies with deep pockets are discounting their products in order to keep their market share, as this is a long-term business. We expect some change to occur with regard to the exchange rate after the June elections, but we anticipate that prices will remain fixed until the end of the year.

Do you expect changes to occur in the second half of 2015?

No, the government's budget will not allow a change in prices because we have a vast cash deficit. It will take longer for prices to change.

What strategies will you employ to increase your business?

We have decided to enter the market for product groups aside from pharmaceuticals, such as food supplements, where the government does not control the prices. Furthermore, we are exploring the potential for exports. We have registered some of our products in

Azerbaijan, Georgia and Kosovo already. We also have ongoing studies to enter Albania and Turkmenistan.

Moreover, we are a member of pharmaceutical civil societies, through which we try to identify ways to increase exports. We are currently trying to conduct commercial visits to different countries, so that we can assess the potential markets by meeting with buyers and government officials. For example, on Africa continent, Turkish pharmaceuticals are perceived as high quality products, and the African people will spend more money to purchase Turkish pharmaceuticals. This gives us the scope to enter markets in several African countries. Latin American countries have a lack of production, making them import-oriented, so there is ample opportunity for us to export to these countries as well. Turkish Pharmaceutical Exporters will be going to Chile, Colombia, Tanzania and Ethiopia this year. In addition, we have invited companies from Nigeria and Ghana to Turkey in order to establish trade relations.

Do you foresee any regulatory changes that will ease market access into specific regions?

The Turkish government supports the idea of exporting pharmaceuticals in order to help correct the trade imbalance. However, supporting an idea and doing something to help implement it are two different things. Nothing has been done to help increase exports by the government. We hope that the government will help in the form of support incentives after the June elections.

Where will Keymen be in 2020?

We hope that we will have succeeded in our vaccine production plans from Ankara and have established a network of countries to which we export our products. •

Barış Özyurtlu

Deputy General Manager

BERKO PHARMACEUTICALS



Can you provide an overview of the milestone projects Berko Pharmaceuticals has been involved with in the past year?

Berko Pharmaceuticals, attracting attention with its rapid graph of growth and innovative products, has made contributing to public health its objective and is giving services with two factories in Istanbul. The third factory is under construction, which we hope to complete by mid 2016. We not only manufacture our own products, but also for other, globally recognized companies under contracts. We are producing products in tablet and capsule forms so as to include the hard gel capsule, pomade and suppository options. Another important breakthrough was the establishment of our OTC group in early 2015. Berko Pharmaceuticals seeks to continue its leadership in this area through the establishment of the OTC Group and to grow further. With the OTC Group, a night shift was started in the production facilities, and production capacity was increased. More than one hundred new workers were employed as field and production staff. New OTC products will be registered in near future.

At the same time, we are a part of CPhI Istanbul and have a booth to demonstrate our products including fish oil tablets. Our target group includes pregnant women and adults in general. Some of these new products are still in the development phase, and we hope to submit a consistent product to the market.

What is the focus of your third factory?

As this is a sizable investment, we are focusing on a center for research and development (R&D) of new products.

What is Berko's R&D strategy?

Due to the change in policy regarding agriculture at the start of 2015, we had to separate our focuses and alter our R&D accordingly. We plan to hire 45 employees for R&D.

What is Berko's growth target for 2015?

We are trying to double our business by the end of 2015 and have assigned new employees from our sales department to reach this ambitious goal.

What are Berko's export strategies?

Our new geographic focus is the Middle Eastern countries. It is difficult to move forward given the regulations enforced by the Ministry of Health, however we are pursuing these countries and are negotiating with Lebanon, Yemen, Algeria and Azerbaijan, Vietnam, Iraq and Moldova to name a few.

Do you employ your own marketing and sales force in these countries?

At the moment, we are exporting products to countries through distributors.

What markets would you most like to enter?

We would like to penetrate the Russian, Ukrainian, Arabian and African markets, as they are vital territories to our business. We would also like to enter Eastern European countries, such as Macedonia, the Balkans etc. After CPhI Paris, we are seeking the most efficient organizations that we would like to be in partnership with in these countries.

Given the Turkish GMP standards, is it easy to enter Eastern European markets?

It is difficult to enter these markets. For

example, we were present in Romania for several years but had to re-register our products conforming to the imposed standards, which increased the work from our end and made doing business more difficult.

What can the government do to better facilitate pharmaceutical trade in an attempt to help correct the Turkish trade deficit?

With the government's assistance, we can gain numerous benefits and enter foreign markets more easily, especially European markets. We share all data and information with the government and ask for their help in entering the European markets as well as the American market.

What portion of your sales do you hope to see from foreign markets in 2015?

We are targeting 2% to 5% of our total sales coming from foreign markets. In 2016, we hope to increase this to 7% to 9%.

Where will Berko be in four years?

We hope to increase our presence in foreign markets, so that 20% of our sales will come from exports. I believe that we will be able to reach this level in five years. We hope to have a strong presence in the European and Russian markets, Arabian Peninsula and African countries. Currently, we are continuing negotiations for distributorships in many countries.

What is your final message to the readers of this publication?

Berko Pharmaceuticals was founded by the pharmacist Berat Beran, who started a pharmacy in 1984 that took its current place in the drug industry. Berko Pharmaceuticals is among the most rapidly growing firms in Turkey within the last seven years with its field and central staff consisting of four groups, 50 products in total, and more than 600 employees. In the global market, however, Berko Pharmaceuticals is a comparatively new company. We believe that we will be able to reach the targets by gaining trust with its special products. We also believe that we can submit unique products and provide better services to the market thanks to our growth. •

Tuğçe Koç & Tuğba Koç

Tuğçe: General Manager
Tuğba: Board Member, Marketing & Sales
ONKO KOÇSEL



Since we last met in 2014, the Turkish pharmaceutical manufacturing industry has faced industry-wide limitations on profitability. How have these limitations affected Turkish society and Onko Koçsel?

Tuğçe Koç: Currency volatility has made more severe the limitations already imposed on Onko Koçsel's profitability by the country's regulatory environment. While this has reduced the impact of Turkey's cross-price referencing issue, we indirectly have suffered as both our excipients and APIs are priced in euro.

Tuğba Koç: A second, and perhaps more far-reaching, implication of decreased profitability is that certain medical products have become increasingly unavailable in the Turkish market. The rise of unmet medical needs has been in direct correlation with the fall of profitability for Turkish pharmaceutical manufacturing. Many, including the government, have portrayed the Turkish pharmaceutical manufacturer as capable of supplying these products but unwilling. In truth, unmet medical needs have resulted from the lack of profitability for certain business lines.

Tuğçe: As a pharmaceutical manufacturer

we cannot be expected to bring these products into the Turkish market to our own detriment. Now, especially in several critical therapeutic areas such as oncology, we have seen many patients go unserved because of these declines. An expectation should not exist that it is the private sector's responsibility to correct this: this is clearly a regulatory failure.

Tuğba: Even distributing these products into the Turkish market is difficult, as market authorization can be a time-consuming process for products that are unregistered in Turkey. Onko Koçsel in a difficult position because of this and has had to drop many of our original product lines.

Onko Koçsel has invested in the development of an oncology manufacturing facility, through which it seeks to meet the needs of Turkish medical market, as well as near markets. How has this facility advanced?

Tuğçe: Our facility is now authorized for the production of non-cytotoxic products. For this, we now produce 36 products. Soon, we will enter into the production of cytotoxic products, for which we have recently completed our audit. We anticipate that by the end of 2016, we will produce 139 products in this facility. In 2014, Onko Koçsel exhibited growth of 26%, despite market circumstances. Next year, we anticipate even stronger growth because we have entered into production at our new plant. We anticipate that this will be aided by interest in toll-manufacturing within our facility, an area that many parties, among them several of the world's most important pharmaceutical manufacturers, have expressed interest.

Which of the many markets that Onko Koçsel seeks to target shows the most immediate potential for supplying oncology products?

Tuğba: Onko Koçsel's facility will play an important role in meeting the medical needs of many near markets, such as the CIS. In addition, our U.S. FDA- and EU-GMP authorizations will allow us to enter to of the world's most mature markets for oncology products. Our facility is truly world class. Currently, we have entered into internal discussions as to which of these markets to approach and will take action by the end of 2015. We must choose the right partnership to enter these

markets.

South American medical markets also interest Onko Koçsel. Brazil, despite of its size, has only two oncology manufacturing facilities, so we could soon extend into this market.

What proportion of total sales does Onko Koçsel expect from foreign markets?

Tuğçe: By the end of 2016, when Onko Koçsel's new facility will have reached its target capacity utilization, we seek to generate 20% of our total sales volume in foreign markets. In developing our facility, our goal was to create a manufacturing plant of world-class standards, which could easily surpass the standards of both European and American pharmaceutical manufacturing facilities. We have achieved this.

Has the Turkish government's current regulatory scheme, which incentivizes the production of value-added, technologically advanced products in the country, succeeded in its mission?

Tuğçe: Onko Koçsel has directly benefited from the Turkish government's aim to improve the sophistication of the Turkish pharmaceutical industry. We are the only company to have qualified for the Turkish government's incentive program for the development of facilities of this caliber for oncology. The greatest problem that the government seeks, though, in increasing the efficacy of its program, is the retrospective way in which these incentives are enacted. One must first invest to benefit.

Tuğba: The Turkish government has made efforts to correct this and acknowledges that the Turkish pharmaceutical manufacturer has suffered in the past decade. The Turkish Minister of Health, earlier in 2015, published a report that shows a direct correlation between the policies of the Turkish government for the health care sector and a decrease in local manufacturing. Multinationals, comparatively, have benefited against local manufacturers because of the government's pricing strategies. We are uncertain whether this will result in regulatory change, but the Turkish government can take several steps, especially related to the country's current incentive program, to encourage the expansion of domestic manufacturing. Increasing the size of incentives for the development of research and development-intensive products is one step. •





Blazing Trails: Turkey's Foreign Market Development

“The Turkish pharmaceutical manufacturer has, largely, been successful in entering CIS. Two markets in which more can be done are Russia and the Ukraine. Given the size of the Russian market, and the manufacturing capabilities of many in similar markets, Russia is underrepresented. In part attributable to regulatory statutes that obfuscate market entry, Russia has proven difficult to approach, but those who are able to successfully position their products should find uncontested market share.”

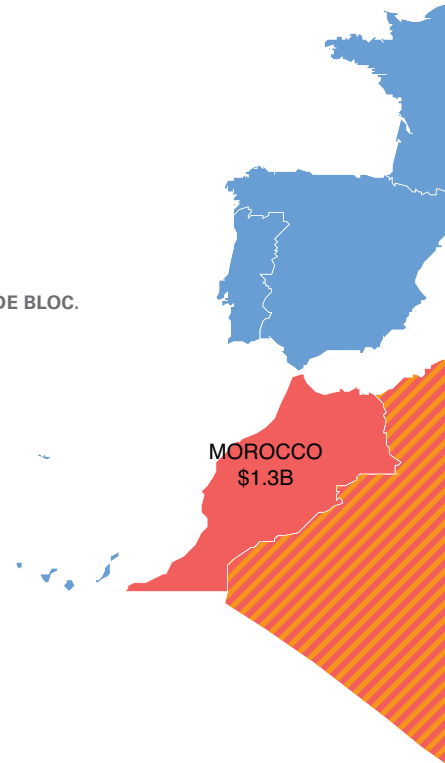
- Cengiz Zaim, Director,
Out-Licensing and Export Markets,
Abdi Ibrahim

Foreign-Market Activity

Battling the Contagion

TURKEY AND ITS NEIGHBORS BY MARKET SIZE AND TRADE BLOC.

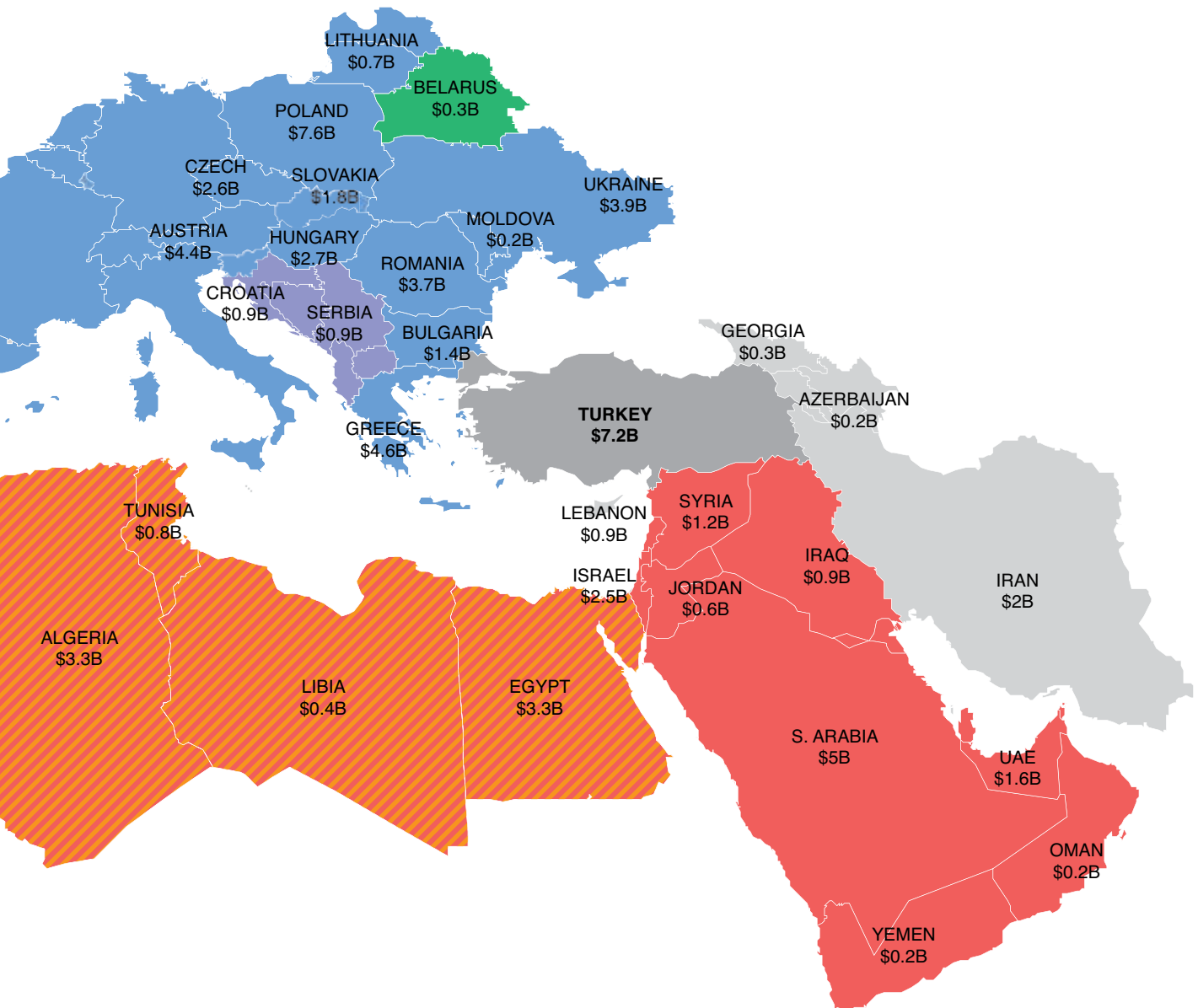
-  European Union (EU)
-  Central European Free Trade Association (CEFTA)
-  Eurasian Economic Community (EAEC)
-  Arab League (AL)
-  European Free Trade Association (EFTA)



Driven from their homeland by an internal regulatory environment that has favored the public budget over domestic industry and the multinational over the local manufacturer – and even imported products over those produced domestically – Turkish pharmaceutical manufacturers placed greater emphasis on the importance of export-led growth with their portfolio strategy in the past year. Foreign market sales continued to rise, reaching \$856.2 million in 2014, reflecting a growth rate of 4.7%, which, though slower than in previous years, still marked a divergence from the strategic priorities of

the manufacturing sector of five years ago, when foreign market sales stood at nearly half of this number. Representing the third largest contributor to Turkey’s current account deficit, the domestic pharmaceutical market’s outward expansion has been welcomed by the Turkish government, supported through the creation of several export-development programs which have helped cover the costs associated with foreign market access for eligible parties. Yet the success of Turkish pharmaceutical manufacturers in entering foreign markets will depend on their ability to promote their

products more easily. A contagion has begun to spread, driven by the Turkish government’s domestic policies, which, if left untreated, could prematurely end the outward growth of the Turkish pharmaceutical manufacturer. The footprint of the Turkish pharmaceutical manufacturer of today is vast, in spite of the relative nascence of foreign market activity. In 2014, the products of Turkish pharmaceutical manufacturers could be found in 170 countries across the globe, in markets that range from the developed to the developing. Last year, the largest importer of Turkish pharmaceuticals



was South Korea, which saw its total import volume spike, increasing nearly fourfold, from \$30,609,999 in 2013 to \$110,255,312 in 2014. Other markets to sharply increase their consumption of Turkish pharmaceuticals included the Russian Federation, whose import volumes nearly doubled in the past year, rising from \$17,895,792 in 2013 to \$32,346,831 in 2014.

These increases, however, were checked by declines in product imports for four markets that have historically been among the largest consumers of Turkish pharmaceuticals: Switzerland, Germany, Iraq, and Iran. Respec-

tively, consumption of Turkish pharmaceuticals within these markets fell to \$59,939,304, a decrease of 5.4%; \$56,746,527, a decrease of 11.6%; \$50,915,905, a decrease of 31.8%; and \$45,019,621, a decrease of 48.5%.

Russia

Underscoring the growth of Turkish pharmaceuticals within the Russian Federation has been the activity of several of Turkey's largest pharmaceutical manufacturers, which have sought to aggressively enter into this market. Numan Balki, member of the execu-

tive board for Nobel Pharmaceuticals, one of Turkey's first pharmaceutical manufacturers to begin foreign market activity, which it did in 2000, and one of the only Turkish pharmaceutical manufacturers to generate a greater proportion of total revenue from external, rather than internal, market activity, explained: "In 2014, Nobel Pharmaceuticals entered Russia and Romania. Though Nobel currently operates in over 20 markets outside of Turkey, Russia will play an important role in driving the future of the company's export-led growth. Last year, Nobel generated \$60 million in export



Image: Abdi Ibrahim

business, an increase of 10% from 2013. We target to grow both of these figures by 20% over 2015, much of which we will be able to derive through the company's entrance into the Russian market."

Others to place heavy emphasis on the importance of the Russian market include two other of Turkey's largest pharmaceutical manufacturers, Abdi Ibrahim and Bilim Pharmaceuticals. Cengiz Zaim, director of out-licensing and export markets at Abdi Ibrahim, said: "Given the size of the Russian market, and the manufacturing capabilities of many in similar markets, Russia is underrepresented in our portfolio. In part attributable to regulatory statutes that obfuscate market entry, Russia has proven a difficult market to approach. However, those that are able to successfully position their products should find uncontested market share."

The barriers discussed by Cengiz Zaim have led both Abdi Ibrahim and Nobel Pharmaceuticals to establish manufacturing facilities in Kazakhstan, which allows for easier market access because of trade agreements. Cengiz Zaim of Abdi Ibrahim continued: "Kazakhstan has a customs union with Russia and Belarus, and these countries will likely harmonize the regulation of their pharmaceutical industries. This is why we have chosen Kazakhstan as our regional hub."

By having a local manufacturing facility within Kazakhstan, these players could also be exempted from future regulatory changes, which, in the case of Russia, are expected to result in stricter local content requirements. Numan Balki of Nobel Pharmaceuticals explained: "The Russian drug authority has made public that by 2020 they would like to have 80% of their total pharmaceutical market supplied through local manufacturing facilities. Our facility in Kazakhstan, however, allows for our products to qualify as locally manufactured products. We anticipate that because of this we will not be subject to this regulatory change."

Although the Russian pharmaceutical market appears promising, it remains out of reach for many domestic man-

ufacturers because of these regulatory policies. This has been the product of Turkey's internal regulatory climate, the limitations it has imposed on domestic profitability, and the Turkish pharmaceutical manufacturer's attendant inability to reinvest, which has and will continue to limit market activity within Russia to all but the industry's largest players.

The GCC

A market far more approachable to the Turkish pharmaceutical manufacturer that lacks the funds to invest in the establishment of a new manufacturing facility, the GCC has seen strong interest on the part of the Turkish pharmaceutical manufacturer. This has, in part, been driven by the comparative advantage that Turkish pharmaceutical manufacturers have in accessing regional markets.

Ismail Yormaz, vice president & regional director of the southeast for Recordati, said: "Having a manufacturing presence in Turkey grants one easy access to the Commonwealth of Independent States (CIS), the GCC, and Russia. Turkey also is in closer proximity to two of the pharmaceutical industries most important supply hubs, India and China. These both make Turkey an appealing destination for regional manufacturing."

Attractive for its geographic proximity, pricing advantages, and the still-underdeveloped state of domestic manufacturing, member nations of the GCC, in particular Saudi Arabia, have been strongly courted by the Turkish pharmaceutical manufacturer in the past several years.

Yet this interest, like so much else for the Turkish pharmaceutical manufacturer, has been impacted by the regulatory climate surrounding product imports which has posed two challenges – the first of which is observed in the market authorization process that one must undergo in approaching the market. Unlike the European Union, the Russian Federation, or even North and West Africa, the GCC is not bound by a set of regulatory agreements that allow for one to easily extend their presence

within one market to an alternate market. Instead, should one wish to enter both Saudi Arabia and Yemen, one must undertake a separate set of regulatory procedures that offer a separate set of regulatory challenges. Ersin Erfa, general manager of Centurion Pharmaceuticals, which currently seeks to enter into the GCC, said: "The countries that comprise the GCC entail a complicated, multi-step market authorization process." This has proven a formidable barrier for some.

However, perhaps the greater barrier that the Turkish pharmaceutical manufacturer has faced in accessing these markets is observed in the price levels on which their products, once in market, must compete. This has been for the role that Turkey, in establishing a system of cross-price referencing for its internal pharmaceutical market, has played in creating a regional regulatory contagion. Turkey's success in expanding medical access and limiting its impact on the public budget has led to the proliferation of economic policies and regulatory structures that, though detrimental to the development of industry, have spread to foreign markets that seek to replicate the successes of the Turkish government. Ersin Erfa of Centurion explained: "The member nations of the GCC tend to be extremely sensitive to product pricing as they employ a system of cross-price referencing not dissimilar to that of Turkey."

Though specific to the GCC, this issue is part of a larger issue encountered by the Turkish pharmaceutical manufacturer in seeking to enter into the foreign market: an issue that could very well define the ability of the Turkish pharmaceutical manufacturer, especially those that lack the capital to establish themselves directly into the foreign pharmaceutical market, to participate in foreign market activity.

The most basic structural problem encountered by the Turkish pharmaceutical manufacturer in entering into the foreign market is derived, like so many other issues that plague the industry, from Turkey's system of cross-price referencing. The price at which a market expects to receive a product – the price at which the Turkish pharmaceu-

tical manufacturer can sell to the foreign market – directly extends from the price at which they are able to retail the product within their country of origin. Though many foreign markets may not directly employ a cross-price referencing mechanism like that of Turkey, indirectly it is because of this that our profitability abroad is linked to our profitability domestically."

Entrance into the foreign market is a task that, given the competitive landscape of the global pharmaceutical manufacturing environment, cannot be undertaken easily. Individual markets require individualized approaches. As Philipp Haas, CEO of Deva Holding, one of Turkey's largest pharmaceutical manufacturers, explained: "Exports to emerging markets, underdeveloped markets such as the CIS or GCC, are quicker to realize but come with certain risks. Exports to developed markets come with less risk, but require more substantial investments in both quality standards and market entry."

The defining characteristic of those that have been successful in accessing the foreign market, however, has been access to capital. Access to capital has underscored the success of those that, through establishing a manufacturing facility within Kazakhstan, have succeeded in accessing Russia. Access to capital has defined the success of those that, in establishing a presence within price-sensitive markets such as the GCC, have been able to take a temporary loss in building their presence within the market. Access to capital, for the Turkish pharmaceutical manufacturer, has been constrained by domestic policies, and unless a change in domestic policy is undertaken, the ability of the Turkish pharmaceutical manufacturer to enter into the foreign market – a policy goal that the Turkish government has, at least, on face supported – will be hindered by the inability of domestic manufacturers to access capital. If this contagion and the consequences attached to it go unresolved, the Turkish pharmaceutical manufacturer could see those strides, which it is now attempting to take in expanding into the foreign market truncated by domestic policy. •

Numan Balki & Gökhan Köse

NB: Member, Executive Board

GK: Business Development Manager

NOBEL PHARMACEUTICALS



NB

Nobel Pharmaceuticals is one of Turkey's most active manufacturers within the foreign market. Which markets drove the firm's growth in 2014?

In 2014, Nobel Pharmaceuticals entered Russia and Romania. Though Nobel currently operates in over 20 markets outside of Turkey, Russia will play an important role in driving the future of the company's export-led growth. Last year, Nobel generated \$60 million in export business, an increase of 10% from 2013. We target to grow both of these figures by 20% over 2015, much of which we will be able to derive through the company's entrance into the Russian market.

Nobel has long been involved and had success in the foreign market. What factors have allowed Nobel to succeed in markets where many others have struggled?

Nobel Pharmaceuticals has succeeded in capturing market share abroad for two reasons. First, Nobel entered early into the foreign markets. We were the first domestic manufacturer to incorporate export-led growth into our corporate strategy beginning in 2000. Second, Nobel

has also insisted, in approaching these markets, that we employ our own marketing teams for promotional activities and business development. We believe in crafting a brand, especially because our foreign market presence is a long-term commitment. This model offers several advantages over operating through a distributor. We can control our presence and therefore better enact our corporate strategies and reflect our organizational values. Today, we employ 1,100 personnel outside of Turkey in marketing, manufacturing and other functions, in markets as dispersed as Mongolia and Albania.

Many of these markets are not easy for the foreign manufacturer to approach and invest directly in local manufacturing. How has Nobel overcome these obstacles?

Not all markets can be approached using the same strategy. We have two manufacturing facilities outside of Turkey, one in Kazakhstan and one in Uzbekistan, which allow us to access several regional markets, such as Russia, through their trade agreements. For example, the Russian drug authority has announced that it would like to have 80% of their total pharmaceutical market supplied through local manufacturing facilities by 2020. Our facility in Kazakhstan, however, allows our products to qualify as locally manufactured products. We anticipate that we will not be subject to this regulatory change. Beyond this, the stringency with which local content requirements are enforced is relative. In several markets, if a product is packaged locally it qualifies as a locally manufactured product. These markets include Georgia, Belarus and Serbia. When crafting market strategy, we consider both Nobel Pharmaceutical's internal capabilities and our ability to access a market. When we first began export-market development, we entered the CIS, where many physicians lacked an understanding of foreign pharmaceuticals and the benefits they offer, so we undertook market education, which was critical to our success.

Turkish pharmaceutical manufacturers face limitations on profitability, namely cross-price referencing and exchange rate fluctuations. What weight have these factors had in your foreign market sales?

The domestic market for products that are reimbursed by the Turkish government shows little growth potential, standing at 5% to 6% per annum. Nobel Pharmaceuticals made a decision to move outside of Turkey long before this became an issue. However, Turkey's cross-price referencing system has certainly strengthened the importance of exports to our continued growth. Today, Nobel is the only Turkish pharmaceutical manufacturer that exports more of its products to foreign markets than it imports as active ingredients or finished products. Pharmaceuticals is the third largest contributor to our country's current account deficit, behind only energy and defense, and standing at \$4 billion per annum. Through export-led growth, Nobel seeks to help mitigate this.

The government has acknowledged the strategic importance of domestic pharmaceutical manufacturing. Are its current initiatives associated with trade development sufficient?

The Turkish government actively supports those who seek to expand outside of the country. A grant program encourages export market development, for which two companies, one of which is Nobel, have received funds to expand the foreign market share of Turkish pharmaceuticals abroad. The program provides incentives and expense coverage for marketing costs and legal expenses. However, for the Turkish pharmaceutical manufacturer to expand overseas, the manufacturer must have a solid position within the domestic market. The Turkish market should be the Turkish pharmaceutical manufacturer's emerald ship. Today, this is far from the case.

What advice would Nobel Pharmaceuticals have for the Turkish pharmaceutical manufacturer in approaching the foreign market? What lessons can be learned from Nobel's experience?

The use of our own marketing team has aided us critically in entering into the foreign market. Equally, we have approached each market with a long-term perspective. In each market, we have assumed a loss during the first two to three years of operation. One must view this cost as part of one's investment, though this might run contrary to the notion that many companies have of export market development. •

Cengiz Zaim

Director, Out-Licensing and Export Markets
ABDI IBRAHIM

Abdi Ibrahim is among Turkey's most active pharmaceutical exporters, with an operational presence spread across the globe. How has Abdi Ibrahim developed its global presence?

Abdi Ibrahim entered the pharmaceutical industry over 100 years ago. We have market authorization for over 200 products and currently export to 50 countries worldwide, including Canada, United Kingdom, Algeria, Kazakhstan, Azerbaijan, Iraq, and Georgia. Each country has its own culture and regulations: we have found that cultivating an individualized understanding of the dynamics that underscore each business environment is critical to establishing a strong operational presence.

To this end, we have a joint venture company with Otsuka Pharmaceutical to sell pharmaceuticals in Turkey, Algeria, and Tunisia. We have also had a presence within Algeria since 1999, though our structure for approaching this market will soon change with the establishment of our local manufacturing facility. Like in Algeria, we are also in the process of constructing a manufacturing plant in Kazakhstan. In both of these markets

we already operate through or own sales force, but a local operational presence will allow us to expand further, facilitating market access to nearby pharmaceutical markets. Kazakhstan has a customs union with Russia and Belarus, and we believe that these countries will harmonize the regulation of their pharmaceutical industries. This is why we have chosen Kazakhstan as our regional hub.

Our strategy of developing regional hubs, however, is not limited to these markets. Typically, a company based in Turkey will use Turkey as its access point for Europe. We operate differently; we have offices in Portugal, which is our sales hub for Europe. Turkey is used to access other regions, including the Balkans and the CIS.

Which markets can Abdi Ibrahim most easily access with its manufacturing plant in Algeria?

From Algeria we can export to francophone West Africa. Algeria has established commercial ties, which will allow for us to easily enter to Ghana, the Ivory Coast, Mali and Nigeria. This said, Algeria has a large pharmaceutical market, which these operations will allow also us to serve.

What growth are you expecting from exporting to foreign markets versus supplying to the domestic market?

Currently, the ratio is 15%. Our aim is to reach 40%, as the scope for growth in the Turkish market has reduced due to the appreciation of foreign currencies while pharmaceuticals are sold with a fixed exchange rate that is 35% lower than the actual exchange rate. Our foreign sales generate revenue of \$60 million, but we hope to increase this to \$200 million. Foreign market sales will allow for us to bridge this gap.

How do you approach markets where you do not have a regional point of access?

We use a strategy of alliance management, which is an important operational component. We are exporting to 50 countries by licensing our products to other companies. We already have an impressive portfolio of registered molecules and are waiting for patents to expire in Europe and in other markets to launch these patent-protected products through our network of strategic partners.

What are the most underrepresented markets for the Turkish pharmaceutical manufacturers abroad?

The Turkish pharmaceutical manufacturer has, largely, been successful in entering CIS. Two markets in which more can be done are Russia and the Ukraine. Given the size of the Russian market, and the manufacturing capabilities of many in similar markets, Russia is underrepresented. In part attributable to regulatory statutes that obfuscate market entry, Russia has proven difficult to approach, but those who are able to successfully position their products should find uncontested market share.

What can be done, on a political level, to further penetrate European markets?

If Turkey becomes a member of PIC/s, it will have easier access to more regulated markets, such as New Zealand and Australia and face fewer regulatory challenges. PIC/s membership would also change the perception of Turkey in the European Union. Another factor that can alter exports for Turkey is our price level, which has become a reference to all other markets. We have not been able to fully penetrate the GCC markets because we are subject to a higher price level as an exporter and cannot compete with local manufacturers.

Is there a better way to penetrate the GCC markets, given that they instituted a reference pricing system?

We need to increase our technical capabilities. Turkey is in Zone II, which limits us from being able to distribute the whole range of our products in GCC. Capital investment often determines the scope of where we can expand and export. Despite all, Abdi Ibrahim entered a strategic alliance in the Kingdom of Saudi Arabia (KSA) to locally manufacture and export many products, which will be first alternative treatment in KSA.

Where will the export presence of Abdi Ibrahim be in five years?

We will launch at least one combination product that we will develop and support with clinical studies, a product of our current research and development program. We hope to have our sales force in at least ten markets and to invest more strongly in international markets. •





Forging Further Afield: Research and Development in Turkey

“In 2004, when Turkey first began to introduce new regulation for the healthcare industry as part of the Ministry of Health’s Health Transformation Program, Eczacıbaşı anticipated that the domestic pharmaceutical industry would never be the same. At the time we speculated that the movement away from a cost-plus system to a reference-pricing system would result in the Turkish government having too many levers for controlling the direction of the domestic industry.”

- Sedat Birol,
Executive Vice President,
Healthcare Division,
Eczacıbaşı

The New Turkish Triumvirate in R&D

Specialty Care, OTCs, and Biopharmaceuticals

The research and development (R&D) activities of the Turkish pharmaceutical manufacturer in 2014 corresponded to three developments that have arisen as a consequence of both the maturation of Turkey's medical market and its internal regulatory environment: expansion into specialty care markets, diversification towards product areas that are less subject to internal pricing controls, and growth in interest in developing biopharmaceuticals. Collectively, these initiatives have spelled death for what has historically been the largest driver of market expansion, the market for generics.

Specialty Care

In 2014, specialty care products showed the largest rate of growth, responding to Turkey's aging demography and the saturation of the market for primary care lines. Oncology was the fastest growing product area, accounting for 11.2% of the total market, if measured by value. Second was diabetic products, which constituted 6.2%. Antibiotics and cardiovascular products continued to lose market share to 8.5% and 5.8%, respectively, down from 11.5% and 5.8%, respectively, in 2010.

Growth in specialty care markets corresponded with investments from the private sector. Onko Koçsel, for example, invested €70 million into a new facility that entered into production in early 2015, and plans to scale its operations, broadening their manufacturing line. Tuğçe Koç general manager of Onko Koçsel explained: "Soon we will enter into the production of cytotoxic products, for which we have recently completed our audit. We anticipate that by the end of 2016, we will produce 139 products

in this facility. Last year, in 2014, Onko Koçsel exhibited strong growth in spite of market circumstance, standing at 26%. Next year, because we have now entered into production through our new plant, we anticipate even stronger growth."

Others that pursue the development of products within specialty care markets include Eczacıbaşı, whose approach to manufacturing foreshadowed the development of the Turkish pharmaceutical market. Founded in 1942 and standing among the industry's forefathers, Eczacıbaşı, whose name in Turkish literally means 'head pharmacist,' abandoned their generic pharmaceutical manufacturing business in 2004 to develop specialty care lines in areas such as nuclear medicine.

Sedat Birol, executive vice president of Eczacıbaşı's healthcare division, explained: "In 2004, when Turkey first began to introduce new regulation for the healthcare industry as part of the Ministry of Health's "Health Transformation Program," Eczacıbaşı anticipated that the domestic pharmaceutical industry would never be the same. At the time we speculated that the movement away from a cost-plus-profit system to a reference-pricing system would result in the Turkish government having too many levers for controlling the direction of the domestic industry. These later appeared in the form of cost controls, including forced discounts and the convertibility ratio now used in translating reference prices into the Turkish lira. We saw the future of Eczacıbaşı outside of the generic pharmaceutical market – in niche product areas such as nuclear medicine, in which we have since established a strong regional presence."

In an extension of this strategy, in 2015 Eczacıbaşı seeks to expand its production of both biotechnological products, for which it is in the final stages of finalizing partnership agreements, and blood products, which, through its joint-venture partnership with Baxter, one of the world's largest supplier of blood products, it anticipates entering into domestic production.

Blood products are an area of hot speculation. A market that has seen consistent growth over the past four years, hematological products constituted 5.8% of the total market by value in 2014. Though at present imported products service the domestic market, there is growing interest from the Turkish pharmaceutical manufacturer to produce blood derivatives and establish a niche in specialty care markets. Aside from Eczacıbaşı, one should keep an eye on Centurion Pharmaceuticals in this regard.

The idea of the domestic production of blood derivatives is not new to the Turkish pharmaceutical market. Over the past twenty years, domestic production has been discussed sporadically and has resulted in several tenders, but projects have failed to advance beyond the initial stages of development.

Deniz Demir, general manager of Dem Pharmaceuticals, a market leader for the supply of blood products in Turkey, said: The question of whether blood derivatives will ever be manufactured domestically is a very difficult question to answer. The State plays an active role in controlling many variables within the Turkish pharmaceutical industry, especially the plasma market. In participating in recent meetings related to the potential development of blood derivative manufacturing facilities within Turkey, I have

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There may one day be a market of sufficient size for blood derivatives within Turkey, however, at present, we believe that the Turkish market is too small to justify the establishment of domestic manufacturing facilities. Should the Turkish government wish to do so, a collaborative effort must be undertaken to establish an export market for these products, or an off-take agreement – at least for the first ten years in which these facilities will produce.

- Deniz Demir,
General Manager,
Dem Pharmaceuticals

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Image: Dem Pharmaceuticals



been given the impression that there is an interest in their establishment, however, that their establishment will be complicated by the regulatory processes that govern the market. As many as three different regulatory bodies would play a role in this market. These bodies – the Ministry of Health, Turkish Red Crescent, the SGK – are not harmonized and lack transparency.”

There are also concerns over the economics of such a project. Demir continued: “There may one day be a market of sufficient size for blood derivatives within Turkey, however, at present, we believe that the Turkish market is too small to justify the establishment of domestic manufacturing facilities. Should the Turkish government wish to do so, a collaborative effort must be undertaken to establish an export market for these products, or an off-take agreement – at least for the first ten years in which these facilities will produce.”

Though initially developed to respond to internal market needs, the feasibility of expanding into the domestic production of specialty care lines such as oncology or hematology will depend upon the ability of the manufacturer to also serve regional markets. For Onko Koçsel, this has underscored their investment. Tuğba Koç, board member, marketing & sales, said: “Onko Koçsel’s facility will

play an important role in meeting the medical needs of many near markets: regions such as the CIS. In addition to this, through receiving U.S. FDA- and EU-GMP authorization, we can also enter into what stand currently as two of the world’s most mature markets for oncology products. Exacting in standards, the United States and the EU are both within the reach of Onko Koçsel.”

OTC Market

A second movement observed in the R&D strategies of the Turkish pharmaceutical industry is to establish a presence in areas that offer greater profitability than the traditional market for generics and are not subject to the government’s system of cross-price referencing. Of particular interest has establishing an over-the-counter (OTC) business.

This is seen in the case of Oro İlaçları, which, first established in 1969, has pursued a development strategy focused on OTC products in fields such as dermatological products rather than the generic pharmaceutical market, citing their relative appeal. Varol Türker, who serves as chairman of Oro İlaçları in addition to acting as the vice-president of SURDER, said: “Oro İlaçları, in evaluating avenues for continuing its growth, has sought to develop its presence in the OTC phar-

maceutical market. This market offers far greater profits than traditional pharmaceuticals. Our OTC products are not subject to Turkey’s system of cross-price referencing, so the unit profitability of these products is far larger. In addition, as this segment of the market, though certainly not without its own standards, is largely self-regulated, we are offered much more freedom than within the traditional market for prescription pharmaceuticals. We are now pursuing the development of new product types in areas such as dermacosmetics.”

Through employing a strategy focused on expanding its activity within Turkey’s OTC market, Oro İlaçları strives to be among Turkey’s 50 largest pharmaceutical manufacturers within the next five years.

Varol Türker, speaking through his position as vice-president of SURDER, a Turkish association that seeks to represent the interests of OTC pharmaceutical manufacturer, said: “Originally, when we first joined SURDER many years ago, there was weak interest in our activities. Our pool of members was limited to less than ten companies. How quickly we have seen this change! SURDER has 82 members today. Over the course of the next year, we expect this number to grow to over 100.”

SURDER’s members now include many

Image: Abdi Ibrahim



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Oro İlaçları, in evaluating avenues for continuing its growth, has sought to develop its presence in the OTC pharmaceutical market. This market offers far greater profits than traditional pharmaceuticals. Our OTC products are not subject to Turkey's system of cross-price referencing, so the unit profitability of these products is far larger. In addition, as this segment of the market, though certainly not without its own standards, is largely self-regulated, we are offered much more freedom than within the traditional market for prescription pharmaceuticals. We are now pursuing the development of new product types in areas such as dermocosmetics.

- Varol Türker,
Chairman,
Oro İlaçları,
and Vice-President,
SURDER

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of Turkey's largest pharmaceutical manufacturers; companies such as Abdi Ibrahim, which, in their last strategic planning period have identified expansion into the OTC pharmaceutical market as one of the company's three most important strategic initiatives.

Biopharmaceuticals

Perhaps the area in which the Turkish pharmaceutical manufacturer has placed the greatest emphasis in their R&D activities is biopharmaceuticals. Responding to an incentive scheme developed by the government, which can cover as much as 50% of expenditures related to R&D, and focused largely on the production of biosimilars and bio-betters, the Turkish manufacturer has invested heavily in developing ventures within this field by partnering with companies from the Far East, which have established product lines. This fervent activity has led some to speculate that Turkey could soon become a global hub for biotechnology, a hope encouraged by the Turkish government. Yet before this can occur, several structural changes must take place to better connect three bodies: private industry, the Turkish government, and the country's intellectual resources. Should this not occur, Turkey could see its ambitions squandered.

New by global standards, biopharmaceuticals pose a unique set of challenges to the Turkish pharmaceutical manufacturing industry, first observed in their resource requirements. Though the industry has been able to establish itself as one of the region's largest production bases without investing heavily in R&D, should Turkey wish to establish itself as a production hub for biopharmaceuticals, this cannot be the case. To become a production base requires fundamental research, which requires capital and knowledge.

Burak Erman, professor of engineering within the Department of Chemical and Biological Engineering at Koç University, said: "The cost of producing a bioequivalent is 90 million TL, and one or two companies are investing in this with the support of foreign partnerships. At the end of the tenure of this project, these companies will come up with nothing of added value."

This position, one held by many within the industry, is underscored by two reasons. First, at the heart of Professor Erman's skepticism are concerns raised over the lack of a nexus between the country's academy and private industry. A key feature of many global pharmaceutical markets, these types of collaboration are new to Turkey, but they would provide the intellectual resources necessary to develop these projects and spread the risks associated with developing them among several institutions.

Dr. Erhan Baş, general manager of Bilim Pharmaceuticals, one of Turkey's largest pharmaceutical manufacturers and a firm that is actively seeking out the development of these products for diabetic products through a network of partners in India, said: "In India and South Korea, regions that lead in the development of technologically advanced products, R&D is part of each country's social fabric: their respective educational systems place strong emphasis on it, and its reflected in the government's incentive structure. Turkey is behind in creating this environment."

Dr. Cengizhan Öztürk, a professor at Boğaziçi University, one of Turkey's premier higher educational institutions that has played an important role in establishing Inovita, a health cluster that seeks to place private sector projects related to

R&D amongst a consortium of Turkish universities, explained: "Collaborations between the university, Turkish government, and domestic industry resemble a triangle. Though individually each of the points are connected, there is little interaction between each body, the result of which being that efforts aimed at expanding into R&D are disjointed. On a broader level, direct engagement between these three bodies must be undertaken should Turkey wish to be successful in expanding into value-added industry."

This is observed in the structure of R&D for biopharmaceuticals. Though the Turkish manufacturer has invested heavily in the development of products, some speculate that these projects will fail to materialize into marketable products because their efforts have been unilateral rather than collaborative.

Dr. Öztürk continued: "For R&D, the Turkish manufacturer still has a long way to go. Ten years ago, the market was near exclusively focused on the development of generic pharmaceuticals, which, from a research perspective, offer little value-added. Today, there is more emphasis, yet this effort is misplaced. The Turkish pharmaceutical manufacturer, in areas such as biopharmaceuticals, has invested substantially in the creation of products that are both risk-heavy and extremely expensive. This is observed broadly across the industry. Yet the majority of these projects will fail, and at great personal cost, because their efforts are disconnected – because, independently, many have sought to create the environment necessary to cultivate the development of these products, rather than working collectively on developing a targeted strategy for R&D through shared infrastructure solutions."

Several Turkish manufacturers have already launched biosimilars using a unilateral approach to R&D, but if Turkey is to expand these efforts, a more far-reaching solution is necessary. Dr. Rana Sanyal, who heads the Bogaziçi University Center for Life Sciences and Technologies (LifeSci), said: "There have been several businesses that, through both internal and governmental financing, have been successful in the development of biosimilar products. This, however, is determined by the availability of capital – and because of the way in which these

products have been developed, but as corporate strategies they lack scalability. The infrastructure that has been built to incubate and produce these products cannot accommodate the production of, say, 50 products: it is limited. If this is to be expanded, one must involve the small research institution and this necessitates altering the infrastructure development strategy for these projects around creating shared facilities. This would not necessarily require heavy capital investments, but rather, the development of lab infrastructure. In this we have not seen investments materialize on an industry level and this could complicate the development of Turkey as a hub for these products."

A second facet of this disconnect is observed in the human resource deficit that has emerged within the pharmaceuticals industry. Part of a larger shortage of qualified researchers within Turkey, the Scientific and Technological Research Council of Turkey (TÜBİTAK), an extension of the Turkish government, anticipates a shortfall of over 120,000 researchers within the country by 2023. This, again, has been for lack of collaboration.

Dr. Sanyal of LifeSci commented: "The Turkish pharmaceutical manufacturer of today is near-sighted, lacking the ability to anticipate how the human resource needs of their organization might change over even the course of a year. When strategic initiatives related to R&D are implemented, there is an immediate demand for certain positions, and these positions can be filled by Turkish researchers, however, time is required to develop the talent capable of meeting the needs of these organizations. One of the greatest problems that the Turkish pharmaceutical industry could face is found in the shortfall of talented researchers, and this is in part a result of poor corporate planning. If the industry showed an interest in working with an organization like Boğaziçi University for personnel development, it would need to begin early on: for our Ph.D. students, within the first year of their program. But unfortunately, because of the immediacy of the needs of the Turkish pharmaceutical manufacturer, by the time that they have communicated to Boğaziçi University that they have need for a specific skillset, one that our organization could

fill, our students are already employed." Setting aside the significant role that academia could play in facilitating the expansion of the Turkish manufacturer, a second concern is the regulatory framework governing these products, both internal and external to Turkey. Globally, those markets that have been most successful in producing biosimilars, such as South Korea, have been regions that have minimized capital requirements for the development of these products. Yet Turkey, in seeking to establish its own regulatory framework, has modeled its quality standards after the European market, which is not a leader. This has come with a high price tag for the development of biopharmaceuticals. Those who have invested in producing biosimilars have invested heavily, while those who have failed to meet these capital requirements have been unable to participate at all. This has occurred during a time when the global regulatory framework for these products remains ambiguous, complicating market access and the efforts of the domestic pharmaceutical manufacturer to capitalize off of their investments. Dr. Erhan Baş of Bilim Pharmaceuticals said: "The foreign market will play an important role in monetizing [investments made into the establishment of a biosimilar business], but these efforts have been challenged by the nascence of international regulations related to biosimilars. It is still unclear how equivalency for biosimilars can be established. This could check our ability to bring these products to market."

Should Turkey seek to establish itself as a regional production center for biopharmaceuticals – a goal that the government has made clear through its most recent policy initiatives – it is critical that private industry, the government, and academic institutions work collectively to forge partnerships for translative research – academic research that can then be developed by the pharmaceutical manufacturer upon maturation – and address how the domestic industry might better take advantage of the country's intellectual resources. Of equal importance, the Turkish government must also play a role in creating a framework that allows for Turkey to minimize the cost at which the pharmaceutical manufacturer can expand into these fields. •

Biotech Startups and Development in Turkey

Doğan Taşkent

Partner, Arkan & Ergin JPA International

President, MIT Enterprise Forum



Innovation and startups are the most recent economic fads in Turkey, as in most of the world. We jumped on the bandwagon later than the United States but are catching up. Our major success stories in startups have been from the Internet (gittigidiyor.com, yemeksepeti.com, markafoni.com, etc.). To the Western eye, the reasons for this success can be devoted to 'fast product development time', 'new generation services', 'fast growth rates', etc. However, this is Turkey, which is perched on the gate of the Orient. There are different market dynamics in this part of the world. Competition prefers, as the UN Secretary General Ban Ki-moon stated by his last visit to Turkey, 'know-who', instead of 'know-how'. This is a great hurdle for startups with merit-based ambitions. However, Internet platforms that enable startups to reach consumers directly, bypassing the middleman (the know-who guy), can democratize the business-to-consumer environment.

The environment for high-tech companies that mostly operate in the business-to-business domain looks tougher. For them to survive, they need a merit-based, market entry platform, which does not yet exist. They also need a knowledge cluster that supports their complex technology with the right lab technicians, test labs, certification labs, regulatory advisors, intellectual property (IP) advisors, financial support mechanisms, etc. When we look for such a cluster, we find three major industrial clusters: automotive in the Bursa region, defense in Ankara, and biotechnology in Izmir. Automotive and defense do not offer startups a fruitful environment, but Izmir with its biotech cluster and strong bridge to some major biotech institutions

in Istanbul gives great hope for Turkish biotech startups.

Few clusters are as dense as Izmir, which makes a difference in the test and certification infrastructure. There are the two major universities, Ege and Dokuz Eylül, each with approximately 60,000 students, focused on the health and life sciences industries. Each has complementary technoparks (ideEGE-Life-sciences Technopark, DEPARK- Health Technopark), hospitals, and labs. Those labs are: Pharmaceutical Sciences Research Center-FABAL; Biotechnology and Bioengineering Research and Application Center- BIOMER; Electronics and Materials Production and Application Center-EMUM, Drug Development and Pharmacokinetics Research and Application Center (ARGEFAR), which is the only accredited Phase I clinical trial environment in Turkey; and International Biomedicine and Genome Institute – IBG. It is critical that those labs also serve the industry. Under the Izmir Biotech Cluster initiative, they offer a biotech startup end-to-end product development as well as testing and certification. It is also critical that this cluster has many collaborative partners outside of Izmir, such as Inovita, ISEK, and Technopark Istanbul in Istanbul.

On the funding side, we also see development regarding high tech investments. TÜBİTAK, the Turkish NSF, supports with its various grants high-tech startups, but the size must be considered 'seed level'. There was a big gap to reach the venture capital (VC) funding. This year, three major funding initiatives should bridge that gap between initial fund and the VC level fund. The joint Technology Transfer Accelerator Turkey (TTA Turkey) fund with the support of the European Investment Fund (EIF) and TÜBİTAK went

life in march 2015 with the Diffusion Capital Partners, TTA Turkey 2 fund is under due diligence process and TÜBİTAK 1514 (deadline June 2015) that should help to establish another six high-tech, early stage-VCs that should focus on high tech (read no internet, mobile or gaming). The entry of professional investment groups will boost biotech startups.

Another stepping-stone is the development of university-industry-government collaboration to support biosimilars under the KAMAG (TÜBİTAK 1007) initiative. In this initiative the government offers grants to companies that develop biosimilars. Although the commercialization know-how resides in the industry, the drug development and testing knowledge resides in universities. This initiative has stimulated organic collaboration between the industry and universities and allowed many R&D-focused labs, with openings for MS and PhDs to work with industry on this research. Even some startups with novel techniques find places in these structures.

In parallel, Bogaziçi University, Ege University and Dokuz Eylül University are leading industrial PhD programs focused on biotech and pharmaceuticals and have opened lab technician education certificate programs. One of the strongest, Turkish Economic Thinktank – TEPAV – has a dedicated team developing strategies to accelerate life sciences, especially biotech industries. Nevertheless, there are entry barriers for biotech production development in Turkey:

- few API manufacturers remain in operation;
- higher cost of initial investment into production, analytical equipment and knowledge;
- no regulatory approval yet for locally produced biosimilars;
- low perception of importance for doctors; and
- difficulty of finding trained scientists for biosimilars production.

There are a handful of universities, early-stage VCs, NGOs and pioneers involved in this sector, but trust needs to be built in biotechnology and especially biosimilars. The groups must support and communicate with each other and with the international community to create the right ecosystem to develop products that can compete in the international arena. •

Dr. Rana Sanyal

LIFESCI



Please introduce us to the operations of LifeSci and, as an organization, your philosophy on research and development.

Center for Life Sciences and Technologies, LifeSci, is a center in Boğaziçi University established by funding from Ministry of Development. The Center aims to become an internationally recognized center of excellence with the ongoing support of both the Ministry of Development and Boğaziçi University. What distinguishes us from other infrastructures is the initial strategic plan we have developed with the participation of academic and industrial stake holders. We have given the highest importance to sustainability and quickly figured out that we can play a leading role in invention and technology only if we adopt inter-disciplinary cooperation and cultivate a corporate culture to interact and serve to the needs of the industry. The biomedical, biotechnology and pharmaceutical industries are the focus of our programs. The center brings over 65 scientists from 13 disciplines together, forming multi-disciplinary teams and three major infrastructures to cater the needs of academicians as well as the industry.

LifeSci has several facilities: Microsystem-based Medical Equipment Development Facility (Clean Room) is established to conduct research and produce clinical quality prototypes for microsystem based medical equipment that can be placed in human body.

The other facilities have attracted higher interest from pharmaceutical industry. Animal Research Facility (Vivarium) focusing on preclinical research, is licensed by Ministry of Food, Agriculture and Livestock and is in the process of receiving AAALAC accreditation for performing animal experiments. With this accreditation we are hoping to be able to cater national as well as international pharmaceutical companies, since we have well developed capabilities in pharmacokinetics, efficacy studies (such as tumor) and toxicity studies and our pricing is very competitive compared to Europe. As the interest of the Turkish pharmaceutical manufacturer has become more international, and more heavily focused on accessing foreign markets that require preclinical research data, such as the FDA, we have seen industry interest in our vivarium grow.

The third facility is called Test & Analysis Unit, where characterization, analysis and purification can be performed on small molecules as well as proteins such as biosimilars. Impurity analysis of pharmaceutical products is among the most popular services we offer to pharmaceutical companies. We now seek accreditation within Europe as the Turkish Accreditation Agency (TÜRKAK), which is charged with determining GLP compliance.

On what time frame did you see private sector interest in research and development turn in Turkey?

In 2010, LifeSci executed its first large-scale “pharma” project in conjunction with Nobel Pharmaceuticals. This was preceded by a number of smaller projects that we undertook, beginning in 2008.

This change in interest was driven by several factors. First, the Turkish universities had to develop better infrastructure. Beyond equipment, which, often, the Turkish pharmaceutical manufacturer is better disposed to invest in, this necessitated the development of human capital. Especially in areas such as biotechnology, Turkey is still poor in personnel. A second caveat was, of course, interest. This first

began as a result of product impurities that were found as the Turkish pharmaceutical manufacturer began to expand into foreign markets with more stringent quality standards.

What impact has Turkey’s political climate had on your ability to operate as a public institution that is subject to government funding?

As a government funded infrastructure, we are very excited about the new law related to research infrastructures that was published in July 2014. We as LifeSci, hope to become eligible to be one of the national research infrastructures. This will provide funding beyond our set-up phase (an equipment investment of over 20 million TL) and enable us to expand into areas such as animal imaging and be able to sustain our well-trained personnel.

How realistic is the Turkish pharmaceutical’s ambition to expand into the production of biosimilars?

Today there have been several businesses that have been successful in the development of biosimilar products. Unfortunately, the infrastructure to produce these products cannot accommodate the production of, say, 50 products: it is limited. If this is to be expanded, smaller research institutions must be involved.

How might the Turkish pharmaceutical manufacturer better capitalize on the country’s intellectual resources?

The Turkish manufacturer is near-sighted and does not anticipate how human resource might change over even next five years. One of the greatest problems that industry faces is the shortfall of qualified researchers, and this is in part a result of poor corporate planning both on the academia and the industry. Again, with the support of Ministry of Development, we have started a program in Boğaziçi University to satisfy the researcher needs of three industries: Pharmaceutical, Biotechnology and Biomedical. The program encompasses the determination of the thesis topic of the MS or PhD student in connection with the industry partner and the company’s excess to the LifeSci infrastructure. The student will be trained in industrially relevant projects and upon graduation will fulfill the needs of the related company. •

Prof. Dr. Cengizhan Öztürk

INOVITA

Could you please introduce us to both yourself and LifeSci, your organization?

I am a medical doctor and a biomedical engineer, with a research focus medical imaging. I spent fourteen years in the United States, first at Drexel and Johns Hopkins Universities, and later working as a researcher for the National Institute of Health. After returning to Turkey to work for Boğaziçi University, I became actively involved in the establishment of the life sciences infrastructure with a new interdisciplinary perspective, today known as BU-LifeSci. The university now has a modern life sciences center with three active modules for drug development: a clean room for in vivo device development; "smart drug" development laboratory; an animal testing center and several related laboratories. A government-funded initiative and collaboration with over 60 academicians from 11 different departments were essential to the center's establishment. Boğaziçi LifeSci was first conceptualized in 2008. Over the next six years, it was set up rather slowly, but today, there are few centers of its scale in Turkey. We seek to take our collective

strengths in academic research and transform this knowledge into translational research. We want to better connect with industry to help it to create products that are efficacious and marketable for Turkey's biomedical device and pharmaceutical industries. Coordinating and improving academic-university collaborations became my second full-time job after I left my post of founding directorship in 2013.

Stemming from our desire to better connect industry with academia, even during the early days in establishing LifeSci, we began to form Inovita platform, which today has become the leading driving force of our Istanbul Health Industry Cluster (ISEK) initiative. I try to coordinate now both the Inovita platform and the more ambitious regional cluster initiative. One of our most urgent goals is to establish several thematic incubators for early biotechnological product development. We try to put these in a supporting environment around research center infrastructures and started at Bogazici University. We coordinate with similar activities regionally, as a consortium of regional universities, which includes Istanbul, Medipol, Acibadem and Sabanci Universities. In addition, we are planning several advanced infrastructures to cultivate large-scale joint-research initiatives. Today, Inovita and ISEK work with over 90 firms, including several of Turkey's largest manufacturers. Our past work was predominately in medical devices, but pharmaceuticals are beginning to catch up.

What services does Inovita/ISEK provide to the domestic market?

Fundamentally, our purpose is to place promising early-level projects within our physical incubators and/or virtual network. Thereafter, our involvement is mostly general mentorship and guidance. It is critical that they operate autonomously for their long-term success. Several members are now undergoing due diligence for their first major round of financing, a significant accomplishment given our short history.

How is your work as Inovita/ISEK funded?

Inovita/ISEK seeks out grants from the

government agencies (e.g. Regional Development Agency, Ministry of Development Ministry of Science, Industry and Technology) to support itself. Actually, there is very little focused, coordinated, and long-term support given by the government for these activities, which is ironic, given that our role in development biotech-focused regional economic development falls within the purview of either the municipal, regional or national government.

In more mature markets, partnerships like those that Inovita/ISEK has sought to establish are more commonplace.

How might the Turkish manufacturer better leverage the intellectual resources of Turkey within their research and development (R&D) strategy?

The Turkish pharmaceutical manufacturer and academician both bear fault for the chaotic state of R&D within the country. Direct engagement between university, government, and domestic industry must be undertaken within a long-term strategy, if Turkey is really serious about creating a value-added industry. This begins with the university better understanding how to build intellectual property, undertake establishing the physical underpinnings of transformative research, and let industry utilize its advanced infrastructure. The Turkish manufacturer, in areas such as biopharmaceuticals, has invested substantially in the creation of products that are both risk-heavy and extremely expensive. The majority of these projects will fail, and at great personal cost, because their efforts are disconnected.

Looking as a relative outsider, there is an urgent need to proceed on two coordinated tracts: industry must work cohesively, sharing the cost of the development of the infrastructure required to build these new biotech products. Secondly, the government should play a more direct role as an economic coordinating body, and nothing else (no need for mega projects in health). Establishing offset agreements for certain types of pharmaceuticals is one much talked government mechanism that shows promise. The future of our domestic pharmaceutical industry will depend on how much it will learn to cooperate and collaborative. •

Prof. Dr. Burak Erman

Professor of Engineering, Department of Chemical and Biological Engineering
KOÇ UNIVERSITY



Can you tell us about Koc's organization and structure in the last year?

Last year, we were optimistic about attempting to collaborate with the Turkish pharmaceutical industry, but we have seen that our expectations are not realistic given the state of the Turkish market. The problem lies with two groups: those organizations that support the Turkish pharmaceutical industry and the foreign drug companies that conduct research in pharmaceuticals. Until the last year or two, the foreign companies, who are chiefly members of the Association of Research-Based Pharmaceutical Companies (AIFD) in Turkey, have not been interested in conducting pre-clinical research in Turkey because they have their own facilities and there is no established regimen in Turkey for preclinical research purposes. Recently, a general interest has taken hold, as Turkey is a regional hub due to its strategic location in relation to other countries that are pharma-oriented. AIFD's activities primarily support clinical research, therefore it provides money to doctors to travel and conduct these types of studies.

Pre-clinical research is designed for academia, as that is a field in which we can conduct in-depth research. Now, we have pre-clinical research actively being conducted at Koc University by excellent scientists, who have been educated in prestigious academic institutions, such as Harvard and Massachusetts Institute of Technology. We are currently being introduced to the pharmaceutical industry. We have signed an agreement with Astra Zeneca and Sanofi.

Overall, there is a lack of well-educated people for pre-clinical research. As a result, we developed a new master's program. To attract people from the industry, we offered this program comprising of coursework only, with no thesis. Our aim is to provide the added value for companies to educate their employees, by reducing the program from two years to one year. We are hoping for a strong response to this program.

Have you seen interest in research partnerships from Turkish pharmaceutical manufacturers?

I have not observed any interest in partnerships for research except from IEES, which expressed interest. We are looking forward to fruitful collaborations with them. We simply want to offer something of value that no one else is already offering to the market. The Turkish industry expressed some interest in bioequivalence, as there are six or seven products whose patents will expire shortly. This is a field where scientists will learn how to imitate, rather than invent, a new approach. The cost of producing a bioequivalent is 90 million Turkish liras, and one or two companies are investing in this with the support of foreign partnerships. At the end of the tenure of this project, these companies will likely come up with nothing of added value. Another avenue that researchers are exploring as a part of pre-clinical research is vaccinations.

How has your research on molecule development for inflammation advanced?

Our research is continuing, and we have established a new facility called the Koc University Drug Research Cen-

ter. We have a large group of members, mostly from the medical school. We enlarged the set of molecules that we are working on and are in collaboration with Istanbul University School of Pharmacy. Professor Karali there is conducting drug synthesis. Synthesis has been the most important bottleneck in pharma research in Turkey. The results of our research will be well received by foreign companies, who will be interested in our findings. There are intermediary steps involved in selling our drug to a foreign company, which we are currently in the process of working on.

What steps are necessary to take your research and turn it into a commercially viable drug that Turkish manufacturers can produce?

Once we finish our research, the drug will need clinical studies. I see no future within the Turkish pharmaceutical industry for our molecules. Investment from foreign partners can change this, in that the Turkish companies will be told where to direct their money. Our main aim has always been to be a liaison between the university and the private sector.

Will the mindset of local companies change in the next five years?

It is possible with bioequivalence that the local companies will start to produce. This, however, will not add to pharmaceutical science.

What will Koc University's Drug Research Center look like in five years?

The medical school researchers are doing well in drug research. We have several people who are trained in issues related to the pharmaceuticals industry. We hope that some day a Turkish company will partner with us for a pre-clinical product, but that is for the future. Our chief focus here is to publish in high-impact journals, in addition to conducting research on new drugs. •





Fighting Forces At Home and Abroad: Turkey's Supply Chain

"Pharmaceutical manufacturers now, more so than ever before, closely scrutinize their cost structure, especially their supply contracts. In the past year, many of our clients have begun to ask for price discounts. Their target price for both APIs and excipients have also become extremely volatile, changing in the course of a week by as much as 50%. This has made it difficult to secure long-standing relationships with suppliers."

- Pinar Cakir,
Division Manager,
Ekin Kimya

Hanging Tough

Supply Chain Dynamics

Though the effect of currency volatility has been the creation a competitive landscape pressurized by low levels of operating profitability for the Turkish pharmaceutical manufacturer, perhaps the greatest impact of the appreciation of the US dollar and the respective declines seen in the euro and the Turkish lira are to be found in the implications that these changes in foreign exchange rates have had on the supply chain dynamics of the Turkish pharmaceutical industry. With cost pressure for the Turkish pharmaceutical manufacturer has come cost pressure for those that supply to the Turkish pharmaceutical manufacturer, the result of which has been the reevaluation of supply contracts and the rise of certain regions – and a consequent decline of other regions – in their importance as a supply base to domestic industry. Collectively, and counterintuitively, the result of this has been the development of an industry of traders whose perceived value will be drawn from the way in which their value proposition, rather than the cost of their products, aligns with the goals of the Turkish pharmaceutical manufacturer.

Currency volatility has deeply impacted the cost of raw materials for the Turkish pharmaceutical manufacturer. In the past year, the greenback, the currency in which most active pharmaceutical ingredients (APIs) and excipients are denominated, has risen by as much as 35% against the Turkish lira. Though accompanied by fluctuations with the value of the Euro, this has been of little relief to the Turkish pharmaceutical manufacturer – or their suppliers – on account of the Turkish government's system of cross-price referencing.

Süha Taşpolatoğlu, CEO of Abdi Ibrahim,

Turkey's largest pharmaceutical manufacturer, said: "All pharmaceutical companies, both those that originate from Turkey and the multinational alike, have seen their profitability constrained in the past year by volatility exhibited by the Turkish lira and appreciation of the U.S. dollar. As Turkey, at present, is still import-dependent both in API and finished products, the cost of these grows sharply in conjunction with this event."

"This has hit at the greatest irony of our current business environment. Though Turkey employs a system of price-referencing that links the price at which the Turkish pharmaceutical companies can sell their products domestically and though the value of the Euro has depreciated sharply in the past years, having fallen by as much as 40 % from its historical high, since 2011, we have been left with market price for pharmaceuticals that does not bear this into account and, because of the Lira's decline, a thickened cost structure. This discrepancy between the cost/price at which we manufacture/purchase our products and the price at which we sell our products has struck the industry hard."

This has translated into closer evaluation of supply contracts. Pervin Ejder, general manager of Ejder Kimya, a raw materials supplier to the cosmetic and pharmaceuticals industry, said: "Ejder Kimya has seen these changes in the Turkish business environment reified in the demands of our customers: there is a desire for cheaper APIs and excipients, a demand for cheaper raw materials. Our customers have come to understand that there are trade-offs associated with using these products, visible in product quality. While we have not seen the Turkish pharmaceutical manufacturer

reduce their quality standards, there is a deep desire on the part of manufacturers to optimize their supply chain dynamics."

This has caused many manufacturers to play a more active role in raw material sourcing, the result of which has not necessarily been positive. Pinar Cakir, a division manager of Ekin Kimya, a leader in the provision of APIs and excipients to the domestic pharmaceutical industry that works closely with Indian raw material manufacturers in sourcing products, explained: "Pharmaceutical manufacturers now, more so than ever before, closely scrutinize their cost structure, especially their supply contracts. In the past year, many of our clients have begun to ask for price discounts. Their target prices for both APIs and excipients have also become extremely volatile, changing in the course of a week by as much as 50%. This has made it quite difficult to secure long-standing relationships with suppliers."

"Many of those that supply the raw materials that we work with, especially in India, lack an understanding of just how difficult the Turkish market is at present. Some have broken ties with Turkish pharmaceutical manufacturers completely because they are frustrated and lack the patience required to deal with the constraints present within the domestic market. They find the Turkish pharmaceutical manufacturer to be too price sensitive and, owing to the high price at which they can sell their materials elsewhere, dismiss Turkey as a market. These manufacturers would prefer to work with either Europe or the United States."

This has consequences for those regions with which the Turkish pharmaceutical

industry is most closely linked. Gamze Çıtıröğlü, general manager of Ekin Kimya, said: "One indirect consequence of the changing nature of the Indian API supplier's relationship with the Turkish pharmaceutical manufacturer has been that, while the Indian API supplier still maintains the largest portion of market share, this is decreasing. We are beginning to see Chinese API manufacturers play a greater role in supplying the Turkish market. This, of course, comes with its own set of concerns: the sustainability of these relationships are tenuous at best, and Chinese manufacturers often lack the quality standards of Indian manufacturers, especially for APIs."

Yet owing to the nature of Turkish pharmaceutical manufacturing, which at least historically has been highly focused on using in-licensing agreements for product development, the process by which contract renegotiations have occurred has been complex. Ali Arpacioğlu, president & CEO of Adeka Pharmaceuticals, said: "The optimization of our supply chain has been difficult to achieve, complicated by in-licensing agreements which bind from whom we can source our raw materials. This said, for those products which do not bear this constraint, we have more closely scrutinized our suppliers."

Regardless, the end result of this has been a movement on the part of Turkey's suppliers to compete on the basis of quality standards, and service rather than price. Pinar Cakir of Ekin Kimya said: "Our value as Ekin Kimya is derived from the depth of understanding that we have of our client's needs. Our expertise is in understanding how our products fit within the portfolio of the Turkish pharmaceutical manufacturer. While price

pressure has resulted in some manufacturers attempting to establish direct buying relations with some buyers, in most cases the outcome of this has been that ultimately our customer returns to working with us as they lack the requisite understanding of product standards."

This focus on quality has become especially important as the industry has moved into the production of higher-value products, such as super-generics and biopharmaceuticals. Serhat Uzum, sales manager at Analitik Kimya, a raw materials material to the domestic manufacturing industry that, established in 2008, has quickly become one of the industry's most important traders, explained: "Today, we strive to add value. As the Turkish pharmaceutical manufacturer has moved into value-added products, we have sought to introduce our clients to the technological advancements and niche products that we believe will play an important role in the future of the domestic industry. This has proven important in customer retention."

As the footprint of the Turkish pharmaceutical manufacturer broadens through investments made into research and development, the supply chain dynamics that support the development of the industry will play an important role in assisting the pharmaceutical manufacturer in enacting their strategic initiatives. While immediately this relationship has been challenged by currency volatility, which has tested these relationships, as a consequence, a better, more competitive business environment has emerged, driven by a base of raw material suppliers more committed to assisting the pharmaceutical manufacturer in product development. •



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MC



PC

MC: Business Development Manager

GC: General Manager

PC: Division Manager

EKIN KIMYA

Since we last met in 2014, the Turkish pharmaceutical manufacturing industry has been subject to constraints in profitability. Has this changed the way in which you source products?

Pinar Çakır (PC): Pharmaceutical manufacturers now, more so than ever before, closely scrutinize their cost structure, especially their supply contracts. In the past year, many of our clients have begun to ask for price discounts. Their target price for both APIs and excipients have also become extremely volatile, changing in the course of a week by as much as 50%. This has made it difficult to secure long-standing relationships with suppliers. Many of those that supply raw materials, especially in India, lack an understanding of how difficult the Turkish market is today. Some have broken ties with Turkish manufacturers because they lack the patience to deal with the constraints.

They find the Turkish manufacturer to be too price sensitive and would prefer to work with either Europe or the United States.

Murat Çitiroğlu (MÇ): This has given rise to the current prevailing global sentiment: the Turkish manufacturer expects European product quality with Chinese pricing, which is unrealistic.

Has their been a perceptible shift in the market share of different regions?

Gamze Çitiroğlu (GÇ): One indirect consequence of the changing nature of the Indian API supplier's relationship with the Turkish manufacturer has been that, while the Indian API supplier still maintains the largest portion of market share, that share is decreasing. Chinese API manufacturers are starting to play a greater role in supplying the Turkish market. But these relationships are tenuous at best, and Chinese manufacturers often lack the quality standards of Indian manufacturers, especially for APIs.

On a strategic level, how do you respond?

PC: Our value is derived from the depth of understanding that we have of our client's needs. Our expertise is in understanding how our products fit in the portfolio of the Turkish manufacturer. While price pressure has pushed some manufacturers to establish direct relations with some buyers, in most cases our customer returns to working with us, as they lack the requisite understanding of product standards. We employ individuals who are specialized in product sourcing from markets such as India. This advantage is particularly salient in cost optimization.

What, on a regulatory level, might block the Turkish pharmaceutical manufacturer from being able to expand their presence in research- and capital-intensive fields such as biosimilars?

MÇ: Though the required investment for biosimilars stands as high as \$150 million, we have seen an interest from the Turkish manufacturer to enter this area. We assist our clients by offering them samples of the macromolecules used to produce these products. This said, participation in research for these products is in part limited by Turkey's regulatory requirements, which emulate Europe's, and therefore are far more capital-intensive than those for other markets in which these products have been developed, such as South Korea. In Turkey, the product registration process for biosimilars alone requires a minimum of \$15 million. EU standards also come with a specific and stringent set of requirements for process controls and equipment. Given that as many as 60% of these ventures fail, these requirements, taken collectively, could be debilitating.

What might Ekin Kimya, and the Turkish pharmaceutical manufacturing sector, look like in five years?

MÇ: Ekin Kimya seeks to double its personnel and in the Turkish pharmaceutical manufacturing sector, but this will depend on the country's regulators. Turkey previously had a strong domestic manufacturing base, but many companies were acquired because of operational difficulties and regulatory handicaps. Today, large-scale domestic manufacturing is limited to five national companies; previously, there were as many as 20. •



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ANALITIK KIMYA



SU



MS

Founded in 2008, Analitik Kimya has made large strides to establishing itself within the Turkish market. How did this process occur?

Analitik Kimya was founded in 2008, with our chief intention to penetrate the pharmaceutical industry and other industries that we were already a part of, including agriculture, mining, textile, detergent, and cement. After we strengthened our connections in the pharmaceutical industry, we eventually became the leading supplier of the pharmacies.

What strategies did Analitik Kimya adopt to capture this market share?

One of the key factors is cultural: we continuously strive to create a culture wherein those that work for us are viewed as partners, rather than employees. This creates an environment where our employees are open to experimentation and innovation. They are comfortable bringing new ideas to the table. This also fosters closer relationships with our customers and inspires customer loyalty, most of whom have been with us since 2008.

How have your clients changed according to the shift in focus to value-added prod-

ucts from generics, as well as the change in cost structures as a result of reduced profitability?

The customers of Analitik Kimya seek a reputable name from whom they can source their products. This has become especially important as Turkey has sought EU membership: Turkish pharmaceutical manufacturers expect to be beholden to higher quality standards. We have sought to develop a strong global presence, attending many of the world's most important fairs and sourcing conferences. Today, we strive to add value. As the Turkish pharmaceutical manufacturer has moved into value-added products, we have introduced our clients to the technological advancements and niche products that will play an important role in the future of the domestic industry. This has proven important in customer retention.

Can you tell us about your network of suppliers or principals?

We are supplying laboratory chemicals (Merck Millipore, Sigma-Aldrich, Carlo Erba), excipients, laboratory consumables and equipment, reference standards (BP, USP, EP). We are the biggest supplier of Merck Millipore products in Turkey, supplying to almost all pharmaceutical companies in Turkey. We import from over 20 countries, including Germany, China, the United States of America, and India.

What portion of your sales is generated from foreign markets?

We are leading in the domestic market, so cannot grow much more. We are trying to gain market share from foreign suppliers, in countries such as Azerbaijan, Syria, Georgia and Uzbekistan. The expansion of our footprint has facilitated the expansion of the Turkish pharmaceutical manufacturer.

What is Analitik Kimya's competitive advantage?

Everything depends on price, and we receive competitive prices from our suppliers. Finding the right product at the right time is also crucial. Finally, understanding customers and their needs is a precursor to offering any type of solution to them.

What are Analitik Kimya's growth projects for 2015?

In 2014, we grew 40%. In 2015, we aim to grow 30% to 35%. •



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Pervin Ejder

General Manager
EJDER KIMYA



When we last met in 2014, the Turkish pharmaceutical was experiencing declining levels of profitability, a problem that continues to plague the industry. In what way has this altered supply chain dynamics?

Ejder Kimya has seen these changes in the Turkish business environment reified in the demands of our customers: there is a desire for cheaper APIs and excipients and a demand for cheaper raw materials. Our customers have come to understand that there are trade-offs associated with using these products that are visible in product quality. While we have not seen the Turkish pharmaceutical manufacturer reduce their quality standards, there is a deep desire on the part of manufacturers to optimize their supply chain dynamics. Price has become the primary concern. Their concern, first and foremost, is their ability to bring their products to market and product documentation.

A second consequence of the current business environment that Ejder Kimya has observed is seen in the payment issues that many of the industry's smaller players have faced. Several – though none of the larger manufacturers – have

had to exit the market, as there was simply insufficient margin to sustain the industry without consolidation.

Ejder Kimya operates in cosmetics in addition to pharmaceuticals. Of these two industries, which shows the stronger growth potential?

Unfortunately, the cosmetics industry has shown far stronger fundamentals than the Turkish pharmaceutical industry. Though the pharmaceutical industry will continue to play an important role in sustaining our business in the future, cosmetics, at least immediately, is a more attractive, and profitable market. This is perhaps due, in part, to the current state of Turkish pharmaceutical manufacturing.

In 2014, Ejder Kimya targeted growth of 30%. How, in seeking to accomplish this goal, did Ejder Kimya advance?

In 2014, Ejder Kimya grew by 27%. We have sought to grow our turnover through expanding our presence in the foreign market, focusing on the Middle East and North Africa. In particular, we have expanded through working closely with Iran, Lebanon and Algeria. We will soon enter Jordan through the establishment of our own office. Though this growth is disproportionately splayed towards the supply of raw materials for cosmetics, our expansion follows a general pattern in the Turkish pharmaceutical industry, where foreign market sales have increased by as much as 50%.

What strategic initiatives will Ejder Kimya execute in 2015 to continue its growth?

This trend towards internationalization has challenged Ejder Kimya. There are barriers that come with market entry that we must address. This will remain a key focus of Ejder Kimya in the coming year. In addition to the outward expansion of the Turkish pharmaceutical manufacturer, we have also seen emphasis placed on altering the portfolio strategy of many companies. Many manufacturers are now focused on the development of biotechnological products. In what way has this altered the product portfolio of Ejder Kimya.

Ejder Kimya has continued to work closely in the supply of excipients and

raw materials for generic pharmaceuticals to the Turkish pharmaceutical manufacturer. However, we have also moved to better accommodate the focus of these businesses on research and development (R&D). We now supply the raw material for biotechnological products, for example for growth media for biotech APIs production. We work closely with Kerry, who has more than ten, blockbuster biotechnological products on the market. On account of this relationship, we will be able to accommodate the growth of the Turkish pharmaceutical manufacturer into these more R&D-intensive products seamlessly.

Ejder Kimya recently completed a partial acquisition of the outstanding shares of the microbiological laboratory that it established in 2012. What led to this acquisition?

Originally this facility was intended for the food industry. Our partner did not want to compete with its current business in Greece, which is also focused on cosmetics, so we decided to start with food industry. But, we saw a great expansion in the cosmetics and pharmaceutical markets. As a result, we decided to have the business as Ejder Kimya alone and focused on our main markets of cosmetics and pharmaceuticals, which are also the markets with which we are most familiar.

Where might Ejder Kimya be five years from today?

Ejder Kimya sees strong growth in its pharmaceutical, laboratory and cosmetics businesses. We can, as an organization, transform into a multinational company involved in the provision of these services. As the Turkish pharmaceutical industry grows outside of its historical borders, we will grow in tandem. We foresee opening an office outside of Turkey, either in the Middle East or North Africa.

This said, the Turkish industry is volatile. Fifteen years ago we might have been able to plan for a five-year period, today, but business environments shift over the course of a period as short as quarters. Much could change in the near future, but we have medium- and long-term targets to achieve. We will progress on our own path. •

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Why exhibit at CPhI Istanbul 2016?

- 01** The Turkish pharmaceutical market is expected to reach USD 23.3 billion by 2023;
- 02** The Middle East and North Africa (MENA) region constitute 2% of global pharmaceutical sales;
- 03** The total end-user spending is projected at USD \$9.1 billion, which makes Turkish pharmaceutical sector rank 7th in Europe and 16th in the world.

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Into the Future: Future Outlook and Company Index

“There is an effort for a change in policy, and concrete solutions are required. Regulators have become more sensitive to our issues. Even the development of a strategy document signifies a supportive change in attitude. Pharmaceuticals are not just another cost to the public but could play a strategic role in correcting larger macroeconomic issues, such as the country’s current account deficit.”

- Philipp Haas, CEO,
DEVA Holding

Elvan Sevi Firat

Partner
FIRAT & IZGI



Can you provide a brief overview of Firat & Izgi's involvement in the pharmaceutical industry?

As an attorney, pharmaceuticals and the life sciences are my industries of focus. I work for multinational pharmaceutical companies, medical device companies, and cosmetic manufacturers that are well known and established in the industry. I am currently a litigator in addition to acting as a consultant to companies within these industries. I started out working on intellectual property related issues, as, upon establishing my practice, the Turkish pharmaceutical industry was undergoing a period of transformation as a result of the implementation of health reforms that had been being drafted since the late 1980s. The institutionalization of these policies led to a time of change. Stakeholders within the Turkish market began to come into conflict with evolving regulatory structures in areas such as product exclusivity and intellectual property limitations. This is a fairly globalized industry. My key duty was to consult to multinational companies so that they could fully realize the benefits associated with operating within the Turkish market.

Since this time, direct investment into Turkey has increased greatly. The pricing legislation of 2004 affected the Turkish market, along with the consolidation of the reimbursement agencies for social security under the SGK. This legislative reform was a busy time for lawyers, and I was involved in these matters being that our clientele consisted of multinational companies.

Since 2011, several dynamics in the Turkish pharmaceutical market have shifted. Consolidation has occurred, driven by the heavy investments required to fund the development of new products and maintain current levels of profitability. Mergers and acquisitions have followed. Currently, several Turkish companies come to us with the intent of investing in multinational companies in order to take their products to the European market or the CIS countries. Therefore, there is a demand for lawyers who have our understanding of the international market.

In what way have recent changes in the local business environment, in particular declining levels of domestic profitability, influenced the Turkish pharmaceutical manufacturer to move into foreign markets?

Many have now turned to product exports and the development over-the-counter (OTC) pharmaceutical products as part of their product portfolio as a mechanism for maintaining their levels of profitability. This is both a product of globalization and internal market regulation. Previously, the Turkish manufacturer was complacent with the profits realized from the country's domestic market. Greater levels of competition, especially from multinationals, have furthered domestic interest in expanding abroad, and we are now seeing unprecedented levels of interest in accessing international markets.

The Turkish pharmaceutical market has the capacity to export, and that they will have a strong international presence, especially those companies that invest in Africa, the Eastern countries, such as the CIS countries, the Middle East and the Far East. The quality of Turkish human capital is high and relatively cheap if compared against that of our regional counterparts in Europe.

Does Turkey have the proper incentive structure in place to allow for the industry to expand further into the development of value-added pharmaceuticals?

The incentive structure that Turkey has in place is a work in progress: though presently insufficient to properly cultivate research and development (R&D)-intensive pharmaceuticals, especially if compared to the frameworks of other regions that have already expanded into this field successfully, this will soon change. The government must improve on the country's incentive structure through addressing those pieces of domestic regulation that so restrict the pharmaceutical manufacturer, such as the government's system of price referencing and cost controls. Prior to the implementation of Turkey's "Healthcare Transformation Program," the industry was capable of independently expanding into the production of these products: internally, there was sufficient profitability to allow for this. Following the implementation of pricing controls, however, this changed. More is now required.

How would the regulatory system be different in five years?

In terms of regulations, I am not expecting major fundamental changes. The social security institution is working on a new reimbursement model and setting up a commission establishment. This will be a positive development for the pharmaceutical industry. Clinical trials may increase in Turkey, as investments in R&D are on the rise among both multinationals and local companies alike. Universities are investing heavily in R&D as well, and they will receive support from the Turkish government. From a political standpoint, the government is showing fatigue. The AKP has been the ruling party for over 10 years. I think that they are very aware that the public views them in this way and so, if they continue to hold power, I expect that they will attempt to add some dynamism to their regime. It is difficult to predict the future today, and it is dependent on the results of the upcoming elections. However, I do not expect a major change on a policy level in spite of the current business environment. •

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CPhI South East Asia, co-located with P-MEC South East Asia and InnoPack is the right platform, where you can meet ASEAN decision makers and business partners

- 01** In 2014 the Indonesia's pharma market was valued at \$6.5 billion, having enjoyed a 12.5% annual growth rate since 2007. The pharma market economy is set for further rises and is projected to maintain the 12.5% growth rate through to 2018; further investment from the Government, and domestic and foreign manufacturers is set to skyrocket development.¹
- 02** The potential of Indonesia's pharmaceutical market is boosted by government's aim to provide universal health coverage by 2018. Enacted in 2014, five-year scheme is expected to scale its plan to cover a forecasted population of 257.5 million by 2019 – 19% of healthcare expenditure will be attributed to pharmaceuticals; 92% of the drugs on "Essential Drug List".
- 03** Explosion of growth in prescription generics over the next 3-5 years as government takes on the financial burden of drug sourcing from the private sector.
- 04** Foreign investment and partnerships predicted; the potential of standardised regulatory requirements could transition Indonesia from largely domestic sales to a regional exporter of drugs.
- 05** Indonesia's domestic companies hold the majority of the market share, 70% – multinationals hold just 30% – Maximum allowed foreign ownership of a company in Indonesia is 75%, with Indonesian partners controlling the remaining stake.

¹ Source: Research conducted by CPhI in partnership with GBR



“In 2014, Nobel Pharmaceuticals entered Russia and Romania. Though Nobel currently operates in over 20 markets outside of Turkey, Russia will play an important role in driving the future of the company’s export-led growth. Last year, Nobel generated \$60 million in export business, an increase of 10% from 2013. We target to grow both of these figures by 20% over 2015, much of which we will be able to derive through the company’s entrance into the Russian market.”

- Numan Balki, Member, Executive Board, and Gökhan Köse,
Business Development Manager,
Nobel Pharmaceuticals

“Until now, Centurion’s actions have been for plasma products. In the future, injectables, orphan drugs, and biosimilars will be exported. Due to the limited supply of raw materials for plasma products, Centurion has developed its exports to countries within its strategic growth fields, including the Balkans and several Western European nations, such as Poland. For these markets, the product registration process continues, distribution agreements are being finalized, and IP studies are ongoing. We have also started to approach India and the GCC, including South Arabia and Yemen.”

- Ersin Erfa, General Manager,
Centurion

“IMS Consulting expects a second transition within the Turkish pharmaceutical market. As a market, Turkey will not continue to grow through larger sales volumes: growth by volume will, comparatively, be far less than what we have seen over the course of the past five years. In place, higher value pharmaceutical markets will drive industry expansion. It is for these reasons that IMS Consulting is bullish on the future of the Turkish pharmaceutical industry.”

- Cem Baydar, Senior Principal, Head of Turkey and the Middle East,
IMS Consulting

“World Medicine is currently heavily focused on completing the market authorization process, the essential part of our product launching within emerging pharmaceutical markets in Southeast Asia, as well as to East African markets. In fact, we have already begun to export to these two regions; however, we now seek to expand our product offering in them. The markets of Southeast Asia and Africa show great promise for their underlying potential. In the future, they will become quite economically profitable.”

- Rovshan Tagiyev, Founder & Chairman,
World Medicine

“The products manufactured at our site are exported to more than 30 countries now, summing up to 10% of our production volume. Hopefully, this figure will double in the near future.”

- Fatma Taman, General Manager,
PharmaVision



“The medical school researchers are doing well in drug research. We have several people who are trained in issues related to the pharmaceuticals industry. We hope that some day a Turkish company will partner with us for a pre-clinical product, but that is for the future.

Our chief focus here is to publish in high-impact journals, in addition to conducting research on new drugs.”

- Burak Erman, Professor of Engineering,
Department of Chemical and Biological Engineering,
Koc University

“Adeka believes that, in line with the strategic development plan that has been released by the Turkish government, we will see the Turkish pharmaceutical industry to be defined by a push for localized production. This has induced our investment in our new manufacturing plant, as it has the investments of many others. As a result, we expect to see a rise in partnerships between multinationals and domestic manufacturers in accessing the domestic market, a dynamic that we hope will help profitability.”

- Ali Arpacioğlu, President & CEO,
Adeka

“As the Turkish pharmaceutical manufacturer has moved into value-added products, we have introduced our clients to the technological advancements and niche products that will play an important role in the future of the domestic industry. This has proven important in customer retention.”

- Serhat Uzum, CEO, and Murat Saral, CFO,
Analitik Kimya

“From a political standpoint, the government is showing fatigue. The AKP has been the ruling party for over 10 years. I think that they are very aware that the public views them in this way and so, if they continue to hold power, I expect that they will attempt to add some dynamism to their regime. It is difficult to predict the future today, and it is dependent on the results of the upcoming elections. However, I do not expect a major change on a policy level in spite of the current business environment.”

- Elvan Sevi Firat, Partner,
Firat & Izgi

“Public authorities are aware of the value that this industry can bring to the economy and therefore have placed special emphasis to our industry within their incentive schemes of all sorts. However, existing pricing policies are totally in contrast with such supportive industrial programs, so our biggest challenge in the next five years is to align government policies from its current contradictory state.”

- Turgut Tokgöz, Secretary General,
Pharmaceutical Manufacturers Association of Turkey (IEIS)



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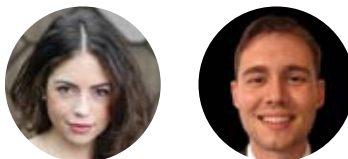
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Image: Adeka



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Additional copies of this book can be ordered through Elif Ozturk (elif@gbreports.com).

THANK YOU

We would also like to sincerely thank all the governmental bodies and associations that took time to share their insights into the market as well as their experience and knowledge.

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