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2014
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# SUPPLYING CHEMICALS FOR A **HEALTHY BUSINESS**

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# Dear readers,

Over the past few months we have had the pleasure to research and meet with an industry that has the potential to become one of the driving forces of the Turkish economy. Europe's sixth largest pharmaceuticals market, Turkey has seen its access to healthcare expand considerably in the last decade. Estimated to reach a value of $36 billion by 2023, Turkey's pharmaceuticals industry shows an enormous growth potential.

The private sector is the engine to this growth. We have met with manufacturing companies investing heavily in the development of the country's technological infrastructure, expanding production capacity and fortifying research and development. The Turkish pharmaceutical manufacturer is adding value to the products, entering a second generation of generics, moving into super generics, biosimilars, and some companies even looking at biotechnology as a viable segment for Turkey to develop in the future.

Turkey has also emerged as a strategic location for contract manufacturing, both due to its strategic geo-political location and for its reputation for quality. Forging international partnerships is therefore essential for the industry to thrive internationally. The competitiveness of Turkish pharmaceuticals in near markets must be improved and exporters should seek government's support to balance the industry's trade deficit.

We would like to thank the Ministry of Health, The Republic of Turkey Prime Ministry Investment Support and Promotion Agency, and IEIS, the Turkish Pharmaceutical Manufacturers' Association, for their help in the research of this project.

We warmly thank our partners UBM and CPhI Istanbul for their support.

And finally, we sincerely thank all the professors, managers and lawyers who took the time to give their insights on the market and share their experience and knowledge.

Regards,

**Clotilde Bonetto Gandolfi**
Project Director

**JP Stevenson**
Journalist


IEIS
PHARMACEUTICAL MANUFACTURERS
ASSOCIATION OF TURKEY
50th YEAR

www.ieis.org.tr

Turkish
Pharmaceutical
Exporters

www.trpharmaexporters.org

# Distinguished executives and representatives of the pharmaceutical industry,

I would like to express my great pleasure in coming together with you through this report prepared by Global Business Reports with the support of the Pharmaceutical Manufacturers Association of Turkey (IEIS). This report provides an excellent opportunity for those executives reading this publication to better understand the considerable accomplishments that have been realized within Turkey's healthcare sector and on the part of the country's pharmaceutical manufacturers.

Significant headway has been made in recent years towards the improvement of human health in Turkey. Turkey has benefited heavily through the introduction and development of new health technologies; drug and medical devices; technical talent capable of supporting a globally competitive industry; and internal healthcare facilities that have played an important role in expanding medical access. These factors have considerably aided the Ministry of Health in ensuring the effective provision of healthcare services within the framework and control functions that our administrative body has established.

Today, the entirity of Turkey's population has been brought under the umbrella of our country's social security system. The satisfaction of our citizenry with our healtchare system has risen dramatically. Our attention has thus now turned to ensuring the sustainability of these reforms and mending extant deficiencies without sacrificing the high quality of medical care that we have so arduously fought to achieve.

An ideal healthcare system must be of high quality, accessible and sustainable. In the last ten years, with the introduction of Turkey's Health Transformation Program, we have succeeded in all three of these criteria to a considerable extent. In the forthcoming period, our work will turn to fighting obesity and chronic diseases. In addition, our work concerning the development of healthcare service and family medical systems will continue, as will our efforts to guarantee the realization of the goals envisaged in "Vision 2023," our country's strategy goals for the Republic of Turkey's centennial.

This process will necessitate great collaboration: collaboration between Turkey and the numerous countries with which we have enacted agreements in the field of public health; and collaboration between the country's health sector and our intellectual resources, our scientific organizations, to better support the commercial initiatives in place by the private sector.

In this period, our ability to ensure the sustainability of our successes will be determined by our determination, our stability, and our collective wisdom. Distinguished representatives in the field of healthcare and members of our pharmaceutical industry, you will be our most important supporters in accomplishing this.

Turkey has long boasted a robust pharmaceutical industry, one which is of great strategic importance to the country though its contributions to the economy in development of value-added industry and the important role that it plays in public health. Turkey has a well-established and dynamic pharmaceutical industry. Our attention now turns to growing it.

Though Turkey's share in the global pharmaceutical export has risen rapidly, more can be done. Turkish pharmaceutical manufacturers have the ability to serve our near geographic markets, a population of over one billion. In fact, our pharmaceutical industry is capable of serving the world. It is within this scope that we seek to develop domestic industry further, so that we one day might realize this ambitious goal.

A critical piece of this will be our efforts to build an industry dedicated to research and development, especially within biotechnology. We strongly believe that we have the requisite strength to become an important player in the production and supply of biotechnological products and devices.

I wholeheartedly believe that this report will play an important role in supporting the further development of our pharmaceutical industry and I would like to take this opportunity to thank all of you who have contributed to this effort.

His Excellency Dr. Mehmet Müezzinoğlu
**Minister of Health of**
**the Republic of Turkey**

## THE HEALTHY ECONOMY

*Turkey and its Pharmaceutical Industry*



## BREAKING WITH PRECEDENT

*Government Strategies and the Regulatory Environment*



## PRODUCING GROWTH

*Pharmaceutical Manufacturing in Turkey*



## INNOVATIVE SOLUTIONS

*Research and Development and Export-Led Growth*



## TRAVERSING CONTINENTS

*Supply Chain Dynamics within Turkish Pharmaceutical Manufacturing*



## INTO THE FUTURE

*Final Thoughts, Index and Credits*




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## Industry Interviews

Exclusive interviews with leading government and industry figures, including the Pharmaceutical Manufacturers Association of Turkey (IEIS), Abdi Ibrahim and Bilim Pharmaceuticals.



## Expert Opinions

A number of companies and universities contribute their expertise on subjects ranging from the regulatory environment for research, university collaborations and patents.



## Regulations

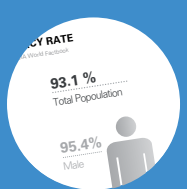
An in-depth look at the regulatory environment governing the Turkish pharmaceutical sector and a forecast of potential changes as the government puts forward grand ambitions.



## Quantitative Data

The most relevant quantitative data presented in the most easily accessible format, allowing you to view economic and market statistics, identify trends and visualise infrastructure.






## Final Thoughts

Industry leaders give their opinions on the future facing Turkey's pharmaceutical industry and its companies: trends, challenges, opportunities. and what they need to do to thrive.




CYSTAR Hütt
The Process & Packaging Group
HDGC-100

# The Healthy Economy: Turkey and its Pharmaceutical Industry

"An ideal healthcare system must be of high quality, accessible and sustainable. In the last ten years, with the introduction of Turkey's Health Transformation Program, we have succeeded in all three of these criteria to a considerable extent. In the forthcoming period, our work will turn to fighting obesity and chronic diseases. In addition, our work concerning the development of healthcare service and family medical systems will continue, as will our efforts to guarantee the realization of the goals envisaged in "Vision 2023," our country's strategy goals for the Republic of Turkey's centennial.

This process will necessitate great collaboration: collaboration between Turkey and the numerous countries with which we have enacted agreements in the field of public health; and collaboration between the country's health sector and our intellectual resources, our scientific organizations, to better support the commercial initiatives in place by the private sector."

- Dr. Mehmet Müezzinoğlu, Minister of Health of the Republic of Turkey

Image: Ilko
The latest, most state-of-the-art technology is used in Ilko manufacturing facility, where the highest care is given to production.

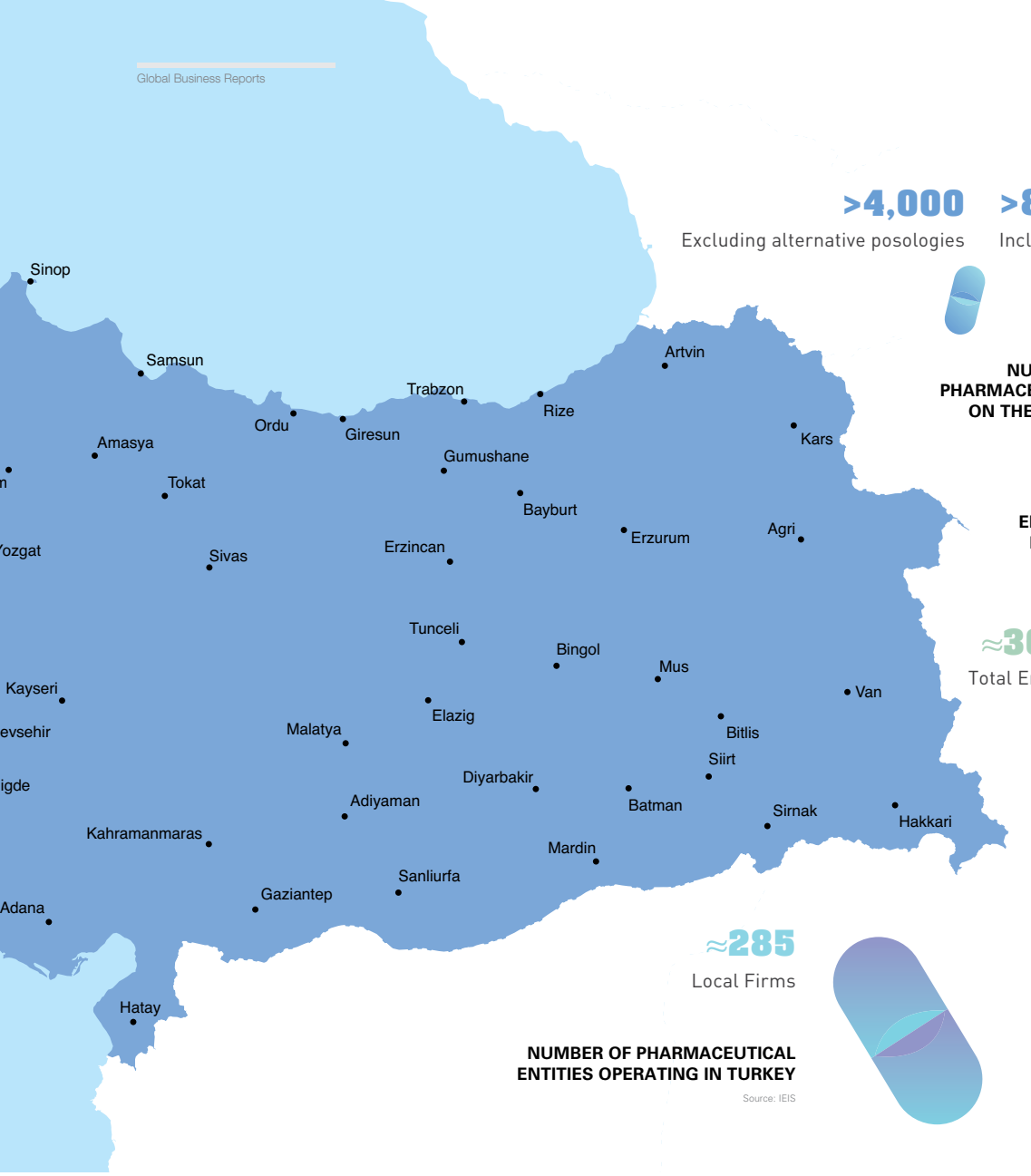
# A Forward to CPhI Istanbul 2014

The Fall and Rise of the Turkish Pharmaceutical Manufacturer


Disconnected from modern medicine and society alike, the traditional practice of pharmacology within Turkey stands among the oldest medical systems in the world. Predating the birth of Islam and the rise of the Ottoman Empire, Turkic folk medicine pervaded throughout Anatolia and Central Eurasia from time immemorial: a system distinct from the medical practices of neighboring regions, such as China or the West. The focus of pharmacology within Turkey then was a practice relatively isolated from the outside world, but strongly entwined within the fabric of local society. Today, its passing, which began upon the acceptance of Western medical concepts into Islam in the 11th century, has gone relatively unnoticed: unobserved by academic or government institutions that might otherwise commemorate its demise and place in early Turkish society. No Museum of Traditional Turkic Medicine exists within Istanbul today. Unfortunately, until recently, the state of Turkey's pharmaceutical manufacturers shared several parallels with its predecessor. With a strong inward-orientation, Turkey's pharmaceutical manufacturing sector has, unnoticed by government and society, developed an important place in within the country's economy.

This is now changing. In what later may be viewed as a point of inflection for Turkey's pharmaceuticals industry, CPhI Worldwide, the world's largest pharmaceutical sourcing conference, has chosen to host one of its first conferences within the country. This event follows a wave of multinationals, ranging from Sanofi to IMS Health, which have chosen to relocate their regional headquarters to Turkey. Driven by a number of variables, fresh interest in the market among them, some estimate that the Turkey's internal healthcare market could reach $80 billion by 2023: a value complimented by the business that could be generated through using Turkey to access external markets.

The potential of Turkey's pharmaceutical industry has long been understood by industry participants. With many of the industry's oldest players dating to the 1920s, Turkish pharmaceuticals, at least historically, has been an industry characterized by a strong national




**>4,000**
Excluding alternative posologies

**>8,000**
Including alternative posologies

**NUMBER OF PHARMACEUTICALS ON THE MARKET**
Source: IEIS

**EMPLOYMENT IN THE TURKISH PHARMACEUTICAL INDUSTRY**

**≈30,000**
Total Employment

**≈50%**
o/w university educated

**≈285**
Local Firms

**NUMBER OF PHARMACEUTICAL ENTITIES OPERATING IN TURKEY**
Source: IEIS

**75**
Foreign Firms

presence. Stemming from Turkey's production culture and tradition of family-run businesses, many of Turkey's largest pharmaceutical manufacturers are now in their third or fourth generation of existence.

More than any other factor, the prosperity of these businesses is attributable to the maturation of the Turkish healthcare market. As Turkey's income levels have grown, 75 million people have come into wealth: spending, at times more than necessary, on medical products. Through the unification of the public under one social security system, the SGK, and increased medical coverage through expanded access to hospitals and primary care facilities, the Turkish healthcare industry has been in a boom rare as of late.

The success of the public sector and private industry in developing this market, however, has not come without a cost. Use of certain prescription medications, such as antibiotics, far surpasses international averages. Rational drug use campaigns are now run annually. More problematic than this though has been the way in which Turkey's demand for pharmaceutical products has hurt the country's vital signs: the public budget and trade balance.

By 2023, the Boston Consulting Group predicts that public sector spending on pharmaceuticals will amount to 41% of the country's total pharmaceutical budget if the current budget formulation methodology is kept intact. The public budget, at present, covers 95% of the population's medical expenses.

**VALUE OF TURKISH PHARMACEUTICAL EXPORTS (US$)**

Source: Ministry of Economy

2013
**$817,745,000**

2012
**$720,090,000**

2011
**620,383,000**

2010
**611,956,000**

Beyond this, although pharmaceutical imports account for only 50% of the country's current medical usage by value, should the market continue to grow in line with the expectations of some, reaching $80 billion in 2023, the value of these imports could weigh heavily on Turkey's trade balance. In 2013, the country posted a current account deficit of $65 billion.

The state of the Turkish pharmaceuticals industry today is a reflection both on the waning power of the Turkish pharmaceutical manufacturer in internal markets as well as their inability to leverage their domestic strength into foreign markets.

In the past decade, Turkey has seen the profile of its pharmaceuticals manufacturing industry change markedly, triggered by the entrance of the multinational corporation. Several of the industry's largest players have sold their assets, perhaps none more representative than that of Eczacıbaşı. Founded in 1942 by Dr. Nejat F. Eczacıbaşı, who both in name and through his company became the forefather of Turkish pharmaceuticals – Eczacıbaşı means head pharmacist in Turkish – Eczacıbaşı, the country's third largest generics manufacturer, sold their assets to Zentiva in 2007. Alongside the sale of Eczacıbaşı's generics business was the acquisition of DEVA Holding, which, in 2006, was majority acquired by Swiss GEM Global Equities Management. The company has since become the industry's fourth largest producer of pharmaceuticals by unit production.

More than anything else, the fall of the Turkish pharmaceutical manufacturer has been caused by government apathy to the industry. More specifically: the Government of Turkey's pursuit of price-cutting in limiting the cost of pharmaceuticals on the public budget has shackled the profitability of Turkish pharmaceutical manufacturing.

An adaptation of a healthcare system that is commonplace in Central Europe – part of Turkey's struggle to align itself with European markets – the Turkish government has enforced a system of cost reimbursement wherein the price paid for pharmaceuticals domestically is linked to the price at which drugs are produced ex-factory within the region. Though not in itself damning – Central Europe has developed a prosperous pharmaceuticals industry – the Turkish government's system of price referencing has proven problematic in that the government has restricted the convertibility of the euro to the lira, discounting the price of pharmaceuticals by over a third. For Turkish consumers, this has meant the absence of Turkish medical products from Turkish shelves. For the Turkish pharmaceutical manufacturer, the consequences have been more dire. On one level, it has resulted in a slanted cost-structure: the cost of imported APIs and excipients are now far higher than previously and their final price suppressed. Beyond this though, Turkey's adaptation of Europe's price referencing system has prevented Turkish pharmaceutical manufacturers from being able to claim an edge in the global pharmaceuticals market.

Turgut Tokgöz, secretary general of the Pharmaceutical Manufacturing Association of Turkey (IEIS) explains "Turkish prices are well below their European counterparts and that puts enormous pressure on profitability. We need those profits to be able to reinvest in infrastructure as well as in R&D, to be able to produce value-added products for the global market, otherwise we will struggle to claim a competitive edge."

Though Turkish pharmaceutical manufacturers might find respite in external markets – Turkey's attraction, both today and historically, is rooted in its role as a nexus – the country's pharmaceutical manufacturers have struggled to access these markets.

Having first introduced Good Manufacturing Practices (GMP) in 1984, Turkey has established a reputation for the quality of its products: superior to those produced in Asia, yet below the price of their European counterparts. The inability of Turkish pharmaceutical manufacturers to access foreign markets has not been for lack of demand. Tokgöz explains that: "we have received many requests from African nations alongside complaints about product quality from other countries. Consumers are approaching the Turkish producers in search of better quality."

The larger hurtle that Turkey's pharmaceutical manufacturers have struggled to vault is found in market authorization. Turkish pharmaceutical products have been slow to receive clearance to enter into several markets of importance, namely the United States and Europe, because of the length of the production registration and inspection process of each region. The development of mutual-recognition trade agreements and, in particular, Turkey agreeing to the Pharmaceutical Inspection Convention, an informal free-trade agreement which seeks to increase collaboration between its 35 signatories through establishing confidence in the quality of traded goods, would remove these barriers.

Although these problems continue to challenge Turkish pharmaceutical manufacturers, since the private sector first identified these obstacles in 2011, significant headway has been made in lobbying for more active support for Turkey's pharmaceuticals industry. Recently, the Government of Turkey identified the pharmaceutical industry as one of the country's five most important industries for the Turkish economy, issuing with it a suite of incentives for those that wish to enter into Turkish manufacturing. Regulators are now drafting a strategy document which will outline the planned course of the industry's development: a first for the country. IEIS has played an important role in crafting a strategic vision for the place of Turkey in the global pharmaceuticals market. For this vision, the industry targets $17 billion in Turkish pharmaceutical exports by 2023, the Republic's centennial.

The attention that Turkey's pharmaceutical industry has garnered, as evidenced through the arrival of CPhI Worldwide in Istanbul and the number of multinational companies that have chosen to establish their regional management centers in Turkey is significant in that it heralds in the role that Turkey's pharmaceutical industry could play in the development of value-added industry for the country and in shifting the position of Turkey's pharmaceutical industry globally. This – more than anything else – should be a matter of public interest. •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# Saim Kerman

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

**Could you please provide us with an overview of your mandated responsibilities as an organization?**

Our organization was officially established to take over the duties of the General Directorate for Pharmaceuticals and Pharmacy, which we did as of 19 March 2012, in accordance with Article 27 of the Decree-Law No. 663 on the "Organization and Duties of the Ministry of Health and its Affiliated Institutions" that entered into force on 2 November 2011. In this sense, we are a new institution in name, even if the role that we play is not new. Our basic mission is to serve human health through the development and application of regulatory policies intended for the pharmaceutical, medical device and cosmetic industries.

**The Turkish Government has named the Turkish pharmaceutical industry as one of its five key industries for economic development. What will this mean for the industry with regard to strategic initiatives executed by the central government for its further development and for the agency's role within the industry?**

To the realization of this objective, the Ministry of Economy, supported by our Ministry of Health, has developed an incentive scheme with the intention of increasing investments made into medical production. This will narrow Turkey's trade deficit. Pursuant to this, the Ministry of Health seeks to develop what will act as health zones, dedicated to the production of medical products and the provision of medical services. In this way, we aim to improve pharmaceutical production in Turkey, which requires advanced technology as well as incentives for domestic manufacturers.

The investments made in the fields of biotechnological medicines, oncology products, and blood products have been evaluated by the Ministry of Economy and named 'first priority areas of investment.' Both domestic and foreign investors will be able to benefit from investment support into these fields. In this context, there are some incentives such as tax reductions or exemptions, allocation of investment location, employer support for insurance premiums, and interest support that will be extended to investors in these fields.

As can be seen, our country, with all its institutions and organizations, shows great determination to increase its capacity for innovation and become a powerful country that has a voice in the field of value-added pharmaceutical products.

**Turkish pharmaceutical manufacturers have struggled to gain access to foreign markets: in particular, the United State and Europe. One specific obstacle has been Turkey's stance on international trade treaties, such as the Pharmaceutical International Convention (PIC/S). Turkey has since, in May 2013, applied for PIC/S Membership status. What further support will the Turkish government extend to Turkish pharmaceutical manufacturers for the development of export markets?**

The required legal and administrative arrangements should be of a supportive nature to the industry in order to enable the Turkish pharmaceutical industry to become a center for research and development, production

and management within the region. In this context, the provision of incentives in priority areas that have higher export potential is of great importance for the industry to reach its future targets. Development of the production of medicines having high export potential, that require advanced technology, and the development of incentive policies for domestic manufacturers by both our Ministry of Health and the Ministry of Economy would enhance the effectiveness of the Turkish medicine manufactures in foreign markets.

Today, Turkey's pharmaceutical industry stands compliant with the requirements of the European Union. The study of harmonization with EU legislation started before the establishment of the Customs Union between Turkey and EU, and gained speed in recent years upon the establishment of the Customs Union and then the commencement of negotiations with the EU in 2005. Turkey's transition from candidate-country to accession-country status within the EU also helped with this transition. In this context, we are continuously revising legislation and making new arrangements in such a way so as to enable medicine and health services to reach international standards.

Providing skilled manpower for the pharmaceutical industry is an important issue. The provision of specialist personnel from the industry can be ensured by making arrangements in the curriculums of undergraduate and graduate programs of the relevant departments that bear in mind the needs of Turkey's pharmaceutical manufacturers. This can be accompanied with legal arrangements and the provision of incentives for the prevention of brain drain. Our country must retain its intellectual capital.

This touches on a larger issue that must be addressed: university-industry collaboration. The concept of "partnership" could be the greatest driver of growth for domestic industry. Financial power, knowledge and experience can come together through public-university-industry partnerships. These partnerships can play an important role in establishing a place for our industry in foreign markets. Within the scope of this objective, the Ministry of Science, Industry and Technology expects that further research and development support and the development of Technology Development Zones will facilitate the establishment of these partnerships and the agglomeration of domestic industry.

**The Turkish government is known internationally for the quality of the healthcare that it provides to its citizens. This, however, has come on with a trade-off: systemic price cuts in the form of a freeze on the convertibility of the euro-lira within Turkey's reference pricing system. This system has had widespread ramifications, both inside of Turkey and in foreign markets. Will we see this system rethought?**

Foreign exchange regulations on pricing and reimbursement policies are under the coordination and management of the Economic Coordination Committee composed with the participation of the Ministry of Finance, Ministry of Labor (and through it, the Social Security Institution), Ministry of Development, Ministry of Health, and Secretariat of Treasury. Decisions on amendments to the way in which the euro is converted into the lira are undertaken by this committee.

There are nuances to this policy. As stated in the "Communication On The Pricing Of Medicinal Products For Human Use" dated 14 April 2012, retail prices of important and critical medicines can be increased by 15%. Besides this, blood products (containing human albumin and immunoglobulin) are priced on the basis of the current exchange rate, for the continuity of their availability. We have begun to publish drug reference prices, containing only the product name, the license holder and the actual reference (in the euro). In this way, we aim to prevent underpricing of pharmaceutical products in the countries that take Turkish pharmaceuticals as a reference, either directly or indirectly.

Within the scope of the Tenth Development Plan prepared in line within our country's 2023 targets that covers the period 2014-2018, studies will also be carried out to assess the viability of restructuring the government's reimbursement and pricing policies by considering its impact on Turkey's pharmaceutical manufacturers.

**Do you have a final message for the executives that will be reading this publication?**

We believe that our country will be one of the key players in the global pharmaceutical industry in the following years, by means of the policies we apply, our strong economic infrastructure, valuable scientists, qualified and skilled labor force and demographic features.

On behalf of the Ministry, we will continue to strive for change within the industry. Pharmaceuticals manufacturing is of great strategic importance to the development of our country. Through it, we hope to increase our country's medical production and export capacity so that Turkey might become an important country for the development of new molecules and the production of high value-added medicine. •

# M. İlker Aycı

President

**THE INVESTMENT SUPPORT AND PROMOTION AGENCY, THE REPUBLIC OF TURKEY PRIME MINISTRY (ISPAT)**

**Could you please provide us with an overview of the mandated responsibilities of ISPAT as established through the "The Law for the Incorporation of the Investment Support and Promotion Agency of Turkey"?**

In order to provide foreign investors with better services, in 2006, Turkey established the Investment Support and Promotion Agency of Turkey (ISPAT), which is directly attached to the Prime Minister.

ISPAT provides investors with assistance before, during and after their entry into Turkey. It serves as a reference point for international investors and as a point of contact for all institutions engaged in promoting and attracting investments at national, regional and local levels. It works on a fully confidential basis and combines the private sector approach with the backing of all governmental bodies. ISPAT's free-of-charge services include, but are not limited to, providing market information and analyses, industry overviews and comprehensive sector reports, site selection, coordination with the relevant governmental institutions, facilitating legal procedures and applications, such as establishing business operations, incentive applications, obtaining licenses and work/residence permits.

As a part of free-of-charge services of ISPAT, investors can easily find 15 sector reports on our website. Parallel to the variety of sectors and industries that ISPAT supports and studies on, professionally prepared sector reports are available for many sectors such as pharmaceuticals, machinery, energy, mining, ICT and tourism. These reports present a general outlook and analysis for the sector as well as up-to-date investment opportunities.

In brief, according to the law, there are three main responsibilities of ISPAT: promoting Turkey's investment environment abroad, facilitating and supporting investments in Turkey and preparing national investment support and promotion strategy of Turkey.

**As the main point of reference between Turkish industries and global investors, which regions in particular have taken a strong interest in investing within Turkish industry? Could you please provide a geographical breakdown of FDI in 2013 and 1Q 2014?**

Turkey attracted USD 12.9 billion of FDI in 2013. At the country level, Germany was the largest investor in Turkey in 2013, followed by the Netherlands, Russia, Azerbaijan and Austria. When we take a glance at 2014 first quarter figures, we see that Turkey attracted approximately USD 4.2 billion of FDI in January – March period, a 50% increase year-on-year.

Another positive indicator were increased greenfield investments, which are seen as offering greater added value and are therefore more highly desired. For greenfield investments, Turkey is among the top 20 FDI recipient countries with USD 9.5 billion worth of projects announced last year. Turkey enjoyed an 8% increase in greenfield investments in 2013, making Turkey the 19th most attractive investment destination for greenfield investments. With its favorable investment environment, Turkey continues to be a safe harbor for international investors in the region and the rise on greenfield investments is a good indicator of the investors' high confidence in the Turkish economy's future. We expect for strong levels of investments into this field to continue into the future.

**Could you please provide us with an overview of the major public works projects that are currently being executed that will make Turkey a more attractive destination for investment capital in line with the country's strategic "2023 Vision"?**

Infrastructure must be improved for any country that aims to have more international investors. In order to reinforce its infrastructure and make Turkey one of the most attractive destinations for investors globally, we have made huge investments in infrastructure. For example, total traffic in ports has more than doubled over the last eight years as a result of increasing trade and infrastructure development. We have greater targets in maritime transportation with very important port projects such as Çandarlı Port in the Agean Sea, Filyos Port in the Black Sea and Mersin Second Container Port in the Mediterranean Sea. With these three projects each in one of the

three seas surrounding Turkey will triple our container handling capacity.

In the rail sector, which the government has attached special importance to, we are connecting provinces with high speed train lines. We aim to have 10,000 kilometers of high speed train lines in 2023, connecting over 29 provinces of Turkey with each other. And we are not only connecting cities with train lines, but also continents. We inaugurated Marmaray in the last October, at the ninetieth anniversary of Turkish Republic. With Marmaray project, now you can travel via railway from Asia to Europe with an undersea tunnel. This project also enabled Beijing to reach London through railway. We can call it "Rail Silk Road".

One of Turkey's mega projects, the third bridge on Bosphorus Strait, will also provide railway transportation infrastructure. Two other huge projects in road transportation are currently being constructed. The first one is the Eurasia Tunnel. Similar to Marmaray, it will enable cars to pass from two continents to each other, with an undersea tunnel. The second one is Gebze – İzmir highway which contains İzmit Bay Bridge. This bridge will be one of the biggest suspension bridges in the world. Along with these big projects, new highway projects are also on the way. In the last ten years, Turkey built 16,000 kilometers of dual carriageways, while we had only 6,000 kilometers in 2002. We aim to reach 37,000 kilometers by 2023, connecting all provinces of Turkey with each other with dual carriageways.

**Could you please provide an overview of what ISPAT considers to be a successful case study for FDI into the Turkish pharmaceutical industry? What makes this company a successful case study?**

Most recently, Recordati, a leading Italian pharmaceuticals company decided to invest in Turkey. It has announced a manufacturing investment of USD 50 million in Turkey in cooperation with ISPAT.

The plant to be built in the Cerkezkoy Organized Industrial Zone will supply drugs for various therapeutic uses, at a rate of 80 million packs a year, creating 130 new jobs in the process.

**Could you please provide us with an overview of the incentive structures governing the pharmaceutical industry?**

Within the Turkish incentive system, there are four incentive systems in place: general incentives, regional incentives, incentives for large scale investments, and strategic incentives. Those investments within the pharmaceutical industry amounting to more than TL 50 million are supported by this third system, which offers the most lucrative benefits to investors of any of the four systems. As a whole, investments in pharmaceuticals are also supported under the regional incentive system. These incentives are similar to those benefits offered by the large scale incentive system, and include but are not limited to tax and social security exemptions or deductions, land allocation and interest rate support. Investors are offered a variety of options to benefit from investment incentives in Turkey. Almost all types of direct investments can benefit from these incentives in different levels. I must add that too, foreign investors can benefit from all incentives without any discrimination, thanks to the principle of equal treatment.

**What incentives, specifically, will help support the movement of the Turkish pharmaceutical manufacturing industry into higher value research and development?**

Turkey offers a very convenient environment and incentives to high-tech industries and R&D activities. As of today, we have 52 technology development zones, of which 37 are operational and 15 are currently under construction. Over 2,200 companies have developed plenty of projects in technology development zones, in other words technoparks. More than 16,000 Research and Development experts are working on around 6,000 software and R&D projects in these zones. Technoparks offer unique advantages to the investors. They offer office spaces ready to rent and infrastructure facilities provided. Software development and R&D activities in technoparks are exempt from corporate and personnel income taxes, as well as value added tax for the sales of software produced exclusively in technoparks. 50% reduction in the employer's share of social security premium is also available in these zones.

Moreover, Turkey has introduced an exclusive incentive scheme to support R&D and innovation activities. 142 R&D centers are operational within this exclusive incentive scheme. Companies establishing R&D centers in Turkey can benefit from all incentives with the same degree regardless wherever the investment takes place. Similar to incentives offered in the technoparks, the incentives for R&D centers include tax reductions, VAT exemptions, and social security premium support. As in the case of technology development zones, over 15,000 R&D experts are also employed in these R&D centers.

In order to establish an R&D center eligible to receive these incentives, the center must employ at least 50 R&D personnel, according to R&D Law. However, with an amendment in the relevant law in last February, this threshold now can be reduced to 30 by the Council of Ministers. Hence, in a near future, pharmaceutical companies might benefit from R&D incentives even they have 30 R&D personnel.

**Do you have a final message for the executives that will be reading this publication?**

Our motto is "All-ways Turkey". This is a great time in Turkey's history. As a booming country with a GDP growing at an average annual rate of more than 5 percent for ten years, Turkey offers tremendous potential with ample investment opportunities for global investors. Experts agree that this trend will continue into the future as the country vigorously pursues its goal of becoming one of the top ten economies in the world over the next ten years. It is the right place, because Turkey's strategic location, proximity to major markets and qualified labor pool allows investors to access 1.5 billion people and a combined GDP of USD 25 trillion in Europe, MENA, the Caucasus and Central Asia.

My advice for investors would be: "do not be late for Turkey." Many global investors have taken their part in the fertile investment environment of Turkey and they are now growing with Turkey.•

# Prof. Dr. İbrahim Kiliçaslan

General Director of Industry
**REPUBLIC OF TURKEY MINISTRY OF SCIENCE, INDUSTRY AND TECHNOLOGY**

**To begin, Dr. Kiliçaslan, would you please provide us with an overview of your responsibilities as General Director of Industry for the Republic of Turkey?**

The position of the General Director for Industry was established for the purpose of conducting studies to ensure stable and rapid development in line with the principles and objectives set forth in the Ministry of Industry's development plans and programs. Some of our most important responsibilities include the preparation of industrial development policies and the creation of solutions to industry problems. We are also heavily focused on increasing the competitiveness of the industries of the Republic of Turkey and the governance of technical bodies serving the industry.

**Dr. Kiliçaslan, you only very recently took up office as General Director of Industry for the Republic of Turkey. Would you kindly provide us with the vision that you have for the country's pharmaceutical manufacturing industry's continued development?**

Turkey aims to become one of the top ten economies in the world by 2023. As an extension of this, we wish to develop exports of $500 billion in this time and develop research and development focused industries that contribute to a minimum of 3% of Turkey's GDP. Achieving these targets depends on powerful industry, capable of creating knowledge and transforming it into products in line with the country's goals of technological and sustainable development.

One of the most important assets to a country is the health of its society. It is from social welfare that all power is derived. As a piece of this, the production of pharmaceuticals in conformity with the industry's regulatory statutes and the provision of medical access to the citizens of the Republic of Turkey is one of our foremost goals. To this end, we have established the "Turkish Pharmaceutical Industry Strategy Document," which has been prepared through the participation of public institutions, the private sector and representatives of universities. Through this document, we seek to improve public health and support the economic targets of Turkey. We hope that through these initiatives we will be able to make a significant contribution to the industry's further development by facilitating the expansion of production, the development of the exports, and innovation in research and development.

**In the past four years the financial health of Turkey's pharmaceutical industry has deteriorated. How will you respond to this, Dr. Kiliçaslan?**

The largest buyer of pharmaceuticals in Turkey is the public. The financial health is therefor, through necessity, linked to the price of pharmaceuticals as determined by the public. Aside from the correction of pharmaceutical prices, rectifying the current situation of the industry will depend upon research and development in the belief of the Ministry of Science, Industry and Technology. This will require collaboration between public institutions, universities, and the private sector. This will also involve the creation of supportive funding models. To this end, within the "Turkish Pharmaceuti-

cal Industry Document" we will focus on the creation of a rational financing structure so as to ensure the sustainability of the globalization of the industry and sectoral investments.

**Aside from the support which will be granted to the industry through this document, how currently is the government aiding the industry in developing an industry strongly focused on research and development?**

In order to increase the innovativeness of Turkish private sector and its cooperation with the universities; several on-going support are in place. These mechanisms provide a range of fiscal incentives for R&D and innovative activities by the private sector. Some specific mechanisms include R&D Centers and Technology Development Regions, or Technoparks.

R&D Centers are the units, having the capacity and knowledge of R&D, of legal equity companies, narrow taxpayer institutions or those the business centers of which are located in Turkey; units which are organized separately within the organizational structure, which are exclusively engaged in R&D activities in the country and those that employ minimum 50 full-time equivalent staff.

Technology Development Regionsallow for companies to make use of high/advanced technologies or engage in new technologies produce/develop technology or software using the facilities of a particular university, high technology institute or R&D centre or institute, where they operate to convert a technological invention into a commercial product, method or service, whereby contributing to the regional development, within or nearby the area of the same university, high technology institute or R&D centre or institute; the site where academic, economic and social aspects integrate or having such characteristics. By the end of 2013, 6.888 projects are carried out, 6% of them is in the field of health.

**Dr. Kiliçaslan, you state that that one of the Ministry's goals is the further development of export markets. What has this meant in way of strategic initiatives related to the sector's development?**

Exports are an important piece of the country's continued development. The Ministry of Economy, to support further development of exports, offers support for those participating in foreign fairs and that seek to develop their brands internationally. Under one of its newest programs, the Ministry of Economy will grant companies involved in international publicity and marketing activities cost relief of 50,000 TL. For national publicity, this amount will stand at 25,000 TL.

**Which areas, specifically, do you see promise in for the research and development activities of Turkey's pharmaceutical manufacturers?**

In recent years, the development of biosimilars have become an important focal point for the global pharmaceutical industry. Turkish pharmaceutical manufacturers, for their part, have also focused heavily on this area. We seek to encourage this as well as research and development acitvities in other fields. To do so, TÜBİTAK has launched project calls in the field of biomedical equipment, biomaterials, vaccines and pharmaceuticals. Appropriate projects can benefit from support in these areas.

**Many have commented on the absence of academia from the Turkish pharmaceutical manufacturing industry. How does the Ministry view the importance of these institutions?**

Universities are one of the most important actors for the country's pharmaceutical industry to attain the goals which have been set out for it. A globally competitive pharmaceutical industry requires strong research and development capabilities; universities can provide these capabilities. Creating a nexus between these institutions is extremely important. To further this, the "Technology Transfer Office" has been established: to help provide a commercial outlet for the studies of Turkey's universities.

**What final message do you have for our readers?**

The Ministry of Science, Industry and Technology's vision is to contribute to Turkey's goal of becoming one of the ten most developed countries in the world with a competitive economy based on entrepreneurship, innovation, scientific development and technological production with high added value.

The pharmaceutical industry is one of the most significant sectors in Turkey. It is critical to boosting the place of value-added industry, with its attendant benefits, within Turkey. Therefore, pharmaceutical industry is regarded as a priority sector in Turkey. In order to cover the foreign trade deficit in pharmaceutical industry in Turkey and increase its competitive power, the government had to adopt a strategic planning approach which would introduce sustainable and efficient structures in the industry and support public health and development goals.

Finally, I should have mentioned that "health" has been determined as a priority field in our country. We think that, our efforts to develop the industry shall bring momentum to R&D and innovation in health and Turkey shall become a country that is capable of producing its own drugs and molecules. •

# Nezih Barut

Chairman of the Board
**PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF TURKEY (IEIS)**

**Industry profitability has deteriorated over the course of the past decade. Could you please provide us with an overview of the factors that have driven this event?**

Over the last decade, the Turkish healthcare system has undergone a significant transformation under the Health Transformation Program, which was first enacted by the Ministry of Health in 2004. The purpose of this program was to increase the quality and efficiency of the country's healthcare system and to improve access to healthcare. As a piece of this, several reforms were introduced, including the introduction of a family practice system; the establishment of a national electronic patient record system; the implementation of a performance based payment system for healthcare providers; and the integration of what were the country's three social security systems under one system.

As a result of reforms, social security coverage expanded rapidly: hospital visits almost tripled. Prescription volumes and access to pharmaceuticals rose as well. This came with the consequence, though, of added healthcare expenditures.

The government's approach during this period was not supportive of the pharmaceutical industry. To contain the resulting increase in pharmaceutical spending, the authorities chose to suppress prices. However, supply-side measures can only work to a certain extent and need to be supported by demand-side measures as well. In fact, during this period, severe supply side measures caused the market to shrink in value despite an increase in volume. All in all, although the Turkish economy registered successful growth rates during this period, the share of the pharmaceutical industry within the country's GDP declined.

**Setting aside the price cuts that the Turkish government has imposed on the pharmaceutical industry, in recent years the Turkish government has adopted a more supportive tone with regard to policy making in the industry. How you seen this reflected in specific policies for the industry?**

The Turkish pharmaceutical industry has a strategic and social importance to the country. There must be policies that reflect this. This is occurring, albeit slowly, through several initiatives.

One initiative, executed by the Ministry of Science, Industry, and Technology with the participation of our association and interested parties, has been the development of a strategy document produced for the pharmaceutical industry. We expect this document to soon be submitted to the Economic Coordination Committee in the near future. Our Association proactively supported the preparation of this document and we assured that this document accurately reflects the demand and challenges of IEIS' members. A second initiative has been the incentive package announced by the government in 2012 which gave special attention to the pharmaceutical industry. Although some fine tuning is still necessary, this will help improve the investment climate for the industry.

In addition, our Association has undertaken the rapporteur role of the "Drug Working Group" established in the framework of the Tenth Development Plan, prepared by the Ministry of Development. The working group has completed its report. The strategic standing of the pharmaceutical industry has particularly been emphasized within the Development Plan.

A fourth positive movement has been the inclusion of the healthcare field in the priority list of industries by TUBITAK within one of its most recent strategy documents.

Be this as it may, drug pricing continues to be the overarching issue faced by the industry. This system, in place since 2004, links the price at which Turkish pharmaceuticals must be sold to the lowest ex-factory price of manufacturers within five EU member states. Currently, Turkey's drug reference countries are France, Greece, Italy, Portugal and Spain. Different public discounts are implemented according to a product's type and price. This system also takes into account the euro-lira exchange rate. However, the exchange rate for converting the euro has been fixed at 1.9595 TL/euro since April 2009. Due to the huge difference between the fixed conversion rate and the current euro exchange rate, our already low prices have been suppressed even further.

**You have named export-market development to be one of the key focuses of the Turkish pharmaceutical manufacturing industry. What success has the industry had in this attaining this goal?**

The industry exports to almost 150 countries: largely to the European Union, Middle East and North Africa, as well as the CIS. Our top ten countries by exports are Iran, Iraq, Germany, Switzerland, the USA, South Korea, Azerbaijan, the Turkish Republic of Northern Cyprus, Slovenia and England. We have to admit that Turkish pharmaceutical exports are still quite low and far away from their true potential. However, thanks to the efforts of individual companies and our association, we have seen improvement.

**A second goal you have mentioned is the development an industry that places greater emphasis on research and development. Specifically, what will this mean?**

In Turkey, generic drugs constitute the main activity of the industry. There are opportunities for generic drug producers to develop better existing products in the world. Therefore, it is important for us to focus on incremental and stepwise innovation. If research and development is supported by correct strategic planning, our country will not only be able to produce value-added generic products and biosimilar products but we will also be in a position to export them. To this end, pharmaceutical companies in Turkey have already begun to increase their focus on research and development. •

# Turgut Tokgöz

Secretary General
**PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF TURKEY (IEIS)**

**Could you explainthe vision upon which the IEIS was founded and tell us about the role that the association plays in the industry today?**

IEIS is celebrating its 50th anniversary this year: it is quite an old and established industry association. We have a very diverse range of members, amounting to a total of 60 today. We operate on a holistic approach that allows us to represent all business models present in the Turkish pharmaceutical industry. Our mission is to help the Turkish pharmaceutical industry become a global player. Thus, our primary focus areas are exports and R&D. We are organizing a conference this year in October and the theme is going to be "R&D in Turkey." We are bringing R&D experts from all over the world, but especially from peer countries such as Brazil, India, and China: countries that are Turkey's competitors in the developing world and that who are also enhancing their R&D capabilities. We need to make a greater effort to bridge the gap and learn extensively from their experiences. Another objective of this event will be to bring the industry together with academia, and to establish a synergy with TÜBİTAK.

**Where do you believe export opportunities lay for Turkish manufacturers?**

Turkey supplies pharmaceutical products to 150 different countries. Despite this, the Turkish pharmaceutical industry is still a contributor to the Turkish trade deficit and current account deficit, which highlights the importance of exports. Augmenting exports serves the country and I think the Turkish pharmaceutical industry is ready to take up its part and contribute to the solution of this problem. We try to cater to all different types of players in the market and to help them with their needs. For this we have established the Turkish Pharmaceutical Exporters (http://www.trpharmaexporters.org/), a 27-member platform. This platform was set up to increase the international competitiveness of the Turkish pharmaceutical industry.

Every major market around the world is potentially important to us. The EU and the US are very large and should never be neglected. Immediate options would be the MENA region, but we are also experiencing an influx in business from sub-Saharan African markets as well. Since we formed this export platform we have been receiving two, three requests a day from African markets interested in representing Turkish goods. Iran and Iraq have shown the largest rates of growth. Some Turkish producers also have a strong hold on the Caucuses and Balkan regions.

**The Turkish Government was once criticized for its lack of strategic planning for the pharmaceutical industry. Does the Government continue to show so little support for the development of the industry?**

I have to say we have mixed feelings on this. One side of the policy makers is still pretty unsupportive. But we feel we also have supporters. IEIS produced a report with the Boston Consulting Group at the end of 2011 and the main target was to attract the government's attentionon the pharmaceutical sector and to make them consider it as a strategic industry. This has happened. We lobbied intensively towards this end and now pharmaceuticals are one of the five industries the government has declared strategic to Turkey. We have also lobbied for greater incentives and again, pharmaceuticals became one of the sectors with the most comprehensive incentive scheme. However, despite such improvements, the government continues to suppress the industry's prices. Turkey's healthcare provision leads tovery high costs and needs to be looked after. The government has been severely restricting reimbursement prices of pharmaceutical products. So although we received some valuable support, this is hugely undermined by existing pricing policies.

**Regarding theTurkish system of drug price referencing and euro-lira convertibility, do you think this is the right system for a market like Turkey?**

I would not be able to argue on the merits ofwhether this system iscorrect or incorrect. It is one type of regulation, it has been here for the last 10 years, and it has both pros and cons. Having said that, Turkish prices are well below their European counterparts and that puts enormous pressure on profitability. We need those profits to be able to reinvest in infrastructure, technology as well as in R&D. Such investments will pave the way for the Turkish pharma industry's capacity to introduce value-added products for the global market. Otherwise we will struggle to claim a competitive edge.

**An issue that IEIS strongly supports is thepositioning ofTurkey as a center for value-added generics. Have you seen manufacturers adopt this issue?**

Turkish manufacturers are, in fact, bringing value-added products through their pipeline. However reimbursement prices have been very unfavorable. Combination products, for example, are only being reimbursed if they are below the price of the component products individually summed: the value-added entailed in that new product is being ignored. Ironically, most of these products have been developed under TÜBİTAK grants, so they have R&D support from the state. This remains a critical barrier. •

# Dr Ali Akyildiz

General Manager
**IMS HEALTH**

**IMS Health, both in Turkey and worldwide, is recognized as a leading organization for market intelligence on the pharmaceutical industry. Can you tell us about IMS Health's history of operations within Turkey?**

IMS Health has been operating in Turkey for almost 30 years. We first published our databases in 1968. Since 1990 we operated in Turkey as a company through IMS Turkey Ltd. At that time, almost 25 years ago, we changed our strategy and started to collect information concentrated on the pharmaceutical marketplace. We also began to collect data from wholesalers and calculate local consumption in Turkey. In parallel to that, we started collecting doctor prescription information. Based on this, we developed three services: a pharmaceutical index, a medical prescription index and a promotional index in Turkey.

We have evolved significantly since then; todayIMS Health is not only a data provider, but we also provide analytics to our customers, technological solutions and applications, and consulting services for management and customer effectiveness. We focus our work on Turkey as well as the wider region. We use Turkey as a hub for the Middle East, North Africa, CIS and Balkan countries for consultant services and data processing.

**Of the services that you provide to the industry today, can you provide us with a breakdown of the relative contributions of each to your revenue as a business?**

The growth drivers in the last years have been consulting, technology and applications, and customer effectiveness services. We have been growing in double digits in recent years. Our analytics and information services are still a big portion of our revenue.

**Which segments of the industry make up your client profile today?**

Almost all of the pharma companies in Turkey are IMS clients, from local small to mid-sized pharma players to international companies who are not operating directly in Turkey but are interested in observing the country's developments. We also work with investors who are looking at acquiring companies in the Turkish market, in addition to finance organizations and government bodies.

**The industry has set a goal for the market to reach a size of 80 billion TL by 2023, the 100th anniversary of the republic. How realistic do you think this goal is?**

According to IMS Health's market prognosis report, we expect to see 3-5% growth in the next five years. The growth in the pharmaceutical market will go in parallel to overall economic growth; therefore we cannot expect double-digit growth.

**The domestic market has become constricted as more international companies have entered. Given the shrinking space in the domestic market, there is a heavy focus on export-led growth. What are your projections on local companies being able to reach external markets?**

For large Turkish players, export opportunities are high. The potential is there, as is the capacity. The prices for local manufacturing are relatively low in comparison to many surrounding countries. Even for international companies, Turkey can be used as a base for exports to the region.

**Some Turkish pharmaceutical manufacturers would like to see their products on the shelves in the US and Europe. What barriers need to be reduced in order for this to happen?**

There are already companies who have registered their products in the US and Europe, however until Turkey is a member of the EU this process will be difficult. Registration is not easy under current circumstances.

**Currently there is a large focus in the market on R&D; how do you see this balance shifting in the future towards value-added products?**

Almost 85% to 90% of local consumption is paid by the Social Security Institution (SGK), so there is strong governmental control over prices. In the past years, innovative products have had much more chance to enter Turkey because the country needs new products; however, pricing is an issue. Turkey has some of the cheapest prices in Europe, which is a big barrier for innovation. The other issue is the exchange rate policy following the lira's devaluation. This means that the cheapest product is taken as a reference and is translated to the current exchange rate, significantly reducing profitability.

**Looking at Turkish per capita drug consumption, it stands at about $200, far below many other pharmaceutical markets. The industry has plans to bring it up to average to reach $600, however rational drug use is already a problem within Turkey. How do you reconcile these two dynamics?**

Consumption per capita in Turkey is at the lowest within OECD countries and the major reason for that is pricing. New therapies and high-tech products will not be cheap. When it comes to rational drug use, it is a factor in the market particularly for antibiotics. It is out of the scope of doctors and is not part of the general health system.

**Looking at market sales in the industry, what product segments have the highest growth projections?**

Turkey's drug consumption has always been different from other European countries. In the top place is antibiotics; however in the past year this is changing as oncological products, cardiovascular products and diabetic products are increasing. •

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*Pharmactive was founded in November 2011 by acquiring a land of 108.000m² in Cerkezkoy. The first phase manufacturing site became operational in August 2013 after getting the Turkish GMP approval. The site is capable of manufacturing non-betalactam solid, semisolid and non-sterile liquid products in 45.000m² total closed area with 330 million boxes/year capacity in 3 shifts. The facility has a state of the art R&D center at 3.200m² closed area, where there are 70 scientists. Pharmactive aims to penetrate to oncology, biosimilar, biotechnology and inhaler products at the second phase of investment plans which need separate R&D and manufacturing facilities.*

*Having a well-established R&D center with its highly skilled and educated scientists, state-of-the art production facility and its 400 people of sales and marketing team, Pharmactive targets to be within top 5 pharmaceutical companies in Turkey in 5 years.*



*Pharmactive is keen on developing strategic collaborations with international partners by;*

- In-licensing of generics, biosimilars, biotechnology products and specialty products for TR market,
- Out-licensing of its own dossiers with supply commitments from its state of the art facility,
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# Breaking with Precedent: Government Strategies and the Regulatory Environment

"We believe that Turkey will be one of the key players in the global pharmaceutical industry in the following years by means of the policies we apply, our strong economic infrastructure, talented scientists, qualified and skilled labor force and demographic features.
On behalf of the Ministry, we will continue to strive for change within the industry. Pharmaceuticals manufacturing is of great strategic importance to the development of our country. Through it, we hope to bolster our position within export markets so that Turkey might become an important country for the development of new molecules and the production of high value-added medicine on a global level."

- Saim Kerman, President, Turkish Medicines and Medical Devices Agency

Image: Atabay
Atabay's production plant in Gebze

# The Government and the Market

Foreign Healthcare Models and Turkey

Though many of Turkey's most prominent pharmaceutical manufacturers, such as Abdi Ibrahim, trace their heritage back nearly 100 years, the same period in which the modern Republic of Turkey was founded and an era characterized by a heavy-handed, Statist approach to economic planning, the development of Turkey's pharmaceutical manufacturing industry has historically been isolated from the government's efforts to plan the growth of certain sectors.

The history of operations of what stand as many of the industry's largest players today is a testament to this relationship. In the case of Atabay Pharmaceuticals and Fine Chemicals, which was founded 75 years ago as a trader, it was through the support of foreign aid that the company was first able to enter into manufacturing. Bülent Atabay, chairman of Atabay Pharmaceuticals and Fine Chemicals comments that, in the 1940s, "Atabay was interested in entering into the manufacturing of pharmaceutical products. This became possible in 1955, when Turkey received aid under the Marshall Plan. The Marshall Plan enabled us to import equipment from the United States. We were one of the first companies to use aid for this kind of operation. In 1955, we started making simple tablets for use against pain and fever." Today, with revenue of over $95 million in 2013, Atabay stands as a leader in the production of generics and active pharmaceutical ingredients (APIs) in Turkey and is Europe's sole provider of paracetamol.

This disconnect between the Turkish government and its pharmaceutical industry would continue through the turn of the century, into the country's more recent rounds of economic planning. Though in the Ministry of Industry's Strategic Plan for 2010-2014 specific strategy documents were crafted for the development of Turkey's furniture, paper, and wood industries, pharmaceuticals would be treated as a subset of the country's chemical industry, an umbrella encompassing the economic policies which would govern the development of paints, cosmetic and plastic manufacturing, in spite the pharmaceutical industry's very different nature.

However, the past two years have seen an end to this historic dynamic. Recognizing the importance of pharmaceutical manufacturing to the development of value-added industry in Turkey, the central government has declared pharmaceutical manufacturing as one of the country's five key industries for continued economic development. With this, the Ministry of Industry has released "The Pharmaceutical Sector Strategy Document and Action Plan", which seeks to respond to several of the industry's core concerns.

"The Pharmaceutical Sector Strategy Document and Action Plan" proposes six strategic goals to further the industry's development. First among these changes to be made will be the development of new regulations to boost investment into the sector and an administrative body, formed under the Ministry of Science, Industry and Technology, to help execute the goals of the document. The government will seek to better prepare Turkey's labor force for work within the sector, and, additionally instill in the country's healthcare professionals an understanding of the importance of the rational use of medicine. Collaboration between the public sector, Turkey's universities and the private sector will be encouraged. Perhaps most importantly for the private sector, the Ministry of Industry will, first, facilitate the development of value-added products through R&D planning and assisting in the coordination of economic activities among the industry's participants and, second, support the sector in its goal of developing export markets.

Although what the release of "The Pharmaceutical Sector Strategy Document and Action Plan" will mean with regard to specific policy initiatives is unclear, its release is part of a larger change in the government's attitude toward the industry: an acknowledgement that the sector's continued development will depend upon collaboration between the private and public sectors. For many, this support has been long overdue. Professor Burak Erman of Koç University's Department of Chemical

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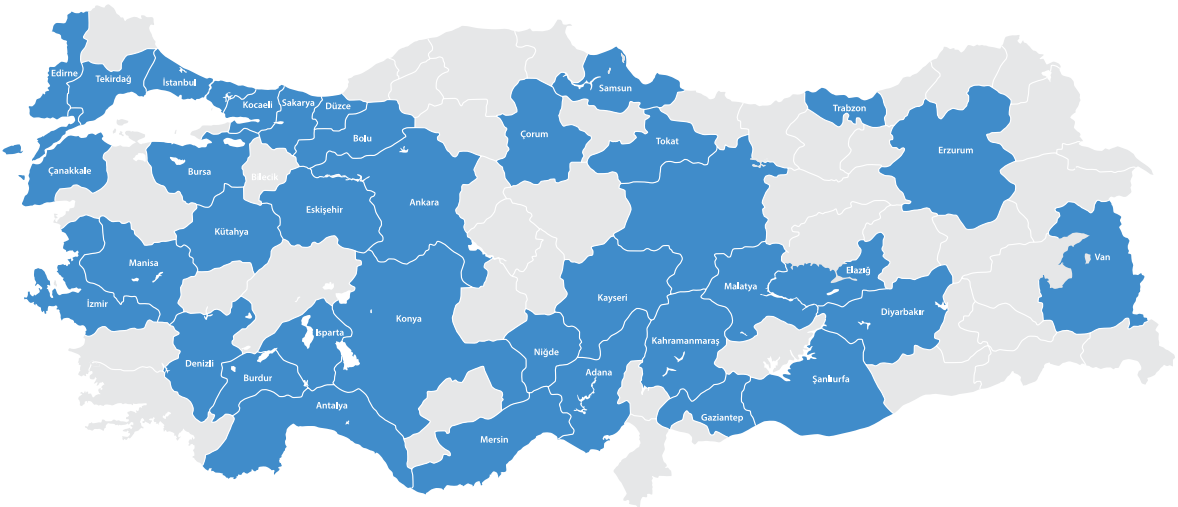
## TECHNOLOGY DEVELOPMENT ZONES (TECHNOPARKS)

Source: Invest in Turkey

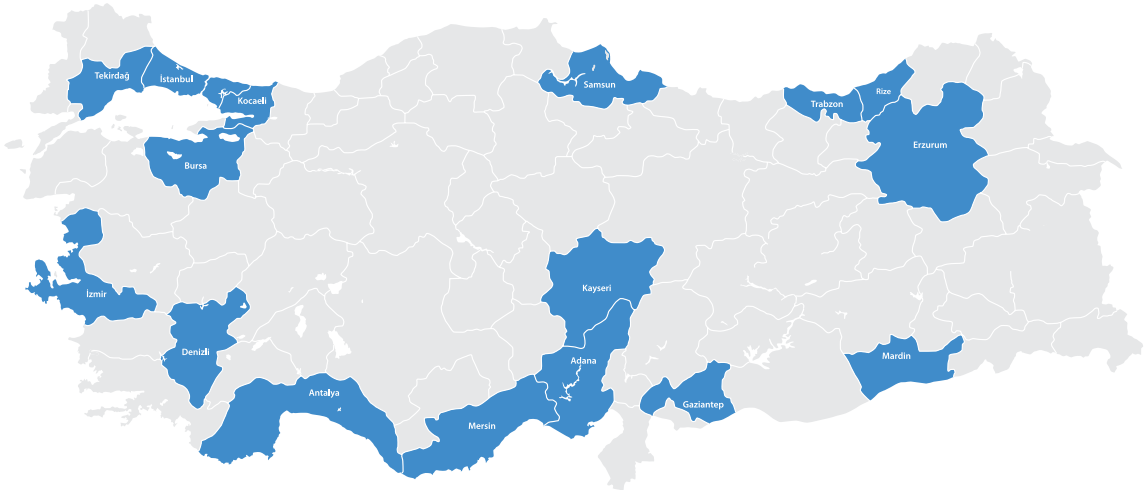



## ORGANIZED INDUSTRIAL ZONES (OIZS)

Source: Invest in Turkey


## FREE ZONES

Source: Invest in Turkey




Recordati's site in Istanbul occupies a surface area of approximately 14.000 m2. It produces 40 milion packages per year, of which 20% is dedicated to third party production. It produces oral solid and liquid formulations and products for topical use.

and Biological Engineering, who has gained considerable attention in the last year through having developed Turkey's first original molecule, explains that, "The industry requires greater support from the government. Only 10 years ago, Ireland, South Korea and Singapore embarked on the development of their pharmaceutical industries. The governments gave great support to pharmaceutical companies, which attracted the attention of Western companies, and a lot of money was poured into these projects. These companies are now leading the world in production, especially in South Korea."

The Turkish government's new-found warmth for the sector could play an important role in supporting the expansion of its pharmaceutical manufacturers both into foreign markets and value-added products. In seeking to better support the industry, already, the Turkish government has begun to look outside to foreign healthcare models. The success of the Turkish government in importing these models, however, will depend on its ability to change several policy structures which otherwise could thwart their effectiveness.

Underscoring South Korea's success in developing its pharmaceutical industry has been governmental support in two areas: the cultivation of research and development and the facilitation of knowledge transfer from foreign personnel to the local workforce. For organizations with research and development facilities with ten or more staff, cash grants are granted. For those that invest a minimum of $1 million in the development of these centers, tax exemptions are applied.

Today, research and development in Turkey is incentivized. Those designated as a "Research and Development Centre" receive numerous benefits, including tax incentives in the form of exemptions from income tax; tax deductions for all research and development related expenses; and research and development expenditure support, which covers 60% of all staff expenditures.

Access to these benefits, however, has been limited. Only those with 50 staff or more employed in research and development are eligible to receive "Research and Development Center" status and its attendant benefits. While following a petition of the IEIS, the Turkish Pharmaceutical Manufacturer's Association, this requirement was lowered to 30 personnel for those industries that the Ministry of Science, Industry and Technology deems strategic, pharmaceutical manufacturing has yet to receive this designation. Until this is rectified, the pharmaceutical industry will continue to lose out on a class of entrepreneurs. At present, 142 Research and Development Centers operate within Turkey: only eight of which are dedicated to pharmaceuticals

The larger problem faced in encouraging research and development, however, is not found within the incentive structure in place, but rather the government's interactions with the market through other policies. Bülent Atabay, chairman of Atabay Pharmaceuticals and Fine Chemicals, explains that "a sufficient incentive structure is in place. Beyond this, the Ministry of Health has been very supportive in assisting in the registration of our products. However, government policies can still be challenging for the market. The government pays a significant amount for medicine, which is important, but they have also set drug prices at very low rates. This creates limitations for us as researchers and developers. To survive in the market, one must be able to create new products."

Erol Kiresepi, chairman and CEO of Santa Farma, a leader in the sale of hormone products that has invested €100 million in the construction of a new production facility that will strengthen its research and development capabilities and allow for the company to improve its position as an exporter notes, "The government has given incentives for the construction of production facilities and this has influenced our decision regarding our new plant. What has to be done now is tackling the current account deficit, and to do that one must invest. This, however, demands profitability. With the current price referencing system we are running out of investment capabilities. The 1.95 euro-lira conversion rate is not sustainable. The government's pharmaceutical budget must be readjusted." Full implementation of a South-Korean style model for research and development will, therefor, depend upon the government's treatment of what stands as perhaps its most contentious policy for country's pharmaceutical manufacturers: Turkey's system of price referencing.

Setting South Korea aside, several lessons can be learned from the development of the pharmaceutical industries of India and China. For India, government planning led to the development of centralized manufacturing and research centers. Those operating within these centers were exempted from duty, income tax, service tax and sales tax, and subjected to a simplified

set of export procedures. An economic clustering strategy was also employed in China to similar results. Economic clusters facilitate strategic planning; improve the ability of business to generate synergies among one another; and allowing for businesses to more easily generate economies of scale through minimizing infrastructure requirements. This is reflected in the strength of China and India's pharmaceutical industries today.

Economic clustering is not foreign to Turkey. The Turkish government has devised a strategy for industrial development that encourages agglomeration through three incentive structures: Technology Development Zones (TDZs), Organized Industrial Zones (OIZs) and free-trade zones.

With 37 currently operational of a planned 52, TDZs offer several strategic advantages. İlker Aycı, president of the Investment Support and Promotion Agency explains that, "Technoparks offer unique advantages to investors. They offer office spaces ready to rent. Infrastructure facilities are also provided. Software development and R&D activities in technoparks are exempt from corporate and personnel income taxes, as well as value added tax for the sales of software produced exclusively in technoparks. A 50% reduction in the employer's share of social security premium is also available in these zones."

Established with the aim of encouraging job creation within high technology sectors, these technology parks have attracted interest from the pharmaceutical industry. As of the end of 213, 413 projects within the field of health had been carried out within these zones.

Turkey's OIZs have played an equally important role in encouraging centralized investment within the pharmaceutical industry. Offering tax exemptions and low utility costs, many of Turkey's pharmaceutical manufacturers have chosen to establish themselves within these regions. These companies range in scale from Helba Ilac, which chose to establish itself in Ankara's Başkent OIZ through a $20 million investment, to Pharmactive and Recordati, which recently joined many other pharmaceutical manufacturers in the Çerkezköy OIZ with investments of $120 million and $50 million, respectively.

DEVA Holding's Çerkezköy Production Plants are located around 110 km from Istanbul, in Çerkezköy Organized Industrial Zone. Çerkezköy-I, on an area of 52,000 sqm with an indoor space of 32,000 sqm, produces Liquid/Semisolid, Solid, Betalactam 1, Betalactam 2 and Hormone products. Çerkezköy-II, on an area of 67,551 sqm with an indoor space of 18,742 sqm, produces Solid, Oncology and API products.

Though these structures have certainly encouraged the development of centralized industry, the introduction of Turkey's system of health campuses, a newer and less common clustering strategy, could exert a stronger force on the country's pharmaceutical manufacturers.

A cross-application of a healthcare model found in several Middle Eastern countries and the United States, Turkey's healthcare campuses will boost access to medical care and offer research and development facilities. Dr. Akyildiz, general manager of IMS Health, comments on the impact that these campuses will have on the industry. "The development of Turkey's system of health campuses will change the industry dramatically. Hospitals, pharmacies and hotels will emerge around these areas. Accordingly, the industry must change its strategy to fit these new systems. The health sector will be reorganized and concentrated together. Marketing and sales activities will change. Industry players must be ready to deal with these big centers. Automatically the payer will have more opportunity to fix prices. Tender business will grow. When the system will be fully implemented, it will fully change the landscape on the market."

These facilities, which will be developed over the course of the next decade through public-private partnerships, represent one of the largest government efforts to implement health campuses anywhere. The Ankara Bilkent Integrated Health Campus alone, one of the 35 facilities which are planned, will become the largest healthcare facility in Europe upon completion. Through this model, the Turkish government seeks to add between 30,000 and 40,000 beds, addressing one of Turkey's healthcare systems largest problems: over-crowding in hospitals. Through their research and development facilities, these facilities could offer a number of applications to the country's pharmaceutical industry, especially in areas such as clinical trials.

The Turkish government's introduction of this model underscores a larger need of Turkey's pharmaceutical industry that has gone unaddressed: collaboration between the private and public sectors in research. Although several Turkish universities have developed strategic relations with the country's pharmaceutical manufacturers, as a whole, these partnerships are rare and have been largely driven by the interest of foreign pharmaceutical manufacturers.

This, again, has been influenced by the country's system of price referencing. Professor Burak Erman explains that, "Now, as a result of Turkey's drug pricing system, even the industry's largest players are in survival mode. They need to maintain their profitability. It is for this reason that those that have ap-

proached us to conduct collaborative research have been largely foreign. Many European companies want to bring research to China and India, but there are disadvantages, like security and the time difference, within these countries. Turkey is a more strategic choice for these reasons."

Through his work, Erman has established partnerships with Sanofi and AstraZeneca. Others to tap into the vast potential of Turkey's intellectual resource base include İlko Pharmaceuticals, which has a partnership with Hacettepe University in one of the country's TDZs, and Novo Nordisk, which partners with Kocaeli University. Be this as it may, these partnerships remain uncommon though they play an important role in the pharmaceutical industries of the United States and South Korea.

Hatice Öncel, general manager of Ilko Pharmaceuticals, which houses their partnership with Hacettepe University in one of Turkey's TDZs comments that, "For R&D, coordination between the industry and university is very important; however, Turkey has struggled in developing these partnerships."

Köksal Ülgen, general manager of Pharmactive, which will dedicate a portion of its 3,200 square meter research and development to partnerships with universities, notes that, "If one is to look at the success of the South Korean pharmaceutical industry, three agents are responsible for the industry's position today: the country's entrepreneurs; the incentive structure developed by the South Korean government; and the country's universities. More than anything, it was how these three factors worked together that drove the industry's expansion. One element of this model that needs to be developed better from the structure of Turkey's pharmaceutical industry is a link between the country's intellectual resources and the pharmaceutical industry. Developing this connection will be very important in developing technically intensive and time intensive products, such as biotechnological products. Biotechnological products can require a substantial financial investment – say, $150 million to $750 million – and a long gestation period, even up to 10 years. At the end of this time period, the product may fail. A country's businesses are not suited to handle the risk associated with the development of these projects. However, an integrated model with the involvement of universities, entrepreneurs and government, this burden and risk can be decreased for all parties and NCEs can be developed in the future by the Turkish pharmaceutical companies as well. Aside from South Korea, this model has been responsible for accomplishments of Israel, Iceland and the United States pharmaceutical industry. Turkey must forge linkages with its universities.

Yet in Turkey, universities lack the infrastructure to support the development of these projects. Professor Burak Erman continues, "the problem with R&D in Turkey is atmospheric. We have 10 molecules that have been injected with a disease. We can develop it to a certain point with our means, but once we complete animal trials, we need to turn it over to a company. If the right climate existed, we could continue with this on our own."

Attributable to this dynamic, Turkey faces a growing human resource issue. Erol Kiresepi of Santa Farma, who also acts as vice-president of the Turkish Confederation of Employers Associations (TISK), explains that, "Turkey currently suffers from a skill mismatch… Employers cannot find people with the skills they need since universities are not teaching the skills industry needs. Governments, universities and schools should develop their curriculum in conjunction with the business community. When this is not done you have a market with skill mismatches." In part driving this dynamic has been the nascence of research-focused businesses in Turkey. Those Turkish graduates that wish to enter into fields such as biotechnology go overseas, for lack of domestic employment opportunities.

Correcting this problem involves encouraging further collaboration between Turkey's pharmaceutical manufacturing industry and the country's universities. It also requires building the venture capital required for universities to be able to develop their products independently. This may come through the development of "The Pharmaceutical Sector Strategy Document and Action Plan."

The creation of this document is undeniably an important step in improving healthcare for the country and fortifying the position of the Turkish pharmaceutical manufacturer as the industry begins to grow outside of its traditional boundaries. Much can be gained through learning from foreign healthcare models. Yet developing the country's pharmaceutical manufacturing base requires a distinctively Turkish solution. The ability of the sector to maximize the utility of foreign healthcare models in its development will depend upon the Turkish government's readjustment of certain policies which might otherwise render these models ineffective. •

> "When I first returned to Turkey from US in 1990, I had noticed the absence of this dynamic. Though partnerships between universities and businesses were common in the United States, they were rare in Turkey. This trend has continued through today. Universities have limited relationship with businesses. This has been on account of the country's politics. There is no continuity in Turkey's economic policies. When offices change hands, policies of the previous regime are dropped. Our focus on ideology has preempted the successful development of many policies: this included. These partnerships require government input: instead, the government's input has precluded their development.
>
> - Sedat Birol, Executive Director - Healthcare Division, Eczacıbaşı

# Cem Baydar

Sr. Principal, Head of Turkey and the Middle East
**IMS CONSULTING GROUP**

**Can you provide us with an overview of the scope of IMS Consulting Group's consulting activities within Turkey?**

Our operations in the Turkish market started as a delivery center for global projects taking place within the country. This was in 2007-2008. Today, from a global perspective, IMS is the largest consulting division dedicated to the pharmaceutical industry, with more than 500 consultants deployed globally. In Turkey we have 20 consultants coming from both reputable consulting houses as well as from the pharmaceutical industry itself. We work with multinational and local companies to address their business issues along the lines of strategic planning, investment, expansion and restructuring. We are involved in critical merger and acquisition projects, such as that of Amgen and Mustafa Nevzat, working on both the buy side and the sell side. We also conduct market entry studies for multinational companies looking to enter into Turkey, and help companies in Turkey with growth strategies and global expansion plans.

**Through the Turkey office, IMS Consulting Group is also servicing the Middle East. What is the rationale backing the decision to use Turkey as a regional hub?**

Turkey, both from a geographic perspective and from a knowledge and talent perspective, is an epicenter in the region. The surrounding area is growing rapidly and Turkey itself is a big market for pharmaceuticals. Back in 2010, we decided to build up a consulting hub in Turkey from which we could also service the Middle East and Africa. Our primary intention is to serve the Turkish market itself, which is about $6.9 billion, while we are also serving this high-growth region. We find that both from a cultural perspective and from the perspective of disseminating best practices out of Turkey, it was a very good decision to use Turkey as a hub.

**Historically the Turkish market has been driven by national companies; however there are also many new entrants into the market. What position does this leave for local manufacturers?**

The Turkish market grew by 6.5% last year; however looking at the growth rates of the top ten companies, you do not see many growth rates exceeding this number. Many of the larger companies are on the lower end side of overall market growth, meaning that there are many small and mid-sized players coming up and growing rapidly. These companies are taking advantage of new opportunities, such as in-licensing specialty products. The hospital channel is growing as much as three times faster than the retail channel, while we are also seeing specialty care grow at twice the rate of primary care. Fast-forward five to ten years, it would not be a surprise to see that the Turkish market will be a specialty care driven market. Local giants are not tailored towards this, while smaller companies have the agility to act fast. We expect that the top local players in the next 10 years will be very different.

**Market access is a key issue for the industry. How do you advise companies to approach their market access strategy to reach the most discerning markets, such as the US and Europe?**

Many companies are not interested in tapping into the US and Europe anymore. The number of high-growth markets has gone from 17 two years ago to 21 markets today. The new additions are Saudi Arabia, Algeria, Colombia and Nigeria: three out of four of which are close to this region. These markets have the potential to grow incrementally by $1 billion within the next five years. Many local companies are interested in entering into these pharmerging markets.

**One of the changing dynamics of the internal market is the introduction of health care campuses. How will this affect companies' pharmaceutical strategies going forward?**

There are already several examples in the Middle East of these campuses. It is a very good initiative in terms of establishing access to healthcare, especially in rural areas. Overlaying this information with the high growth seen in the hospital channel, we expect the campuses to further escalate this growth. Since these are big institutions, purchasing will be on a tender basis. In order to deal with this, companies should think about their team structure, their value proposition structure, and how they can establish and maintain relationship with the key stakeholders of these campuses. These campuses will transform the entire industry.

**Looking over the course of the next five years, what is your growth strategy for IMS Consulting Group in Turkey?**

We believe in IMS Consulting Group's growth potential in the region. We grew by 400% in terms of our headcount, making us the second largest hub in Europe, after the UK. We intend to keep the same size and scale and continue to be competitive in all areas where we are working. We are also looking to be more involved in other geographies, where we have built up credibility and knowledge, such as sub-Saharan Africa, Eastern Europe and CIS countries. From a regional perspective, we believe the market will see double digit growth, which will resonate very well with IMS Consulting's growth ambitions in the coming years. •

# Av. Dr. Cahit Suluk

Attorney at Law
**CAHIT SULUK IP LAW FIRM**

**Could you tell us about your career trajectory? What led you to establish Cahit Suluk Intellectual Property Law Firm?**

After becoming a lawyer, I decided to pursue a graduate degree, but once I earned my PhD I realized practicing law was the proper path for me, rather than becoming an academician. Further to this, I decided to set up a boutique law firm that would only lead with intellectual property. The two most important topics in intellectual property, from a Turkish point of view are: the EU Customs Union and the World Trade Organization (WTO)/TRIPS. Both of these subjects intrigued me greatly.

**Who are your clients today? Which industries matter the most when it comes to patent protection and how is your law firm prepared to handle the demand?**

Today, pharmaceutical companies are our most important clients. Our office has been working on the request of the Ministry of Health to help draft patent law, highlighting our commitment to the industry. When it comes to patent protection, the pharmaceuticals sector is far ahead of any other industry in Turkey. There is a conflict between innovators and generic companies. The majority of our clients are domestic, generic players.

**The length of time to launch a new product is critical for competitiveness. How long does the patent application process takes for a new pharmaceutical product in Turkey?**

We have three types of patent protection in Turkey. First, we have patents with examination: these are exactly the same as those enforced elsewhere globally. Our second structure is a patent without examination. The third is our utility model, where there is no examination procedure. For mechanical innovations, the Turkish Patent Institute is able to do examinations; however, for pharmaceuticals or software they send the examinations abroad, to the European Patent Office (EPO) or elsewhere. It takes three years on average to obtain a patent with examination. However, protection begins when the application is filed. A patent with examination will give you 20 years of protection, whilst a patent without examination will only guarantee you seven years of protection. The utility model allows for 10 years of protection.

In practice in Turkey you may go to a patent attorney and present an innovation. He will write a description and make an application. The Turkish Patent Institute then conducts a search globally for similar innovations. This is a simple but an important search report; it will provide detailed information, determining whether one will be successful with a patent by international standards. According to this document, if it is worth proceeding with a patent, one may decide to go for examination. This initial process takes about one year.

**How have ınternational agreements and bodies shaped Turkish IP law?**

Turkey is already a member of almost all of the international bodies and agreements on Intellectual Property Rights such as WTO/TRIPs, PCT, and the Madrid Protocol. This has required harmonizing our laws with international standards and considering if one wishes to be a member to international bodies. You need to be a member of WTO first of all, and for that you will need to accept regulations of more than 20,000 written pages, which includes the TRIPS agreement. In some international agreements, countries may enter reservations to some articles, but for WTO you cannot do that: it is all or nothing. The TRIPS agreement ensures the protection of intellectual property; you need to do it at some point while joining international bodies. In this context, we may call the TRIPS agreement the military constitution code on Intellectual Property.

**Turkish pharmaceuticals industry is undergoing a moment of transition. Some would say there is a trend towards value-added product, which imply R&D investments. Which consequences do you think have resulted from the flaws within Turkey's intellectual property system that have affected the willingness of the pharmaceutical manufacturers to invest in R&D until now? What are the basic problems faced by the Turkish Pharmaceutical Companies?**

Frankly, R&D has never been on the agenda of most Turkish pharmaceutical manufacturers. The total amount of investment made by the generic companies into R&D in Turkey amounts to only €70 million.

There are two handicaps that stand out for Turkish generics manufacturers: the price system and the pharmaceutical patent protection. The Turkish government has played a large role in price setting for pharmaceuticals within the past five years, the result of which has been the sale of pharmaceutical companies. However, issues related to patent protection have also contributed to this dynamic. Patent protection is all part of a big game played by innovator companies. One pharmaceutical product may have many patents where it deserves to have quite less in accordance with slight changes. Innovator companies try to block generic companies by using tools like patent linkage or patent bush court cases, or by obtaining patent protection for the secondary elements of their innovations towards the end of the patent protection period of the molecule patent. This is called an evergreening strategy. It has been seriously detrimental to the industry. •

# The Government and the Industry

## The Public Budget and Pharmaceutical Manufacturing

Public policy initiatives have played a critical role in shaping the current landscape of Turkey's pharmaceutical manufacturing industry. In 2003, the Turkish government launched a series of ambitious reforms for its healthcare sector under the Health Transformation Program: a program aimed at increasing public access to healthcare services and modernizing Turkey's medical system. The introduction of this system was transformative, both in the effects that it would have on Turkey's citizenry and the country's pharmaceutical sector.

Five years later, the successes of Turkey's Health Transformation Program were apparent: through merging the country's insurance schemes, 98% of Turkish citizens were granted access to health services, 94% of which were covered through the Turkish government's social security program, the SGK. Medical access rose as well: from 2002 until 2009, visits to primary care facilities more than tripled while visits to hospitals doubled.

Hasan Ulusoy, Chairman of Nobel Pharmaceuticals, who stands among the five largest Turkish pharmaceutical manufacturers with net sales of over $300 million in 2013, explains, "10 years ago the Turkish government embarked on a set of ambitious reforms for its healthcare industry through the creation of the "Health Transformation Program." Today, the general public is highly satisfied with the results of this program: the country has succeeded in its aim of extending and providing better access to quality healthcare services to the general population. There has been a significant increase in the number of visits to public health facilities, as well as in the consumption of pharmaceutical products among other related healthcare services."

In conjunction with the introduction of Turkey's Health Transformation Program, the Turkish government developed several policy tools that would limit the impact of Turkey's growing demand for medical products on the public budget, now the largest carrier of the country's medical expenses. Ulusoy continues, "This increase in the expenses for the last years has been reflected to the pharmaceutical sector as a burden that has been very difficult to manage."

The first of these measures to be introduced was a system of price-referencing. Launched in 2004, this system would link the price at which Turkish pharmaceuticals were sold to the price at which pharmaceuticals were produced elsewhere in Europe. Sedat Birol, executive vice president of Eczacıbaşı, previously one of Turkey's largest generic manufacturers comments, "Prior to 2004, the Turkish government employed a cost-plus pricing system. This was later changed to a reference-pricing system, which linked the price at which pharmaceuticals could be sold to the lowest price available in five selected reference countries in Europe."

A cross-application of a pricing system common in Europe, Turkey's system carried with it two important stipulations: that the profitability of industry participants be built into the model and that the European reference price used would be converted into the lira at a fixed rate. Initially, profitability constraints were concentrated on generics and the price conversion rate was, in effect, floating. This would later change. The second mechanism introduced by the Turkish government operated more directly. Beginning in 2005, the price of generic products were discounted by 11%. All other products were discounted by 4%. This would soon change as well.

As medical access expanded and Turkish drug consumption rose, the stringency of both these measures increased, spurred by the growing encumbrance of the country's medical expenses on the public budget. In 2009, the price ceiling off-patent originator products and generics was set at 66%: this was later tightened to 60% in 2011. Prices experienced further direct discounting: 28% for generic products and 41% for originator products without generic competition. Concurrently, the exchange rate used in calculating the lira-price of a pharmaceutical product was fixed at 1.95 TL per euro: a secondary discount of over one third. As the Turkish lira began to depreciate in 2011, the latter requirement would become the most constraining of these three conditions, providing an additional discount of over 30% under current market conditions.

Ulusoy of Nobel comments: "the price of pharmaceutical products has to be updated as TL/Euro exchange rate changes. Our prices have had to remain the same for the last four years, in spite of currency fluctuations. The approved price of pharmaceutical products should have been increased by at least 50%. Under these circumstances, it is very hard to speak of a favorable business environment."

Collectively, these price cuts have resulted in heavily discounted market

prices for Turkey's pharmaceutical manufacturers. Dr. Erhan Baş, general manager of Bilim Pharmaceuticals, the country's third largest manufacturer by revenue with sales of over $760 million in 2013, notes: "in the last five years, Turkish manufacturers have experienced large price cuts, a discount of nearly 50%."

Today, Turkey's system of pharmaceutical pricing has heavily shaped the dynamics of Turkey's pharmaceutical manufacturing industry. This is observed in three changes that the industry has experienced as a result of this system.

First, the Turkish pharmaceutical manufacturer is now more heavily focused on exports than previously; however, their ability to develop a position within these markets has been limited. Even in foreign markets, the profitability of the Turkish manufacturer has been tied to the Turkish government's pricing regime. Erol Kiresepi, chairman and CEO of Santa Farma, explains that, "the impacts of Turkey's price referencing system go beyond the domestic market. When one exports, their customers ask for a reference for the price of a product if sold domestically. A low internal reference price diminishes our profits abroad."

Second, drug access within the country has been stunted. While certain medications have been dropped by domestic manufacturers because they can no longer be profitably manufactured, the Turkish government's system of price referencing has also discouraged the introduction of medication available elsewhere, internationally. "selling to Turkey is admitting to a lower price reference, and it has been because of this that Turkey has not seen many innovative new products introduced. Price constraints have prohibited access to certain treatments in our country," continues Kiresepi.

Gökhan Gökçe, partner at YükselKarkınKüçük, a domestic law firm, confirms: "many multinational companies choose not to manufacture new medication in Turkey. Equally, certain products can no longer being produced in Turkey as there is no way in which they can be produced economically. This has led to product shortages and unmet medical needs, especially in critical areas such as oncology and diabetes."

Third, and perhaps most damaging, this system has undermined the sector's confidence in investing domestically. Tuğçe Koç, general coordinator of Onko Koçsel, which has invested €70 million in the development of a new manufacturing facility through which the company seeks to satisfy the entirety of Turkey's demand for oncological products, explains that, "In order to be an innovative company one has to invest considerable amounts of money. Investments in pharmaceuticals take a long time to pay back; the industry is about long-term commitment. We might run out of investment capability if conditions remain as unattractive to business as they are at present."

Collectively, the effect of these factors has been to move Turkey's healthcare market further away from domestic manufacturing. In 2008, prior to when the government implemented its heaviest set of discounts, the total value of the Turkish pharmaceutical market stood at $9.75 billion, in sharp contrast to the $8.06 billion it stood at in 2013. Though the value of the market contracted, unit sales increased steadily over this period: a reflection on an industry that has sought to maintain its profitability through volume. Innovation, however, has been lost. Concurrently, the market share of the Turkish pharmaceutical manufacturer has fallen relative to that of the distributor. In 2013, the value of pharmaceutical imports climbed above 50%, for the first time since 2013. Simultaneously, the market share of Turkish pharmaceutical manufacturer by volume fell to a historic low of 77%.

Both of these dynamics point to a larger forthcoming problem for the Turkish government, the consequences of which could outweigh the marginal benefit associated with price suppression. Turkey's pharmaceutical manufacturing base has an important role to play in influencing the country's trade balance. Since the introduction of Turkey's Health Transformation Program, the country has seen the value of the country's pharmaceutical imports quadruple. Pharmaceuticals have contributed as much as 10% of the country's total trade deficit, exclusive of energy products. Should Turkey's healthcare industry continue to expand and reach its projected size, these incremental changes in the industry's market share will exert a much larger influence on the macroeconomic health of the country.

Beyond this though, local manufacturing plays an important role in price suppression. Philip Haas of Deva Holdings, writes: "It is important to acknowledge that if the Turkish pharmaceutical industry did not exist, prices would probably be 10 times higher; imports would rule. For that reason, having a strong generic industry is hugely important."

A decline in local manufacturing foreshadows a rise in aggregate price levels. These prices will further eat into a budget that is already projected to be insufficient to cover the Turkish public's medical needs. By some estimates, under the government's current budget calculation methodology, in 2023 the Turkish government will only be able to cover 41% of the country's health expenses. Cultivating and fortifying local manufacturing is paramount to minimizing the impact of these expenses on the public budget.

Though the Turkish government has shown that it is aware of the impact of its pricing formula on the country's manufacturers, substantive change will be critical to ensuring that Turkish pharmaceutical manufacturers are able to invest in building a value-added industry and establishing a stronger presence in foreign markets. A 5% readjustment of the price at which the euro is converted into the lira – what the government has offered as salve – is insufficient. The government must reach a conclusion as to how it will continue to pay for the country's medical expenses.

"The consequences of Turkey's system of price referencing are many, but we must understand what is beneath it," explains Ismail Yormaz, CEO of Recordati, which has invested aggressively in Turkey through two acquisitions. "The cross price referencing system is not the issue. The budget is the problem. These regulations are the fruits of creative minds in the government wishing to foster the expansion of pharmaceuticals consumption without growing the expenditures. The budget was maintained throughout the years while access to medication has soared. What we need to address now is one out of two things: budget or consumption. The government is keen on protecting people's access to medication, which is a remarkable deed. What we need now is the government to pay for what it desires to do.

A readjustment of the country's public budget for medical expenses must take place and, on a policy level, the government must acknowledge that Turkish pharmaceutical manufacturers cannot be expected to singularly shoulder the burden of the country's growing need for medical products. The government must move beyond price cuts.

"Even if something happens this year it will be a small change, a single digit price increase. We have to try harder to convince the government this situation is not sustainable. We are an essential industry for the future of Turkey and to grow we need resources… The industry needs to feel safe if it is to continue investing and pursuing the goals the government wishes us to achieve," explains Serdar Sozeri, general manager of Biofarma, a Turkish pharmaceutical manufacturer that is now heavily focused on biosimilars.

Philip Haas of Deva Holding notes, "If the Turkish pharmaceutical industry is to tap its potential, the government would need to strengthen it by giving some sort of compensation for late currency losses. There must be some kind of rebalance in the market."

This, more than anything else, should be part of the public budget. •

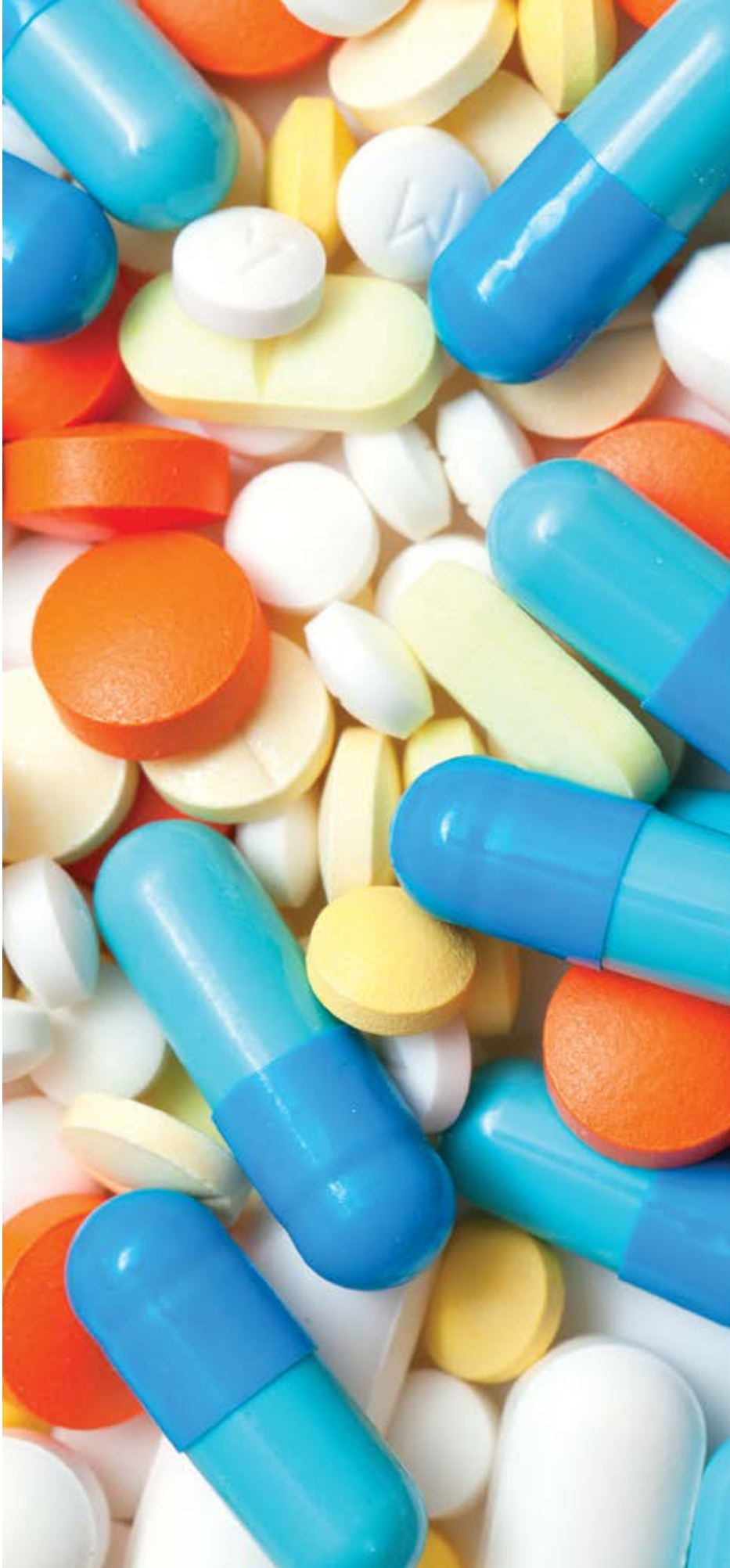




Image: Shutterstock

# Dr. E. Seyfi Moroğlu

Managing Partner
**MOROĞLU ARSEVEN**

**Moroğlu Arseven is recognized for its quality of work particularly in Intellectual Property (IP) and covers a number of industries including automobiles and education. What is the importance of pharmaceuticals and the key services that are increasing growth in this sector?**

We have a very strong IP team, adding substantial value to our pharmaceuticals practice. It is a highly regulated area especially in Turkey. Our team has expertise in a variety of commercial agreements specific to the sector. Corporate law, merger and acquisition (M&A) restructuring also has an important effect on the labeling of a product, albeit corporate law is less pharmaceutical-specific. Our involvement with pharmaceuticals has furnished us with a broad expertise and deep understanding of this sector.

**The demographic structure of the Turkish pharmaceuticals industry has changed significantly over the last five years with many buy-ins taking place, and generic businesses becoming more interested in R&D as external markets are sought. In line with these two changes, how has your client profile evolved?**

We see it more as a relationship with the client and less as a business in terms of a client's profile; a lot of our business is repeat business developed through client satisfaction. Global names have approached us to represent them in Turkey for the establishment of an import-system of parts for refurbished medical devices for one of the three big medical equipment producing companies, for example. Our strategy is also to secure work in new projects, innovative products, some being subject to marketing authorization, and others that are not in semi-pharmaceutical and semi-cosmetic areas. Entrepreneurial groups are exploring these areas. Moroğlu Arseven is also advising ambitious groups that are working globally in medical devices, forming a design team in Turkey and then going to the United States to build up an industrial team to apply for Food and Drug Administration (FDA) approval. Our work evolves as technology and Turkish entrepreneurs develop. Basically, we rely on customer satisfaction.

**In addition to pursuing other external markets, Turkish pharmaceutical manufacturers are now investing more heavily in R&D. There have been many complaints about Turkish patent law. Given the current structure of IP law within Turkey, do you think there is a sufficient framework to allow for Turkish pharmaceutical manufacturers to transform themselves from being just generic-focused to value-added products?**

Arguably, it is ambitious for Turkish generic companies to transform themselves in a matter of years to original product manufacturing companies; albeit it is good to have this ambition to develop but the amount of required investment is inhibitive. For example, the investment of Swiss research into the cure of malaria is close to outweighing the collective annual investment for biomedical research in Turkey. If innovative medicine is addressed to ambitious entrepreneurial groups that have the necessary expertise, with capital infusion they could produce some interesting pharmaceutical advancements, increase the number of R&D companies, and at the same time save the cost of building an R&D team in individual companies.

**Could this strategy be developed in conjunction with Turkish universities through a Public Private Partnership (PPP) model?**

Universities would be a perfect tool to develop the relationship between academics and representatives of companies. It is not in the interest of global companies to stand all the cost of investment of expertise for medicine development but to encourage entrepreneurial activity. Research and products are becoming much more modular; it is an exciting area where more knowledge, work and revenues will be shared. If a special product is developed, it will be purchased by companies like Johnson & Johnson, or Novartis International AG. Moroğlu Arseven is actively involved in the entrepreneurial-side of product development.

**The problem with Turkish IP law is commonly characterized as being rooted in enforcement. When we met with Dr. Cahit Suluk, however, he argued that the true problem with Turkish IP law stems from a damaged legal framework. Is this so?**

Looking at pharmaceutical legislation in Turkey, arguably it is time to introduce a clearer legal framework. Currently, there is not a clear precedent of documents. Consultation with the market would be advantageous to create clearer pharmaceutical legislation with defined headings. Recent efforts by the Competition Authority of Turkey in producing a national pharmaceuticals report established a noteworthy communication among the actors and the regulators.

**Looking forward to the next five years, what would you identify as the two or three largest structural trends that will shape the industry?**

My structural trends are more hope-and-wish, and are: innovation in pharmaceutical products and medical devices, especially in biosimilars, particularly in the areas not covered by global players which may appeal to them; the continued modularization and teaming agreements for R&D; and license exchanges or new patents and calibrations between companies coming from the newest sectors. •

# Gökhan Gökçe

Partner
**YÜKSELKARKINKÜÇÜK**

**The Turkish pharmaceutical industry has seen many acquisitions, like that of Mustafa Nevzat by Amgen. In what way will the profile of Turkey's pharmaceutical manufacturers continue to change?**

In the early 2000s, the Turkish pharmaceutical industry began to lose its national character. Many equity funds bought Turkish generics businesses. Originator companies will continue to extend their businesses to the generic sector via acquisitions. At present, we know of many large global companies that are looking to make buy-ins to the Turkish market.

Turkey offers multinational companies attractive acquisition targets for several reasons related to the commercial dynamics of the country. High standards are employed by manufacturers, as compliance with Good Manufacturing Practices (GMP) is requisite. Also, Turkey's system of reimbursement covers the medical expenses of 95%. This is enticing. Aside from this, though, as the Turkish government understands the importance of cultivating a domestic manufacturing base for pharmaceutical products, an attractive incentive scheme is in place. Even contract manufacturing is looked upon favorably by the state. For these reasons, in the coming five years we will continue to see multinational corporations invest into the Turkish market.

**Some assert that Turkey's intellectual property laws do not offer sufficient protection for the cultivation of research-based industries within the country: specifically, value-added pharmaceuticals. By European standards, how satisfactory is Turkey's system of IP protection?**

Although certain negative impressions exist, it would be fair to state that Turkey's system of intellectual property law is closely aligned with European standards. We offer not only civil protection but also criminal protection in the case of trademark and copyright violations. Further, patents are also protected under civil terms. There is a satisfactory level of IP protection in Turkey; this is evidenced in the activities of the industry, not only innovator but also generic pharmaceutical manufacturers, which have begun to patent many of their own products: a reflection on their growing trust in Turkey's system for IP protection. Today, patents registered in Turkey can easily be cross-applied to other regions. Turkey is a signatory of the European Patent Convention and Patent Cooperation Treaty. Once one has a patent filed in either the United States or European countries, it is fairly easy to register that patent within Turkey.

**In the past decade, several changes have occurred that have reshaped the industry: the introduction of a price-referencing system, the entrance of the multinational corporation into the industry. What changes in industry dynamics has YükselKarkınKüçük seen emerge?**

In the past decade, the Turkish pharmaceutical industry has experienced three major structural changes. First, industry profitability has significantly declined. This is, in part, attributable to public spend cuts and regulatory changes. The introduction of Turkey's system of price-referencing and, more specifically, the Fx rate that is employed in converting the euro to the Turkish Lira in determining the prices at which MA holders are remunerated is responsible for this dynamic. On behalf of the innovator industry we have been handling two lawsuits related to the Fxrate system used for pricing: the first one of which we won, and the second of which is still pending. In the case of the first suit, the Ministry of Health refrained from executing the court decision and it has been for this reason that the industry continues to suffer. This foreign exchange rate model should be applied strictly in accordance with the legislative requirements in a country like Turkey, as otherwise national currency fluctuations would lead to significant losses. Other factors impeding on industry profitability related to pricing include the pricing model at which generic products are reimbursed. If one produces generics and there are competing generics already produced within the country, one is only eligible to receive 60% of the reference price for the product.

The implications of these flaws in Turkey's pricing system are broad. Many multinational companies choose not to present new medication in the Turkish market. Equally, certain products can no longer be produced in Turkey as there is no way in which they can be produced economically. This has led to product shortages and unmet medical needs, especially in critical areas such as oncology and diabetes.

Second, an expectation of reciprocity in the approval of manufacturing sites a has emerged globally. Consequently, the market authorization process is delayed and, as a result, it has become more difficult for multinationals to manufacture and distribute their products in Turkey.

The third change that the industry has experienced has been in the way in which pharmaceutical manufacturers can promote their products in Turkey. MA holders can no longer market their products as easily as previously. The Ministry of Health has become more controlling and there is a greater degree of scrutiny used in the inspection of foreign products. The industry has also been self-regulating for period of time. As industry organizations have published their own codes, the promotion area is subject to much more complicated constraints. Ten years ago the industry was far less regulated. •


# Producing Growth: Pharmaceutical Manufacturing in Turkey

"The Turkish pharmaceutical industry has a long-standing culture of production as well as a well-developed infrastructure. The industry complies with today's international standards in terms of its production technologies, capacity and qualified human resources. With its 77 production facilities, 300 companies and 30,000 employees, our industry produces more than 6,000 products. Turkey first adopted GMP standards in 1984. Today, the production standards of the industry are accredited not only by the Turkish Ministry of Health, but also by other international authorities. Turkey complies with international treaties in the field of intellectual property and complies with European Union rules and regulations. These strengths that we have developed encourage us to move forward and try to ignore short-term problems. We hope these problems will soon be resolved, though, allowing us to succeed in our efforts to make the Turkish pharmaceutical industry a global player."

- Nezih Barut, Chairman of the Board, Pharmaceutical Manufacturers Association of Turkey

Image: ABDIIbrahim
High-speed production and packaging lines using the latest, world-class technology are used in the production and packaging divisions of Abdi Ibrahim's high-tech facilities in Esenyurt, Istanbul

# The View in 2014

Pharmaceutical Production in Turkey

Following a course first set upon in 2011, pharmaceutical manufacturing in Turkey in 2013 was driven by one overriding dynamic: a net decline in profitability. This occurrence has given way to several structural readjustments for the industry: a shift in the profile of Turkey's pharmaceutical manufacturers and a movement on part of the country's manufacturers to restructure their operations. These movements away from what has been the industry's modus operandi have resulted in new drivers for the industry's continued growth, value-added products and export-market development. Through these levers, a better industry is being built.

In 2013, growth of the Turkish pharmaceuticals market stagnated, following a precedent set in years prior. From 2012 through 2013, pharmaceutical sales rose from $8.03 billion to $8.06 billion, an increase of .4%. Since 2010, the value of Turkey's pharmaceutical market has fallen by nearly 18%.

A contraction in the size of Turkey's pharmaceutical market or stagnation in growth, however, has not meant that the industry has seen lower production volumes, or that consumer spending on pharmaceuticals has decreased significantly. Sales volumes from 2012 to 2013 rose by 10 million boxes, returning to the level at which they stood in 2010: 1.78 billion units. Concurrently, per capita drug spending remained nearly static, shrinking from $106.1 in 2012 to $105.2. Nor has this decline in profitability been for lack of potential within the domestic market. Turkey, in fact, remains a very attractive market for healthcare products for several reasons. Jacques Nathan, country manager of Sanofi in Turkey, which stands among the company's 15 most important healthcare markets globally explains: "Turkey's demography is unique; the country offers a population that is young, 50% of the Turkish population is below 30, but aging: the population of those over 65 in Turkey is growing three times faster than the general population. This provides an attractive mix for any healthcare provider. Simultaneously, the Turkish's economy has developed rapidly. Over the course of the past 10 years, Turkey's GDP has led the world in growth, trailing behind only several Asian economies, such as China. These two factors, Turkey's demographic structure and the country's economic development, drew Sanofi to Istanbul from Dubai, where we were previously had our regional headquarters."

Underscoring the current state of industry profitability has been the development of two governmental policies: Turkey's Health Transformation Program and system of drug price referencing. Implemented nearly simultaneously, Turkey's Health Transformation Program sought to dramatically increase medical coverage within the country while Turkey's system of price referencing sought to limit the impact of growing medical coverage on the public budget. Since their introduction, though medical consumption as measured by volume sales of pharmaceutical products has risen by close to 40%, per capita drug spending has increased by a paltry 9%. Limited growth in per capita drug spending has been a consequence of policy tightening. It was in 2011 that industry profitability changed. Although from 2005 to 2010 per capita drug spending increased by nearly 40%, from $96.2 to $133.2, following the implementation of further price cuts through Turkey's drug pricing program, per capita drug spending began to fall to its current level. Coupled with the introduction of a strict convertibility ratio between the euro and lira in 2009, the effect of which became more pronounced in 2011 as the lira began to depreciate, margins for the industry began to shrink.

These resulting declines in profitability have occurred within an environment already rife with competition, owing to the large investments that Turkish pharmaceutical manufacturers have made in expanding their production capacity. Sedat Birol, executive vice president of Eczacıbaşı's healthcare division, which used to stand among the industry's largest manufacturer of generic pharmaceuticals prior to the sale of their assets to Zentiva, commented on Eczacıbaşı's decision to exit the generic pharmaceutical manufacturing market. "Underutilization of capacity is an industry-wide problem. Competition within the sector has therefore become extremely intense." By some estimates, utilization of production capacity at Turkey's pharmaceutical manufacturing plants stands as low as 60%.

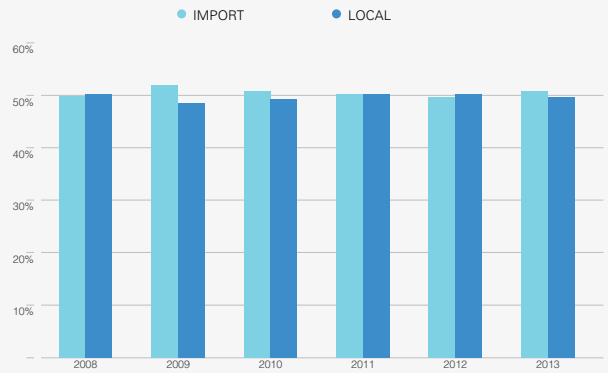
Compounded with a decline in industry profitability, higher levels of competition have reshaped the landscape of Turkey's pharmaceutical manufacturing industry. This is observed both in the implications that this has had on the balance between foreign and local production within the Turkish market, as well as changes observed within what have two of the industry's pervading characteristics: its focus on generics and internally driven growth.

Current industry circumstance has led to a rebalancing of the market away from the local manufacturer. This is seen in two events: the exit of certain manufacturers from the industry and declining market share for local manufacturers. Since 2006, the Turkish market has seen over $1.6 billion in mergers and acquisitions as multinationals and funds have purchased the assets of several of the industry's largest players, such as of Eczacıbaşı and Mustafa Nevzat. Since 2008, the relative market share of local pharmaceutical manufacturers fell to its lowest point in 2013: 77% of the total market by volume.

In tandem with this shift, the ground on which industry participants compete has changed as well. The short-term focus of the market has moved towards higher production volumes, which have become necessary to both continue industry profitability at time when profit margins have been suppressed and amortize the industry's investments in expanded production facilities. In the past decade, production volumes have risen by close to 1.5 billion boxes. Perhaps more significant than this increase: the industry has also acknowledged that new growth

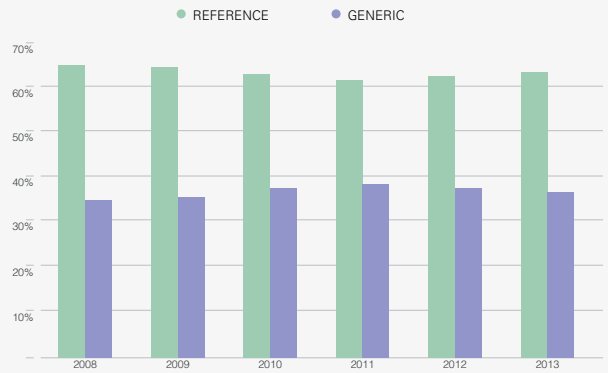
**BREAKDOWN OF RX MARKET - IMPORTS VS. LOCAL - VALUE**

Source: IMS, IEIS



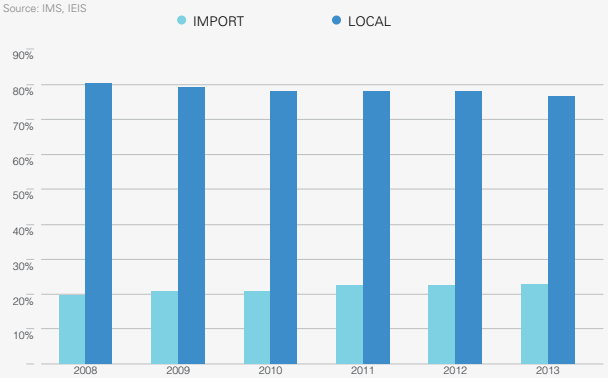

**BREAKDOWN OF RX MARKET - REFERENCE VS. GENERIC - VALUE**

Source: IMS, IEIS



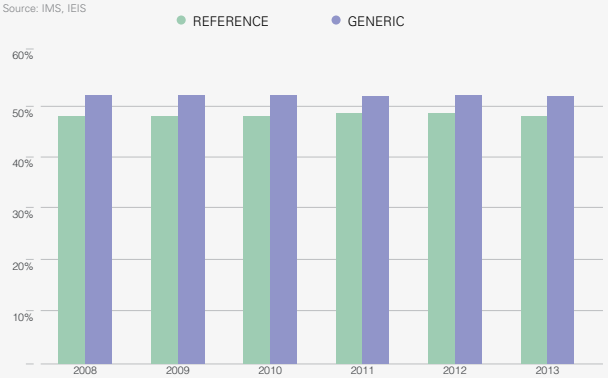

**BREAKDOWN OF RX MARKET - IMPORTS VS. LOCAL - VOLUME**

Source: IMS, IEIS




**BREAKDOWN OF RX MARKET - REFERENCE VS. GENERIC - VOLUME**

Source: IMS, IEIS




will depend upon new products. "Gaining market share, more than anything else, requires new product launches," noted Köksal Ülgen, general manager of Pharmactive, which entered into the market recently through the construction of a $120 million production facility.

The focus of these product launches has evolved in recent times, in line with market conditions and the ambitions of Turkey's pharmaceutical manufacturers to stake out a place in the development of value-added products. Turkey has long been a generic pharmaceutical market. Backed by their focus on generics, many Turkish pharmaceutical manufacturers have built strong, reputable business. However, even the industry's largest generic businesses have now acknowledged that their continued growth will depend upon more than just their generics division.

Süha Taşpolatoğlu, CEO of Abdi Ibrahim, Turkey's largest pharmaceutical manufacturer by revenue in 2013, comments that "looking at the current governing policies and severe price competition within Turkish pharmaceutical industry, it is appropriate for a pharmaceutical company to give more focus towards development of in-house value-added generics and differentiated products. Such an approach will help industry to recover investments and generate more revenue on fast track in order to expand the business globally in a more effective manner." To this end, Abdi Ibrahim has successfully launched first-to-file generic formulations for as Valsartan and Valsartan/HCTz film tablets, both complex products, in Europe. Reflecting this development, the Turkish market has observed a rebalancing of this division between the sale of reference products and the sale of generic products. In two years, the market share of generic products in Turkey has fallen from 38% to 36.7% in 2013.

This, again, has been underlined by declining industry profitability. Kemal Yildiz, general manager of Berko Pharmaceuticals, a mid-sized manufacturer, comments that, "Only those companies that are very large in the production of one type of generic are able to remain profitable: they do so through operating on a very thin margin." Others, like Berko, have specialized areas such as combination products.

Even within pure generics, many pharmaceutical manufacturers have had to alter their approach. Serdar Sozeri, general manager of Biopharma, a leading Turkish generic manufacturer, said, "Biofarma made a shift from large-volume generic business to brand-oriented generic business. You need to have strong brands if you want to augment your profits. If you only play on the discounted generic side, you will be only look at 20% of the market. Otherwise, if you choose to strengthen your brands, you can make a successful turnaround. Bearing in mind our meager financial resources, we gradually increased our profitability by carefully choosing which products to promote. This was all part of a big rationalization process. Now we are

investing our resources in accordance with the quality of the products we have: different products receive different investments. As a result, we doubled our sales per representative over the course of a year."

Some portend that the net effect of current market conditions will be further consolidation. Ersan Erfa, general manager of Centurion, a mid-sized manufacturer that has invested itself heavily in expanding into research and development capabilities and the development of export markets notes: "The place of the Turkish manufacturer in the domestic pharmaceutical industry is shrinking. Profitability is in decline. Small- to mid-sized companies will not survive in the long-term. These companies have now reached a juncture: they must grow and transform themselves into global companies, or they will be swallowed… It is a decisive moment for Turkish pharmaceuticals industry."

Many of Turkey's manufacturers have already begun this process of transformation. Historically, Turkey's pharmaceutical manufacturers had been strongly focused on production for the Turkish market. A population of over 70 million, Turkey offer attractive demographics, but beyond this, continuously expanding medical access through the country's Health Transformation Program and a centralized buyer: the State. However, as market conditions have deteriorated, Turkey's pharmaceutical manufacturers have now acknowledged that their continued growth will depend on more than just the Turkish market.

Dr. Erhan Baş of Bilim Pharmaceuticals, Turkey's third largest pharmaceutical manufacturer by revenue with over $760 million in product sales in 2013, said: "In the last five years, Turkish manufacturers have experienced large price cuts, a discount of nearly 50%. As a result, Bilim Pharmaceuticals has chosen to focus more heavily on external markets. We have placed a strong emphasis on export market development, especially in MENA and the CIS. Our products can now be found in 52 countries. We have very good opportunities to expand further. Compared to neighboring countries, Turkish pharmaceutical manufacturers are very strong. Our exports are increasing each year in double digits. Since focusing more heavily on these markets, we have seen our profitability grow greatly as well."

Constricted space within the domestic market has meant that Turkish pharmaceutical manufacturers have focused more heavily on the development of export market in recent years. Since 2011, the year in which the industry changed, pharmaceutical exports have grown by over 30%. With this, the export-import ratio of the Turkish pharmaceutical manufacturing industry has grown from 10%, the rate around which it has historically fluctuated, to 18.2% in 2013.

The clearest blueprint for how other industry participants must develop has been set by these businesses – those that have altered their growth tactics in response to changes within the market. Since 2011, the industry has embarked upon an irreversible course. Continued growth must be derived through new products and new markets. Through these investments, a better industry is being built. •

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# Süha Taşpolatoğlu

CEO
**ABDI IBRAHIM**

**Abdi Ibrahim, founded in 1912, is among the oldest companies operating in Turkey's pharmaceutical industry. Looking back on this history, can you touch on the most important milestones for the company and its development?**

Abdi Ibrahim was founded by a pharmacist who had a keen interest in production. The first factory was built in 1919, at a time when the pharmaceutical industry in Turkey was based on pharmacies and not on manufacturing. Abdi Ibrahim's founder saw that the future for the industry was in production and distribution across the country. Through the company's three generations,its main driver has been making stronginvestments in manufacturing. Our second factory was built in 1952, and thethird, and most recent,was built in 1999.

**Since 2003, Abdi Ibrahim has been the leader in sales for the industry. Can you introduce us to the firm today and where it stands as a global organization?**

After accomplishing its goal to become the number one company in Turkey's pharmaceutical industry in 2003, Abdi Ibrahim set its sights on becoming strong in surrounding countries and becoming a global player. Our first objective was to be one of the top 100 companies in the pharmaceutical industry worldwide, which we accomplished in 2007. Today we are a regional player and we are working towards becoming a global company in the near future.

**Abdi Ibrahim has made aggressive strides into several key markets, especially among the CIS countries. From a global perspective, whatis your overall production capacity and capacity utilization?**

Revenue coming outside of Turkey accounts about 10% of Abdi Ibrahim's total turnover. We have mainly three types of business model to penetrate into more than 25 countries that we have presence. We have our own teams and structure in Kazakhistan, Algeria, Georgia and Azerbaijan. Indeed, following our purchase 60 % shares of a leading Kazakh company in 2013, we will start manufacturing at the end of this year in Kazakhstan and we are close to conclude an agreement in for a joint venture in Algeria for local production. Having manufacturing sitesat three different locations within the region would give us flexibility to supply nearby markets from those manufacturing hubs. Additionally, we are working with partners under Abdi Ibrahim trademark in 15 more countries, out of which Iraq, Albania and Germany are the largest ones. Finally, we have a licensing business where we license out our products to global and regional pharmaceutical companies in multiple territories. In the coming years, our objective is to have a balanced distribution of revenue and capacity utilization between local and international markets.

**When it comes to entering into foreign markets, a key challenge for Turkish pharmaceutical manufacturers has been marketing authorization. Has it been difficult to obtain authorization in the international markets where you are active?**

Registration process has its own difficulties everywhere. Indeed, regulations in some countries like the US and the EU are tougher than the CIS and Middle Eastern countries however the gap is closing swiftly. Though, we selected initially CIS and Middle East for expansion, since 4 years, we have also reasonable presence in the EU via our affiliated company in Portugal. However, CIS and MENA region still havetheir regulatory and market access advantages to those investors who are willing to contribute to the pharmaceutical industry especially via coloborating with local partners who havemoreopportunities to overcome potential obstacles.

**Abdi Ibrahimnot only manufacturesits own products, but also carries out toll-manufacturing and out-licensing. What is the breakdown with regard to relative contributions to revenue for the group?**

Abdi İbrahim has a different business set-up compared to the other companies in Turkey. We have a balance between original products and branded generics. Nearly 50% of our turnover comes from in-licensed original products. We are representing almost 40 companies from different regions of the world, such as Japan, Korea, the USA and Europe, for both marketing and manufacturing. We are also representing some of those companies internationally and trying to increase the share of our original products in the countries where we are actively operating by using our long lasting relations with those companies and our growing market shares in these countries. Our out-licensing busi-

ness is also growing for the last 3 years, thanks to our experience of working with 40 countries across the world and our growing pipeline. We expect to reach to sales of 50 mio. USD in a couple of years.

**One of Abdi Ibrahim's most impressive contributions to the industry has been through its R&D, given that the company has the largest R&D campus in the country and dedicates 5% of its annual turnover to R&D. Can you tell us about the current initiatives at your laboratories?**

With its own infrastructure and technical capabilities, Abdi Ibrahim already established its global presence by successfully launching first to file generic formulations of complex products such as Valsartan and Valsartan/HCTz film tablets across Europe. Abdi R&D center was awarded by Ruban d'Honneur in European Business Awards among 3500 companies.

The current initiatives of Abdi Ibrahim involves the development of value added complex generic formulations designed by adopting novel innovative technologies such as emulsion based nano-particulate based, and dry powder for inhalations etc. Recently, Abdi Ibrahim successfully launched its first dry powder inhalation formulation in the Turkish market.

Apart from regular generic formulation development, Abdi Ibrahim has also acquired in-house technical capabilities and expertise in the development of new fixed dose combinations and complex ophthalmic suspensions meant for regulatory markets.

**Considering R&D within Turkey, some industry players advocate for spending considerable amounts in developing APIs and new molecules, while others believe that the future is in development and product formulation. Which do you believe is the appropriate path for development of the Turkish pharmaceutical industry?**

Because of the scale, in-house API manufacturing is considered to be not feasible and therefore most of the major pharmaceutical companies are strategically involved in the development of finished drug products.

Looking at the current governing policies and severe price competition within Turkish Pharmaceutical industry, it is appropriate for a pharmaceutical company to give more focus towards development of in-house value added generics and differentiated products. Such an approach will help industry to recover investments and generate more revenue on fast track in order to expand the business globally in a more effective manner.

**Directly linked to companies' ability to invest in R&D is their profitability. How have the current issues of Turkey's system of price referencing and, more specifically, the freeze on euro-lira convertibility impacted the industry's profitability?**

These are real issues for all of the pharmaceutical industry, includingmultinationals. Multinationals in particular are struggling against parallel trade issues and the possibility of Turkey's becoming a reference country. For local companies, the issue is earning enough money so that they can invest in the future.

For all companies on the other hand, it isa burden to make the necessary investments because prices in Turkey are generally low due to constantly decreasing prices in the reference countries.

**The government is increasingly acknowledging the importance of the pharmaceutical industry to the national economy and has identified the sector as one of the top five most critical industries for the country's development. Looking at its initiatives within the industry, in what ways can the government better support the Turkish pharmaceutical manufacturing sector?**

Based on the vision 2023 plan, the government has choosen several areas where it is willing to invest within the pharmaceutical industry, the fist ones are onclology and biologicals, the second is positioning the country as a hub for exports to region, and the third is promoting Turkey as a managment hub for multinationals.

Turkish pharmaceuticals sector thinks in the same direction with the government for the vision 2023 plan, however, in order this vision to become real, the sector needs more support, especially, for its internationalization. Among all the relevant fields, research and development as well as new dedicated manufacturing site investments, governmental initiatives for international accreditation of Turkish quality and good manufacturing practices certificates to ease the market access are curucial to become a strong player as a country in pharmaceuticals field in the region.

**In the next five years, what is the growth strategy you have envisioned for Abdi Ibrahim?**

We plan to grow mainly in areas of biological and oncology products whereas we want to grow our export and OTC businesses and explore new products to license.

**Do you have a final message for the executives that will be reading this publication?**

Turkey is a huge country and its pharmaceutical market will be one of the world's biggest pharmaceutical markets in the future. While the country has currently its challenges, those who invest in Turkey today will earn. •

Image: Abdi Ibrahim. Abdi Ibrahim's production facilities.

# Dr. Erhan Baş

General Manager
**BILIM PHARMACEUTICALS**

**Last year, Bilim Pharmaceuticals celebrated 60 years of operations. Looking back over the course of the firm's history, can you provide us with an overview of the company's recent milestones in development?**

In the last five years, Bilim Pharmaceuticals had the largest growth rate in the domestic market. The major reason for this is our R&D program, which produces many new products and value-added generics. Starting from 1998, Bilim began a strategic plan to focus on new products. We planned to establish Turkey's biggest R&D force, and today we have two factories, one of which is approved by Germany and the other which is approved by the UK. This means that we can manufacture products from Europe.

We also have a very powerful sales force in the market and a broad range of products in our portfolio. Looking at our operations, in 2011 we received the EFQM Excellence Award and all of our processes are benchmarked at European standards. Bilim is also a leader in sustainability for the industry. Our sustainability report received an A+ from The Global Reporting Initiative (GRI), making us the only company in any sector to receive this grade.

**In 1998, when Bilim made the decision to focus on R&D, most manufacturers in the industry were focused on the generics business. What vision did you have in mind when you made this shift in strategy?**

At that time, the generics market was not as competitive. There was a good chance that if you had a strong product you could go to the market quickly. If you compare this with today, all major segments in generics are very crowded. Bilim saw that life expectancy was increasing in Turkey and that each year 1 million babies were born, which meant that we should focus on the acute and chronic diseases markets. Within these markets, the most important were diabetes and asthma. We are leaders in both of these fields, as well as oncology, which is a growing segment today. Now our strategy is focused on the production of biosimilars, which we believe will be very important for Turkey in the near future.

**Many Turkish manufacturers have acknowledged that as a result of the cross price referencing system that the future for the industry lays in foreign markets. Today what is the relative importance of your domestic business versus exports?**

Bilim is now focused on exports. In the last five years, Turkish manufacturers have experienced large price cuts, a discount of nearly 50%. As a result, Bilim Pharmaceuticals has chosen to focus more heavily on external markets. We have placed a strong emphasis on export market development, especially in MENA and the CIS. Our products can now be found in 52 countries. We have very good opportunities to expand further. Compared to neighboring countries, Turkish pharmaceutical manufacturers are very strong. Our exports are increasing each year in double digits. Since focusing more heavily on these markets, we have seen our profitability grow greatly as well.

At the same time, the Turkish market is large and will grow in the near future by 5% to 6%. Each year we are sending almost 50 new products to the Ministry of Health for the domestic market. Almost 95% of people are under the reimbursement umbrella, which means that they can get their products free of charge. There is also a family practitioner system, which has increased access to doctors. We will widen our portfolio, not only for exports, but also for the domestic market.

**Turkish manufactures focused on foreign market growth are faced with the challenge of market authorization. What do you think is most important in crafting an access strategy for some of these difficult markets?**

The Turkish markets are first going to neighboring countries, then Europe and then the United States. We are lucky that Bilim's two manufacturing sites are approved by Europe. As well, Turkish regulations are comparable with Europe. There is still a lot of competition in Europe with Chinese and Indian companies, which is why we are focused on value-added generics and combinations.

**Bilim has found success in your focus on chronic diseases. Looking at the lay of the market, in which specific therapeutic areas are you focusing your R&D strategy?**

We are focused on diabetes. In the last five years, the number of diabetic people has doubled in Turkey to 14 million and obesity is increasing globally. Globally, pollution is rising, meaning that we will also focus on asthma. We are also looking for biosimilar products for oncology, as well as anti-depression products. Because of the increase in life expectancy, many diseases such as Alzheimer's are increasing and we are looking into products for this area, as well as eye products. We are also the sales leader in acute diseases.

**Some have argued that Turkish companies do not have the necessary financial strength to adequately invest in biosimilars. As a Turkish company that is investing in this area, what is your approach to biosimilar R&D?**

It is difficult to find new biosimilar products, which is why we are looking to partner with Asian companies. We will manufacture some part of the process in Turkey, which will increase our sales. It is also important for biosimilars to have approval in either the United States or Europe, as well as to find alternative APIs. Bilim has 100 people working in R&D and has brought in experts from India. After the market's price cuts, profitability is much less; therefore one part of our R&D is only focused on APIs.


Image: Bilim Pharmaceuticals. Bilim has a plant in Gebze and one in the Çerkezköy Organized Industrial Zone. Gebze entered operation in 2008, and it is Turkey's largest drug manufacturing plant according to production forms. Çerkezköy entered operation in 1998 and was built on an area of 22,000 m2 including an indoor area of 9,250 m2.

**Most recently Bilim won the EFQM award from the European Quality Association, which has not been won by a European company in three years. What do you think is most important about developing systems that are effective in maintaining product quality?**

The main factor is related with human resources. Bilim's focus is on recruiting talented people and keeping them. Leadership is also important. We have 11 assistant general managers in the company, in addition to 42 teams working in the company. Our performance management system is also very strong and we have a very good training, carier, performance and internal promotion systems.

**As the local industry profile's has changed over the past decade with many buy-ins and sell-outs, what do you foresee for the development of Turkey's pharma industry in the medium term?**

The growth rate of the market will decrease year by year but still we have a good potential compared to Europe. Turkey is a regulated market, so many multinational companies are setting up their regional headquarters here and we expect multinational companies to continue making acquisitions in Turkey. Turkey can also be an important site for production for Europe; labor costs are lower and our manufacturing sites are of good quality. We can also be a center for R&D and a site for clinical studies.

**In the next five years, what is the growth strategy you have envisioned for Bilim?**

Bilim has the third largest position in the Turkish market and we will maintain this position. We own 96% of our products, which is much higher than our competitors. We are also the first or second company in terms of the number of products submitted to the Ministry of Health. We believe this to be key to business growth. We will be powerful in the near future, and we will increase our exports with a focus on healthy growth and profitability. •

# Hasan Ulusoy

Chairman
**NOBEL**

**Nobel dates to 1964. Could you provide us with an overview of Nobel's development over the course of the past half century?**

This past half century has witnessed the development and modernization of not only Nobel, but also the Turkish pharmaceutical industry. In 50 years we have evolved from being a small scale production facility with limited capacity to a leading business capable of producing almost all forms of pharmaceutical products with an important place in global pharmaceutical markets.

**Could you please provide us with an overview of Nobel's activities today?**

Nobel has long had a focus on establishing itself as an integrated business. We carry out all pharmaceutical related activities, from product development to marketing and sales of the products, within our own organization. We have one of Turkey's largest research and development departments. We also produce our own active ingredients in our API production facility in Cerkezkoy for captive use. We also sell these APIs to other companies in Turkey and abroad. In our pharmaceutical manufacturing facility in Duzce, in addition to producing our own products for domestic and global markets, we are also contract manufacturing for both national and international companies. We export finished products to nearly 50 countries. We have more than 600 medical representatives in seven marketing groups who visit thousands of physicians and pharmacists every day, promoting our products.

**As one of the industry's most important manufacturer, what changes have you observed within the business environment surrounding Turkey's pharmaceutical industry over the course of the past two years?**

Ten years ago the Turkish government embarked on a set of ambitious reforms for its healthcare industry through the creation of the "Health Transformation Program." Today, the general public is highly satisfied with the results of this program: the country has succeeded in its aim of extending and providing better access to quality healthcare services to the general population. There has been a significant increase in the number of visits to public health faciltiies, as well as in the consumption of pharmaceutical products among other related healthcare services.

The consequence of this program has been to increase healthcare expenses for the government. This increase in expenses has been weighed on the pharmaceutical sector as a burden that has been very difficult to manage. For instance, according to the pricing guideline, the price of pharmaceutical products has to be updated as TL/Euro exchange rate changes. However, this rate has remained the same for the last four years while the approved prices of pharmaceutical products should have risen by at least 50%. Under these circumstances, it is very hard to speak of a favorable business environment.

**Could you please provide us with an overview of Nobel's financial performance in 2013?**

According to IMS data for the year 2013, we achieved over $160 million in domestic sales. Our export sales stood at over $50 million. Our sales abroad, carried out by our own marketing and sales teams, have reached $ 100 million level.

**What trends has Nobel observed in product sales?**

Turkey is one of the best examples in the world for social security implementation. Almost the entirity of the population is covered by the country's social security system. It is also the same case for medical reimbursement. The social security system covers a wide range of pharmaceutical products that are reimbursed at a very high percentage. Up until recently, almost 95% of the products sold in the country were reimbursed. Owing to this dynamic, pharmaceutical consumption has grown by 20% in recent years.

**A key issue for the Turkish pharmaceutical manufacturer has been in accessing foreign pharmaceutical markets. Could you please provide us with an overview of Nobel's activities within foreign markets? What is the strategic importance of exports to the country's continued development?**

Nobel leads the Turkish pharmaceutical industry in product exports. In addition to the 20 countries in which we actively carry out our own promotion and sales operations, our products are also available in more than 30 countries in European, African and Far Eastern markets. We are supplying these countries' demand for our products largely through our manufacturing facility in Turkey. Our activities in Turkey are complemented by two manufacturing plants we have outside of the country: one in Uzbekistan and one in Kazakhstan.

The development of export markets for Turkey's pharmaceutical manufacturers remains a critical issue with which the industry must grapple. While there has been progress in recent years, the ratio of exports to imports is still below 20%.

**In what way has Turkey's system of price-referencing impacted on Nobel's profitability?**

Today, on the 10th anniversary of the reference pricing system, there are severe concerns about the future of the industry. Prices of many pharmaceutical products are lower than a decade ago. Still, the TL/Euro exchange rate applied to pharmaceutical products is 1.9595: the actual conversion rate sits at around 3.00 TL/Euro. As per our industry's pricing guideline, drug prices should be more than 50% above the value at which they are currently priced. Continuous decline in European reference prices and a lack of updates to exchange rates aside, inflation, which has plagued the country for the last ten years, raising prices by more than 100%, has placed the pharmaceutical industry in a difficult position. We are aware that, as an industry, responsibility for ensuring high quality and broad access to pharmaceutical products also falls upon our shoulders. However, there must be a change in policy on the part of the government. Be this as it may, we feel confident in the bright future of our country and the success of our actions abroad.

**Many Turkish manufacturers are now interested in the development of biotechnological products. How has Nobel focused on this?**

Interest in biotechnological products is on the rise in Turkey, fueled by the government's identification of biotechnology as a strategic area of interest. We are proud to support the government in reaching its goal through our work in this critical area. Nobel is heavily focused on the development of these products. •

Santa Farma,
leading pharmaceutical company
in Turkey in branded generics

**With Core Values**

- Respect for the individual,
- Continuous improvement,
- Rational power,
- Respect for the work,
  workplace and society.

Santa Farma
www.santafarma.com

# Erol Kiresepi

Chairman and CEO
**SANTA FARMA**

**Santa Farma celebrates 70 years of history in 2014. Could you provide us with an overview of the company's development?**

Santa Farma began operations in 1944 as Farma Laboratories; in 1946 it joined Santa Laboratories, thus becoming Santa Farma. In 1953, Santa Farma decided to construct a production facility: this is still being used today, having undergone several upgrades and additions. In 1964, we signed our first contract manufacturing agreement with the Dutch company Organon, a hormone manufacturer. Organon was then acquired by Schering-Plough, with whom Santa Farma continued to work. In 1989, we started importing biotechnological products into Turkey, and in 1997 we reshuffled our marketing department and upgraded our systems. Santa Farma started producing its own generics mainly from 2000 onwards. The latest milestone for the company was in 2012, with the groundbreaking ceremony of our new plant. This plant will be our greatest step forward and a key element of our new growth strategy. It is being built on 80,000 square meters of terrain, from which 43,000 square meters will be constructed area. This is a €100 million investment: around 85% of the machinery used is brand new. As we seek FDA and EU GMP approval for the plant, we have actively engaged consultants from the US and Europe. We plan for our facilities to be compliant with the standard manufacturing practice of tomorrow. We have taken into consideration new trends already being discussed by the major regulatory institutions. Santa Farma's new strategy puts exports as the main driving force for growth, and, to export, we need bigger production capacity and new, high-quality products.

**Many Turkish pharmaceutical manufacturers have now acknowledged that, given the shrinking space available at the domestic market, the future lays overseas. You mentioned that Santa Farma is targeting FDA approval: what markets are you currently in and which ones are you targeting for the future?**

Today Santa Farma exports to a number of countries in the Balkans, the CIS, Southeast Asia, South America and the Middle East. However, our targets for the future are the western economies. Mature markets can offer better prices. The challenge lies in the premise that entering these markets with pure generics is unfeasible. Alongside our new plant we are inaugurating a new R&D center. This will be a 3,500 square meters facility with 100 employees. This new R&D will help us develop more new combinations and value-added generics to enter these markets.

**Some say that for Turkey to carve a niche in the global market with biotechnological products it would have to partner with multinational companies. Does the Turkish manufacturer have the financial strength to embrace such endeavor?**

It is not a matter of financial strength but rather technology and time. Some Turkish manufacturers are looking for joint ventures with known global biotechnological companies. When you invest in biotechnology you cannot manufacture only for Turkey. You need to target larger markets. There are not that many local companies pursuing aggressive export-led growth strategies while introducing value-added products into the market. And some are even looking for a potential buyer. Regardless of that, the core companies shall remain. Santa Farma wants to grow by itself: we have our own financial means. Santa Farma is investing without the help of any partners or foreign capital and the development of biotechnological products is one of our goals. We foresee a good future without selling out. We would only team up with a solid partner for a joint venture company, if he can provide the means for a significant strategic expansion well beyond the current capabilities and reach of the company.

**Having a strong pharmaceutical sector is in the interest of the country. In recent times the government has become more embracive of the Turkish pharmaceutical sector. Moving forward, what kind of support can the Turkish government provide manufacturers?**

The government has given incentives for production facilities construction and this has influenced our decision regarding our new plant. What has to be done now is tackling the current account deficit, and to do that one must invest. This, how-

Image: Santa Farma. Santa Farma's new production plant and R&D center is being built in Dilovası Gebkim Organize Sanayi Bölgesi on an area of 80.000 m2 and its production capacity will be 150 million boxes.

ever, demands profitability. With the current price referencing system we are running out of investment capabilities. The 1.95 euro-lira conversion rate is not sustainable. The Government's pharmaceutical budget must be readjusted.

The impact of Turkey's price referencing system goes beyond the domestic market. When one exports, customers take as reference the price of a given product in its domestic market. A low domestic reference price diminishes our profits abroad. It has a similar effect on multinational companies, which prefer not to introduce new products into Turkey, if it means losing worldwide profitability. Selling to Turkey is admitting to a lower reference price, and it has been because of this that Turkey has not seen many innovative new products introduced. Price constraints have prohibited access to certain treatments in our country.

**In addition to being the chairman of Santa Farma you also hold a position as vice president of the Turkish Confederation of Employers Associations (TISK). Can you briefly introduce us to TISK and the work the organization undertakes?**

TISK is the umbrella organization to represent Turkish Employers in Industrial Relations both at home and abroad. TISK is composed of 23 Member Employer Associations of various economic sectors with 9600 enterprises and 1.230.000 employees. In Turkey, TISK is responsible for social issues: we deal with trade unions, labor laws and related issues. TISK represents the Turkish employers at the International Labor Organization (ILO), Business Europe and OECD amongst others. I am the Vice President of that organization and I have been representing Turkey internationally since 2011, during the French, Mexican, Russian and Australian G-20 presidencies. I have been reporting our views as a business community to the governments, ministers and presidents at G-20 conferences. At the moment we are preparing for next year's round, which will be held in Turkey.

**A country is only as successful as the talent of its people. Do you think Turkey has sufficient human resources to transition into R&D-intensive industries?**

Turkey currently suffers from a skill mismatch, but this mismatch is not a Turkish problem only: it is a global phenomenon. In the European Union today you have four million unfilled positions while having high unemployment rates. Employers cannot find people with the skills they need since universities are not teaching the skills industry needs. Governments, universities and schools should develop their curriculum in conjunction with the business community. When this is not done you have a market with skill mismatches.

**Taking a broader view on Santa Farma and considering the expansion plans the firm has, what is your five-year plan for the company?**

Santa Farma will have new manufacturing facilities and a new R&D hub opened by the end of the year. Our first target is to become a top-three local company in the Turkish market, having a market share above 2.5%. As a second goal, we want our exports to reach 15% to 20% of total sales. Santa Farma is also aiming at enhancing its contract manufacturing business: we are already talking to some international companies in order to produce in Turkey for export. Our plant today has a 55 million-unit output. When we take into account toll manufacturing, this rises to 65 million to 70 million units. But these figures will more than double in the new production facility.

**Do you have a final message to the executives that will be reading this publication?**

Trust the Turkish pharmaceutical industry and its future. I have this trust, and that is why I am committing resources into a new production plant for Turkey. •

# Hakan Atay

CEO and Country Head
**SANDOZ**

**Sandoz's presence in the Turkish market dates back over 50 years. Could you provide us with an overview of the firm's operations in the country?**

Sandoz is the generic pharmaceuticals division of Novartis and a worldwide leader in generics. Our roots in Turkey can be tracedback to the foundingof theİlsan-Pharmaceuticals in 1964. In 1999, İlsan was acquired by the Hexal Group, which in turn was acquired by Novartis in 2005. Our presence today comprises two manufacturing plants, one active pharmaceutical ingredients (API) plant, and a head office.

We are proud of our long history of producing high-quality, affordable medicines and the contributions we make to Turkey and its economy.However, our work benefits not only Turkish patients. In fact, Sandoz Turkeyexports drugs to 29 countries across the world andhas been recognized as a Turkey Pharmaceutical Products Export Leader since 2005.

**Could you provide us with an overview of your facilities in Turkey?**

Globally, Sandoz has a portfolio of approximately 1,100 molecules and holds the #1 position in biosimilars as well as in generic injectables, ophthalmics, dermatology and antibiotics, complemented by leading positions in the cardiovascular, metabolism, central nervous system, pain, gastrointestinal, respiratory, and hormonal therapeutic areas.

With the advantage of global heritage and product range, we provide a broad portfolio that includes RX, OTC, Biosimiliars and Oncology products to Turkish patients. As a differentiation point, our operations of our facilities in Turkey are strongly oriented towards the exportation of products. Through these activities, Sandoz is the largest exporter of pharmaceutical products operating in Turkey.

Sandoz has long understood the importance of Turkey as a manufacturing center; Istanbul was always envisaged as a strategic location. Exports will continue to be an important focus of our Turkish operations. Our research and development centers are dispersed throughout our global operations.

**The profitability of many operating in Turkey's pharmaceutical manufacturing industry has declined in the past several years on account of the Turkish government's system of price referencing. What implications has this system had on Sandoz, a business that is heavily focused on exports in Turkey?**

The pricing policy of the Turkish government has been and remains very clear. The Turkish government is the largest buyer of pharmaceuticals in the country. They also are the sole arbitrator of the country's pricing system for this reason. As a company operating in Turkey, we must comply with the standards set by the local government.

**Recognizing the strategic importance of the Turkish pharmaceutical industry to the country's continued economic development, the Turkish government has shown a greater level of support to the industry in recent years, particularly so as to encourage the development of value-added industries. Is the framework that the government has in place today sufficient? How is this system evolving?**

The Turkish government is actively working to better support the industry by incentivizing the development of research and development. This incentive scheme, which is certainly sufficient, is set within the larger framework of the government's pharmaceutical pricing system. It is in this area that the government is focusing its policy making efforts.

**Sandoz, globally, is known for the strength of its biosimilars division. Many Turkish pharmaceutical manufacturers are now focused on the development of biosimilar products. What does the successful development of a biosimilars business depend upon?**

Sandoz is the global leader in biosimilars with over 50% market segment share which includes all the biosimilars approved in the highly regulated markets of US, Canada, EU, Japan and Australia.

As Sandoz Turkey, we currently market human growth hormone and we will continue to provide differentiated high quality and affordable biosimiliars products in coming years.

**What will Sandoz's five-year growth strategy entail?**

The fundamental goal of Sandoz in Turkey is to increase access to high-quality,affordable medicines, in line with our global strategy. In Turkey, our strategy is to be among the top five largest companies in the Turkish generic industry. Currently, we are ranked 12th. Our initiatives in the next five years will focus on the development of difficult-to-make generics and biosimilars.

**Please provide an overview of Sandoz's manufacturing facilities. What is the production capacity of each facility? At what does capacity utilization stand? Which therapeutic areas do these facilities focus on?**

We have two manufacturing plants in Gebze and one API site in Tuzla. All of the sites arelocated on the Anatolian part near Istanbul.

The Gebze sites are amongSandoz's main production centers.The products produced at the Gebze sites are distributed all over the world and also delivered to the local market through a well-integrated Supply Chain network.

Through our active pharmaceutical ingredients plant in Tuzla, Sandoz supplies API's both to the company's operations within and outside of the country. Some of the therapeutic areas that we focus on in our API site are products for anti-ulcer, muscle relaxant, anti-coagulant, cardiovascular, animal health and antifungal. •

# Rovshan Tagiyev

Founder/Chairman
**WORLD MEDICINE**

**To begin with, could you provide us with a brief overview of some of the important milestones in the development of World Medicine Company?**

Our company was established and started to carry out its business activity in the USA. We initially focused on creating a product assortment and gaining the distribution rights for international markets by entering into license and distributorship agreements and, of course, on marketing our products. Later on we realized that we would accomplish our objectives more effectively and establish footholds for penetrating new markets if we transferred our headquarters to the United Kingdom (UK). So, in 2004 the company World Medicine UK was established, and World Medicine USA transferred all its rights to the newly created company. Subsequently, World Medicine Company has grown swiftly; due to the location of headquarters in Great Britain it has been easier to administer and manage the company's business in operating countries. Aimed at business expansion, affiliated companies under the identical name of World Medicine have been created in Greece, Bulgaria and Turkey. Within a short time frame over 40 strategic partnership agreements have been concluded, and our company's products are available in more than 16 countries. We are a successful pharmaceutical company with a history of introducing high quality and effective medicines aimed at increasing the quality of life, and we are committed to maintain our reputation as a reliable partner, supplier, and employer respected for our high level of professionalism.

Nowadays, World Medicine Group is a successful leading company in many operating countries. We have our own research and development laboratory, as well as our own production facilities. Our company's portfolio contains more than 350 products. World Medicine Group employs more than 4000 people. Our products are available in morethan 23 countries.

Our motto is "Health is a treasure we share".

**What factors motivated the establishment of World Medicine Turkey in 2011?**

In 2007 we initially came to Turkey to create a logistics center in a free-trade zone for our group of companies, and we succeeded within a short time frame. Being in Turkey, we started to conduct market research and to study Turkish market opportunities, whereupon we took the decision to set up an R&D laboratory and establish own production facilities. This decision was based on the idea that Turkey is a logistical hub, as well as the fact that the pharmaceutical market of Turkey is quite developed, and Turkish products are in great demand incontiguous countries.

The pharmaceutical industry of Turkey is renowned for its highly-qualified work force and the implementation of high technologies for production. Also, the pharmaceutical sector is rapidly growing, and the Turkish government provides the industry with terrific support. The government has implemented reforms of regulatory affairs authorities for the pharmaceutical industry, resulting in more streamlined and effective processes compared to other countries. Ultimately, we respected the geographic position of Turkey: its location in an area of strategic importance, advantageous for expanding the coverage of operating countries for our company worldwide, and the government of Turkey shared our goal of increasing the export of high quality pharmaceutical products.

**What have been the growth patterns and main milestones since World Medicine was established in Turkey in 2011?**

We set up the R&D center to support all of our companies in 2011. We have just completed the construction of our own production facility in Istanbul, which has a production capacity of 65 million boxes per year. It took us three years to finish the construction and arrange the production process. We invested considerable resources in new product development. These investments resulted in a $12 million valueincrease of our export volumes from Turkey in 2012-2013,in a very short time frame. Although Turkey only accounts for 3 percent of the total business of World Medicine Group, we aim to grow. Our targeted export turnover from Turkey is $150-$200 million by 2016-2017. We are currently exporting our products to 23 countries worldwide and we are planning to expand our markets by two or three countries per year. Our main targeted territories are the ex-Soviet countries, Asia, Middle East, Africa, as well as Eastern Europe. On a long-term horizon we are planning to enter the markets of more than 10 countries in South and North America, as well as Europe.

**World Medicine is very upbeat about its business operations in Turkey, but there is one challenging aspect of Turkish pharmaceutical industry: the pricing system of the internal market. Will this affect your company or will you export most of your products?**

This pricing system considerably affects the policy of all pharmaceutical companies; our company is not an exception. But unlike other companies, we are focused on exporting our products, for this reason the issue of price adjustment does not have a great


Images: World Medicine.

influence over our plans. Pricing is quite a complicated issue, and the careful attention of relevant governmental authorities should be focused on keeping producers interested in the pharmaceutical market of Turkey.

**World Medicine conducts its research and development activities in Turkey, working closely with local universities. Could you please describe your R&D operations and your collaboration with universities?**

Out of more than 300 total employees, we have over 75 people committed to R&D. Our research and development team is top-notch, as are our facilities. Our R&D staff is working on over 100 products at the same time, coordinating with many different departments. We also work side by side with Turkish universities. We have successfully completed two projects in collaboration with local universities. We primarily work on new molecule formation and new products. We are constantly maintaining contacts with scientists, who work in different universities of Turkey in order to gain access to important knowledge. As you know, development does not exist without scientific support.

**Could you please tell us about the local workforce and how World Medicine sources its employees?**

It is not easy to find qualified people for new projects and products. There are many specialists who can work in our R&D laboratory or at the production facility. There is an abundance of excellent professionals working in our company. As far as new technologies for the production of pharmaceuticals are concerned, there are specific difficulties while searching for experienced personnel. For instance, it is rather complicated to find experts in biotechnology.

**It is not too late for Turkey to enter the wave of biotechnology that is revolutionizing in global pharmaceutical industry. Is World Medicine focusing on biotechnology products or planning to develop partnership with other companies in the sphere of biotechnology?**

We are not engaged in any joint ventures at this time but we are looking for them and imagine future partnerships in biotechnology. The market for biotechnology is rapidly growing, and 100 % of products are imported. The government of Turkey renders significant support for companies involved in developing biotech products. I think in 3-4 years the first biotechnology products arising fromlocal manufacturing will become available on the market.

**What does the future hold for World Medicine in the next five years?**

As a group of companies, we are planning to improve and increase our production capacity. We also expect to be active in more countries, spreading our footprint all over the world. And we surely want to grow our business and increase our income. We are currently building another factory in Belarus which will cost approximately $55 million. In 2016 or 2017, we plan to construct a second factory in Istanbul for the manufacturing of sterile pharmaceutical products.

**Do you have any final thoughts for our readers?**

The Turkish pharmaceutical industry has already become a part of the global market but we hope and expect that it will play a larger role in the future as the local pharmaceutical market is expanding rapidly. For example, this year the CPhI Worldwide conference

Image: World Medicine.

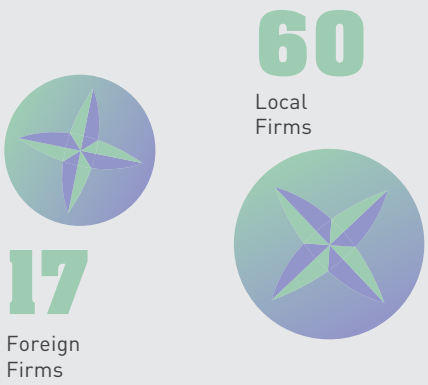
was held in Turkey for the first time. We strongly encouraged UBM (United Business Media) to arrange a conference here in Istanbul, and finally this event has taken place;we believe that this is an exceptional opportunity to showcase Turkish production to the entire world. Turkish factories are technologically superior to many factories in the world, and this is something for which Turkey should be recognized and appreciated by global community. Global recognition will attract new investments to Turkey, resulting in increased market competition, and therefore Turkey will turn into a global player in the pharmaceutical sector.

We salute the government of Turkey for its contribution to the development of the pharmaceutical industry. Going forward, we would hope that the government of Turkey performs an in-depth study of the practical application of the regulatory frameworks of other countries. This will improve the local pharmaceutical industry of Turkey. For example, there is a general discussion for joining the Pharmaceutical inspection cooperation scheme (PIC/S) which would favourably affect the pharmaceutical sector by facilitating the entrance of Turkish producers into new markets. Joining the above mentioned system would ease registration formalities and promote the recognition of Turkish companies in the global community.

I am sure that the medicinal products manufactured by Turkish pharmaceutical companies are of the highest quality, and over time Turkish production will gain the confidence of international consumers, and therefore the Turkish industry will occupy a relevant place in the global market. •

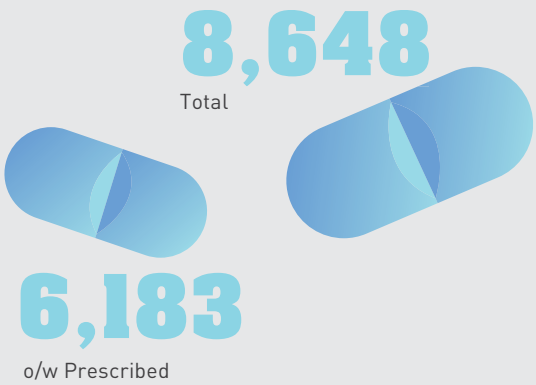
## NUMBER OF PHARMACEUTICAL MANUFACTURING FACILITIES IN TURKEY

Source: IEIS




## NUMBER OF PHARMACEUTICALS ON THE MARKET (2013)

Source: IEIS

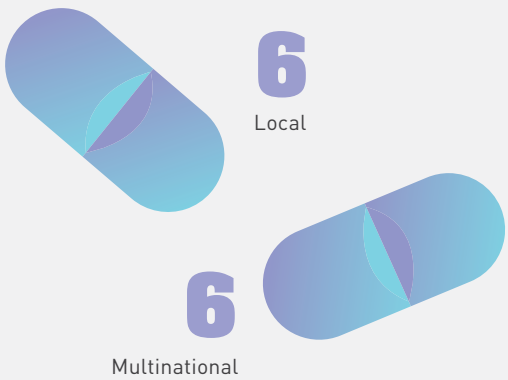



## RAW MATERIAL MANUFACTURING COMPANIES

Source: IEIS

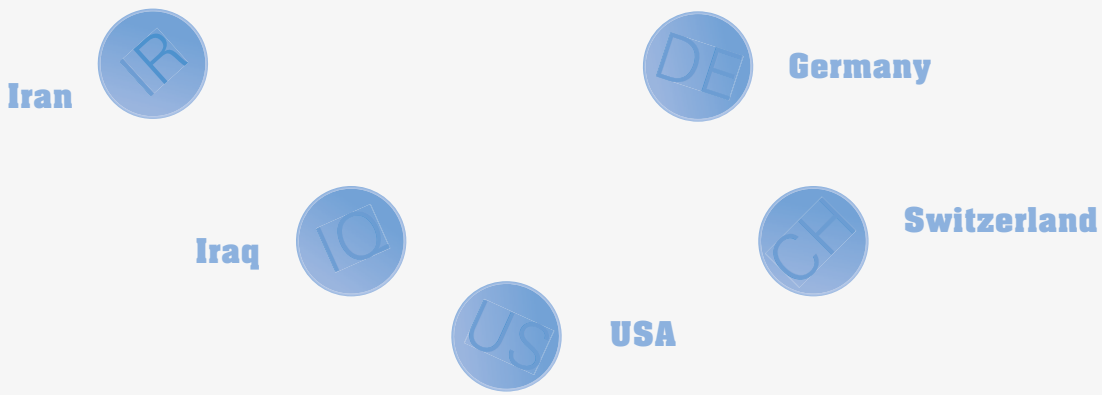

## RAW MATERIAL PRODUCTION FACILITIES

Source: IEIS




## MAJOR EXPORT MARKETS FOR TURKISH PHARMACEUTICALS

Source: Ministry of Economy



# Ersan Küçük

General Manager
**DROGSAN PHARMACEUTICALS**

**Drogsan Pharmaceuticals was founded over three decades ago. Looking back at the history of the company, can you provide us with a brief overview of some of the most important milestones in the company's development?**

Drogsan was founded by the pharmacist Nevzat Karpuzcu who had previously established the second pharma wholesale company in Turkey.In 1975, he decided to create a pharmaceutical company to produce natural products and tea. In the beginning of the 1990s, Drogsan shifted its focus away from natural products to pure pharmaceutical products. The first human medicine product we manufactured was Mentoseptol Rinse.In 1999, we launched a specific combination formulation in Turkey, Klorhex Rinse, containing chlorh exidine,which is the key product for our pharmaceutical business. Each year we have added new products to our portfolio. Today we have our manufacturing plant in Ankara, and two head offices in Istanbul and in Ankara.

**What does production capacity stand at today at your manufacturing facility and what is capacity utilization?**

We have a 20,000 square meter area in the plant and in one shift we can produce 30 million units, which is 90% utilization. Our plant is European Union CGMP-certified, Gulf Cooperation Council-certified, Jordan FDA-certified, Ethiopian DACA-certified and Nigerian NAFDAC-certified. We have three different production lines: a solid line where we can make tablets, capsules and sachets as well as a spray line and a liquid line.

**Of your production capacity, how much of it is focused at the present time on contract manufacturing versus manufacturing proprietary products?**

93% of Drogsan's production is our own products; however we are trying to increase our contract manufacturing. We have several deals with multinational companies to produce products for the Europe markets and in two months we will start manufacturing products for German companies.

**Drogsan has had a strong focus on exports, which you began in 2000 when you entered the Nigerian market. Can you tell us about your export strategy?**

Drogsan's export business is 8% to 10% of our total turnover; however we are trying to increase this share of the business to more than 15% in the next two years. Drogsan exports products to approximately 16 countries and each year we try to add one to three countries to our portfolio. After the price system changed in the Turkish market in 2009 each year pricing has been decreasing dramatically and we have had to add in other activities to our business like contract manufacturing and exports.

We export to many non-regulated markets; in addition we are targeting EU countries because of our EU GMP certification.Today we have a deal with an Italian company, for which we will be contract manufacturing. Drogsan also exportsits products to Turkish-speaking countries, CIS countries, Jordan and Saudi Arabia. The Middle East region requires GMP authorization, which takes one year, as well new tests for their warmer climate, making the whole registration process more than three years. We have also registered products in Hong Kong, Vietnam, Cambodia and Malaysia. We are waiting for GMP certification from Ukraine in the beginning of 2015.

**Market authorization has historically been a challenge for Turkish manufacturers. Do you think the government has given adequate support to the industry in developing its export markets?**

There is no support from the government in developing export markets, although is a very important area for the economy. The industry has set goals for itself to increase exportation; additionally the prime minister announced in the Vision 2023 high targets for pharma exports. In Turkey there is a large deficit between the importation and exportation of pharmaceutical products. Each year if we can increase exportation we can shrink this gap. For Drogsan, we cover 75% of our imports with our export business. This year we are aiming to have a positive balance between exports and imports.

**To further your R&D, which is a key factor for the global growth of the industry as a whole, Drogsan first commissioned its R&D facility in 2002. Can you tell us about Drogsan's R&D strategy today?**

Drogsan has 18 people in its R&D department, and our work has been focused on

the development of value-added products, especially for combination products. Our first product, chlorh exidine, is a combination product we have developed. We are focused on other combination products with the assistance of Tübitak. We arealso concentrating on sachet-type products to replace tablets.

**Some players in the industry have identified oncologicals as the strategic niche for Turkish manufacturers in the global market, while others argue that the future lies in biosimilars. Which area do you see showing growth potential?**

Turkey is already late to the issue of biosimilars, as other countries like South Korea have developed significant experience, while Italy and Germany have strong oncology experience. Many local companies are investing in the oncological area, however if they are just targeting the Turkish market it is not feasible because it is not large enough to justify the scale of this investment.

**In 2013, Drogsan's revenue stood at 76 million TL. How do you plan on growing this and your relative position in the industry's ranking over the course of the next three to four years?**

Drogsan is focused on increasing our profits and our export business. We have a balance in the Turkish market where all of our costs are covered, while we can alsomake profits from both our export business and our contract manufacturing arm. The Turkish pharmaceutical market is a very competitive area and there is new price legislation which may be announced and could assist the industry in improving profitability by limiting huge discounts to pharmaceutical wholesalers.

**Do you have a final message for the executives and regulators who will be reading this publication?**

The budget problem is a huge challenge for the industry. Looking at IMS figures, before the pricing system legislation our market was increasing each year by 10% to 15%, compared to today where it is increasing by just 5%. If we can get price increases and this new legislation passed, pharmaceutical companies will have a better chance to make profits and focus more on export markets.•

Image: Drogsan Pharmaceuticals
Various forms are manufactured and packaged in Drogsan's facilities. High-speed production and packaging lines utilised in the related sites are all equipped with the latest technology.

# Serdar Sözeri

General Manager
**BIOFARMA**

**Next year Biofarma will celebrate 70 years of existence. Could you tell us about the company's development throughout its history?**

The company was founded in 1945. In 1990 Biofarma inaugurated a modern production facility. Until 2006 it was managed as a family-owned, profitable, quality-oriented generics company. That year Biofarma was acquired by international venture capital funds. Simultaneously, Turkey's pharmaceuticals business environment started deteriorating and Biofarma started experiencing difficulties. I was called in 2012 for a business turnaround and managed to take it from loss-making operation to profitability. The last two years corresponded to he first phase of this project and now we are aiming at strengthening the shareholders structure. This second stage is being executed with the help of Goldman Sachs. The market has changed radically in the last decade and R&D is now much more important then it used to be. We have already invested substantially in innovation and we have a strong R&D center, but we need to keep on investing. At the moment we are looking for a new external financial source.

**Looking at the strategy you have in place today and the attempts to sell a stake of the company to a new partner: what would be the profile of any strategic partner?**

The preferred option is for a strategic partnership with a pharmaceutical company that could bring us know-how. Biofarma can be an excellent platform for any company willing to explore the Turkish pharmaceutical market and its neighboring countries. There might also be an option of having a new private equity fund as an investor.

**Looking at the areas you would like to enter and further delving into the profile of a new partner, which segments do you believe are particularly promising for the future?**

We wish to keep growing in the therapeutic areas in which we are already strong. In addition to this, we would like to increase our presence in dermatology and OTX, the prescription-based over-the-counter drug market. We are not willing to make a radical shift but rather develop value-added generics and, at the same time, make a move into biosimilars. We are about to sign an early agreement with a multinational company to launch their products gradually: from packaging to manufacturing and exporting. If you want to grow and survive in the current market conditions you need to seriously explore opportunities in biosimilars

**The conditions of the market have not been easy in the past two years. In executing the turnaround of Biofarma, what strategies did you find most effective in getting to where you are today?**

Biofarma made a shift from large-volume generic business to brand-oriented generic business. You need to have strong brands if you want to augment your profits. If you only play on the discounted generic side, you will be only look at 20% of the market. Otherwise, if you choose to strengthen your brands, you can make a successful turnaround. Bearing in mind our meager financial resources, we gradually increased our profitability by carefully choosing which products to promote. This was all part of a big rationalization process. Now we are investing our resources in accordance with the quality of the products we have: different products receive different investments. As a result, we doubled our sales per representative over the course of a year. An aggressive sales scheme was also instituted.

**Biofarma is present in countries ranging from Afghanistan to United Kingdom, one the world's most requiring markets for pharmaceuticals. What is the sales breakdown between imports and exports?**

This year we expect our exports to be 17% of our revenue. We have probably one of the highest export rates in the country. Biofarma is one of the two hormone manufacturers in Turkey, and we sell in almost all regulated markets in Europe. We also want to develop in the Middle Eastern and CIS countries, but these are more price-sensitive and less predictable markets. We do not have subsidiaries in any of these markets: rather, we make use of partnerships that help us solving market entrance hurdles.

**Current production capacity stands about 70 million boxes per shift. Do you have plans to expand? What about Biofarma's capacity utilization figures?**

Our capacity utilization stands around 60% at the moment. We will do a few small investments over the course of the next three years. For hormones and soft gel products, we are tripling our production capacity. When it comes to the more conventional products we will contract manufacture if needed. Biofarma will specialize in the production of a few niche products and at the same time outsource the conventional side of our portfolio.

**Some argue that the Turkish manufacturer does not have the financial strength to develop value-added products. What is your opinion on that?**

This is only true for some niche areas like APIs manufacturing. I think we are already improving on value-added products, but what we do not have is adequate coordination between academia and industry. On the other hand, we have developed good human resources and R&D centers, something we did not have five years ago.

**Looking into the future, what do you think the role of the Turkish pharmaceutical manufacturer will be?**

Local manufacturers might change hands: families have shown a tendency to sell. Turkey will remain a production hub, but the question is what are we going to be producing? Will we produce what is being produced currently or are we going to differentiate ourselves and win international markets? Our challenge is to find a way to be competitive enough and sell our products abroad.

**Perhaps one of the most challenging issues has been the cross-referencing price system and the euro-lira convertibility rate. Are we likely to see any relief?**

Even if something happens this year it will be a small change, a single digit price increase. We have to try harder to show the government that this situation is not sustainable. We are an essential industry for the future of Turkey and to grow we need resources. The government has a budget for pharmaceuticals that amounts to 17 billion liras this year and the budget is likely to increase 6 to 7% next year. The industry needs to feel safe if it is to continue investing and pursuing the goals the government wishes us to achieve.

**Do you have a final message for the executives that will be reading this publication?**

When life is relatively easy, one does not need to develop strategy. But, when the market conditions deteriorate and margins start to suffer, one cannot afford not to have a clear cut strategy. Strategy firstly means making sound choices and sticking to them decisively. Besides the turbulence of the market conditions, we are also suffering from not having proactively developed focusing, development and export strategies. Differentiation of products and technology is key to the creation of a sustainable industry. •

# Sedat Birol

Executive Vice President Healthcare Division
**ECZACIBAŞI**

**Eczacıbaşı is, quite literally, the godfather of the Turkish pharmaceutical manufacturing industry. Could you please provide us with an overview of the company's history?**

Eczacıbaşı was founded in 1942 as one of the first pharmaceutical manufacturing companies established in Turkey. Eczacıbaşı was started by Dr. Eczacıbaşı, whose work within the industry focused initially on the production of vitamins; this later extended to include the licensing of pharmaceutical products from multinational companies. In the following decades Eczacıbaşı built one of Turkey's largest generic businesses. In 2007, Eczacıbaşı sold 75% of the equity of this business to Zentiva. In 2009, Zentiva acquired the remaining 25%. This marked Eczacıbaşı's exit from generic manufacturing, though the company continues to operate within the industry as a distributor of imported and contract manufactured pharmaceutical products, especially within niche markets.

Eczacıbaşı's decision to sell its generics business was driven by several factors. Prior to 2004, the Turkish government employed a cost-plus pricing system. This was later changed to a reference-pricing system, which linked the price at which pharmaceuticals could be sold to the lowest price available in five selected reference countries in Europe. In addition, a mandatory discount system was introduced, as well as a positive-list, which stipulated which products would be eligible to receive reimbursements for sales to the government. Collectively, the introduction of these instruments convinced Eczacıbaşı that Turkey's pharmaceutical industry would no longer be the same and business for the local manufacturer was no longer sustainable.

**Yet in 2008 Eczacıbaşı established a JV with Monrol for the production of nuclear medicine. What, in spite of Eczacıbaşı's decision to exit the generics business, led the company to develop a radiopharmacology business?**

In spite of these changes, Eczacıbaşı had an interest in staying in the health sector. Nuclear medicine interested Eczacıbaşı because few manufacturers produce these products and, on account of their short half-lives, radiopharmaceuticals (FDG) cannot be imported into the market. As the company was already well-established in Turkey and through this, had business units that could support the development of such a business, we chose to stake a position in this market.

We initiated production at three plants in Turkey. Today, Eczacıbaşı-Monrol Nuclear Products has 17 plants in operation, 7 being in Turkey and 10 abroad.

**Several of these plants stand outside of Turkey. Could you provide us with an overview of how these operations fit together?**

We chose the location of our facilities in certain countries because of the very short half-lives of these products. Eczacıbaşı has chosen to become the regional leader in this area. As these products cannot be imported, this required taking a position in certain key markets like the Middle East, North Africa, Central and Eastern Europe. We have invested in facilities in Poland, Romania, Bulgaria, Egypt, and Libya and will soon enter Northern Iraq. Today, 60% of our revenue for this business unit is generated in external markets.

**Has Eczacıbaşı evaluated expanding into alternate niche markets, aside from nuclear medicine?**

Currently, Eczacıbaşı is not planning to reenter generic pharmaceutical manufacturing. The export of pharmaceutical products remains difficult. The government's pricing strategies are debilitating. Underutilization of capacity is an industry-wide problem. Competition within the sector has therefore become extremely intense. We are interested in expanding into complementary areas for nuclear medicine. For example, in 2012, we acquired a company headquartered in the United States, Capintec. Capintec is a leading producer of radioactivity measuring devices. We will continue to look for more opportunities within this area in both the United States and Europe. In addition to businesses which compliment nuclear medicine, we will also look for broader opportunities in the health sector. Oncology, for example, is very interesting. The government has provided an attractive incentive structure for this therapeutic area. We currently operate in this field as a distributor. Furthermore, Eczacıbaşı

is interested in developing an over-the-counter (OTX) business. OTX products are not as heavily regulated by the government as other areas within the health sector. Owing to the country's pricing system, this is attractive.

**How do you believe the Turkish government can better assist domestic industry?**

The Turkish government must consider the implications of their budgeting system on medical access within the country. The age of the Turkish population is shifting. The Ministry of Health has done an excellent job in guaranteeing medical access since its Health Transformation Program was first enacted in 2004. However, the attention of the Ministry must now turn to addressing the medical needs of those with chronic diseases, for which diagnoses have risen in recent years. Treating chronic diseases involves long-term treatment. The medical products required to treat these diseases are expensive to develop. Under the current budget, it is difficult to imagine that these investments will be made.

Certain forms of medication in Turkey must also be better monitored. Irrational drug use has been hugely problematic for the country's citizenry because the use of certain types of pharmaceutical products is not regulated. For example, until recently antibiotics could be purchased without prescriptions, though this has changed recently due to increasing controls and penalties. Now, most pharmacies do not sell antibiotics without a prescription.

Export markets must also be developed for the country's pharmaceutical manufacturers. For over ten years, the export-import ratio for pharmaceutical products stood at 10%. Today, this ratio stands at 18%. We have seen an improvement, but pharmaceuticals continue to have a negative impact on Turkey's trade-deficit. This is not sustainable. The Turkish government must provide substantive support to Turkish pharmaceutical manufacturers establishing export markets. The development of export markets depends upon the creation of value-added products: on research and development. Research and development requires returning profitability to the industry. This is linked to our budgeting and reimbursement system.

Image: Eczacıbaşı. The manufacturing site of Eczacibasi's joint-venture with Baxter, through which the company focuses on the creation of medical solutions dedicated to critical diseases

**Though many in the industry are heavily focused on the development of biosimilar products, several individuals have asserted that the Turkish pharmaceutical manufacturer lacks the financial strength to support these endeavors. Will the Turkish pharmaceutical manufacturer be able to develop itself independently, or are partnerships necessitated by the industry's present conditions?**

There is no need for the Turkish pharmaceutical manufacturer to reinvent the wheel. Partnerships could play an important role in expanding into strategic areas. However, if Turkish pharmaceutical manufacturers were to do this independently, a readjustment to the rate at which the euro is converted into the lira is necessary, so that companies can raise some funds for the necessary R&D activities.

**Some assert that the solution to this problem can be internally, in forging stronger links between Turkey's universities and private industry. What potential does this model hold?**

When I first returned to Turkey from the US in 1990, I noticed the absence of this dynamic. Though partnerships between universities and businesses were common in the United States, they were rare in Turkey. This trend has continued through today. Universities have limited relationship with businesses. This has been on account of the country's politics. There is no continuity in Turkey's economic policies. When offices change hands, the policies of the previous regime are dropped. Our focus on ideology has preempted the successful development of many policies, this included. These partnerships require government input; instead, the government's input has precluded their development.

**What does the future hold for Eczacıbaşı?**

Eczacıbaşı strives to be much larger in nuclear medicine. We would like to extend this business far beyond the regions in which we currently operate. We would also like to become the key manufacturer of biological products. To this end, we are currently assessing the viability of a significant investment in a partnership with our JV partner, Baxter, to develop biological products. Another focus of Eczacıbaşı's healthcare division will be the development of a business unit dedicated to health and safety. The Turkish government has introduced a new law for health and safety that requires any business with over 50 employees to have certain health and safety systems in place, necessitating the employment of doctors, nurses, and safety specialists. As it is unfeasible for every business to develop these systems internally, this is an area that Eczacıbaşı feels it can assist companies in implementing. Eczacıbaşı is one of the few companies that can provide this service in a systematic and professional way. We would like to be the leader in this area. •

# Hatice Öncel

General Manager
**ILKO**

**Ilko Pharmaceuticals draws upon over 50 years of experience in the pharmaceutical industry. Looking back at the history of the company, can you provide us with a brief overview of some of the most important milestones in the company's development?**

Our founder Mustafa Öncel was a pharmacist who worked for government hospitals before entering into the private sector in 1956 with the establishment of his own pharmacy. Over time he ran several independent pharmacies while developing his own product formulations and in 1973 he entered in the pharmaceutical industry. This business resulted with the successful sale of the previous pharma company to international partnerships in 2006. Following the end of our non-competition period in 2009, Ilko Pharmaceuticals was established.

Today Ilko is under the umbrella establishment of Selçuklu Holding which belongs to Öncel family. The Holding has strong institutions across various economic sectors and currently we have five main areas of interest and nine companies in our organization. Besides the pharma industry, we are active in the packaging and printing industry, cooking wares and metal industry, construction and real estate, agriculture and stock breeding. While we are active in many fields today, the base and working philosophy of all our companies are founded on our culture and discipline from pharma industry.

**What is the importance of pharmaceutical to the future of Selçuklu, relative to your other areas of activity?**

Pharmaceutical manufacturing is at the center of what we do, though other sectors are also important for us. In addition to Ilko, we have an R&D company which is a separate entity located in the technological park of Hacettepe University. We have also recently established ILKOGEN, a joint venture with the South Korean biotech company Genexine.

**Since Ilko's establishment, how has business developed for the firm?**

We started out with the planning and construction of our manufacturing facility and R&D center. We have always believed that to be competitive in the industry, we must focus on R&D and our manufacturing capabilities. After finalizing with R&D center and the construction of the facility, we began our business activities in 2012.

**Ilko's manufacturing facility is state-of-the-art with 120 million units of production capacity. Can you provide with an overview of your facilities?**

Our manufacturing facility is located in Konya on 250,000 square meters of property, which will allow for future investments. Our R&D facility is located at Hacettepe University, which is the first R&D center in pharmaceuticals to be established in conjunction with the university. For R&D, coordination between the industry and university is very important; however, Turkey has struggled in developing these partnerships.

In our first stage we will produce 25 million units per year on one shift. In the second year, we are planning to utilize 50% of the capacity as we continue to ramp up production. We expect to reach full capacity utilization next year and we will then start with the addition of new machineries.

**Ilko has a wide range of products from antidepressants to anti-infectives. What are the specific therapeutic areas that you are focusing on for R&D?**

Ilko is focused on value-added, difficult to do generics. We have been working on several products for the past three years in our R&D and in 2015 we expect to receive the registrations for these products. We have selected particular therapeutic areas to focus on, but as a generics company we have a broad range, going from gastrointestinal and CNS to cardiovascular, respiratory and dermatology.

**Within the manufacturing industry there is a significant push for value-added products, although where to focus R&D efforts is a divisive issue. Some feel that the industry should invest in molecule development, whereas others believe that the industry should focus on product development. Where does Ilko stand on this debate?**

Diversified research and development activities are critical to pharmaceutical manufacturing in Turkey. We should focus on value-added products for the time

Image: Ilko. Ilko's new production complex in Konya is one of the biggest investments in Turkey. Located on a 250,000 square-meters land, the plant is designed in accordance with GMP and GLP and features a horizontal flow system focusing on the shortest material flow.

being, but for the future the development of new molecules must be placed on the table. New molecules take time and are risky and need more financial strength, which is why it is not realistic to focus only on them now. We see biological products as a chance for Turkey in this field; it is a new industry, Turkey can still progress in this area.

**Can you tell us about your joint venture Ilkogen and its chief activities?**

Ilkogen is a 50-50 partnership with a research company that has novel biotech products in their pipeline, as well as knowledge of biosimilars. Ilkogen is dedicated to develop and offer several advanced-stage biopharmaceutical products. Our target is to have our first product in 2017.

**Some say that it is too difficult for a Turkish capital company to invest in biosimilars. What obstacles do you see to Turkey's development as a center for biosimilar production?**

The investment costs for biosimlars are too high and development is much longer than a small molecule. Regulatory gray areas have set back the industry several years, as regulations were only clarified for biotech products a couple years ago. Turkey's pharmaceutical industry is large and growing, however compared with the global industry it remains relatively small. It is not possible for the private sector to succeed by itself. We need effective strategy, public support and sustainable politics to meet the higher risk of developing biosimilars.

**The industry is undergoing a period of internationalization and manufacturers are focusing not only on internal markets, but also neighboring countries. How is Ilko's business developing with regards to exports?**

Because we are new in the industry, last year we started with registrations in several countries, including Iraq, Libya and CIS countries. This year we started exports in April. The Turkish pharma industry already has experience with these territories. For us it will be very easy to enter and penetrate these markets by adding new products. As Ilko, we are focusing also on regulated markets. The market authorization process depends country-to-country, but on average it takes one to two year. This is why you should analyze the market well and select strategic products. Ilko already has GMP approval for the EU and we will start with our export activities to the UK market .

**The industry's profile has changed markedly in the last ten years as more international pharma companies have entered the market. As the Turkish pharmaceuticals industry becomes more international, what do you think will be the role of Turkish capital companies like Ilko?**

Our intention is to be a leading global Turkish market player, therefore we will focus on increasing in a short period in the domestic market and internationally. To be a global company, we need to have value-added and innovative products. We are open to every kind of business partnership to be more powerful globally.

**Looking to the future, what is your strategy for Ilko's growth in the next five years?**

Ilko will be in the top ten Turkish companies in five years. We follow a strategy to double our turnover each year, in our first three to four years.

**Do you have a final message for the executives who will be reading the report?**

The Turkish pharma industry has had success in the past, which should not be lost. There is a big opportunity for the industry and the pharma industry can be one of the leading industries for the country. We can play a big role in Vision 2023, but it is important that the right policies and strategies are followed. •

# Bülent Atabay

Chairman
**ATABAY PHARMACEUTICAL FINE CHEMICALS**

**75 years ago Atabay began operations as an importer and trader of pharmaceuticals in Turkey. Can you tell us about Atabay's history, touching on the main milestones of the company's development?**

Atabay was founded in 1939 by my father, who was a pharmacist. At that time, importation of pharmaceuticals was difficult because of the lack of foreign currency in Turkey. In Turkey,trading in thepharmaceutical industry was further limited because there were not many medicines that had been developed yet. For these reasons, Atabay was interested in entering into the manufacturing of pharmaceutical products. This became possible in 1955, when Turkey received aid under the Marshall Plan. The Marshall Plan enabled us to import equipment from the United States. We were one of the first companies to use aid for this kind of operation. In 1955, we started making simple tablets for use against pain and fever..GraduallyAtabay's operations grew to become substantial. Our main product was sulfonamides, which were in high demand in Turkey because it was the first method available to treat simple bacterial diseases. Following this, the era of antibiotics began, followed by penicillin and its derivatives, and Atabay's business developed.

We started our chemical plant in 1970 to produce APIs, which at that time were very important. If you did not have access to APIs, you were dependent on other companies to provide them, so it was important for Atabay to be able to control its raw materials.In addition to pharmaceutical fine chemicals, we were also supplying raw materials for agriculture, public health and the veterinary field. We have developed over 100 products at Atabay, about half of them which where for agricultural chemistry.

**What underscored Atabay's decision to sell to these other industries?**

Agriculture is very important in Turkeybecausethe climate is well suited for wheat and cereals and also because the country could not import food due to foreign currency being extremely limited. We were producing herbicides, insecticides and fungicides for the agricultural sector; however we saw that the industry was moving away from using chemicals because of public opinion and we decided to do more work on the pharmaceutical side. Today Atabay is almost exclusively active in the pharma sector.

**Looking at your production facilities, what does your capacity stand at and what is its utilization?**

Today we have our production plant in Gebze. We are the first producer in Turkey of paracetamol, a product which has developed well for us because we have a very good process. We received FDA approval of the plant in 1985 and it has been audited several times by FDA, EU authorities and many customers. We are producing 4,000 tons of the product and it is sold throughout Europe. For paracetamol, we are using 80% of our capacity. Our paracetamol production requires "big chemistry," however we are also working more with specialized batch chemicals and developing these kinds of products with our R&D team.

**Atabay's business has been heavily focused on R&D. Looking at your growth strategy, are there are certain therapeutic areas where you are pursuing more R&D to add to your product line?**

We believe not in big turnover but in technological development. We are actively pursuing the development of new chemical products and biotechnology. Biotechnology is a difficult area; you have to, again, acquire specialized capabilities as we did for chemistry, which took 50 years. Biotech has a very interesting future and we are working on developing this expertise.Atabay is also focused on developing important technologies in pharmaceutical finished product formulations, making controlled-release pellets for example.

**Can you provide us with an example of products that you have successfully developed and marketed to meet a growing need in the Turkish healthcare sector?**

With our experience, we are in a position to make products like Tamiflu. We produce the raw material and prepare the quality control, conduct bio clinical studies, obtain the registrations and launch the product. This year we had a very serious flu problem in Istanbul. In countries like Turkey with high and dense populations, flus or diseases spread quickly. Our

product is the only antiviral product available today and it is a life-saving drug. We have similar products for Hepatitis B and thrombosis. These are all very difficult products to make and require very specialized skills. We now have four to five products like this, with more in the pipeline for which we are waiting for approval.

**Do you believe the Turkish government has the correct incentive structure in place to effectively encourage research and development?**

In R&D, the Ministry of Health has been very helpful. A sufficient incentive structure is in place. Beyond this, the Ministry of Health has been very helpful in supporting the registration of our products. However,government policies can still be challenging for the market.The government pays a significant amount for medicine which is good, but they have also set drug prices at very low rates. This creates limitations for us as researchers and developers. To survive in the market, you must be able to create new products.

**Atabay has made headway in several difficult markets. What percentage of your sales is driven by the internal market versus external markets?**

To compensate for the low prices in the Turkish market, we are focused more on exports.We cannot go into high-priced markets like the United States with finished products because registration of imported products is exorbitant; however, we can sell APIs to the United States. In Europe it is possible to sell finished products, but so far we have been selling to countries such as Iraq, Syria, Afghanistan and Balkan countries.

**What is your strategy for Atabay's growth within the next five years?**

We will continue investing in technology. The government has called upon the pharmaceutical industry to develop biotechnology products. We want to have a place in this area with technology that will enable us to seriously manufacture biotech products. We see potential in biotechnology, as well as the many new chemical-based products coming off patent. We will continue to manufacture and improve our processes to offer top quality products at good prices to the Turkish and international markets.•

# İsmail Yormaz

General Manager
**RECORDATI**

**Recordati acquired Yeni Ilaçin 2008 and Dr. Ilaç Frick in 2011 to establish itself in the Turkish market. Could you tell us a little bit about the company's development during its time in Turkey?**

Recordati arrived to Turkey through licensing agreements in 1994. In 2008, Recordati decide to have a site in Turkey; this drove the acquisition of Yenillaç. After the first acquisition, our operationshad total turnover of around 30 million to 35 million Turkish liras. We started growing these figures in 2009, when we decided to make use of licenses through our recently acquired infrastructure.

The arrival of Recordati group coincided with political changes in government regulation. I arrived in Recordati in August of 2009. Turkey's first piece of price legislation was published that October. Recordati had just invested heavily in the country and set its targets. These were shattered by this piece of legislation as the business environment soon turned. Even so, we have been growing organically in volume ever since. We actually have grown since 2009 two times the average of the market in units. Buying Dr. Frik Ilaç as Recordati did in 2011was a bold move considering all of this, but this was part of the long-term vision Recordati had for Turkey. As a result of our persistence, Recordati now figures in position 25 in the IMS Health ranking, coming from 63rd when we entered Turkey.

**Considering all of the structural challenges you had to face and the difficult posed by the integration of these twocompanies, what did you find more important in overcoming the hurdles that traditionally stand out while executing mergers?**

Turks are a quite emotional people. For being successful in a acquisition you have to be regardful of the emotional side evolvedin the process. The key for our success was to bet on candid and direct communication. We were also extremely quick in executing our goals. It was a sharp but flexible approach in the way we decided to be open to change when confronted by unforeseen market realities. I was lucky to have a management team that understood the message very clearly and made the decision to bet on our project. The most important thing for one's success is the quality of the people you are working with. Human resources were very important to our success: placing the right peoplein the right places with enough responsibility.

During this process we managed to harmonize three different cultures. I am proud to say that still, today, in our current production facilities more then 75% of our people are from Yeni, while half of my marketing team is from the former Frik operation.

**Recordati is opening a new facility soon, an investment of $50 million, which will grow capacity significantly. What is the objective of this expansion? Are you aiming at exports?**

Our new facility will double production with space for further expansions that could allow for us to double our production capacity once more. Today we are producing around 40 million packs a year, but in future we could reach 160 million packs of capacity.

At this moment, almost all of our sales is generated from the domestic market. But with the addition of capacity of our new plant we are aiming at exports targeting the nearby countries, taking advantage of Turkey's special geographical position.

**Could you tell us more on which therapeutical areas do you see good growth prospects?**

Recordati group focus on conventional pharmaceutical areas. I have no plans for biotechnology, although the Turkish government might have some ambitions to encourage the development of these products. Recordati is very strong in urology, cardiovascular, gynecological and musculo skeleton diseases in Turkey. These four therapeutic classes will remain the focus of our R&D activities.

**What do you believe the role of the local pharmaceutical manufacturer should be in future? Can Turkish manufacturers be innovators?**

Turkey's government has an ambition of creating its own molecules, which brings many challenges. This requires a backing by a scientific community that Turkey does not have. Should the country build proper links between its industry and academia, this may change. I am not optimistic when I take a look in the short-term, but Turkey certainly shows potential for this in the long run.

This country can be a good production hub for conventional medications as well as for new technologies, such as biotechnological products. Again, what is critical for this venture are human resources. Turkey has a lot of young and well-educated people, now it has to start making use of then.

**The price referencing system has been one of the most challenging issues for the industry. What are the implications of this system??**

This has created many problems for the Turkish pharmaceuticals industry; it is not a logical and sustainable path for the industry. But we have to understand what is beneath that. The cross price referencing system is not the issue. The budget is the problem. These regulations are the fruit of creative minds in the government wishing to foster the expansion of pharmaceuticals consumption without growing expenditures. The budget was maintained throughout the years while access to medication has soared. What we need to address now is one out of two things: budget or consumption. •

# Jacques Nathan

Country Manager
**SANOFI**

**Six years ago, Sanofi significantly strengthened its position within the country through the acquisition of Zentiva. Today, the company ranks as the eighth largest manufacturer within Turkey according to IMS Health. What allowed Sanofi to successfully transition?**

Our Turkish operations have employed the same strategy as our larger, global operations in transitioning into a diversified producer of pharmaceuticals. Six years ago we prioritized the acquisition of a generic platform in Turkey. Sanofi did not stop there though: we also developed a Consumer Health Care (CHC) division, an Over the Counter (OTC) business, a vaccine business, and a position in niche pharmaceuticals such as orphan drugs and rare diseases. Our success in the Turkish market has emanated from this strategy. This strategy, however, could not have been implemented on an operational level without our people, who have continually shown their value through proving their ability to challenge themselves and welcome new ways of examining the Turkish market. As a team, we have shown our strength in being able to adapt to change.

**In 2012, Sanofi decided to relocate its management center to Turkey. What underscored Sanofi's confidence in the Turkish market?**

Turkey offers several very attractive benefits to those that choose to use the country as a hub for their healthcare business, as Sanofi decided. Turkey's demography is unique; the country offers a population that is young, 50% of the Turkish population is below 30, but aging: the population of those over 65 in Turkey is growing three times faster than the general population. This provides an attractive mix for any healthcare provider. Simultaneously, the Turkish's economy has developed rapidly. Over the course of the past ten years, Turkey's GDP has led the world in growth, trailing behind only several Asian economies, such as China. These two factors, Turkey's demographic structure and the country's economic development, drew Sanofi to Istanbul from Dubai, where we were previously had our regional headquarters. Turkey is among Sanofi's 15 most important markets globally. Few countries offer these benefits.

**Zentiva, who Sanofi acquired in 2008, had one of the country's three largest research and development facilities. Could you provide us with an overview of the activities of the company's research and development department today?**

Sanofi has placed a heavy emphasis on the importance of research and development within its Turkish operations. In Turkey, we have thousands of patients that are involved in our clinical research programs. Our facilities in Istanbul play an important role in driving innovation for our global operations.

In Turkey, we are very interested in investing further into research and development for our CHC business. We consider the CHC market to be underserved in Turkey. Developing products within our OTC business is equally a focus of our research and development activities within the country for similar reasons: we consider this area to be underdeveloped as well.

**Some contend that Turkey lacks the human resources and legal infrastructure required to effectively develop itself as a global center for research and development activities. Has Sanofi found either of these areas to be problematic?**

For Sanofi, neither human resources nor the legal infrastructure of Turkey – its intellectual property system, for example – have proven problematic. Neither of these two areas have stopped Sanofi from investing heavily into our research and development activities within the country.

**The Turkish pharmaceutical manufacturing industry has undergone several structural transformations: the entrance of new players into the market, such as Sanofi, and industry-wide movement to focus on the development of export markets. Aside from this, what structural trends does Sanofi believe will define the industry moving forward?**

The further growth of Turkey's pharmaceutical industry will depend upon a readjustment of the government's pricing model for pharmaceutical products. As an aggregate, profitability has greatly fallen for the industry in the past five years on account of the Turkish government's system of price referencing. Turkey's system of price referencing has established the price at which pharmaceuticals are referenced across Europe, and now beyond, in more distant markets. A constrained conversion rate has crippled the industry, discounting prices by a third. This is not sustainable. •


Image: Sanofi. Sanofi's Luleburgaz plant

# Philipp D. Haas

Chairman and CEO
**DEVA HOLDING**

**DEVA Holding dates to 1958. Could you please introduce us to the company?**
DEVA Holding was founded by doctors, pharmacists and veterinarians in 1958. The acronym DEVA actually represents the initials in Turkish for these professions. Back when DEVA was founded, there was a low supply of pharmaceuticals in Turkey, the country was relatively isolated. DEVA was one of the first companies in the sector to start producing domestically and this has been our philosophy ever since. When GEMGlobal Equities Management took overin 2006, we targeted Turkey because of its attractiveness as a manufacturing hub. This made the transition smooth. However, I can also say that we have turned this company upside down. When we arrived, we replaced all of the existing facilities for brand new ones. Today, all of our products are manufactured by state of the art machinery. DEVA might have the most modern oncology production plant in Europe. All of our facilities are approved by the GermanMinistry of Health and are compliant with both Turkish and European GMP standards.Our vision is to become a leading company in Turkey's pharmaceutical industry:a market that will always be our first priority.

**What was the rational underscoring your logic in investing in DEVA Holding?**
At the time we realized the local pharmaceutical market was growing and it wasnot fully covered bydomestic manufacturers. It had also a relatively low spend rate per capita:currently around $100, whereas these figures might be 10 times higher in the USA. TheTurkish location also has exportpotential. Turkey is at a very important geopolitical position, straddling Europe and Asia and sitting at the doorstep of attractive Middle Eastern markets. We have better quality and reliability when compared to most of ourAsiancompetitors, while being closer to Europe and having a better understanding of what the European consumer wants.

**DEVA has three production facilities. At present, what does capacity utilization stand at for DEVA's facilities?**
DEVA Holding can theoretically produce one billion units, seven billion tablets as well as a whole range of injectables. But it is hard to accurately determine capacity utilization; it fluctuates. We would have toconsider a non stop production site that does not exist in reality. Looking at it from that point of view it would be something around 30% of our machinery capacity. Our productivityfigures represent our own needs. We are not opposed to toll manufacturing to fill this; it is just not our main strategy.

**In entering the Turkish market in 2006, what long-term strategic objectives did GEM Global Equities Management have for the company?**
Our first step was to put manufacturing capacity in place and to be audited. We have since been successfully audited by the Germans. Following this, DEVA focused on developing the dossiers required by equivalence studies. After we completed this, we turned our focus to R&D, launching our R&D center in 2009. We have named it DEVArge, a play on words: Dev is Turkish for giant. Today it is fully equipped and operational, with 160 staff.

**The Turkish pharmaceuticals industry is attempting to position itself globally as a provider of niche products. Which niche products does DEVA see the most potential in?**
DEVA has launched quite a large number of respiratory inhalation products, both as MDIs and dry powder inhalers. Another important area is oncology;we created the first generic for Imatinib available in the Turkish market. We have also developed an API for it, vertically integrating our supply chain.It is a rarity to find vertical integration in Turkey's pharmaceutical industry. We do it in very limited basis though. We have 400 different products; we cannot manufacture APIs for all of them. Vertical integration in the pharmaceutical industry is a very big undertaking and I do not believe that many Turkish pharmaceutical producers can do this themselves. Not at current prices at least.

**Are we likely to see any modifications made on a policy-level to Turkey's system of price referencing?**
I understand that there is a real budget constraint at the governmental level. I think it is reasonable that the government would want to have a tight budget: this is a legitimate strategy and the industry needs to help the government in keeping healthcare costs at a reasonable level. But it is important to acknowledge that if the Turkish pharmaceutical industry did not exist, prices would probably be 10 times higher; imports would rule. For that reason, having a strong generic industry is hugely important. If the Turkish pharmaceutical industry is to to tap its potential, the government would need to strengthen it by giving some sort of compensation for late currency losses. There must be some kind of rebalance in the market. The industry's export capacity is a direct function of its financial strength.

**Given difficult market conditions, how has DEVA performed?**
DEVA has performed rather well. We managed to double our sales through pursuing several strategies: selling products developed at our R&D center and brokering deals to purchase products from Roche and BMS.These actions brought astonishing results, especially as all these products are today produced our own facilities in Turkey. •

# Muzaffer Bal

General Manager
**ALI RAIF**

**Ali Raif ranks among the oldest companies in the industry, dating to 1928. Can you provide us with a brief history of the organization?**

Ali Raif was founded as a tobacco company and diversified into other industries such as construction and mining. During the 1950s, the company formed a joint venture with Pfizer Turkey, holding more than 50% of its shares which it has since sold back to Pfizer. In 1963, Ali Raif was reorganized to trade in pharmaceuticals as a representative of multinationals in Turkey. At this time, the Turkish economy was closed and importation was very difficult;Ali Raif started producing and marketing products under license for its multinational partners.

After 1984 the Turkish economy became more liberal, making it possible to import finished pharmaceutical products. As a result, Ali Raif began to register products for importation and marketing when it was more economic than licensing products and manufacturing them locally. In the 1990s, we entered into the generics business and started developing our own formulations. In 1999 we constructed a new GMP plant to improve our manufacturing facilities.

**How much of your business is driven today by manufacturing your own products, versus cooperation with international brands?**

With globalization, the market has changed. Years ago Turkey's market was small and companies were looking for good distributors to market their products. For example, with GSK we have been distributing Sensodyne for more than 25 years and have doubled or tripled its market share. We have been very successful in establishing long-term agreements with our partners.

Our business used to be split about 50-50 between imported and locally manufactured products. Today our products are about 70% locally made, while the other 30% is licensed and imported. This percentage has changed as we have entered the generics business and with the addition of new products that come out every year from our R&D department. We have also obtained licenses for important products to bring them into the Turkish market.

**Given the constricting space of the domestic market, which new markets are you targeting?**

Ali Raif has been very successful in the local market. In the last ten years, we have built up a good portfolio of generics and manufactured in-licensed products for our territory. Although we export some amounts, we have remained focused on the domestic market.

Regarding markets where there is opportunity, however, the number one market is America. If you can sell to America, you can sell anywhere.We are working on expansion and building up our export business intensively. Ali Raif already has a good record for this; for example, our anti-diabetic products at one point were the number one generic in Europe. We currently sell to neighboring countries such as Georgia, Azerbaijan, Moldova and Uzbekistan, as well as the Philippines, Spain and Poland.

**Local manufacturing has been challenged recently by Turkey's system of cross price referencing and the inconvertibility of the Euro to the lira. Has this changed the perceived attractiveness of external markets to Ali Raif?**

The Turkish market by volume is increasing, the population is growing and people are aging. Our consumption is still low in comparison to developed countries, so there is a lot of potential. In the last four years, the market has been affected by global price reductions, which is why we are adding in new activities to our businesses. Ali Raif has intensified its cost reduction, but we are not reducing our R&D.

**One of the critical challenges confronting local industry is to carve out a niche in global market, looking at products like value added generics which can be competitive on an international scale. How is R&D structured at Ali Raif and what niches are you looking at in particular?**

For the last ten years, Ali Raif has had an independent R&D department, which we have intensified. We are focused on slow-release products, which have become our expertise and for which we have developed many products that have European and local patents. We are also looking at combination products. While we do not have resources for large R&D projects, our activities have had a good impact. Local market and neighboring countries come to us for the co-development and co-marketing of products. We see our future going further in this direction. There are not too many new products coming out in the world because of patent issues, so this is an important area where we have an advantage.

**In the next five years, what can we expect to see from Ali Raif?**

The pharmaceutical world is changing and we are adapting ourselves and dealing with narrow margins. We must make future plans that involve a low cost structureyet effective investments. The pharmaceutical business is becoming a commodity business. Twenty years ago, we would get the license for one product and look for an API, which would be very difficult to find. Now we can source APIs easily. This has made competition tough. In the next five years there will be some consolidation, both with regard to products and companies that operate in the market. •

# Köksal Ülgen

General Manager
**PHARMACTIVE**

**Pharmactive is a startup: a recent entrant into the market. The company was established in December 2010. Could you provide us with an overview of the company's vision in entering into the pharmaceutical industry?**

The owner of our organization is the co-founder of Hedef, which today is known as Hedef Alliance and stands as one of the largest pharmaceutical wholesaler in the Turkish market. Following our owner resigning from his active management position in the company, 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 would like to utilize all their experience and resources gained from the pharmaceutical industry, again in the pharmaceutical industry and entered the industry, this time as the manufacturer and sales and marketing side of the business. . In February of 2011, we began construction of our manufacturing facility: a state-of-the-art facility and investment of $120 million, through which plan to aggressively expand into the local and international markets. Pharmactive has a vision of being in the first 5 generic companies in the Turkish market within 5 years time. The success story of Hedef, which gained 42% market share in 6 years of its establishment, shows that Pharmactive's ambitious vision is an achievable vision with the experience of the owners and its management team. In the course of 21 months, Pharmactive has already completed the construction of what will be one of the industry's largest manufacturing facilities, got the GMP from Turkish MOH and has submitted numerous molecules for approval. We have manufacturing capacity to produce 300 million boxes per year, in three shifts. Few multinationals would be able to undertake such a rapid transformation.

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

We chose to enter into the market with such a large facility because we believe that as the Turkish pharmaceutical manufacturing industry is a mature industry, it would be futile to attempt to penetrate this market as a small operator. Gaining substantial market share quickly requires a large investment. Our facilities were designed to both minimize the company's operating expenses as the company grows in scale.

Only through such a sizeable investment would Pharmactive be able to fulfill the vision upon which the company was founded: to produce 25% of our sales through international markets; to generate 40% of our revenue through contract manufacturing; and to become one of the five largest generics companies operating in Turkey by 2019.

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

Contract manufacturing is a strategic industry for pharmaceutical producers within Turkey. The introduction of the Turkish standard for Good Manufacturing Practices (GMP) in 2010 changed the market dynamics of the country's pharmaceutical industry. While previously many multinationals were able to enter the market as distributors, the introduction of these standards has challenged these businesses. In response to the introduction of Turkey's own manufacturing standard, European nations issued a requirement that all Turkish manufacturers that distribute their products into Europe must undergo plant approvals by the Ministry of Health of the relevant country to ensure their compliance with European GMP standards. In response to this, the Turkish government issued a reciprocal degree, mandating that all foreign manufacturers that wish to sell their products into the Turkish market must comply with Turkish GMP standards. This closed the Turkish market to many pure distributors. As a result, participation in the Turkish market today requires local manufacturing. This has given rise to the importance of contract manufacturing within the country. In addition to that, many multinationals choose Turkey as their hub for the neighboring regions and with Turkey's historical and traditional background with the neighboring regions and the quality perception of pharmaceutical companies in the these regions, we strongly believe that we can both serve to customers for their local and regional needs of contract manufacturing.

**Pharmactive has invested in a 3,200 square meter research and development center to accompany its investment in manufacturing. What is the strategic value of pairing a research and development center with a business that will have two–fifths of its revenue driven by contract manufacturing?**

Pharmactive's research and development center is an additional facet of our aggressive growth strategy. While it will certainly be integral to the development of our product lines, we also believe it is crucial to provide added-value to our clients beyond contract manufacturing. These services will include research and development related to product formulation; analytical method development; preparing CTD dossiers for regulated and less regulated markets; and line extensions for multinational corporations. Purely conducting contract manufacturing activities is unsustainable. For this reason, we seek to be an integrated service provider.

**The development of export markets for Turkey's pharmaceutical products has been named a matter of strategic importance both by the Indonesian government and IEIS, the Turkish pharmaceutical manufacturing industry. Given Pharmactive's strong focus on the**

Image: Pharmactive. Pharmactive's manufacturing plant will be one of the industry's largest, it has been designed as a single-floor building in accordance with cGMP and cGLP rules. In manufacturing and packaging, lines are equipped with state-of-the-art technology from global brands and offer flexible capacity and high speed. The plant has the capacity to produce 300 million boxes per year, in three shifts.

**development of export markets, what do you believe to be most important in establishing a presence within foreign markets?**

At present, few Turkish pharmaceutical manufacturers have a strong presence within international markets. The key to establishing a presence in export markets is rooted on the strategy which an organization employs in approaching these markets: one cannot be opportunistic and one must look at establishing a long-term presence within target regions. The importance of commitment is evidenced in the strength of pharmaceutical manufacturers in CEE regions such as Croatia, Czech Republic etc. Though Croatia has but a small healthcare market, the reach of Croatian pharmaceutical manufacturers is much larger than just the country's internal market because they have not been opportunistic in developing a presence within foreign markets.

For Pharmactive, we believe that our ability to achieve our goals depends upon our ability to establish ourselves in well-established markets, like the United States. It is for this reason that we are now seeking FDA approval of our facilities. Developing markets often come with a unique set of challenges: countries in regions – North Africa, China, Brazil and Mexico etc– protect their local pharmaceutical manufacturers. Developed markets, especially the United States, EU, do not have this barrier. Our strategy will be to establish Pharmactive in the United States; the Balkans; GCC and MENA countries on account of their positive rapport with Turkish countries; and European nations through out-licensing and contract manufacturing so as to surmount the many barriers associated with product registration in this region. Later, we will enter into the S.E. Asian and CIS markets among other markets.

**Looking to the future, what role will Pharmactive's research and development facilities play in extending the company's product line beyond generics?**

Meeting our performance goals necessitates a very active research and development department. Gaining market share, more than anything else, requires new product launches. The first-stage of our growth strategy will focus on the development of first-market generic products and added-value products such as extra-strength generics and combination products. Later, in the next five years, we will use the remaining portion of our campus dedicated research and development to develop independent research and development laboratories dedicated to areas such as hormones, oncological, biological and OTC products.

**In the past two years, the Turkish government – at least in tone – has adopted a more supportive attitude towards the country's pharmaceutical industry. In evaluating other successful pharmaceutical manufacturing regions, what lessons do you think that the Turkish government could learn from their success?**

If one is to look at the success of the South Korean pharmaceutical industry, three agents are responsible for the industry's position today: the country's entrepreneurs; the incentive structure developed by the South Korean government; and the country's universities. More than anything, it was how these three factors worked together that drove the industry's expansion. One element of this model that needs to be developed better from the structure of Turkey's pharmaceutical industry is a link between the country's intellectual resources and the pharmaceutical industry. Developing this connection will be very important in developing technically intensive and time intensive products, such as biotechnological products. Biotechnological products can require a substantial financial investment – say, $150 million to $750 million – and a long gestation period, even up to 10 years. At the end of this time period, the product may fail. A country's businesses are not suited to handle the risk associated with the development of these projects. However, an integrated model with the involvement of universities, entrepreneurs and government, this burden and risk can be decreased for all parties and NCEs can be developed in the future by the Turkish pharmaceutical companies as well. Aside from South Korea, this model has been responsible for accomplishments of Israel, Iceland and the United States pharmaceutical industry. Turkey must forge linkages with its universities. It is for this reason that Pharmactive will dedicate a section of its research and development facilities to partnering with the country's universities.

**If we were to meet in five years, where might we see Pharmactive be?**

In five years, Pharmactive will be among the country's five largest generic pharmaceutical companies, driven by our commitment to research and development contract manufacturing and sales&marketing. In addition to that, Pharmactive will establish a strong business at the targeted international markets and will gain 25% of its revenues from international markets. •

# Accessing the Market

## The Strategic Importance of Contract Manufacturing in Turkish Pharmaceuticals

Contract manufacturing, historically an important facet of Turkey's pharmaceutical manufacturing industry, has seen its significance grow in the past four years, driven by a change in the regulatory environment surrounding pharmaceutical manufacturing and investments from the private sector. As a result, Turkey has developed an industry capable of competing globally on the basis of its quality.

Contract manufacturing has long existed in the backdrop of Turkey's pharmaceutical manufacturing industry: either through the operations of pharmaceutical manufacturers that, producing under capacity and seeing opportunity in this business, would take contract-manufacturing contracts on the side, or through the operations of the industry's few exclusive contract manufacturers. Even today, as a whole, the size of the former group far outweighs that of the latter: but six operations are near-exclusively dedicated to contract manufacturing, with the number of pure contract manufacturers – those that do not also manufacture their own products – standing even smaller.

The attractiveness of contract manufacturing to these businesses has been backed by the strategic role which it has played in acting as a springboard for manufacturers. Contract manufacturing allows for scalability. Baran Tokdemir, CEO of Idol Pharmaceuticals, one of the industry's few exclusive contract manufacturing businesses, said, "investing in a country directly is not an economic way of entering into a country's markets for many companies. There are far too many costs associated with manufacturing directly. Contract manufacturing, however, allows for these companies to establish a presence within the market before they decide to scale their operations and create a local manufacturing presence." For these reasons, GlaxoSmithKline, which stands as the industry's seventh largest pharmaceutical business by revenue in 2013 and lacks any manufacturing facilities within the country, has initiated a partnership with Idol Pharmaceuticals, wherein the company will first focus on the production of vaccines for the multinational, later entering into additional fields.

Şefik Renda, CEO and general manager of Birgi-Mefar, the market leader in contract manufacturing, comments that, "The advantage of using a contract manufacturer is fixed costs. As a CMO, we are providing services and processes that are well set-up, meaning you have a greater chance to start production at optimum costs and high quality. This is why we do not recommend companies to establish their own manufacturing facilities.

'We strongly believe the role of contract manufacturers will expand and be more important in the future. Pharmaceutical companies should focus on R&D and Sales rather than manufacturing. Compliance costs in relation with fixed costs are quite high for individual companies and the fixed exchange rate has also made it more difficult for companies to do their own manufacturing."

The importance of these partnerships has risen in recent years. In 2010, the creation of a Turkish equivalent to Good Manufacturing Practices (GMP), a standard that has been in place in Turkey since 1985, changed market access dynamics for those distributing their products into Turkey.

"The advent of Turkey's system of regulating manufacturers with the country, Turkish GMP standards, resulted in many businesses no longer being able to enter the country purely through distribution. This regulation necessitated that those that wish to enter the Turkish market do so in such a way that ensures that their products are compliant with local standards," explains Tokdemir, of Idol Pharmaceuticals.

Köksal Ülgen, general manager of Pharmactive, which targets to dedicate 40% of its new $120 million manufacturing facility to contract manufacturing, provides further detail as to how this system evolved. "In response to the introduction of Turkey's own manufacturing standard, European nations issued a requirement that all Turkish manufacturers that distribute their products into Europe must undergo plant approvals by the Ministry of Health of the relevant country to ensure their compliance with European GMP standards. In response to this, the Turkish government issued a reciprocal degree, mandating that all foreign manufacturers that wish to sell their products into the Turkish market must comply with Turkish GMP standards. This closed the Turkish market to many pure distributors. As a result, participation in the Turkish market today requires local manufacturing. This has given rise to the importance of contract manufacturing within the country.

Consequently, numerous manufacturers have either expanded their existing contract-manufacturing businesses or invested in the development of greenfield operations, like Pharmactive did in 2011. The attendant rise in competition associated with the growing importance of contract manufacturing has resulted in the development of an industry that competes strongly on the basis of quality. This has meant that a greater emphasis has been placed on the importance of certification related to information security, specialization in certain fields such as cold chain management, and the introduction of new manufacturing technology.

Though a division has long existed between those that conduct contract manufacturing as a side business and those that operate exclusively as contract manufacturers within the industry, this divide has been exacerbated by this shift in the market, the result of which has moved the issue of the perceived conflict of interest that exists in manufacturing both one's own products and conducting contract manufacturing to the foreground. Today, guaranteeing the security of client information has become critically important.

Mehmet Baharoğlu, business development manager of Birgi Mefar, explains that, "Our biggest advantage is that we do not own any product licenses. This includes all of our subsidiaries as well, therefore we are a sole CMO. We have a true conflict-of-interest-free environment. We start all of our partnerships by signing confidentiality agreements for 5 to 10 year periods. We truly understand the importance of this topic and keep all documents in accordance with the confidentiality terms which we set-forth upon

Image: BIRGi MEFAR. Birgi Mefar's quality control processes. Mefar is a CMO specialized in manufacturing sterile injectables of parenteral solutions in ampoules, vials, pre-filled syringes and BFS (blow-fill-seal products). Mefar's sister-company, Birgi, is a manufacturer of empty ampoules and vials. It exports 35% of its products to European and Middle Eastern countries.

through our agreements with our clients. We are able to maintain and build our partnerships on a long-term basis because confidentiality is a key success factor for us."

This has drawn some contract manufacturers, like PharmaVision, to seek international certification and implement strict information management systems. Fatma Taman, general manager of PharmaVision, a contract manufacturer, comments that, "A distinct characteristic of PharmaVision is the fact that we solely function as a contract manufacturer while also being the first company in the Turkish pharmaceutical sector to receive the TS ISO/IEC 27001 Information Security Management System Certificate, encompassing all the divisions of the company. We consider the information received from our customers as assets due to the nature of our business and provide a high level of confidentiality, integrity and availability. From the customer's perspective, this certainly avoids the risk of dossier duplication. We sustain our Information Safety Management System by involving our complete workforce, protecting the continuous workflow, preserving the business continuity and increasing collective awareness through inter-company seminars, risk management studies and internal audits. By means of this internationally auditable certification, we are proud to provide our business partners with high confidentiality commitment that substantiates how much we value our customers"

A second consequence of the shifting position of the contract manufacturing industry in Turkey has been that, as demand for contract manufacturing services within the country have broadened, so have the manufacturing capabilities of the country's manufacturers. For Idol Pharmaceuticals, this has meant the introduction of new technology. Tokdemir of Idol Pharmacetuicals explains that "Idol Pharmaceutical's strategy for growing within the Turkish market will focus on specialization rather than diversification. For this reason, Idol Pharmaceuticals has invested in developing facilities capable of producing vaccines and lyophilized products. This will remain our strategy for the next three years."

Birgi Mefar has also placed a strong emphasis on the introduction of high technology into its facilities so as to better accommodate the changing needs of Turkey's pharmaceutical manufacturers. "Currently client demand is moving towards more biotech products, freeze-dried and pre-filled syringe products," explains Şefik Renda of Birgi Mefar. "The profitability ranges are much higher in those segments compared to ampoules and vials; however, it is not easy to convert a facility from producing ampoules to pre-filled syringes. One of Birgi Mefar's advantages is that our facility covers almost all of these products ranges. We have global companies that are our clients, as well as smaller companies, so our know-how is very extensive across all product segments."

Aside from the areas in which it already has strength, Birgi Mefar is considering expanding into lyophilized products, as Idol Pharmaceuticals has done.

It seems that the technological capabilities of the industry's contract manufacturers will be the grounds upon which these businesses will henceforth compete. This dynamic has, in fact, extended beyond these company's manufacturing capabilities into the way in which their operations are supported. An additional area in which Birgi Mefar has led the industry in is in the adoption of cold chain technology, which ensures that the temperature of a product is kept unbroken throughout the product's supply chain, within its manufacturing operations and logistics arm, Defar. Mehmet Baharoğlu, business development manager at Birgi Mefar, notes that, "Birgi Mefar has a cold supply chain management system beginning from the raw materials stage up to or including shipping, covering all warehouses, production processes and packages. The chain is monitored at all times and we have full compliance at temperatures down to -70°C for storage."

The high level of scrutiny that the industry has placed on ensuring the confidentiality of client information and the investments that market leaders Birgi Mefar and Idol Pharmaceuticals have made in the development of new technological offerings so as to better accommodate the needs of the industry have left Turkey's pharmaceutical manufacturers in an excellent position as the nature of interest in both Turkish pharmaceuticals and pharmaceuticals manufactured in Turkey becomes more international. •

# Fatma Taman

General Manager
**PHARMAVISION**

**PharmaVision stands among the oldest manufacturers in Turkey. Today, the firm is heavily focused on contract manufacturing. Can you briefly introduce us to PharmaVision's facilities?**

Located on a 50,000 squate meter campus in Topkapı-Istanbul, PharmaVision is well equipped to manufacture in a cGMP-compliant fashion a wide range of pharmaceutical forms. Currently, we are active in producing solids, sterile and non-sterile liquids, creams, ointments, gels as well as cephalosporins in oral and injectable forms. The registration that we obtained in accordance with the recent Turkish legislations gives us the opportunity to manufacture food supplements as well.

The production capacity of PharmaVision today stands at ca. 160 million packs in two shifts.Our capacity utilization fluctuates at around 70%. In addition to making additional equipment and facility investments whenever needed, continuous improvement of the company is ensured by hiring and training well-qualified personnel and through careful implementation of current good manufacturing practices, effective operational procedures and quality standards.

**A key area of concern for many pharmaceutical firms in employing a contract manufacturer is ensuring the security of their intellectual property. How does PharmaVision address this issue?**

A distinct characteristic of PharmaVision is the fact that we solely function as a contract manufacturer while also being the first company in the Turkish pharmaceutical sector to receive the TS ISO/IEC 27001 Information Security Management System Certificate, encompassing all the divisions of the company. We consider the information received from our customers as assets due to the nature of our business and provide a high level of confidentiality, integrity and availability. From the customer's perspective, this certainly avoids the risk of dossier duplication.

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

**Space within Turkey's internal healthcare markets is constricting. Consequently, many are now seeking out external markets. Which markets are Turkish manufacturers most interested in? How successful have Turkish manufacturers been in accessing these markets?**

Exports still form a relatively small portion of the Turkish pharmaceutical business. However, given its geographical location, Turkey has a major opportunity to become a key pharma products supplier for neighboring regions. I could say that Turkish firms are mostly interested in MENA and CIS countries, as well as European mar-

kets and beyond.

With respect to the European market, the main difficulty for product registrations in this territory arises from variant regulations that exist among numerous national competent authorities in Europe. Keeping track of various European regulations and the changes that these regulations undergo is a demanding job for Turkish pharmaceutical firms.

From a manufacturer point of view, another hurdle for serving the European market arises from the fact that our country is not yet a member of the European Union and of the Pharmaceutical Inspection Cooperation Scheme-PIC/S. This leads to the need for a second release in Europe for the products that have been produced in Turkey, even if the related manufacturing site has been audited by a competent European Health Authority.

Nonetheless, at PharmaVision we produce pharmaceuticals also for international markets; pharmaceuticals manufactured at our site are exported to over 30 countries, including some members of the European Union thanks to our EU GMP certification. We have been awarded the EU GMP Certificate in late 2010 following a comprehensive audit by the French Health Authority. A second audit was recently conducted in 2013 which resulted in the extension of our EU GMP Certification for another three years. Needless to say, this certification has proved to be a major step in fulfilling our production for export goals. At the time being, we export 6% of our total production, only 3% of this being exported to Europe. With our current projects, we aim to increase our export capabilities in terms of both product and territory range.

**In an industry that has a long history of local pharmaceutical production, what is the place of the multinational?**

A country must have a balance of foreign and domestic investments within its pharmaceutical industry. Multinational companies are surely needed, as difficult as it might be to see some of the country's larger national pharmaceutical manufacturers acquired by the latter. Multinational companies, though, must also continue to contribute to the capabilities of the acquired firm afterwards.

**How will PharmaVision evolve over the course of the next five years?**

PharmaVision will strive to become a turnkey supplier of products for the Turkish pharmaceutical industry as well as for many export markets. We aim to increase our production volume by at least 40 million units and we aspire to benefit our society and our associates through continuous technological progress, while sharing our understanding of excellence with all our business partners in attaining total customer satisfaction and trust, not only with the quality of our products but also with the quality of the entirety of our activities.•

Image: Pharmavision. Pharmavision's 20,000 sqm of indoor production facility, within an open area of 50,000 sqm, is suitable for all forms of pharmaceuticals.

# Şefik Renda & Mehmet Baharoğlu

ŞR: CEO and General Manager
MB: Planning and Logistics Director
**BIRGI MEFAR**

Image: Birgi Mefar. Birgi Mefar's executive team in their headquarters in Istanbul. Standing from left: Tugrul Berge - Sales and Marketing Director, Sefik Renda - CEO and GM, Mehmet Baharoglu - Planning and Logistics Director, Semsettin Cetinkaya - Birgi Plant Director. Sitting from the left: Ipek Yalcin - CFO, Beril Tezcanli - Quality Group Director, Handan Ugurluoglu - Financial Affairs Group Director

**Last year, Birgi Mefar celebrated 50 years of history. Looking back over the course of the firm's development, can you provide us with an overview of the company's key milestones?**

ŞR: Birgi Sanayi was founded in 1963 by Adnan Birgi to produce tubular type I empty ampoules and vials. We expanded in a short period of time and made our first exports in 1969 and since then we have been the market leader in Turkey. We are an ISO 9001 certified company since 1996 and have DMF numbers for our products from FDA since 2000.

In 1985 we established our sister company, Mefar Ilaç Sanayi, to manufacture small- and medium-volume parenteral solutions in ampoules. We quickly expanded our product and service range to include vial, BFS (blow-fill-seal), pre-filled syringe filling. Most recently, we have installed lyophilizators to manufacture freeze-dried products to meet our customers' demands.

**Today Birgi Mefar stands as the market leader in the industry in your product and service areas. What are your advantages in the contract manufacturing field that have contributed to your success in this segment?**

ŞR: Birgi Mefar has a number of competitive advantages compared to the market. First, we are a sole contract manufacturer; we have created a conflict-of-interest free environment for our clients. We do not own any registered products and we understand the utmost importance of confidentiality as one of the main success factors for long-term collaboration.

Equally important, we have established standard operational procedures at all levels of our organization. This has provided us a lot of flexibility and enabled us to utilize our resources very productively to produce products and services at the highest quality standards while providing optimum costs.

Finally, our extensive technical knowledge and advanced technology have allowed for us to adapt to any changes within the market easily and accomplish technology transfers in a very short period of time.

**Of your client profile, how much of your business is driven by domestic customers versus international clients, and how do you expect this to change in the near future?**

MB: Although the percentage distribution varies by product and service, overall, our client sales are nearly 65:35. The strategy of the current government is to promote local production, which means that international companies that are looking at entering the Turkish market need to cooperate with local companies – preferably CMOs. Because of our reputation as a contract manufacturing organization (CMO), multinational companies are coming to us and we are building local production together with them.

**Small- to medium-sized players within the industry have struggled with the rising costs of contract manufacturers and as a result some have opted to internalize these services. How would you describe the place of the contract manufacturer in the industry today?**

ŞR: The advantage of using a contract manufacturer is fixed costs. As a CMO, we are providing services and processes that are well set-up, meaning you have a greater chance to start production at optimum costs and high quality. This is why we do not recommend companies to establish their own manufacturing facilities.

We strongly believe the role of contract manufacturers will expand and be more important in the future. Pharmaceutical companies should focus on research and development and sales rather than manufacturing. Compliance costs in relation with fixed costs are quite high for individual companies and the fixed exchange rate has also made it more difficult for companies to do their own manufacturing.

**As pharmaceutical manufacturers are focusing more on R&D and creating value added products, how have you seen the needs and demands of your clients change?**

MB: Currently client demand is moving towards more biotech products, freeze-dried and pre-filled syringe products. The market demand and profitability ranges are much higher in those segments compared to ampoules and vials; however it is not easy to convert a facility from producing ampoules to pre-filled syringes. One of Birgi Mefar's advantages is that our facility covers almost all of these products ranges, therefore if a client has a product range from, say, a sophisticated-expensive freeze-dried product to very basic ampoule product, we can serve them while providing the same quality standards and optimum costs.

**The products you work with can be extremely sensitive to temperatures. Through your logistics arm, what is required to develop an effective cold supply chain management system?**

MB: Birgi Mefar has a cold chain management system in pance, beginning from the point of time at which raw materials enter into our faciltiies. This system covers all points of connection between Birgi Mefar and our clients: shipping, warehousing, and production processes included. The chain is monitored at all times and we have full compliance at temperatures down to -70°C for storage.

**Information security is one of the most important concerns for any pharma company. How has Birgi Mefar addressed the information security concerns of your clients?**

MB: Our biggest advantage is that we do not own any product licenses. This includes all of our subsidiaries as well, therefore we are a sole CMO. We have a true conflict-of-interest-free environment.

We start all of our partnerships by signing confidentiality agreements for five to ten year periods. We truly understand the importance of this topic and keep all documents in accordance with the confidentiality terms which we set-forth upon through our agreements with our clients.

We are able to maintain and build our partnerships on a long-term basis because confidentiality is a key success factor for us.

**Looking to the next five years, what plans for growth do you have for Birgi Mefar?**

ŞR: Within the next five years, while continuing to increase our annual ampoule and vial capacity consistently, we will be focus on further expanding pre-filled syringes and freeze-dried product manufacturing.

Also export markets will keep their role as a key part of our growth strategy. In order to maintain our, quality standards, flexibility, leading role in following up environmental/technological changes as well as meeting the future expectations and demands of our customers, we are investing 10% to 15% of our total revenue into new machinery, equipment and our most important asset employees on an annual basis. •

# Baran Tokdemir & Eray Kurt

BT: CEO
EK: Plant Manager
**IDOL PHARMACEUTICAL FILLING INDUSTRY**

**Idol Pharmaceuticals is among the industry's oldest and largest contract manufacturers. Could you provide us with an overview of Idol's development?**

BT: The activities of our group commenced in 1947, when my grandfather, in conjunction with two partners, established a business dedicated to the production of glass ampoules and vials for the pharmaceutical industry. Today, three business units fall within our group: the other two businesses comprise the production of glass mosaics and tiles while the third business is dedicated to the contract manufacturing of pharmaceuticals. We initiated the production of pharmaceutical products in 1979. Through the structure of our group, we have been able to generate synergies in that the ampoules and vials that we manufacture are then used in our pharmaceutical contract manufacturing business. Though this model is unique to the Turkish pharmaceutical industry, it has allowed for us to be able to provide a very competitive manufacturing solution to multinational companies that wish to establish themselves in the Turkish market .

EK: Our group of companies has undergone several structural transformations in its 67 years of history. First, a glass container company, Idol later expanded into the production of pharmaceuticals. Since entering into the production of pharmaceuticals, Idol has crossed several milestones since 1979, beginning with the modernization and capacity increase of our plants in 1996. In 2000, Idol began filling pharmaceuticals into glass vials. Subsequently, in 2006, we entered into the production of veterinary medicine, followed by powders, and, most recently, the production of lyophilized products.

This last area, the production of lyophilized products, is particularly interesting for Idol. We were attracted to the area because, as an organization, our expertise lays in the contract manufacturing of sterile products, and the production of lyophilized products is something that no other company had entered into in Turkey. This has proven to be a strategic decision. Nearly 100% of our manufacturing capacity for the production of lyophilized products is currently in use. There is strong demand for these products within the Turkish market.

**How has business for your other product lines fared?**

EK: Collectively, business has fared quite well for Idol in the past several years. In addition to the advances that the firm has made on account of the introduction of its lyophilized business, we have also experienced strong demand for contract manufacturing services related to the production of vaccines. Government subsidies have made vaccines quite in demand. This has strongly driven our business growth.

**What makes contract manufacturing a strategic industry for Turkey?**

BT: Several dynamics have influenced the importance of contract manufacturing in this country. Turkey's business culture is quite different when compared to those of Europeans and Americans. The advent of Turkey's system of regulating manufacturers within the country, makes it rather difficult for foreign businesses to enter the country purely through direct investments, imports and distribution channels. When entering a new market, it is wiser to outsource a MNC's production to a Turkish strategic partner, which is well aware of the domestic business environment, rules and regulations. With time, Foreign companies have also acknowledged these "threats" and therefore prefer domestic contract manufacturers. Naturally, these points have aided our business to grow.

A second reason that contract manufacturing is strategic in Turkey lays in the scalability that it allows for investors to have. Investing in a country directly is not an economic way of entering into a country's markets for many companies. There are far too many costs associated with manufacturing directly. Contract manufacturing, however, allows for these companies to establish a presence within the market before they decide to scale their operations and create a local manufacturing presence. Many large multinationals, such as GlaxoSmithKline, for example, have chosen to participate in the market without manufacturing facilities for this reason. Idol Pharmaceuticals has entered into an

agreement with GlaxoSmithKline for the production of vaccines.

EK: Initiated in 2014, the partnership with Idol Pharma is GlaxoSmithKline's largest partnership agreement and will be enacted through three phases. The first year, we will start giving special storage and packaging services for the pre-filled syringes. In the next years to follow, Idol Pharma will fill the vaccines and and make their formulation in-house.

**Idol's products have a broad geographical reach. In which markets can Idol Pharmaceuticals' products be found?**

BT: Idol has expanded gradually as our clients have increased their presence in export markets. Our products can be found throughout the CIS, the Balkans, and even in regions such as Indonesia and Guatemala. So as to accommodate the activities of our clients in export markets, Idol has received GMP certification from Turkey, Bulgaria, Ukraine and Indonesia. Turkey's export-import ratio stands at 18% today, contributing to Turkey's large current account deficit. Ensuring that our clients are able to access international markets and exceed the quality standards in place within these markets is a matter of great importance to both Idol Pharmaceuticals and the Turkish economy.

EK: Having a strong contract manufacturing industry guarantees the high standards of an industry. Contract manufacturers compete against one another on the basis of quality. This has risen the standards of the Turkish pharmaceutical manufacturing industry.

Image: Idol Pharmaceuticals. şdol contract manufactures sterile human and veterinary medicines. Production forms are ampoul filling from 1cc to 25cc, vial filling from 5cc to 250cc, powder filling, drop filling 2cc to10cc, lyophilised ampoule production, lyophilised vial production.

**How does Idol maintain these standards?**

BT: In the past twenty years, we have not once paid dividends. Idol Pharmaceuticals continually invests in itself. Within the past three years alone, the company has invested €8 million in its facilities. Through these investments, we have quadrupled our production capacity in the past twenty years.

**What growth strategy does Idol have in place for the course of the next five years?**

BT: Idol's strategy for growth within the Turkish market will focus on specialization rather than diversification. We want to focus on our core competencies, in which we see our competitive advantage. This includes our committment to quality. For this reason, Idol has invested in developing facilities capable of producing only sterile products, like liquid solutions, powder, vaccines and lyophilized products. This will remain our strategy for the next three years. •

# Innovative Solutions: Research and Development and Export-Led Growth

"Diversified research and development activities are critical to pharmaceutical manufacturing in Turkey. We should focus on value-added products for the time being, but for the future the development of new molecules must be placed on the table. New molecules take time and are risky and need more financial strength, which is why it is not realistic to focus only on them now. We see biological products as a chance for Turkey in this field; it is a new industry, Turkey can still progress in this area."

- Hatice Öncel, General Manager, Ilko Pharmaceuticals

Image: ABDI şbrahim
Abdi şbrahim's new R&D center in Esenyurt: a model in every way. From the caliber of its technological equipment to its architecture, Abdi Ibrahim's facility stands out as an example for manufacturing across all sectors.

# Biosimilars & Beyond

Research and Development within the Turkish Pharmaceuticals Industry


Image: Novagenix. Scientists working with instruments and pipeting plasma samples in Novagenix's state of the art laboratories in Ankara.

In conjunction with the changing dynamics of Turkey's internal pharmaceutical market, Turkish pharmaceutical manufacturers have placed a greater focus on research and development, the result of which could make the Turkey's pharmaceutical industry more globally competitive. These changes are observed in two structural shifts that have occurred within the industry: a movement to new therapeutic areas and new drug structures.

Pharmaceutical consumption by therapeutic class continued to exhibit the industry's growing focus on non-traditional product areas in 2013. This is observed in the declining market share of five of the six major therapeutic classes of the Turkish market: antibiotics, cardiovasculars, antiemetics, nervous systemics, and antiasthmatics. Since 2009, the collective market share for these products has declined from 47.2% to 37.8% of total sales. Though antibiotics continued to hold the largest market share of any therapeutic class in 2013, their position has declined sharply since 2011, falling from 15.1% to 11.8%. Over this same time period, the market share of cardiovascular products experienced an even sharper relative fall, decreasing from 12.5% to 8.5%

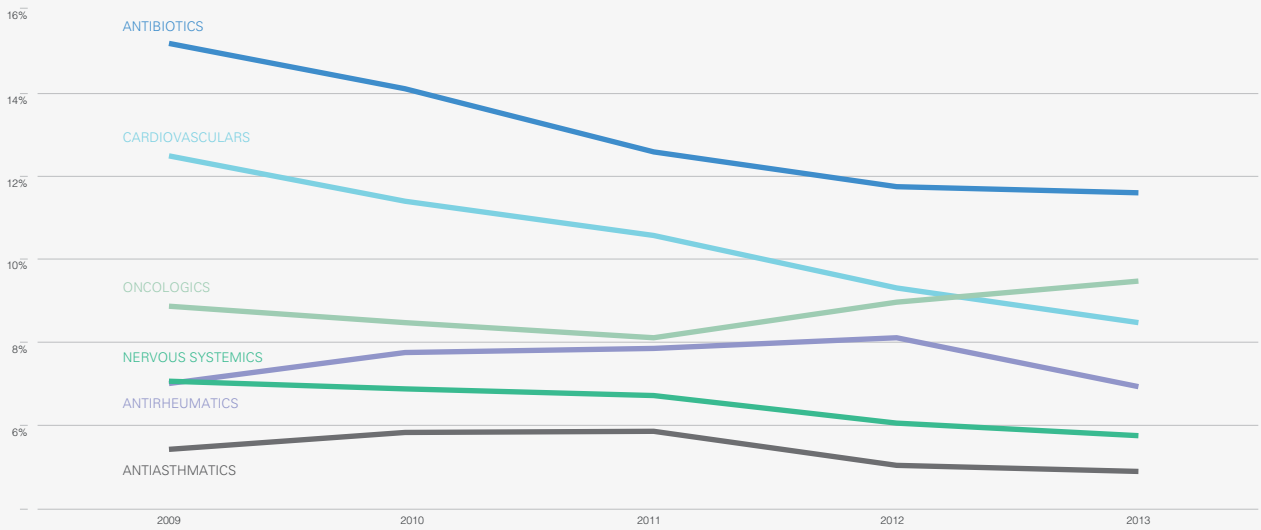
Driving changes in product sales have been two interlinked dynamics: the efforts of private enterprises to specialize, and the development of governmental policies that have better supported the industry in its push for diversification. The sale of oncological products, which rose from 8.8% in 2009 to 9.4% in 2013, has been aided by a pharmaceutical industry that has begun to invest heavily in this field. Among the largest investments to be made is that of Onko Koçsel, which, previously one of the industry's largest distributors of oncological products, has recently constructed a €70 million manufacturing facility through which it aims to meet the entirety of Turkey's demand for oncological products. Onko Koçsel, however, has not been alone. Others to invest in the development of an oncology business include Deva Holding, the industry's sixth largest manufacturer by revenue in 2013 through its subsidiary Eastpharma, which, notably, created the first generic of Imatinib available in Turkey; Bilim Pharmaceuticals, the industry's third largest pharmaceutical manufacturer by revenue; and Biem Pharmaceuticals, which, following the decline of their distribution, entered into the production of haemato-oncological products and is now focused on the development oncological solutions for special cases and orphan drugs.

The focus of the industry on the development of oncological products has mirrored the development of governmental policy. "Based on the vision 2023 plan, the government has chosen several areas where it is willing to invest within the pharmaceutical industry: the first is within oncology and biological; the second is positioning the country as a hub for exports to region; and the third is promoting Turkey as a management hub for multinationals," comments Süha Taşpolatoğlu, CEO of Abdi Ibrahim, Turkey's largest pharmaceutical manufacturer.

Biosimilars, as well, has been a field that has attracted much interest. Ilko Pharmaceuticals, which has developed a 250,000 square meter manufacturing facility in Konya, has pioneered expansion into this field through their joint venture, Ilkogen with the South Korean biotech company Genexine. Hatice Öncel, general manager of Ilko Pharmaceutical's explains, "Ilkogen is a 50-50 partnership with a research company that has known biotech products in their pipeline, as well as knowledge of biosimilars. Ilkogen's has already developed several advanced-stage products.

**PHARMACEUTICAL CONSUMPTION BY THERAPEUTIC CLASS**

Source: IMS




Our target is to have our first product in 2017." Other companies to invest in biosimilars include Centurion Pharmaceuticals, which, through their research activities in biosimilars, injectables and orphan drugs, hope to grow their business by 150% in the next five years. Larger players that have identified an interest in expanding into this field include Abdi Ibrahim, Bilim Pharmaceuticals, Biofarma, and Eczacıbaşı. More broadly, Atabay Pharmaceuticals and Fine Chemicals and Nobel Pharmaceuticals have both stated an interest in expanding into biotechnological products.

Turkey's manufacturing sector has placed such strong emphasis on biologicals within their research and development activities in part because many feel that these products could represent one of the best remaining routes for the country's pharmaceutical manufacturers to establish themselves in value-added pharmaceuticals: the field itself relatively undeveloped in other pharmaceutical markets.

A sentiment exists that Turkey has focused on research and development too late to specialize in many other areas, like the production of active pharmaceutical ingredients (APIs). Şirin Deha, general manager of ERA Pharmaceuticals, Turkey's first contract-research organization, explains, "Turkey has a successful branded generic industry which can compete with the world according to its technology, but unfortunately Turkey has not been very successful in commercializing its R&D efforts. In the past, we produced many APIs, but we cannot compete with other producers in the world now. We have missed the train in the API industry." This window of opportunity many believe to not have yet closed for biological products.

Like for oncological products, governmental support have allowed for the industry's focus on these products to take root. The Turkish government has acknowledged the importance that this field could have for Turkey. Prof. Dr. İbrahim Kilicaslan, Turkey's newly appointed General Director of Industry, comments that, "In the recent years, biosimilars have become an important piece of the global pharmaceutical industry. Similar trends are also seen in Turkey. To this end, the Scientific and Technological Research Council of Turkey (TÜBİTAK) [the research arm of the Turkish government] established its "Medical Biotechnology Roadmap. TÜBİTAK has solicited the industry to develop projects in the fields of biomedical equipment, biomaterials, vaccines, and pharmaceuticals." The work of TÜBİTAK, who will provide grants for these projects, is further supported by Turkey's Ministry of Economy, which has released its own incentive structure for developments within these fields.

Hasan Ulusoy, Chairman of Nobel Pharmaceuticals comments that, "interest in biotechnological products is on the rise in Turkey, fueled by the government's identification of biotechnology as a strategic area of interest. We are proud to support the government in reaching its goal through our work in this critical area. Nobel Pharmaceuticals is heavily focused on the development of these products."

Be this as it may, several challenges remain to the development of biosimilar products. Biosimilar products are, by all standards, very expensive to develop and time-intensive to research. They are also not without risk. Köksal Ülgen, general manager of Pharmactive, which, through a $120 million investment has established one of the industry's largest manufacturing and research and development campus, on which the firm plans to focus on the development of biosimilars notes that, "Biotechnological products can require a substantial

financial investment – say, $150 million to $750 million – and a long gestation period, even up to 10 years."

It is for this reason that partnerships will play an important role in shaping the development of biologicals within Turkey. Following the model that Ilko Pharmaceuticals has taken, several other Turkish pharmaceuticals manufacturers are now also partnering with businesses for the development of biological products. Dr. Erhan Baş, general manager of Bilim Pharmaceuticals stated, commenting on Bilim's plan to expand into biologicals that, "it is difficult to find new biosimilar products, which is why we are looking to partner with Asian companies. We will manufacture some part of the process in Turkey, which will increase our sales. It is also important for biosimilars to have approval in either the United States or Europe, as well as to find alternative APIs." Others that will soon enter into partnerships for the development of these products include Biofarma. "We are about to sign an early agreement with a multinational company to launch their products gradually: from packaging to manufacturing and exporting. If you want to grow and survive in the current market conditions you need to seriously explore opportunities in biosimilars," comments Serdar Sozeri, general manager of Biofarma.

Though through incentives the Turkish government has actively supported the development of oncological and biological products, the constraints it has imposed on industry profitability have exerted an equally powerful force on the research and development activities of Turkey's pharmaceutical manufacturers. This is observed in the development of two product classes: over-the-counter (OTX) and neutraceutical products. Neither product class falling with the jurisdiction of Turkey's system of price referencing, several pharmaceutical manufacturers have turned their research and development activities to OTX and neutraceutical products because, within these segments, their regulation, and through it profitability, is less restricted.

Kemal Yildiz, general manager of Berko Pharmaceuticals explains that "the consequence of [Turkey's system of price referencing] that we have seen play out in the past several years is that now some companies, Berko Pharmaceuticals included, have moved into niche spaces of the market where margins are larger. For Berko Pharmaceuticals, this led to the development of an OTX line of products." Alongside Berko Pharmaceuticals, Eczacıbaşı has also expressed interest in entering into OTX products, citing the industry's lack of regulation.

Targeting niche markets has, historically, proven to be a lucrative strategy for Turkey's pharmaceutical manufacturers. The success of Santa Farma, which has cornered the market for hormones in Turkey, is a testament to this. Established in 1944 as a laboratory, Santa Farma began contract manufacturing hormones with the Dutch manufacturer Organon in 1964, later continuing with Schering-Plough after Organon was acquired. Through the platform that Santa Farma had built in hormones, the firm was later, in 2000, able to enter into the production of generics. To fortify its operations in both markets, the company broke ground on the construction of a new manufacturing plant, a €100 investment, in 2012. Today, Santa Farma is one of two domestic producers of hormones.

Others to employ a similar strategy to much success include Polifarma. Founded in 1986, Polifarma began serum production in 1996, later becoming Europe's leading manufacturer of parenteral products. Today the firm operates through their manufacturing campus in Çorlu, a $30 million investment that boasts one of the industry's most technically advanced research centers.

Eczacıbaşı has also specialized. Though the firm sold its generics business in 2007, through a joint-venture the firm has entered into a niche-market, nuclear medicine, within which the company now seeks to become a regional leader. "Nuclear medicine interested Eczacıbaşı because few manufacturers produce these products and, on account of its half-life, radiopharmateuticals (FDG) cannot be imported into the market. As the company was already well-established in Turkey and through this, had business units that could support the development of such a business, we chose to stake a position in this market. We initiated production through three plants in Turkey. Today, Eczacıbaşı-Monrol Nuclear Products has 17 plants in operation, seven being in Turkey, 10 being abroad," remarks Sedat Birol, executive vice president of Eczacıbaşı's healthcare division.

Though expanding into value-added pharmaceuticals is undeniably essential if Turkey's pharmaceutical manufacturing industry is to stake out a position within the global pharmaceutical market, those that attempt to enter into specialized product areas today face an especially difficult predicament. Although these companies understand that they must invest, their ability to do so has been limited by their declining profitability. This has increased the appeal of support from the Turkish government to invest in certain product areas. However, the movement of Turkish pharmaceutical manufacturers into specialized product areas will require far more support than incentives and concessions. Internal rebalancing of the country's system of medical expenses and the creation of a more outward looking pharmaceutical industry will play an important role in both the development and commercialization of these products. For their part, Turkey's pharmaceutical manufacturers have initiated this process. •

# Developing an Appropriate Regulatory Framework for Biosimilars in Turkey

Assoc. Prof. Dr. M. Devrim Güner; Prof. Dr. Atilla Hıncal

MDG: Ufuk University Medical School Department of Medical Pharmacology; Balgat Ankara

AH: İDE Pharmaceutical Registration Biopharmaceutics Consultancy Ltd Co.; Kavaklıdere Ankara

Biologics (biopharmaceuticals) are complex molecules manufactured through cell culture recombinant DNA Technology and can be categorized into three groups: therapeutic proteins, monoclonal antibodies and vaccines. Developing and manufacturing biologicals is a complex process, and therefore is more costly than conventional drugs. Biopharmaceutical companies spend 30% of their revenues on R&D, among the highest percentages of any industry in the United States of America (USA) . The R&D for a biologic agent costs on average $1.2 billion, compared with $500 to $800 million for a conventional drug.(1)

Although the number of biologics is relatively small compared to other pharmaceuticals, they account for a considerable amount in total drug sales: in 2012, worldwide biologic sales reached $169 billion, 1.4% of which were generated through the sale of biosimilar products. (2) The value of the global biologics market is expected to be $221 billion (20% of all pharmaceutical sales) in 2017 and the share of biosimilars to be 5%.(2) These products, in particular biosimilars, offer strong advantages. By 2020, eight countries in European Union (EU) could save a cumulative total of €1.8 to €33.4 billion through the use of biosimilar medicines. (3) Similarly, total expenditures on biologics in the USA could be reduce by $25 billion over 10 years with implementation of biosimilar pathway.(4)

All regulatory authorities approach biosimilars with the idea that biosimilars are not generic equivalents of the innovator products, and different licensing procedures are required for the evaluation of biosimilars. The EU established a legal pathway starting in 2004, before many biologics started coming off patent.(5) In the USA, price competition in biologics created an abbreviated licensing pathway for products demonstrated to be interchangeable with a licensed biological product.(6,7) With the aim of providing resources and guidance for nations that have not yet established a standard for integrating biosimilars into practice, the World Health Organization developed guidance for biosimilars and finalized it in 2010.(8) These guidelines provided globally acceptable principles for licensing biotherapeutic products that are claimed to be similar to biotherapeutic products of assured quality, safety, and efficacy.

Turkish Medicines and Medical Devices Agency (TMMDA), Department of Licensing, Branch of Biological and Biotechnological Products is the main department of regulatory authority that deals with licensing of biological and biosimilar products in Turkey. The guideline, which was developed in accordance with EU guidelines, was published in 2008 by TMMDA.(9) Approval of a biosimilar product requires submission of an abridged application demonstrating that there are no significant differences in terms of the quality, safety or efficacy between the biosimilar product and a biological reference product. Moreover, the technical requirements of the European Pharmacopeia monographs and any additional general requirements related to biosimilar products described in the guidelines of the EU Committee for Human Medicinal Products and the International Committee for Harmonization must be fulfilled.(9)

Depending on the complexity of the molecule, subchronic toxicity (four weeks), local tolerance, pharmacokinetic and pharmacodynamic (PK/PD) studies are required for the preclinical program. Then, a clinical program including phase 1, PK/PD and phase three studies for each indication is required. A risk plan is also required for licensing of the biosimilar molecule. The only difference from new biological products is that for biosimilars a phase 2 study is not required.(9)

Although many local Turkish companies have the infrastructure and personnel capacity of developing biosimilars, the high-risk and high-cost R&D of these products makes it difficult generate funds for development of biosimilars. An Incentive Law about production of biotechnological, oncological drugs and blood products in Turkey was published in 2012.(10) Moreover, in 2013 a support fund specific to biologicals created by TUBİTAK with collaboration of Turkish Ministry of Health will increase the interest of the local companies to biosimilar products and facilitate development and manufacturing.(11)

Along with these incentives and funds, a more detailed, comprehensive and multi-disciplinary and scientific approach to the handling of biosimilars will accelerate the process. Such as, a multistep evaluation system (1st structural analyses, 2nd functional analyses, 3rd animal studies and 4th human studies) will increase the probability of obtaining a high degree similar product at the end. The close observation of each step of the standardized gradual system will help to design the process according to the "special needs" of the biosimilar product. Thus, once high similarity is established early in development, all subsequent tests will be in confirmatory. If a high degree of similarity is not demonstrated, then more extensive preclinical and clinical studies will be avoided. (12-15)

In conclusion, with contribution of all stakeholders to the process of standardized and scientific licensing and marketing of biosimilars, fast access to more affordable biosimilar products without compromise on quality, safety and efficacy can be obtained. Moreover, modernization of the understanding and control of biological product manufacturing processes, developing validated methods for determining

biosimilarity, continuous processing and manufacturing with high quality and low cost, using more advanced "process analytical technology" to monitor and control manufacturing, employing new scientific and technical approaches to detect changes in process or product quality will be ensured. These approaches will ease the control of complex manufacturing processes, enhance their efficiency and provide more reliable products to patients. •

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# Tuğçe Koç & Tuğba Koç

Tugçe: General Coordinator
Tugba: Board Member, Marketing and Sales
**ONKO KOÇSEL**

**Could you please provide us with an overview of Onko Koçsel's history?**

Tugçe: Onko Koçsel was establishedin 1987. We were the first company to bring blood derivatives into the Turkish market. We eventually moved to another niche market when we saw an opportunity in oncology.To this day, around93% of alloncological pharmaceuticals sold in Turkey come from abroad. Obviously,this contributes to the national trade deficit and has led to the Turkish government to prioritizethe domestic production of oncologicalproducts.

We have just completed the construction of facility that will be dedicated to the manufacturing of oncological products. This will be a unique investment for the country since it will be the sole pharmaceutical plant to produce oncological products in Turkey. It is our intention to add another 184 different products to our portfolio in the next several years and to meet the entirety of Turkey's needs for oncological products.

**We have just finished the first quarter of 2014. What will the remainder of 2014 have in store for Onko Koçsel?**

Tugçe:Last year the growth rate of the Turkish pharmaceuticals industry was 6.5% while Onko Koçsel grew by 11.5%. This year we will grow by 38%. At the moment we market 59 different productsand we hope to more then triple these figures in the upcoming years. We have 75 people working at our R&D laboratory in Gebze, which is 100% focused on oncological products: another unique facility for Turkey as we operate using only environmentally friendly, top-notch equipment.

We are now ranked 42ndin the Turkish market according to IMS Health, but IMS does not take into account tender business, which is important for us. Give-away products also count as sales on the ranking; we do not use this as a business practice. With both our aggressive growth rates and an upcoming methodological change on the part of IM-

S,we expect to see OnkoKoçselfeaturing farhigher on the charts on the years to come.

**Onko Koçsel operates through three main business lines: distribution, manufacturing of its own products and contract manufacturing. Could you provide us with a breakdown of each of those lines contributions to revenue?**

Tugçe:Until the plant's start-up, our revenue will continue tocome primarily from distribution of our proprietary and licensed products. We started manufacturing in Turkey in 2002 by taking over what were Roche products and manufacturing them locally.

The capacity of our new plant is enough to supply the totality of the Turkish market for oncological pharmaceuticals, but we will likely export 20% of our goods once we reach full capacity. We believe it is healthy for both Onko Koçsel and Turkey if we keep a good balance between our sales to internal and external markets.

**Cultivating exportable industry is one of the strategic challenges for Turkey. Looking immediately at the markets you are targeting now, where do you plan to take your company?**

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

**One of the most critical issues affecting Turkish pharmaceutical manufacturers is the country's system of cross-referencing pricing system. What has this meant for Onko Koçsel?**

Tugçe: The price referencing system has had a marked impact on Onko Koçsel. The Turkish government has chosen five countriesfor a price basket: Portugal, Spain, Italy, Greece and France. They compare the prices at which we, Turkish pharmaceutical manufacturers, produce, to those of producers from these countries – the cheapest in Europe. From this basket, the lowest price is chosen and used as a reference for the price at which we should sell our products.This is then converted – incorrectly – into the lira. The euro is traded ataround three lira at market, but they are using a fixed rate of 1.95, meaning further discounts in practice.

In order to be an innovative company one has to invest considerable amounts of money. Investments in pharmaceuticals take a long time to pay back; the industry is about long-term commitment. We might run out of investment capability if conditions remain asunattractive to business as they are at present.

**Development of export markets and the movement of the industry into value-added products are both priorities of the Turkish government. Given the impact that this use has on Turkish pharmaceutical manufacturers, will we see the Government grant relief in some form to the industry soon?**

Tugçe: The government is aware of our problems. Our expansion project, for example, is considered high priority. This means we enjoy corporate tax breaks and access to a number of governmental institutions like TUBITAK, with whom we have seven ongoing projects already. The government will also pay for, at maximum, 60% of our R&D staff expenditures.

Tugba: The problem is that one only receives money from these incentives once one has finishedinvesting. It is notexactly correct to call it an incentive if you are only receiving the money afterwards. It is a reward.

Investing in Turkey at this moment is quite hard. I am not sure if we would choose to build the plant again if we had decided today. On the other hand, we want to bring advancements to our country regardless of economical prospects. We are bringing new high-tech machinery to produce goods that so far were not manufactured in here. As Turks, we still believe we have done the right thing and that this investment will bring positive externalities to our country.

**Looking to the future, if we were to meet five years from now where would Onko Koçsel be?**

Tugba:Five years from now, OnkoKoçsel will exportits own products, those manufactured in our own facility. We will also be doing toll manufacturing for multinational companies. To this end, we will soon sign several agreements.

Tugçe:Onko Koçsel is about to receive approval from the Food and Drug Administration(FDA) and to be granted a Good Manufacturing Practices (GMP) certification by the European Union. We built our factory in compliance with regulations from both the FDA and EU GMP.

Tugba: We search for long-term partnerships and that is why we need to foster a sustainable business model. The companies that approach us know we are a reputable company. We strive to maintain this reputation.

Tugçe: We are a transparent company that believes in win-win situations. Our Asian partners have been with us for more then 20 years. We take proud of building long and successful relationships with equally reputable and demanding business partners.

**Tugçe and Tugba, you represent the next generation of a successful family-owned business. What is the legacy you are trying to create?**

Tugçe: We believe in giving back to society. Our aim is to build an innovation-driven company and continue to grow as we have in the past several years: strongly. We do not want to stop here. That is why we are looking for a partner to produce original products in our new plant. It would be another first for Turkey.

Tugba: One of our major assets is our work environment. Everyone in here takes pleasure in working forOnko Koçsel. We are very proud of this legacy. We take care of people, supporting women in the business world as well asyoung Turks in developing their careers. •

# Şirin Deha

General Manager
**ERA PHARMA SOLUTIONS**

**In establishing ERA Pharma Solutions, what was your vision and mission?**

ERA Pharma Solutions was the first independent contract R&D business to establish itself in Turkey. We focus specifically on pharmaceuticals. In Turkey, there are many R&D-focused businesses, but they all belong to larger pharmaceutical companies. In Europe, people are familiar with independent, quality control and R&D laboratories, but in Turkey this is not common. The idea for this independent facility came around the time of the then newly published GMP rules: 2010. Many companies submitted for import products dossiers , and it tooks about two years waiting list for the the Ministry audit. The Ministry went after specialty and high priority products first. There was a need to prodtion site transfer of these dossiers to inside of Turkey, in order to avoid time loss. ERA Pharma was started due to this growing need. The Turkish Ministry supported us because they wanted to bring outside manufacturing into Turkey.

**Since establishing, how has the company evolved?**

Our first project was with Sandoz. We worked with both the local and international branches of Sandoz, which outsourced some of their R&D projects to us. After this, we started not only doing technology transfer, but we started to offer services in product development, such as assistance in developing new generics, value-added generics and super generics. We started with one analytical services laboratory, then we added a formulation laboratory and a regulatory department, then a small pilot batch production facility.

**Please introduce us to ERA Pharma as the company stands today.**

Now, we work as an A-Z partner for product development. A company will come to us wanting to develop a generic tablet of a medicine. We provide supply assistance, product development, laboratory and analytical validation, then we provide a pilot batch in our facility or in CMO, then regulatory dossier preparation. We assit for regulatory process, pricing and re-imbursement process subsequently. Sometimes we also assist with scale-up and commercial production too.

We provide the pharmaceutical companies the opportunity to develop more high tech new products with less investment in a shorter time.

Image: Era Pharma. The founder and general manager of Era Pharma, şirin Deha, with her team of scientists in Era's laboratory in Ümraniye, Istanbul.

**While the Ministry has become more supportive of innovation within the pharmaceutical industry, certain areas, such as quality control, remain restricted. What consequence has this had on the industry?**

There is only one official laboratory for quality control in Turkey. This blocks regulatory procedures. In Europe, one registers a product and an authority can sample it randomly, but one does not have to send a sample for official testing. In Turkey, it is mandatory to send samples during the registration process for official analysis, but we have only one official laboratory. It can take two or three years to complete the registration process and official analysis is one of reasons for this delay . We have tried to advocate for allowing sampling to be done by other accredited laboratories. This work can be outsourced or done after registration, because after registration, the Ministry has a way to control the products anyway and they already do this control on the products in the market in a random basis .

**IP is of the utmost importance to the clients of any contract research organization. How does ERA Pharma guarantee the security of its client's information?**

Before starting ERA Pharma, I managed the R&D departments of different local and international companies, so I understand this issue well. It is hard to keep information secure when there are so many employees. We have security agreements with all of them, but this does not always guarantee information is protected. The solution we found to this issue is to divide the projects among different departments and people so no one has access to all information. We also give code names to products and companies; no one knows exactly who they are working with or on what they are working. We also have security programs in our computers that prevent anyone from printing, sending or changing paperwork.

**What is the most persuasive argument for outsourcing R&D to ERA Pharma?**

Outsourcing R&D is a new idea in Turkey. We have two types of companies, mid- size and larger companies. The mid-size companies must outsource their R & D because they have no internal means to complete this task. The bigger companies that have their own means to complete R&D usually start working with us in parts. They bring us one formulation, or another part of a project, that they could not solve, and after being impressed by our work, they want to continue the relationship. For example, we have solved a problem in two weeks that the company could not figure out over the course of months. This adds a lot of value because of the quicker results and money saved.

**Have you seen new incentives manifest from the Turkish government to better support R&D?**

R&D incentives are very good in Turkey. This, though, has evolved. Until recently one had to have at least 50 employees to qualify for the incentives offered by the government. This has since been dropped to 30 employees. The government has shown it cares for the industry.

**How successful has the Turkish pharmaceutical industry been in establishing a unique range of products for the global market through the emphasis the government has placed on promoting R&D?**

Turkey has a successful branded generic industry which can compete with the world according to its technology, but unfortunately Turkey has not been very successful in commercializing its R&D efforts. As an industry, R&D is still limited to the development of generics because we are financially constrained. We are too late to specialize in some areas, like biotechnology. We advocated for developing API systems in Turkey, because it is essential. Without it, an industry will be dependent on other countries forever. There is no governmental protection and support to the API producers.

**Do you have a final message for our readers?**

We, as a country, have the technological power to compete in the global market. We want to expand both the quality and technology of products produced in Turkey. We can help companies for this to improve their brands. •

# Mevlüt Yıldırım & Onursal Sāglam

MY: General Manager
OS: Deputy General Manager
**NOVAGENIX BIO ANALYTICAL R&D CENTER**

**This year marks Novagenix's 15th year of history. Could you provide us with an overview of what led to the development of the company, as well as how tNovagenix has evolved since its establishment?**

OS: Novagenix was founded in 1999 as a joint-venture between the Turkish Pharmacists Association, the Technology Development Foundation of Turkey, the all Pharmacists Manufacturing Insurance Distribution and Cooperative Union, Bio Inova Life Sciences International and the Pharmacy Device Corporation. Today, the Turkish Pharmacists Association is the sole owner of Novagenix. The scope Novagenix, today as it was then, includes the provision of bioavailability and bioequivalence studies as well as the execution of clinical trials required to obtain pharmacological data to ensure the compliance of these studies with both national and international standards, such as ICH-E6. Our services are provided in accordance with international quality standards, including Good Clinical Practice standards, Good Laboratory Practice standards, and ISO 9000. Our services are also audited by the Ministry of Health on an annual basis.

MY: From the initial focus of our operations in 1999, we have since expanded to focus on the provision of turnkey contract research services. We are a full-service contract research organization that provides research services in the fields of pharmaceuticals, biotechnology and medical devices. Today, in these fields we have completed over 400 bioavailability and bioequivalence studies through over 150 validated analytical methods. We offer the widest selection of analytical services within the Turkish market. This is what we have developed through our 15 years of history. Our facilities today include over 40 staff that operate through our state-of-the-art research complex in Ankara.

**Specifically, what services does Novagenix offer today?**

OS: Novagenix's service line today includes the completion of pharmacokinetic studies, bioequivalence studies, relative/absolute bioavailability studies, multiple dose studies, and clinical design as well as the auditing and oversight of clinical studies. We also have developed a competency in formulation development and CTD-format drug dossier preparation.

**As the Turkish pharmaceutical industry has focused more heavily on the development of value-added pharmaceuticals, products such as biosimilars or super-generics, how has the importance of Novagenix's work as a contract research organization (CRO) changed?**

MY: Novagenix has seen its importance grow as a result of the Turkish pharmaceutical industry's increased focus on areas that require a higher level of research and development. Many manufacturers are now working with multiple molecules: this is an area that has, historically, been outside of the focus of their research activities and one that necessitates a more complex approach to research and development. Novagenix has expertise in this area and can assist them in this process.

**Novagenix is located in Ankara: center of several of Turkey's best universities and, of course, the country's capital. What advantages does Novagenix**

**exact from its location in Anakara, which stands in contrast to that of many other businesses?**

MY: The location of Novagenix in Ankara is strategic for several reasons. First, Ankara is positioned in the center of Anatolia, placing us equidistant from the operations of many of our clients. Second, as many of our client's already send blood samples to Ankara for testing by the Ministry, our position here allows for us to more easily interact with our clients during the testing process. Though we do have an office Istanbul, it is not necessary for us to be located there.

**In what way has Novagenix leveraged new technology for the development of a competitive advantage within the market?**

OS: Novagenix has developed a special department for data management and biostatistics. When data is collected in analyzing a client's sample, the information gathered through our instruments is automatically transferred to a server from where it can be accessed by our clients. This allows for our work to be monitored remotely from anywhere with secure connections. To a similar end, we have also developed a competency in remote instrumentation, which allows for laboratory tests to be controlled on a client's sample without a physical presence within the laboratory.

**Which service areas will drive Novagenix's growth in the future?**

MY: Novagenix has seen growing interest in our services related to formulation development and CTD dossier preparation. Though historically this has been a smaller division of Novagenix, in 2013 we handled 29 projects within this field. Already, in the first quarter of 2014, we have had 11 more projects. We have also seen stronger interest in the services we provide as a CRO. While in 2012 we handled 32 contract-research projects, in 2014 this number grew to 44 projects. In the first quarter of 2014 alone, we have handled 19 projects in this field. Clinical trial reporting also shown strong growth. In 2014 we have already tripled the number of projects that we have had in this field, from three in 2013 to 11 in the first quarter of this year.

Aside from growth within these areas, Novagenix has a larger vision that it would like to realize. We would like to see growth within our division dedicated to bioavailability and bioequivalence studies. We would like to conduct 100 studies within this field per year and, through this, 9000 injections per month. Novagenix would also like to expand on one area that we feel to be one of our core competencies: the breadth of analytical methods that we offer. It is in this way that Novagenix plans to continue to lead within its field. •

# Dr. Serhan Şimşek

General Manager
**CT PHARMA**

**Could you provide a brief introduction to CT Pharma?**

I formed CT Pharma in 2012 and opened the laboratory in 2013. At Frankfurt CPhI, I entered into an exclusivity agreement with Ideal Cures India, and we are now representing them in Turkey and Egypt, with our laboratory's support for technical needs. CT Pharma has developed from consulting to research, through to selling excipients, and is working for almost all Turkish pharmaceutical companies. Looking forward, we will be developing our own products for areas that do not clash with our customers, such as Parkinson's disease.

**The domestic market is becoming constricted with strong interest from multi-nationals, forcing the evaluation of new markets. What external markets hold the most potential?**

US and Turkish markets are similar; in these markets, multi-nationals are stronger than generic companies. Europe and Brazil have potential. For developing countries, generic companies are always stronger than MNCs due to the governments' reimbursement policies. Generic companies present new market opportunities for the marketing and selling of technical dossiers for the registration departments; CT Pharma will be entering this market. CT Pharma is looking to partner and market its dossiers in Israel.

**Turkish pharmaceutical manufacturers acknowledge they can no longer just produce generic products, and R&D is receiving increasing attention. How successful do you think they will be in carving out a stake in the global pharmaceutical industry?**

Currently, it is difficult to envisage Turkey being a world-wide player in the pharmaceutical market. Turkish manufacturers should focus on new technologies including biotechnology, blood products, derivatives; there is too much emphasis on generic products. If the Turkish pharmaceutical industry does not invest in new technologies, it will continue to fall behind in global pharmaceutical standings. The volume of pharmaceutical generic products in Turkey is increasing. The market is so aggressive that prices are having to be reduced to stay competitive and margins are being eroded.

**Looking at what CT Pharma has accomplished, what do you think is critical in establishing a culture of innovation within an organization?**

Personnel in an organization are the root of innovation or research culture, permeating from their education and industry experience. Academies can help to support the pharmaceutical industry's research. •

# Kemal Yildiz

General Manager
**BERKO PHARMACEUTICALS**

**Berko Pharmaceuticals celebrates 30 years of history this year. Could you provide us with an overview of the company's development?**

In 1973, our founder, Mr. Berat Beran, began what would later become Berko Pharmaceuticals. A pharmacist by training, Beran, upon leaving school, set up a laboratory. In 1984, seeing greater opportunity in production, Beran formally established Berko Pharmaceuticals as a manufacturing business.

Today, following 30 years of operations, Berko Pharmaceuticals is proud to be one of Turkey's few diversified pharmaceutical production companies. Not only do we manufacture generics; we also have our own brand of pharmaceutical products. We have more than 20 patented products within our portfolio. Within this, we focus heavily on combination products. Aside from these two business lines, we are also a contract manufacturer for many of the world's largest pharmaceutical companies such as Sanofi. At present we are among the five largest local companies operating within the industry.

**Could you provide us with an overview of Berko Pharmaceutical's production facilities?**

Berko Pharmaceutical operates two production sites. We are currently developing our third; we will open it next year. Our current production capacity cannot match demand for our products. Our current production capacity totals 30 million units per annum. With the addition of our new facility, we will produce 100 million units per annum. This facility is an investment of €60 million. We are confident that it will prove invaluable in extending our business lines.

**Many producers are now investing more heavily into research and development. What structural changes to the industry have underscored this transformation?**

The Turkish market, at least historically, has focused heavily on the production of generic pharmaceuticals. This is, in part, attributable, to the reimbursement scheme that the Turkish government has put in place. Under the current system, the government covers over 80% of total medical expenses. In minimizing the impact of medical expenses on the public budget, the government has made it difficult for pharmaceutical manufacturers to produce anything but generics.

As an aggregate, the profitability of the pharmaceutical industry in Turkey has fallen. This is, again, attributable to the downward pressure that the government has put on drug prices as part of its efforts to minimize the impact of medical costs on the public budget. The mechanism that the government has employed in attempting to do so has been the convertibility of the euro to the lira. Turkey employs a medical reimbursement system wherein the price at which a pharmaceutical manufacturer can sell their product to the government is linked to the cost of production of that product in other European countries. The cost of manufacturing in these countries, denominated in euro, is converted into the price that a Turkish pharmaceutical can receive, denominated in the lira. The problem associated with this has come about as the Turkish government has fixed the exchange rate used in converting the euro to lira. The euro at present is worth approximately three liras. Instead, the government approximates this value to 1.95 lira to the euro. This is a very large discount indeed. An unintended consequence of this policy: many pharmaceutical manufacturers, including Berko Pharmaceuticals, have moved to develop products that are not subject to the Turkish government's price referencing system. This, equally, has influenced Turkish pharmaceutical manufacturers to strengthen their research and development departments.

**Some have argued that the areas in which the Turkish pharmaceutical manufacturing can specialize are limited. Has Berko Pharmaceuticals found this to be true?**

Unfortunately, the Turkish pharmaceutical industry lacks the financial strength, technical expertise, and time required to enter into the development of new molecules. This cannot be the focus of our research and development efforts as a country. Instead, the industry must focus on new applications of existing products. Berko Pharmaceuticals has structured its research and development strategy on this philosophy. We are committed to the development of combination products wherein we take a product, enrich it with the elements of another product and thereby restructure it, then release it as a new product.

**The Turkish pharmaceutical industry has seen many major acquisitions in the past decade. What has attracted many of these multinationals to the market?**

Turkey offers an attractive market to many large, international pharmaceutical manufacturers because of the structure of the Turkish government's reimbursement system. As the Turkish Government is the industry's largest buyer of pharmaceutical products, there is little risk associated with selling in the country. These companies, though, mistakenly believe that the focus of their operations in Turkey should be on the development, production and sale of generics. The profitability of generics in Turkey is in decline. The future of the industry is found in niche products. Unless MNCs can develop these products, they will struggle locally. •

# Levent Canyurt

General Manager
**BIEM PHARMACEUTICALS**

**In establishing Biem Pharmaceuticals 25 years ago, in 1990, what was your vision and mission?**

In the beginning, Biem Pharmaceuticals focused heavily on the distribution of the products of multinational companies. We worked extensively with Bayer in particular, however, following their acquisition by Talecris, this changed. After this buy-out, we had problems with the supply of the products and our agreement was terminated mutually. Biem Pharmaceuticals thus decided to enter into manufacturing, focusing on hemato-oncology As we work at that area more than 25 years. We are producer, but more than this, we are an explorer. The company focuses on niche products in oncology: special cases and orphan drugs. We strive to provide the first and only cure for several illnesses. Through this philosophy, we seek to operate on a global level.

**What led Biem Ilac to decide to go from a distributor to a manufacturer of products?**

The company made this decision because SGK (Social Security Institution) was having difficulties due to high reimbursement prices and Biem Pharmaceuticals aimed to makethese products available for more people during those times. Also, Turkey, like most other countries supports local manufacturing to decrease the cost of drugs. Local manufacturing is supported by the government. It also grants a company full control of its products. If one is just a distributor, one faces limited export potential. Now, though, we can be present in many markets with low prices and high quality because drugs are not luxury, they are urgent for peoples live and with this vision we started producing our own products

**What is the R&D strategy in place at Biem Pharmaceuticals?**

The company does not have its own facilities, so we have two options: one, we outsource these R&D services to one of our partners, ERA Pharma Solutions; or we use another partner facility, which is located in Latvia. The other option is technology transfer to Turkey through contract organizations. For the latter, we currently work in conjunction with a Korean company. Turkey has much to benefit from strengthening ties with this region but mainly, we focus on producing generic products by R&D activities which able us to reduce prices of original products but not compromise from quality.

**Is it in the firm's vision to start its own manufacturing facilities, rather than outsourcing it?**

Right now, R&D is a long-term event and we have started manufacturing 3 years ago. We do not have enough products to run a facility for 12 months; it is more appropriate for us to outsource this work. For the company, the main issue is a lack of contract manufacturers for oncology in Turkey. The small number of oncology plants that do exist in Turkey may not want to do contact manufacturing at all; they do not want to create products for their competitors. The main issue is producing the company's oncology products without its own facility. Today we manufacture our products through one contract manufacturer in Turkey, and another in Latvia. •

# Ersin M. Erfa & Dr. Alper Mengi

E.E.: General Manager
A.M.: M.D, Vice General Manager
**CENTURION PHARMA**

**This year, Centurion was established over 65 years ago. Could you provide us with an overview of the company's development?**

Ersin M. Erfa (E.E.): Centurion began operations under a different name and different business model. Centurion's operations, at least initially, were focused on warehousing. In 1984 we changed our corporate strategy; we decided to import vaccines and plasma products into Turkey. Today we manufacture and sell products in over 25 countries. Our involvement in the distribution of products is supplemented by our R&D activities, which centers on the production of generics for hospital injectables: a first of its kind for Turkey.

Initially we chose to produce through contract manufacturing, though recently we decided to establish our own manufacturing plant. Estimated to cost €20 million, these facilities will be fully operational in 2018. Now, through our activities in the global arena, we are able to justify such an investment.

**On which geographic markets is Centurion focused?**

E.E.: Turkey stands as our main market, but within the next 10 years we would like to have 80% of our sales generated through foreign market activity. We have designed our product portfolio with this in mind. Since making this decision, our sales volume has experienced double-digit growth.

The geographic distribution of our clients follows geographical and socio-cultural proximity. We have customers in the Middle East, the Balkans, North Africa, and the CIS. We are also trying to enter India and South East Asia, which has been a challenging task.

**Market access has proven a difficult barrier for the Turkish pharmaceutical manufacturer to surmount. How have these barriers affected Centurion?**

E.E.: Barriers prohibit Centurion from accessing the European market, yet difficulties in market access are not limited to this region. We also have faced barriers in entering into Saudi Arabia, United Arab Emirates and Ukraine. Our involvement with niche products, however, has meant that it is easier for Centurion to overcome these obstacles.

Dr. Alper Mengi (A.M.): We have a huge advantage when compared to other countries like India, China, Brazil and Argentina. Our products are much more in line with European regulations. Aside from this, Turkish pharmaceutical manufacturers are quality-oriented. This sets us apart from our competitors. We do face stiff competition from Indian companies, but our clients can perceive the difference between our products and those of Indian manufacturers and therefore perceive greater value in what we have to offer as a Turkish pharmaceutical manufacturer.

**Can you tell us about your R&D strategy?**

E.E: Since we began our R&D activities in 2010, our revenue has grown substantially. Within the next five years, our R&D activities will focus on the development of new molecules in conjunction with foreign partners. When we first began our R&D activities, we were mainly targeting the Turkish market. We have since learned the importance of understanding the needs of the global market in developing an innovative, exportable product portfolio.

**Turkey's system of manufacture price-referencing has limited the profitability of many manufacturers. What has it meant for Centurion?**

E.E: Turkey's system of price referencing is one of the biggest obstacles that

Turkish companies face in developing innovative product lines: especially if one considers developing new molecules and biosimilar products. We invested significantly in these areas. Some of our projects failed due to the price-referencing system.

A.M.: There is a logic in the system, but certain adjustments must be made. The ratio used in converting the euro to the lira must be altered. Aside from this though, the price-referencing system has spurred Turkish pharmaceutical manufacturers to become more globally competitive. There is greater interest in R&D-intensive niche products and Turkish pharmaceutical manufacturers are now more interested in entering foreign markets.

**What is the place of the national industry in this context?**

E.E.: The place of the Turkish manufacturer in the domestic pharmaceutical industry is shrinking. Their profitability is in decline. Small- to mid-sized companies will not survive in the long-term. These companies have now reached a juncture: they must grow and transform themselves into global companies, or they will be swallowed. Those that do survive will be in a very good position. It is a decisive moment for Turkish pharmaceuticals industry.

**If we were to meet again in five years, where would Centurion be?**

E.E: Five years from now Centurion hopes to be involved in several new areas. Our export markets will be a much larger contributor to our business. We aim to grow 150% through these investments in injectables, biosimilars and orphan drugs over the five year period. Much of this growth will come from export markets.

A.M.: In the next five years we will become a key player in the industry: not just in Turkey, but also within near markets such as the Balkans. •

### Fields of Treatment

Since 1949, Centurion Pharma cooperates with key organizations worldwide to treat rare diseases in Turkey. The company provides treatments for diverse fields, such as:

- Hereditary Angiodema
- Clotting Factor Deficiencies
- Human Immunoglobulin Deficiencies
- Influenza
- Rabies
- Hemorrhages resulting from Warfarin Use
- Albumin Deficiencies
- Hepatitis B
- Tetanus

# The Role of the University in the Turkish Pharmaceuticals Industry

Prof. Dr. Erem Bilensoy co-written with Prof. Dr. Atilla Hıncal
EB: Hacettepe University Faculty of Pharmacy Department of Pharmaceutical Technology 06100 Ankara Turkey
AH: IDE Pharmaceutical Registration Biopharmaceutics Consultancy 06100 Ankara, Turkey

## University-Industry Cooperation

Scientific cooperation between academia and industry in Turkey started in the mid-1980s through the advent of governmental funding for university projects. In the last ten years, funding for these projects has peaked with the creation of a funding mechanism by TÜBİTAK, the research arm of the Turkish government, through which the organization has incentivized the establishment of research partnerships within the country's Technology Development Zones (TDZs).

In the last decade, several legislative regulations have been established and applied by the state to facilitate bilateral agreements between universities and pharmaceutical companies for R&D in Turkey. These bilateral agreements can be made on both an institutional and or individual level, wherein the agreement pertains to research on one particular project.

These institutional agreements typically involve R&D studies on analysis, production formulation, method development for dissolution, or cell culture studies for generic product formulations. However, due to confidentiality agreements, generally this form of bilateral agreement between universities and companies remains inactive and a company's relationship with a university through this structure is limited to the organization of scientific meetings and the discussion of specific issues that are of interest to a pharmaceutical company.

Comparatively, the use of the latter structure, individualized agreements, is common. In part attributable to decreased concerns over confidentiality owing to the structure of these agreements, this structure has led several academics within Hacattepe University, Gazi University, Ankara University, Istanbul University, and Bilkent University to develop consultancy services. Monitored by the Turkish Government's Technology Transfer Office which acts as the point of interface between academicians and private companies, this structure has allowed for university professors to keep their full-time professor status while simultaneously pursuing work in the field R&D, something which would otherwise be legally prohibited.

## Public Support and Promotion of University-Industry R&D Collaboration

In order to create critical mass for advanced R&D in terms of facilities and researchers, Turkey has invested in the financial support of R&D projects, new facilities and even research-based ideas proposed by students, post-doctoral researchers, academics, SMEs and large pharmaceutical companies through TÜBİTAK, which acts as the major stakeholder in support and promotion of R&D in Turkey. Currently, TÜBİTAK has issued 18 different calls for project support, for which it will contribute from 60% to 100% of total project expenses. Though this support, several generic Turkish companies have benefited to develop and launch their new products, which include bioequivalent formulations, orphan drugs and advanced technology products. As a consequence of government policies, TÜBİTAK has also accepted the field of biotechnology as a priority area.

## University Technocities/Technoparks

First established by the Turkish Parliament in 2001, and then subsequently updated in 2011, universities within Turkey have been encouraged to establish Technological Development Zones (TDZs) for the purpose of incubating new companies formed either by academics or through partnership with academics. These campuses today offer several benefits, the most attractive of which have been tax exemptions which strongly contributed to the development of several private sector ventures through these structures. Initially framed around a certain period of time during which the partnership will take place, these partnerships have also proven to be helpful in integrating academia within industry, as through these structure professors can pursue commercially focused research and development with the private sector without sacrificing their full-time professor status. They have also proven successful in their ability to cultivate long-term ventures: many of these partnerships have graduated from TDZs and now contribute to Turkish industry.

TDZ have been embraced by the state. The government has worked to improve support to these zones and through it hasten the development of projects within these regions. In Ankara alone, five different TDZs are now in place. The challenge that remains for the government is found in more closely tying work within these zones to the pharmaceutical industry. Engineering, metallurgy, and computer software have historically been the focus of ventures within Turkey's TDZs.

## General Overview on the Industrial Perspective on Pharmaceutical R&D Collaborations

In view of the current status of pharmaceutical R&D in Turkey and the role of universities in this field, it should be kept in mind that effective university-industry collaboration is still very new in Turkey. Extant collaboration has focused on the transfer of knowledge and expertise through consultancy services rather than concrete partnerships within TDZs. The main reason for this could be attributed to the fact that academicians do not perceive themselves as sufficiently ready for such a cooperation due to lack of experience. Nevertheless it should be noted that significant advancement has been achieved in the establishment of this university-industry collaboration in the last 20 to 25 years.

Industrial R&D investment to universities have not yet come to life as most companies are actively building their own R&D facilities with government support and public incentive programs. It is of major importance to form an environment able to support collaboration between Turkish universities and pharmaceutical companies. This would allow for these partnerships to reach the critical mass required to promote innovation and advanced technologies in Turkey for better and safer medicines for the people of Turkey as well as the end user of our pharmaceutical products in regions such as US, European, Balkan, MENA and Asian regions. To facilitate this, in addition to working to creating this environment for the next generation of researchers, the current structure of partnerships must be reconceived. Creative and scientific project directors are required to realize these university-industry joint projects through support from different sources. •

Image: Hacettepe. Erem Bilensoy is Vice Dean of Faculty of Pharmacy and Professor of Pharmaceutical Technology in Ankara's renowned Hacettepe University.

# Burak Erman

Professor Department of Chemical and Biological Engineering
**COLLEGE OF ENGINEERING, DEPARTMENT OF CHEMICAL AND BIOLOGICAL ENGINEERING, KOÇ UNIVERSITY**

**Professor Erman, you are known for your work in the field of molecule development, an area of research that remains nascent in Turkey. Could you tell us about your work within this field?**

Last year, through a consortium of six universities led by Koç University, I received a grant from Istanbul Development Agency: a government agency that seeks to bolster collaboration between the private and public sectors for the purpose of regional development. The grant had two aims: first, to strengthen ties between Turkish drug companies and Turkish universities, and second, to generate original molecules.

The grant was for one year. During this year we networked extensively with the Turkish Pharmaceutical Manufacturers Industry (IEIS) and the Association of Research Based Pharmaceutical Companies (AIFD). Within our research, we focused on the development of original molecules related to treating inflammation and cancer. Through our work, we developed several lead molecules for inflammation which are now at animal testing stage. This is the first time molecules have been made in Turkey.

**In networking with the private sector, who did you sense was more eager to pursue research partnerships: the domestic pharmaceutical manufacturer or the multinational?**

There are several Turkish companies who are interested in these types of collaborations. This, however, is an exception and not the rule. Now, as a result of Turkey's drug pricing system, even the industry's largest players are in survival mode. They need to maintain their profitability. It is for this reason that those that have approached us to conduct collaborative research have been largely foreign. Sanofi and AstraZeneca are two companies interested in collaboration with us. The latter is very eager to bring research to Turkey. Many European countries want to bring research to China and India, but there are disadvantages, like security and the time difference. Turkey is a more strategic choice for these reasons.

**Historically, what do you think have been the barriers that have prohibited the industry from pursuing research and development focused on molecule generation?**

A lack of qualified people to conduct research has prohibited the industry from focusing more on molecule generation, as has the hesitance of companies to challenge what has been their usual business model. During profitable years, Turkish pharmaceutical manufacturers were earning so much money from selling generics that they did not spend time on research. There was also no venture capital to support independent research.

Beyond anything else, though, the major obstacle to the development of a more research-focused industry has been time. Real drug research – from beginning to end – takes ten years. For these years, it is not easy to find a company in Turkey that will have a continuous interest. Research was deemed unnecessary and too risky: only one out of one hundred would succeed.

**Do these conditions exist now?**

Venture capital is starting to accumulate. As to talent: In academia, we have all been spectators and not players. By this I mean, we read, learn and watch, but do not act. We need players. There are, of course, exceptions. This mentality has just recently started to change.

**Focusing on the legal structure, do you think Turkey's IP protection system is sufficient to cultivate an R&D sector?**

Koc University, one of Turkey's leading private universities, this year has announced the development of what will be one of the largest investments made by academia into research through the development of its new R&D facility.

The private sector might state that this is an issue, but I disagree. Personally, I have several patents; it does not require an extreme amount of effort. I have given several talks to research boards of companies on this subject. Continually they argue that lack of IP protection is a great hindrance. I think it is lack of knowledgeable people who can generate excitement. The university and company relationship is all based on packaging: not on original research. There is a relationship in clinical studies, mostly funded by foreign companies. There are bypasses in Turkey, so companies will find a medical doctor and bring him into the clinical study, but it is not an original study; it is at the behest of a foreign business. Turkey has 1510 clinical trials at present: none are original.

The problem with R&D in Turkey is atmospheric. We now have ten lead moleculesthat can inhibit pathways to inflammation. We can develop it to a certain point with our means, but once we complete animal trials, we need to turn it over to a company. If the right climate existed, we could continue with this on our own.

**What does the development of this "right climate" depend on?**

To rectify this dynamic, the industry requires greater support from the government. Only ten years ago, Ireland, South Korea and Singapore embarked on the development of pharma industries. The governments gave great support to pharma companies, which attracted the attention of Western companies, and a lot of money was poured into projects. These companies are now leading the world in production, especially in South Korea. This began with tax incentives.

**Five years from now, will we see an industry more focused on research and development?**

Last year, I became aware of the market's hunger for research. There are opportunities and people are seeing them. The best starting point for the industry is drug repositioning, testing all known drugs on diseases for which they were not made. Within the next year, there will be a strong desire to go on this path. This is important because NIH decided to put all its efforts of drug design into drug repositioning. The drug industry cannot come up with original molecules. Thousands of molecules are tested, but for example, only five or six new molecules entered the market last year. If you focus on already used drugs, which have passed the FDA, then all you need is a new patent. For original drugs, there is excitement. There are several people who work in the same areas and want to develop original drugs, but the system has not caught up yet. I am sure there will be strong collaboration between companies and universities, and a strong climate that will attract young people. For capital, it is easy to attract it for medical devices, because there is less of a risk. For drug design, it is harder. The next five years will be a test.•

# PHARMACEUTICAL PATENTS IN TURKEY:
## The State of Turkish Patent Protection and Challenges Remaining to the Implementation of an Effective Legal Framework for Patent Protection in Turkey

by Cahit Suluk

### I. The Process of Incorporating Drugs under Patents

A regulatory system governing patent protection in Turkey was first adopted during the Ottoman period under the "Patent Law of 1879," which was the sixth patent law system to be established in the world. Inspired by the French "Patent Law of 1844," the law excluded pharmaceutical products from patent protection under article three. This system was abolished in 1995.

Important reforms in Turkey have almost always been introduced as a result of external influences. This tradition has also been followed with respect to intellectual property in general; however, for pharmaceutical patents this has been especially true. Patent protection for pharmaceuticals under Turkish law first took effect after Turkey became a member of TRIPS and following the signing of a customs union with the EU, on January 1st of 1999. As a developing country, Turkey was granted a transition period under TRIPS: until January 1st, 2000, ensure that its manufacturing practices were up to date and until January 1st of 2005 in order to ensure that its compliance were TRIPS-compliant. Legal protection for pharmaceutical patents has extended from the TRIPS system.

### II. The Bolar Provision

Under Turkish law, the Bolar exemption has been applied broadly. Accordingly, the "activities for trial purposes involving an invented drug, including registration of the drug as well as tests and trials required for registration," are exempted from patent protection (Decree-Law on Patents, Art. 75/f).

As per the Bolar exemption, a generic firm is allowed to conduct a bioequivalence study and to apply for drug registration before the expiration of the patent term, so that a generic drug can be introduced to the market the day immediately following the expiration of a patent term. If the generic firm is unable to conduct the bioequivalence study and to apply for the registration of the drug during the term of patent protection, the patent term of 20 years will extended.

Neither the drug registration authority in Turkey, nor the Turkish judiciary, accepts the making of an abridged drug application, or even granting drug registration for a generic drug as a patent infringement. However, because sales permission for a generic drug granted by the registration authority automatically reduces the price of the original drug by 40%, this is accepted as a patent infringement.

### III. Pipeline Protection

When drafting TRIPS, it was proposed that drugs protected by patents in countries recognizing pharmaceutical patents also be taken under patent protection in those countries, such as Turkey, which have subsequently recognized pharmaceutical patents. In this way it was intended that inventions which are not new but which have been patented in other countries also be registered in countries subsequently recognizing pharmaceutical patents. Turkey has not accepted this means of protection, referred to in the literature as pipeline protection, on the grounds that it is under no obligation to do so; neither under the terms of any international treaty nor under the terms of its relations with the EU.

### IV. Supplementary Protection Certificate

An average of 8 to 12 years passes from the date of application for pharmaceutical patent until the introduction of the drug onto the market. For this reason, a patent protection of 20 years can be used for only 10 to 12 years. In order to prevent this loss of time, which is called the "bitten term", some developed countries have adopted a supplementary protection certificate particular to drugs. The EU has mandated that Turkey introduce regulations concerning this supplementary protection, however Turkey has rejected this demand on the grounds that it has undertaken no commitment in this regard either under TRIPS, or Decision No. 1/95 of the Association Council. The supplementary protection certificate is not currently on the agenda in Turkey.

### V. Data Exclusivity

Another intellectual property protection measure specific to drugs is data exclusivity. The discussions over Article 39/3 of TRIPS aside, the duration of data exclusivity protection was 6 years in the EU at the time when Decision No. 1/97 of the Association Council was adopted. For this reason, Turkey has accepted a data exclusivity period of six years. However, the EU subsequently extended this period to 8+2+1 years. The EU has mandated that Turkey adopt this regulation, however Turkey has refused to do so on the grounds that it is under no obligation in this regard under Decision No. 1/97 of the Association Council. Turkey has declared that it will fulfill this requirement only after attaining full membership of the EU.

The practice of data exclusivity under the Regulation on the Registration of Medicinal Products for Human Use 2005, which is still in effect, is as follows in summary:
Before 1.1.2005 - If the original firm within the EU-Turkey customs union registers a drug after 1 January 2001 but does not make any application for generic in Turkey until January 1st, 2005, such a drug is granted data exclusivity for six years (but being limited to the term of the patent) from the date of first registration of the drug within the customs union.
After 1.1.2005 - If original drugs are registered for the first time within the customs union after January 1st, 2005, such products are granted data exclusivity for a period of six years (but being limited to the term of the patent) from the date of first registration within the customs union.
As per the practice in Turkey, data exclusivity does not preclude the generic firm from making an abridged application for registration and carrying out the registration formalities. However, once the drug registration certificate has been obtained, right arising from data exclusivity may be claimed.

**VI. Patent Law?**

Apart from the patent law of 1879 passed during the Ottoman era, there has been no patent law enacted by the parliament of Turkey. Decree-Law No. 551 is not a law, but a disposition of the government. The basic reason for this is pharmaceutical patents. The reason why Turkey refrained from becoming a party to the European Patent Convention (EPC) for a prolonged time, although it was one of the founders of the International Patents Institute, is that the government wished to exclude pharmaceuticals from patent protection. As a result of the inclusion of pharmaceuticals under patents since January 1st, 1999, after the establishment of the customs union with the EU in 1995, no excuse remained for Turkey to not accept the EPC. Thus, Turkey has been party to this convention since the 1st of November, 2000. During the discussions concerning TRIPS, which lasted nine years, the only issue brought forward by Turkey was pharmaceutical patents.
A draft law consisting of approximately 100 articles proposing amendments to the legislation on industrial property rights, including Decree-Law No. 551 on patents, has recently been submitted to the general assembly of the parliament. In the discussions over the draft, which bears the marks of an ad hoc, patchwork affair, the issue under discussion was, once again, predominantly pharmaceutical patents. In sum, there is, as yet, no patent law in sight on the horizon. •

*Adv. Dr. Cahit Suluk has been active an attorney at law at Istanbul Bar since 2001. He conducted research on his habilitation thesis "Pharmaceutical Patent Infringement" at Max Planck Institute in Munich. He is not only a distinguished and reputable IP litigator and strategist but also a highly-respected academician and lecturer. He has devoted a considerable amount of his time on IP related academic research studies and publications that are followed by a large audience, which includes judges, lawyers and academicians who are interested in IP matters. He contributes to drafting of IP laws in Turkey. Dr. Suluk also provides training sessions in related to various aspects of IP to domestic and foreign clients and provides an expert advice on IP and unfair competition cases.*

# Michael Weiss

Partner
**AT KEARNEY**

**AT Kearney has operated in Turkey for over 10 years. Can you tell us about the firm's work with the pharmaceutical industry over this period of time?**

AT Kearney has been here in Turkey on a cooperation basis for some time, and established a presence fully in 2009. In the pharma industry, we work in different parts of the value chain. We help clients with operating topics, advising on business models, pricing, patents and out-phasing.

**Throughout the time that you have been active in Turkey, what structural changes have you seen in the local pharma industry?**

We are in an environment where the Turkish market has been nicely developing over the past years. We have seen a shift toward more local manufacturing. There has also been a shift towards broader portfolios with more attractive margins. The OTC market is an embryonic phase. The question for the future is whether we have reached a level where people are spending significantly on health in the mainstream market.

Turkish players have quickly developed generics, however even established players are finding themselves in a challenging environment today. There is discussion about how to grow the spectrum here to bring in innovation. We are observing entrepreneurship; however we do not have enough platforms for entrepreneurs. It is still difficult to compete and enter foreign markets. We need to focus on innovation and new product launches and marketing. Manufacturers should be teaming up and sharing manufacturing and R&D resources.

**AT Kearney provides consultant services to a wide range of industries. Relatively speaking, what is the importance of your pharmaceutical business today?**

For AT Kearney, pharma is one of the top five industries where we work. This has been our business model from the beginning. We work from platforms and bring people together. We are a seamless organization and move people to where clients need them. We are capable of relatively quick know-how transfer and can provide good accessibility of our people.

We expect the pharma market will plateau. On one side we have international players' products being pushed by holdings, with their patents providing motivation to people to sell. There are also local players who are relying on their entrepreneurship and their scientists to push themselves forward with new molecules. This is not an easy direction.

If you compare overall Turkish foreign outward investment, not just for pharma,it is one of the lowest worldwide. Considering outward investment for both developing markets and mature markets, Turkey has a gap of a factor of 7.5-10.

**What will be the relative importance of pharmaceuticals to AT Kearney's business in Turkey within the coming years?**

Turkey wants to catapult itself to tenth place among global economies and has set high export targets for the pharma industry with the Vision 2023 plan. AT Kearney is happy to continue to support the market. You see a lot of industry players that have moved upwards and are no longer flexible. They need to embrace different business models, ways of governance, organization and supply management. The next chapter for the industry is to become a niche player to fight against international companies. Turkish companies are well-equipped with a talent base, but they need to find a way to better forecast product trends and consider possible market scenarios.

**Market access has been a strategic issue for pharmaceutical manufacturers. What are the key barriers that you would identify to the internationalization of the Turkish pharmaceutical industry?**

We must look at how Turkish manufacturers identify attractive markets, whether it is based on having the right molecules on the shelf, or because it is either a growing marketor a valuable high-priced market. Sometimes we have the tendency to look only at high-growth markets, but these markets also have the tendency to be volatile, have short lifecycles and regulatory challenges. The question is how you want to make a difference; internationalization will happen byteaming up and gaining scale quickly.

**It has been said that it will be the local startups that have emerged in the past five years that will make the greatest headway in R&D in the future. Do you agree with this forecast?**

Turkey has very strong entrepreneurship;however we do not have classic startup platforms here such as private equity or venture capital. The market is not a pure entrepreneur pharma market. We have local pharma players struggling to find the right business model amidst pressure from international players. We do not see enough commitment to innovation. Being a successful generics player means at the end of the day you are a manufacturer, not an R&D player. If you want to be successful, niche players must commit solely to niche products and not do generics at the same time. If we do not see a significant change in innovation for Turkish players, we will not see relevant players emerging in the next five years. •

# Remapping the Empire

## Turkish Pharmaceuticals and Export-Led Growth

Collectively, Turkey's pharmaceutical manufacturing industry has placed greater emphasis on the development of export markets in recent years: a product of both internal market conditions and the efforts of private enterprises to diversify business growth. In approaching these markets, though, Turkey's pharmaceutical manufacturers must craft market-specific strategies that bear regard for their organizational capabilities.

Pharmaceutical exports in 2013 rose on aggregate, following a trend set in previous years. In 2013, pharmaceutical exports reached a historic high, standing at $818 million: a growth of $100 million from the previous year and nearly double the value of pharmaceutical exports but five years before. Within the same period, also owing to a decline in the value of product imports, Turkey saw its export-import ratio rise to 18.2%, a recent high as well. Historically, this ratio had stood at around 10%.

Though for some this process began in the 1990s, greater attention has been placed on export-led growth following declining profitability within the domestic market. The largest gains in pharmaceutical exports began in 2011, the year in which the profitability of the industry became most restricted as a result of heavy price cuts and the depreciation of the lira, which, jointly, significantly discounted the margin of Turkey's pharmaceutical manufacturers.

These initiatives have been backed by an increasingly sympathetic government, which, although at times more problematic than beneficial, has recognized the importance of export market development to the Turkish economy and, accordingly, altered its policy-making strategy. In line with Turkish government's larger goal of increasing Turkish product exports to $500 billion by 2023, the republic's centennial, the Turkish government has worked to better align itself with foreign markets. Though the industry faced a large setback in 2010 when the Turkish government introduced its own set of Good Manufacturing Practices (GMP) – in effect barring all Turkish manufacturers that have not directly received approval from the relevant European country's health official from exporting – the Turkish government has taken a step to remove trade barriers through the Turkish Drug and Medical Device Agency submitting an application for membership to the Pharmaceutical Inspection Co-operation Scheme (PIC/S), as it did in 2013. An unofficial trade agreement between the drug agencies of 35 countries, PIC/S was devised to build networking and establish mutual confidence in the trade of pharmaceutical products between member countries. Turkey's lack of membership to the PIC/s – or lack of membership application, for that matter – had long stood out.

In the place of governmental support, private industry emerged to help facilitate the industry's internationalization. To a similar end as the PIC/S, one industry participant, Ekin Kimya, has partnered with the United States Pharmacopeial Convention, an organization that works closely with the United States Food and Drug Administration in the development of drug standards for US market, to establish a series of annual seminars related on building ties between the industry and foreign government. "These meetings are attended by CEOs, U.S. Food and Drug Administration (FDA) and USP personnel, the Turkish Ministry of Health deputies and academicians, as well as industry representatives. Last year we hosted above 200 attendees for two full days and in this year's meeting, we will concentrate on the recent changes in regulations. These meetings have become a scientific and networking platform of the sector, addressing specific needs of the industry in terms of regulations and trends," explains Murat Çıtıroğlu, business development manager at Ekin Kimya.

Today, Turkey's pharmaceutical manufacturing industry has high ambitions for their foreign market operations. To aid in this process, İEİS, the Pharmaceutical Manufacturers Association of Turkey, has established the Turkish Pharmaceutical Exporters Platform, a 26-member group which aims to increase the international competitiveness of the Turkish pharmaceutical industry. Providing a road map to the industry's growth, Turgut Tokgöz, secretary general of İEİS, comments, "Every major market around the world is potentially important to us. The EU and the US are very large and should never be neglected. Immediate options would be the MENA region, but we are also experiencing an influx in business from sub-Saharan African markets as well. Since we formed this export platform we have been receiving two, three requests a day from African markets interested in representing Turkish goods. Iran and Iraq have shown the largest rates of growth." Through their operations, İEİS targets pharmaceutical exports of $17 billion by 2023.

This confidence is backed by the strategic advantages offered by operating in Turkey. Philipp Haas, chairman and CEO of Deva Holding, which, through the operations of their subsidiary Eastpharma stood as the industry's sixth largest phar-

Image: Drogsan. Various forms are manufactured and packaged in Drogsan's facilities. High-speed production and packaging lines utilised in the related sites are all equipped with the latest technology.

maceutical company in 2013, explains, "Turkey is at a very important geopolitical position, straddling Europe and Asia and sitting at the doorstep of attractive Middle Eastern markets. We have better quality and reliability when compared to most of our Asian competitors, while being closer to Europe and having a better understanding of what the European consumer wants."

This logic has driven inward investment, as observed in the case of Vefa Ilaç. Backed by an Azeri pharmaceutical distributor, Vefa Ilaç began construction of a manufacturing facility dedicated to contract-manufacturing and private label products within Turkey in January 2013. Nine months later, in September of 2013, Vefa Ilaç began production. In commenting on what spurred him to invest in Turkish pharmaceutical manufacturing, Haleddin Guliyev, chairman of Vefa Ilaç, said, "if I was to endeavor such an investment back in Baku, it would be thinking only about Azerbaijan. When you are in Turkey, you are in the middle of the world and I want Vefa to be a global company like the city of Istanbul itself." Through this investment, Vefa Ilaç has established strong export relations with Azerbaijan, Georgia and Iraq, and will soon enter into Saudi Arabia, Yemen, Jordan, Egypt and Afghanistan as well. Symbolic of both the condition of the Turkish market and the strategic advantages the country offers to manufacturers in developing export markets, at least immediately, Vefa Ilaç will focus only on developing an export business.

Owing to the proximity of the region, the nascence of regional pharmaceutical manufacturing and a shared religion – and, as an extension, the concept of "halal" pharmaceuticals – Turkey's pharmaceutical manufacturers have established a strong presence in Middle Eastern and North African markets. Those to target this region have ranged in size from Eczacıbaşı, which has established a manufacturing presence for its nuclear medicine business in Egypt and Libya, and Biofarma, which distributes into Afghanistan, Iraq, and the CIS to mid-range companies such as Centurion and Biem Pharmaceuticals.

Though some might perceive these markets to be low-hanging fruit, winning business in the Middle East has not come without its own set of challenges. Süha Taşpolatoğlu, CEO of Abdi Ibrahim, comments that "indeed, regulations in

some countries like the US and the EU are tougher than the CIS and Middle Eastern countries however the gap is closing swiftly."

Ersin Efra, general manager of Centurion, comments that, "barriers prohibit Centurion from accessing the European market, yet difficulties in market access are not limited to this region. We also have faced barriers in entering into Saudi Arabia, United Arab Emirates and Ukraine."

The most difficult of these barriers to overcome has been the region's registration process. "The Middle East region requires GMP authorization, which takes one year, as well new tests for their warmer climate, making the whole registration process more than three years," explains Ersan Küçük, general manager of Drogsan Pharmaceuticals, a manufacturer that currently exports to Jordan and Saudi Arabia. Upon entry into the Middle East, however, Turkish manufacturers face additional difficulties, found in internal market dynamics. Middle Eastern pharmaceutical markets tend to be both price-sensitive and unpredictable. Compounded with the difficulties found in product registration, this has led many pharmaceutical manufacturers to employ a niche-market strategy when approaching the region, supplying only products which would be first in market. This strategy has been critical to the successes of Biem Pharmaceuticals, which, through a partnership with an American company, acts as a distributor of orphan drugs that have no regional originator, and Centurion in building up a regional presence. Erfa of Centurion continues, "Our involvement with niche products… has meant that it is easier for Centurion to overcome these obstacles."

For those that wish to extend their generics business into other near-markets, in particular those with their own pharmaceutical manufacturing industry, a more difficult, and possibly capital-intensive, strategy has been required. Many regions now require that business construct local manufacturing facilities and heavily encourage the development of local manufacturers within the marketplace.

Though some might attempt to circumnavigate this through local partnerships, this strategy has not proven successful in accessing all near-markets. This has certainly been true for the Kazakh market, which has eluded the grasp of Turkish pharmaceutical manufacturer employing a pure distribution model. To enter into the local market, two of Turkey's most formidable manufacturers, Nobel and Abdi Ibrahim, have established a manufacturing presence within the country. Nobel, which generated $100 million through foreign market sales in 2013, operates within the country through one facility. Abdi Ibrahim, which in 2012 acquired a 60% stake in one of Kazakhstan's largest companies, began construction of the country's first GMP-certified pharmaceutical manufacturing facility in 2013. By the end of 2014, the firm hopes to enter into production.

While near-markets such as those found within the Middle East and the CIS continue to be a focus of many, some have also begun to develop of a presence within what are perhaps the world's most mature, and therefor discerning, pharmaceutical markets: the United States and Europe. Underscoring this decision has been a simple a premise: "If you can sell to America, you can sell anywhere," as Muzaffer Bal, general manager of Ali Raif, a Turkish manufacturer that dates to 1928, explains.

Although the United States healthcare market is not without its own challenges, especially related to product registration, which can entail a costly and time-consuming process, several of Turkey's pharmaceutical manufacturers have chosen to approach this market first, viewing the barriers associated with the US market to be more easily surmountable than those found in emerging markets. Among those to utilize this strategy is Pharmactive, which entered into the pharmaceutical production in 2012 through the development of a $120 million manufacturing campus.

Köksal Ülgen, general manager of Pharmactive explains that, "developing markets often come with a unique set of challenges: countries in regions – North Africa, the CIS, Brazil and Mexico – protect their local pharmaceutical manufacturers. Developed markets, especially the United States, do not have this barrier." As a result, the company will first target entry into the United States, Europe, the Balkans and GCC countries, later entering into the CIS among other markets.

Turkey's pharmaceutical manufacturers now stand at a juncture. Confined for space within the internal markets in which they have built their strongholds, the country's manufacturing base must internationalize if their profitability is to be maintained. The success of these companies in approaching these markets, however, will depend upon the development of market specific strategies which pay regard to the resources that each manufacturer has at their discretion and the requirements of their target market. Though the notion of low hanging fruit is fictitious, Turkey's pharmaceutical manufacturers have developed a strong springboard from which they can launch themselves into new regions. A more supportive government will only facilitate internationalization of the industry. This process has already begun. •

# Besim Şeref

General Manager
**HELBA İLAÇ**

**Helba İlaç was founded in 2007. In establishing the company, what was your vision and mission?**

Helba İlaç was founded with the purpose of becoming a pharmaceutical manufacturer in Turkey and a big market player in the pharma industry. We were also founded with the purpose of manufacturing APIs in Turkey. Our company's mission is to improve medicine production techniques, and to produce and sell medicine.

We currently work in generic medicine in the areas of neurology, cardiology, psychiatry, child neurology, gastroenterology, orthopedics, physiotherapy, otorhinolaryngology, obstetrics and gynecology.

**What background experience led you to enter into the local pharmaceutical manufacturing market with the creation of Helba İlaç?**

I studied law and health, and have training as an MD. I worked for ten years in a university as an assistant professor, teaching medicine. After that, in 2005, I entered into the pharmaceutical market and gained experience in marketing. Two years later, I decided to found Helba İlaç.

**After seven years in the industry, what does the company look like today in terms of your licenses and manufacturing capabilities?**

In 2007, we founded an R&D team for formulation and the preparation of dossiers. For two years, we made formulations and prepared dossiers. After that, we submitted these drugs to the Ministry of Health to receive licenses, which in Turkey is a very difficult process. Helba İlaç received its first license in 2010 and by 2011 we had received licenses for 11 products that we were now manufacturing in Turkey. In 2011 we also started contract manufacturing. In the last quarter of 2011, we started to sell these products in Turkey's market. At this same time, we bought land to construct a factory in Ankara'sBaşkentOrganized Industrial Zone.From 2011 up to today, we have received 25 licenses from the Turkish Ministry of Health. We currently have 40 files in the ministry which we are waiting to be approved. We also export to other countries, such as Georgia, Azerbaijan and Kazakhstan.

**In 2015 when your facility in the AnkaraOrganized Industrial Zone will be active, what will be the capacity of the factory?**

Our final investment in the facility will total $20 million. We will make three lines: liquids, solids and semisolids. Up until now, we have only been carrying out contract manufacturing. Once we start up our factory in 2015, we will begin making our own products.

**At your new facility, you will also have an R&D facility. How will that fit into the larger manufacturing piece of the organization?**

Our R&D work is in formulation. In 2015 we will start to manufacture APIs on a laboratory-scale. We currently have six chemists and four pharmacists on our R&D team. The therapeutic areas where we will focus our efforts will be in three main groups: oncology, cardiology, and gynecology. We will also continue work in antibiotics.

**API manufacturing is very new for the Turkish pharmaceutical industry. By manufacturing APIs, what strategic advantage does this offer to you?**

Helba İlaçis planning to manufacture its own APIs for our own needs for some of the drugs that we are producing. In Turkey, API manufacturing is minimal. Manufacturers in the industry have difficulty securing API supply and we are seeking to avoid this challenge. Through this strategy we plan touse our R&D to decrease our manufacturing costs.

**There has been speculation that we have not seen more API production in Turkey because of a lack of government support. How have you seen the government approach API manufacturing?**

The government does not assist us in the manufacturing of APIs. We are making all of our investments ourselves. The government is decreasing drug prices, which is creating difficulties for the industry; however, we are focused on maintaining our profitability and staying competitive in the market. We can act independently from government support and would only like to see better drug prices.

**What is the relative division for Helba İlaç between sales in the domestic market and in external markets; and how do you imagine that ratio shifting?**

In Turkey, we are waiting to see what the increase in drug prices will be. Because of this pricing issue in the domestic market, we have already sold products to Iraq, Syria and neighboring countries like Greece and Georgia.

**Has market access been difficult in pursuing these external markets?**

Our biggest problem in these markets is FDA and GMP approvals. Helba İlaç's manufacturing facility meets FDA and GMP standards, which will help us significantly in the market. •

# Haleddin Guliyev, Aytekin Pahsa & Denis Tunca

HG: Chairman
AP: General Manager
DT: Export and Import Manager
**VEFA ILAÇ**



**Could you provide us with a brief overview of Vefallaç's operations within the country?**

DT: The capacity of our factory is quite big, especially our soft gel manufacturing facilities. The demand for soft gel products are high; there are only three soft gel machines in the whole of Turkey and some of them are outdated. We have contract manufacturing agreements with big players such as Abdi Ibrahim, Bilim, Ali Raif, Eczacibasi, amongst many others.

AP: Vefa can produce 250 million tablets per year, 250 million units of film coating, 65 million hard capsules, 105 million soft gel capsules. We can say that our capacity utilization for soft gel is around 70%. For the other products it should be 50% per one shift.

DT: We do not have a sales team. Vefa is focused contract manufacturing and private labeling and therefore we do not want to interfere with our costumer's products. Trust is something we value the most. Our focus now is exporting. Azerbaijan and Georgia have been our main markets so far and we just starting exporting to Iraq. Vefa is negotiating with Saudi Arabia, Yemen, Jordan, Egypt and Afghanistan at this moment but we intend to enter Europe and Asia soon as well.

**Do you imagine your entire business being, at least immediately, driven by external markets?**

DT: At this moment 100% of our owned products are exported. Vefa has a medium-range goal to market its own products inside Turkey, but so far we only contract manufacture. There are a couple of ongoing projects for pharmaceuticals for the Turkish market, but these projects will take time to materialize. The mix of quality standards and affordable prices makes us quite attractive to Middle Eastern markets, which in turn can be more lucrative for us.

**Considering the R&D investments Vefa Ilaç has done towards novel drug development systems, could you tell us a bit more about the philosophy underscoring this commitment to innovation?**

DT: Going organic is a trend in the market. All of our food supplements are made out of herbal extracts, vitamins and minerals. We do not use chemicals. It is quite hard to achieve the expected effect and stability when you choose this path and our commitment to this highlights our decision to enhance our R&D efforts.

AP: Last August, the Ministry of Agriculture instituted new rules regarding food supplements. Up to that moment anyone could produce them: it was not a regulated market. From January this year they have started performing quality checks. Due to the fact that we are mainly using herbal extracts this imposes a challenge, which we are trying to overcome by developing new methodologies with our R&D department. We will be one of the first companies using herbal extracts in the whole world to accomplish such a thing and this will separate us from the regular manufacturer.

It is important to mention that the head of our R&D department has more than 40 years of experience. He himself holds more than 10 patents for pharmaceuticals. Today our sales are coming mainly from exports of food supplements and cosmetics, but we will be very soon adding pharmaceuticals to that. We have been in CPhI India and we will be at CPhI Istanbul and Paris. •


EKOL

# Traversing Continents: Supply Chain Dynamics within Turkish Pharmaceutical Manufacturing

"We have seen a change in the mindset of the government. Not only has it set infrastructure targets for 2023, but it has also examined infrastructure needs and planned investments accordingly. We have seen major changes in customs organization, as well as within e-business. Investments in sustainable types of transportation are now being made. We hope that these projects will be developed fast enough so that they are able to have a substantive impact on domestic industry."

- Nil Tunasar, Managing Director, Transorient

Image: Ekol
Ekol's Warehousing (Contract Logistics) Services Unit provides services at 16 locations, with a total indoor space of 400,000 m2. Ekol allocated bonded warehouses at 6 distinct locations and 22,000 m2 of indoor spaces for customs clearance operations.

# Supply Chain Dynamics

## Raw Materials & API Procurement

A strong feature of many global pharmaceutical industries, the production of active pharmaceutical ingredients (APIs) within Turkey remains nascent. This dynamic looks poised to continue through 2014: a reflection on both the comparative advantages that several countries have been able to develop in the production of these products and the limited resources that Turkish pharmaceutical manufacturers have had to draw upon. As a consequence, a strong industry of raw material distribution has grown within Turkey. It will be the activities of these businesses – those focused on raw material distribution – upon which the continued growth of Turkey's pharmaceutical industry will depend.

Both historically and today, API production in Turkey has been limited to all but the industry's largest pharmaceutical manufacturers. Those that have focused on the production of API, did so out of necessity. Bülent Atabay, chairman of Atabay Pharmaceuticals and Fine Chemicals, one Turkey's few producers of APIs for commercial use, reflects that, "we started our chemical plant in 1970 to produce APIs, which at that time were very important. If you did not have access to APIs, you were dependent on other companies to provide them, so it was important for Atabay to be able to control its raw materials." Atabay Pharmaceuticals and Fine Chemicals stands as one of Turkey's largest API manufacturers today.

A similar logic has driven the activities of those businesses that have more recently entered into the production of APIs: a desire to better control the dynamics of their supply chain. Investing on a far smaller scale than those that were able to build up commercial enterprises for API production, recent entrants into API production have done so to vertically integrate. These companies include Deva Holding, which has done so for the production of one of its generic oncological products, and Nobel Pharmaceuticals, which produces APIs both for captive consumption and commercial use.

As a result, these two classes of business have been isolated from what has been one of the Turkish pharmaceutical manufacturer's most troubling problems: delays in production. As Turkey's pharmaceutical manufacturing base has diversified, as have the needs of the country's manufacturers, in turn challenging the industry's raw material suppliers to keep pace with the development of the country's pharmaceutical producers. Equally, as the profitability of Turkey's pharmaceutical manufacturers has become constrained, many of Turkey's pharmaceutical manufacturers have had to renegotiate their API supply contracts. A consequence of both these dynamics, delays in API shipments and, as a result, delays in production, have occurred.

Given the impact that these delays – which, for some, have been rumored to be as long as 14 days – have had on the industry's profitability, the expansion of Turkish pharmaceutical manufactures might seem possible, or even lucrative. However, the production of APIs within Turkey has and will continue to remain small for two reasons.

First, Turkey lacks the requisite environment to allow for the competitive production of API on an industrial level, especially if those that were to manufacture these products are to compete against what have become the world's largest manufacturers of APIs, China and India. China and India have both built strong API producers on the back of the strength of their chemical industries, which lead the world, low utility and wage costs, and well-developed partnerships between their universities and manufacturers. Though several other regions have developed API production – for example, several western European countries have API producers

Image: Ejder. Ejder Kimya adds value to its chemical distribution activities through its in-house formulation laboratory in Istanbul.

– they cannot compete globally on the basis of price.

Second, though these conditions might have once existed within Turkey, today, this is no longer true. A strong sentiment exists within Turkey's pharmaceutical manufacturing industry that the door for API production has now shut: those producers that attempted to enter into this field undermined by a lack of support from the government. "We are too late to specialize in some areas... We advocated for developing API systems in Turkey, because it is essential. Without it, an industry will be dependent on other countries forever," comments Şirin Deha, general manager of Era Pharma, which has pioneered the field of contract research within Turkey and sought to enter into the production of API within her business. "There is no governmental protection and support to these API producers." As a result, considerable power has been vested in those charged with procuring APIs for the country's pharmaceutical manufacturers, the country's distributors.

A consequence of this dependence, growth within raw materials trading has been particularly strong over the course of the past 10 years. Today, several Turkish pharmaceutical distributors have built formidable businesses through their operations within the sector: among them, Ejder Kimya and Ekin Kimya. Founded in 1999, Ejder Kimya has expanded through focusing on the procurement of raw materials for the pharmaceutical industry, as well as for the food supplement and cosmetic industries. Established in 1995, Ekin Kimya today supplies excipients and APIs to Turkey's pharmaceutical industry, in addition to laboratory chemicals.

Through the strength that they have built within their respective business lines, both businesses now seek to expand more directly into raw materials procurement. Within the next five years, Ejder Kimya plans to expand into the manufacturing of intermediates. To a similar end, Ekin Kimya has established several partnerships in India for direct procurement of APIs. An understanding of the importance of their operations to the industry exists amongst these businesses. Murat Çitiroglu, business development manager at Ekin Kimya comments that, "we need to be prepared to deliver a variety of products to our clients so that their products can reach shelves in time. We foresee that APIs are going to play an ever more important role in our portfolio due to the needs of Turkish pharmaceutical manufacturers to better manage their cost structure and diversify their product range. We have to be prepared to accommodate the industry's focus on innovation."

As the production of these products is no longer possible within Turkey, Turkey's raw materials distributors must focus on closely aligning themselves with the industry's needs. This, first and foremost, means guaranteeing a consistent supply of raw materials to the industry. A failure to do so could mean that the industry will enter into distribution directly, or that the industry's current distributors will be pushed out. Much will depend upon future collaboration. •

# Murat Çitiroğlu

Deputy General Manager
Business Development Manager
**EKIN KIMYA**

**Ekin Kimya celebrates 20 years of existence in 2015. Could you tell us about the key milestones the company has touched throughout its history?**

When I was doing my PhD at the University of Strathclyde in Glasgow, I met owner of Lab-Scan,Gerry Kennyfrom Dublin in 1994. He wanted to enter Turkish market andEkinKimyahas become their agent and distributor. The product range of Lab-Scan was short of customers' demands, thereforewe needed to find more suppliers to meet our company's growth targets. By 1995,a globalbrand was added to our portfolio:J.T.Baker at that time was part of Mallinckrodt, which is one of the most well-known Paracetamol producer in the world. Now J.T.Baker brands belong toAvantor Performance Materials. After the J.T.Baker partnership,EkinKimya hasgrown stronger in the pharmaceuticals market. When we look at our partnership timeline, Acros Organics, which belongs to Thermo Fisher Scientific, has also become our business partner by 1999. Coming to 2000s, U.S. Pharmacopeial Convention (USP),Mallinckrodt Pharmaceuticals and BASF have chosen Ekin Kimya as distributor in Turkey.

**Ekin Kimya is also known for reference standards. Could you tell us more about the partnership with the U.S.PharmacopeialConvention (USP) and what this means to EkinKimya?**

We are proud of being recognized by the quality of our services. In Turkey, we have been chosen as the authorized distributor by the USP, an institution that has been setting the regulations, reference standards.The selection process was scientific, long, and detailed.They have also granted us a series of awards, including the 'golden award' and the 'crystal award'. In the last five years we have been organizing 'Scientific Meetings' with USP. These meetings are attended by CEOs, U.S. Food and Drug Administration (FDA) and USP personnel, the Turkish Ministry of Health deputies and academicians, as well as industry representatives. Last year we hosted above 200 attendees for two full days and in this year's meeting, we will concentrate on the recent changes in regulations. These meetings has become a scientific and networking platform of the sector, addressing specific needs of the industry in terms of regulations and trends.

At this moment we are selecting this year's subjects in close contact with USP who has been advising us as usual. We want this meeting to give a 360 degree view of the sector, covering industry, Turkish Ministry of Health, universities, associations, and all relevant stakeholders. Therefore, top executive speakers are expected from Turkish Ministry of Health, academicians, companies and associations such as IEIS (Pharmaceutical Manufacturers Association of Turkey),AIFD (Association of Research-Based Pharmaceutical Companies), and others.

We are now consideringto expandthese Scientific Meetings on a regional base, due to the strategic positioning and relevance of Turkey.

**Are Turkish pharmaceutical manufacturers obliged to follow the European Pharmacopoeia by the Ministry of Health current regulations?**

Turkey is an active member of the EU Customs Union. The Turkish Ministry of Health has instituted that Turkish producers should follow the European Pharmacopoeia (EP). The blue book, the European Pharmacopoeia, is specialized in APIs. The USP book, on the other hand, will give userboth API and the final formulations' monograph.Therefore USP is used in Europe and Turkey besides EP.

**Ekin Kimya is considered to be a major player inTurkish pharmaceutical industry. Could you provide us with an overview of EkinKimya's operations?**

Together with the scientific background of the founders of EkinKimya, well-trained and experienced team, and a very strong financial background, EkinKimya attained a leading position in the market.

EkinKimyahas been strong in four segments: Laboratory Chemicals,Reference Standards &Publications, Functional Excipients and APIs. Last year we have launched our 'Formulation Laboratory' at GEBKIM plant serving pharmaceutical companies as a solution center.

These capabilities together with the understanding of the trends in the pharmaceutical industry we cooperate with the leading global companies to meet the demands of the customers especially in the fields of Drug Delivery Systems, biotechnology, combinational products, high functionality excipients and others.

Ekin Kimya also cooperates with Indian

companies, to complete our product range, and for tech-transfer.
Ekin Kimya uses education and training as an interface tool with stakeholders to create synergy for the current business also to drive the future for both parties.

**There has been strong interest in Turkey from multinational companies as evidenced in the many acquisitions the industry has seen. What do you believe has attracted these companies?**

The GDP per capita in Turkey more than tripled in the last 12 years reaching almost $11,000. Turkey has an aging population and social security coverage is around 97%. The health system has been systematically increasing its infrastructure and the number of physicians keeps rising. It has become relatively easier to reach health services. For all these aspects, Turkey is a promising market for pharmaceutical investments. Also Turkey enjoys healthcare demand from neighbouring, CIS and even some European countries. Turkish government considers pharmaceuticals industry as a strategic sector, therefore receives considerable support.
Most of the global brands are showing interest to invest in Turkish pharmaceutical industry. Turkey has more than 300 pharmaceutical related companies in activity, these have good infrastructure and state of art plants with high-tech equipments, full cGMP compliance and huge capacity. An important portion of these companies are acquired by multinationals.These acquisitions are realized for future expectations due to the reasons explained above. The government is trying to protect the local industrybysupporting domestic production.
The message the Turkish government is clear: invest in Turkey. We still import some $5 billion in high-tech pharmaceuticals and this is what the government is trying to change. Local projects and manufacturing of value-added products are supported with incentives. Currently, there is no biopharmaceuticals production in Turkey. Branded generics are easy to make, but to move into value-added high-tech products we will need huge investments, know-how,and experienced human resources that could lead our industry to a different stage of development. Biopharmaceuticals require a more sophisticated form of R&D, and know-how,that is why many big Turkish companies are considering joint ventures with foreign partners. It is not only a matter of money.

**Which product line do you think will drive your business growth?**

Ekin Kimya expects to grow in Pharmaceutical Materials Division, in parallel with the Turkish pharmaceutical industry. Also we expect a concurrent growth in business in the four main areas I have mentioned above.
To be a first generic in the market is essential for pharma companies. Knowing this vital issue, innovation in this field requires high functionality and tailor made solutions, where EkinKimya focuses on. For this purpose, we have established a formulation support laboratory to provide solutions to specific needs of our customers.
Excipients are the most important driving force to the date. Now there is a lot of talk regarding high functionality excipients. These are easy to produce and license, since they are a blend of some five or six other products. Big brands in the pharmaceutical sector are also working on drug delivery systems and super generics, which combine two or three layers in just one pill. We need to be prepared to deliver a variety of products to our clients so that their products can reach shelves in time. We foresee that APIs are going to play an ever moreimportant role in our portfolio due to the needs of Turkish pharmaceutical manufacturers to better manage their cost structure and diversify their product range. We have to be prepared to accommodate the industry's focus on innovation.

**What does the future hold for Ekin Kimya? What are your growth targets for the next five years?**

Based on the strengths of Ekin Kimya, such as flexibility, well trained team and modern infrastructure, we are going to continue to be one of the major players of Turkish pharma industry. For this reason, we have invested in a brand new warehouse in GEBKIM Organised Industrial Zone, with 6,500 pallets capacity. This warehouse meets all the regulatory requirements such as GDP and ISO certifications.
To couple with this, we continue with intense education in-house and in industry. We plan to concentrate in working with innovative product manufacturers, we are strong in this area since we are working with the leading companies of the world.
Constantly we are reevaluating our strategies in accordance with market needs to provide means and ways to increase innovative and competitive edge of our customers. Thus, be 'the first recognized company' to be assigned the needs of our partners. The market is very dynamic. EkinKimya is a very young and dynamic organization, with a well-trained team. We want to use all our assets to keep enjoying double-digit growth. •

Ekin Kimya's headquarters in Istanbul. The firm has also established a new, 10.000 m2 plant within the GEBKIM Organized Industrial Zone.

# Pervin Ejder

Managing Director
**EJDER KIMYA**

**Could you please provide us with an overview of the operations of Ejder Kimya today?**

Ejder Kimya, for now, operates as a distributor of API and intermediates for the pharmaceutical, cosmetics and food supplement industries. Many of our relationships operate through exclusivity arrangements with our principals. We represent 12 companies: a mix of businesses from both the US and European, which are known leaders within their field. Aside from Turkey, we also market their products across the Middle East and North Africa.

Within our technical services division, we provide services related to research and development for the cosmetic industry, and technical training for the pharmaceutical industry. In addition, through a separate company within our group, EQ Laboratories, we also provide laboratory testing services.

**Some speculate that, by 2023, Turkey's healthcare market could reach a size of 80 billion TL. This will require the globalization of the industry. How will this come about? What dynamics will spur this change?**

The Turkish pharmaceutical industry is not well known or understood outside of Turkey. But, the Turkish pharmaceutical industry has technically advanced facilities. Our human resources are excellent as well. The Turkish pharmaceutical manufacturer has invested a great amount of resource into research and development over the course of the past 15 years. This has broadened the product offerings of the industry, as well as enhanced the sophistication of the businesses operating with it.

The largest difficulty that the industry has struggled with in the past nine years is rooted in the way in which the government converts the euro into the country's currency, the lira. The Ministry of Health has mandated that the price at which Turkish pharmaceuticals are sold to state's social security agency, the SGK, is directly linked to the lowest cost at which European businesses manufacturer products and, through this, subject to a currency conversion ratio that the government chooses to employ. As a result, Turkey's pharmaceutical manufacturers have seen their prices heavily discounted. The tradeoff to this, however, has been that Turkish citizens now have access to medication and that the cost of this medication has had less of an impact on the public budget. While prices may be down, this has been compensated for by a considerable increase in sales volume. It has been in this way that the industry has continued to grow. As an unintentional consequence of this, Turkish businesses are now more eager to consider external markets.

**You have built a formidable business in Ejder Kimya. What will the future hold for the company?**

The first quarter of 2014 was very encouraging for Ejder Kimya. We expect to grow, by over 30% in 2014. Long term, our growth depends upon several strategies. Within the next five years, we would like to manufacture intermediates here in Turkey with a partner, if possible, and grow our laboratory testing business.

We would like to see Turkey grow as an access point to near markets and, through this, expand Ejder Kimya. Turkey's geographical position as a nexus between Middle East and Europe, but especially, its proximity to MENA and the Balkans, provides us with a strategic advantage. We understand these markets. Through this understanding we will be able to penetrate them. •

# Turkish Pharmaceuticals and Logistics

Advancing Together

Standing as a gate between East and West, Turkey has long been one of the world's most attractive logistic markets. Owing to its geopolitical position, the country has been able to cultivate a strong network of logistics service providers which have led Europe in the provision of technologically-leading services, both historically and today. Evidenced within their service offering to the country's pharmaceutical industry, Turkey's logistic service providers are both a point of strategic advantage within Turkey as well as an asset for the industry to draw upon as it continues to globalize.

The development of Turkish logistics has been backed by a strong history of public works projects. Though it was not until 1885 that rail tracks would first cut into the country from Europe, allowing for the passage of the first charter of Express d'Orient from Paris, Turkey's first rail network, which connected Izmir to Aydin, opened in 1860. Following subsequent expansions, this line would reach 700 km in length by 1912, far larger than many other train networks within Europe and only one piece of Turkey's rail network.

Today, much line then, Turkey continues to offer a well-developed transportation grid. High speed railways traverse the country, new airports have opened in even Turkey's most remote provinces, and, many major cities are served through the country's large network of ports. These assets will only be further bolstered by commitments from the Turkish government to, by 2023, build 15,000 km in additional carriageways, broaden the country's existing railway network, construct an additional 9,000 km in line, and build three new seaports in each of the seas that surround Turkey. Through these commitments, the government has helped developed several formidable businesses within logistics. Included with this is been Ekol, which, founded only 25 years ago, today employs 6,000 personnel, 1,200 of which operate through their international offices in Germany, Romania, Italy, Bosnia, France, Greece, Hungary, Spain, and Ukraine. The market leader in logistics within the country, Ekol's operations are symbolic of the state of Turkish logistics: agile and technologically innovative.

For the country's pharmaceutical manufacturers, this, specifically, has meant the development of several services which, although unavailable within many other global pharmaceutical markets, can be found within Turkey. One of these services is cold chain management. Hakan Şen, general manager of Ekol's healthcare sector explains that, "Cold chain management is critical for the effective provision of logistical services to the pharmaceutical industry. An ineffective cold chain management system compromises product quality. Ekol has invested heavily in the development of its cold chain management system; we provide international transport, bonded warehousing, warehousing and national distribution services to our several customers requiring cold chain systems. Our solutions within both of these areas are tailor made to the industry, based off of the understanding that we have gathered on a company's needs as specified by their SOP. Today, Ekol has several cold chain bonded warehouses as well as a fleet of vehicles dedicated to the healthcare sector."

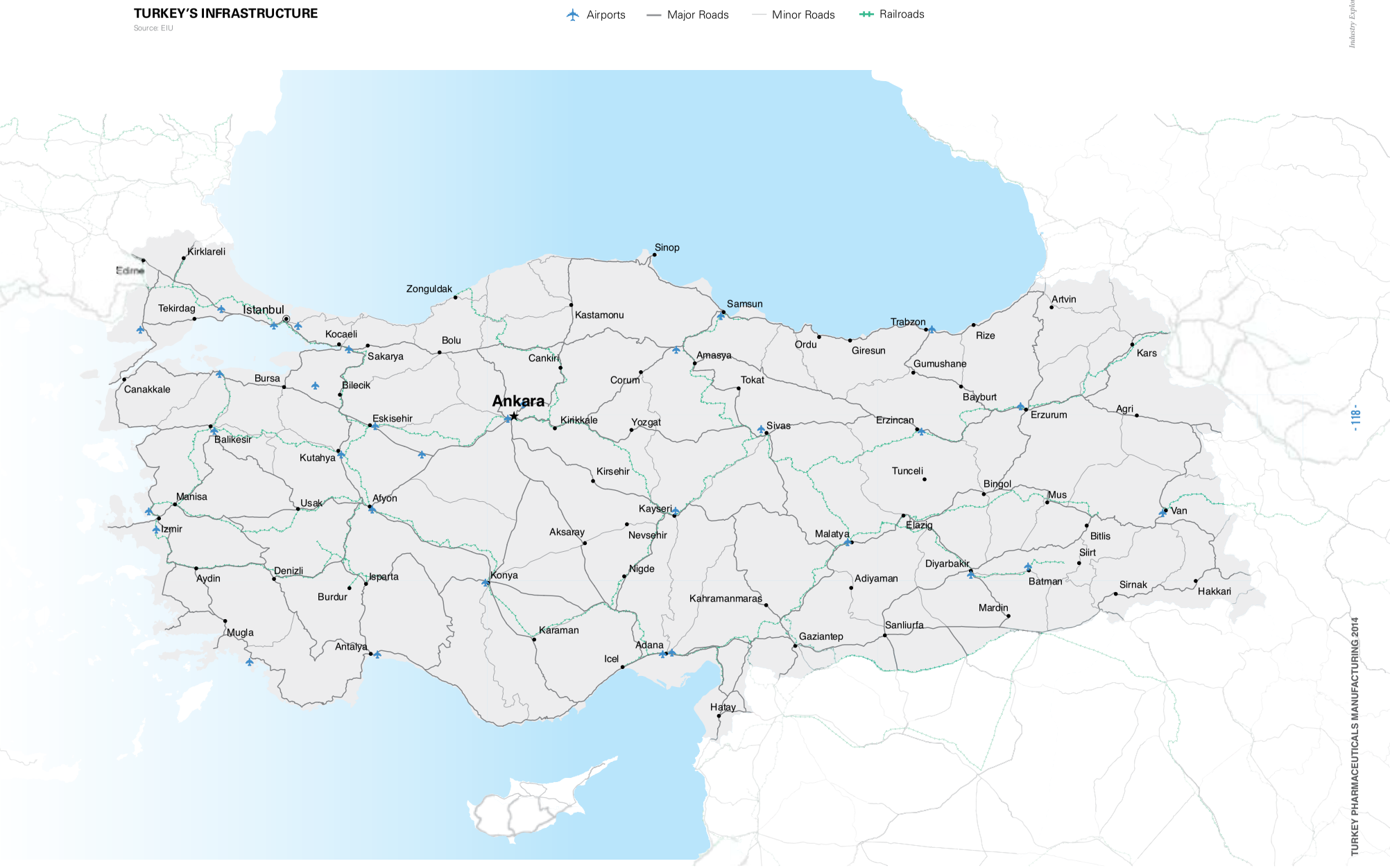
A second service that Ekol has developed in correspondence with the changing needs of Turkey's pharmaceutical manufactures and Turkish government requirements has been the advent of two-dimension marketing systems. Not yet in place throughout Europe – in fact, the only other country to institute such a system has been Brazil – two-dimension marketing is a system of quality control that helps guarantee consumer safety. First introduced in Turkey in 2010, this service could soon become compulsory. Ekol hopes to help the country's pharmaceutical manufacturers manage this transition. Şen explains that, "Two-dimension barcoding requires that each product, each unit in the case of the pharmaceuticals industry, have a unique identity number which allows for that product to be tracked at any point in time across its supply chain. This information is stored by the Ministry of Health and plays an important role in consumer safety. The Turkish government now requires that pharmacists, when fulfilling a product prescription for a customer, identify this number. If this number is unavailable in the system, pharmacists cannot legally fulfill a prescription for a patient using the product in question. Two-dimension barcoding has high technological barriers: the data requirements of this system are immense. Ekol provides this service to its clients. Two-dimension barcoding has certainly provided Ekol with a technical advantage.."

Beyond the advantages that Ekol has been able to develop within the domestic market through this service offering, Ekol also believes that will play an important role in winning European business, both as this system is implemented within other European countries and as Turkish pharmaceutical manufacturers expand into these regions.

Ekol, like many companies within Turkey's logistic industry, sees a bright future for itself, driven by both their own commitments to implement technology and the support that the Turkish government has continued to provide in upgrading and expanding the country's infrastructure. Healthcare, which stands among Ekol's most important industries, will inevitably be an important piece of this industry's continued growth. Already, this relationship between logistics and healthcare has made for a stronger, more globally competitive pharmaceutical industry. •

## TURKEY'S INFRASTRUCTURE

Source: EIU



# Nil Tunasar & Cem Kolak

NT: Managing Partner
CK: Director Biopharma Logistics
**TRANSORIENT**

Transorient's Managing Partner Nil Tunasar accepting the 50 Years Milestone Certificate awarded by Istanbul's Chamber of Commerce.

**Transorient has a history of over 50 years in the logistics sector. Could you provide us with an overview of the key milestones in the company's development?**

NT: Transorient is one of the oldest privately-owned logistics companies in Turkey. Transorient, which was founded by Zeki Pakyurek in 1961, was established to connect the west and east in road and railway freight, as well as to provide customs clearance. Several years after its founding, Transorient began working with foreign companies and the diplomatic services in Turkey, providing services in custom clearance, transportation and warehousing. An important milestone for the company was when we became an IATA agent in 1995 and began working in air freight. We were also chosen as agents by multinational logistics agents such as DHL Heavy Freight, and we enlarged our network, becoming members of well-known networks like FFSI. Customs brokerage remained our core business; when the Turkish regulation changed we established a separate customs brokerage company.

**What prompted you to enter the bio pharmaceutical business? Are there any new sectors that you are engaging with?**

NT: We entered the pharmaceuticals business in late 2008 after we adopted international service standards, and could attract global business partners across various different sectors. Within the pharmaceuticals sector, we are experts in the clinical trial sector, which is a very time-sensitive business. Pharmaceuticals are currently one of our three most important business areas, and we see a very promising future in the industry. We are particularly interested in moving into the organs transportation sector.

CK: We recently completed a highly time-sensitive request from the Swiss anti-doping federation. They wanted samples from athletes to be transported and placed in the laboratory in just 38 hours. We provided special packaging and devices that maintained the samples at the right temperature during the transport. These projects are not planned in advance; when we see a proposal, we can respond in a very short period of time and have a quick turnaround.

**What stand Transorient's competitive advantages?**

NT: What sets Transorient apart from its competitors is not what we do, but how we do it. We adopt a methodological and analytical approach in offering our logistics solutions to our clients. We analyze and measure a client's requirements and then design and implement diverse solutions to meet them, relying on measurable service performance. We also possess the ISO-9001 and ISO 27001 certifications. During the last five years, we have seen a clear increase in business volume, which can be attributed to our strong team and IT platform.

**Transorient employs one of the industry's most advanced cold chain managemeny systems. What was required of the firm in developing this system?**

CK: One of the most important factors in cold chain management is the packaging—it is not always possible to provide temperature-controlled vehicles, and smaller quantities often need to be sent by air. Until a few years ago, up to 40% of the drugs were spoiled in Turkey due to lack of appropriate packing solutions. As a result, companies began to develop better solutions, also widening their logistics budgets. We were the first company to start importing cold-chain packaging from the United States, and we are now able to guarantee the cold-chain for about 72 hours. Transorient also has two temperature-controlled vehicles which are based in Istanbul for urgent projects. We demand that temperature readings be taken every five minutes throughout the trip, which we then present to our clients.

**The Turkish government has set aggressive infrastructure goals for 2023. What impacts do you think these investments will have on domestic logistical networks?**

NT: We have seen a change in the mindset of the government. Not only has it set the 2023 infrastructure targets, but it has also examined infrastructure needs and planned investments accordingly. We have seen major changes in the customs organization, as well as towards e-business. There is also a lot of investment in more sustainable types of transportation. We all hope that these infrastructure projects will be conducted fast enough to change the industry.

**What strategic initiatives does Transorient have in place to ensure the firm's continued success over the course of the next five years?**

NT: We plan to be increasingly involved in environmental projects, or sustainable logistics. Transorient can set an example in sustainability, having been in operation for over 50 years. We plan to invest in more environmental projects, and broaden our creativity in the pharmaceuticals sector. Our goal is to operate in niche markets; we are less interested in large quantities than we are in higher quality businesses. We also hope to see Transorient work on more international projects in the future.•

# Healthcare priorities
# Done & Done!

Whether there is a new regulation or need for GMP standart warehousing, secondary packaging, quality assurance, order management, traceability or GDP standart international and domestic distribution... We provide world class service from a single point of contact at Ekol.

EKOL® health care

healthy supply chain for a better world

health@ekol.com
4443565

# Hakan Şen

General Manager, Healthcare Sector
**EKOL**

**Ekol was established in 1990, 25 years ago. Could you please provide an overview of Ekol's development?**

Ekol began its operations in 1990. Since its first day of operation, the focus of Ekol has been on ensuring customer satisfaction. This philosophy has always been at the core of our operation, underpinning the accomplishments that we have had in our mission of becoming a leader in the field of logistics both within Turkey and abroad, in Europe. Today, Ekol stands as the country's largest providers of integrated logistics.

Ekol's service offering includes services related to transportation, product warehousing, foreign trade and supply chain management. We are noted for the expanse of our facilities, which include indoor distribution centers with more than 400,000 m2 in Turkey, and facilities of 100,000 m2 in Germany, Italy, Greece, France, Ukraine, Bosnia, Romania, Hungary and Spain. Our fleet includes 3,000 vehicles and our staff numbers nearly 5,000: 4,000 of which are Turkish and the remainder of which are European.

We entered into the healthcare sector in 2005. Our investments in this sector were incremental; we expanded as our knowledge of the industry grew. Currently we stand as the leading provider of logistic services to the pharmaceutical industry. Our market share stands at 25%, and ranges from the industry's largest multinational corporation to many domestic pharmaceutical manufacturers.

**In what way has Ekol had to adapt its model of business to suit the needs of the pharmaceutical manufacturing industry?**

At Ekol, we believe that the pharmaceutical industry has specific needs. We have thus had to tailor our service offering accordingly. We have placed increased emphasis on quality standards, as high standards are of extreme importance to the sector, as well as understanding the requirements governing the industry closely focusing on GMP standards. We strive to integrate within our clients organizations.

We also believe that business in the industry must be handled separately from business in all other sectors. While it is common practice to combine the provision of logistical services for the automotive and textiles industries on an operational level, the same cannot be done for pharmaceuticals. For this reason we have developed three separate warehouse facilities to meet the unique needs of the industry. We believe that through these commitments, our work in the pharmaceutical industry will be key driver of growth for Ekol's future.

**In what way has Ekol employed technology, an important focus of the company, to leverage a competitive advantage?**

Ekol has long understood the importance of providing high quality and technically innovative solutions to its clients. It is for this reason that we developed the first and only research and development center within Turkey's logistics industry. Those employed as part of our research and development team focus closely on the development of software, technology and operational processes that will improve our value proposition. We have had considerable success as a result of the projects executed within our research and development center. One area in which this has been especially apparent is in the implementation of two-dimension barcoding within Turkey.

New by global standards, two-dimension barcoding has only been introduced into several countries worldwide. Turkey began using this system in 2008, the system reaching full functionality in 2010. Though present in Brazil, elsewhere within Europe this system is not yet in place.

Two-dimension barcoding requires that each product, each unit in the case of the pharmaceuticals industry, have a unique identity number which allows for that product to be tracked at any point in time across its supply chain. This information is stored by the Ministry of Health and plays an important role in consumer safety. The Turkish government now requires that pharmacists, when fulfilling a product prescription for a customer, identify

this number. If this number is unavailable, pharmacists cannot legally fulfill a prescription for a patient using the product in question. Two-dimension barcoding has high technological barriers: the data requirements of this system are immense. Ekol provides this service to its clients. Two-dimension barcoding has certainly provided Ekol with a technical advantage.

Our investments into technology, like in the case of two-dimension barcoding, have developed through Ekol's deep understanding of company needs. Our customers certainly feel that it has made the difference.

**The pharmaceutical industry has very specific requirements, such as the implementation of cold chain management technology. What has the development of cold chain management technology meant for Ekol?**

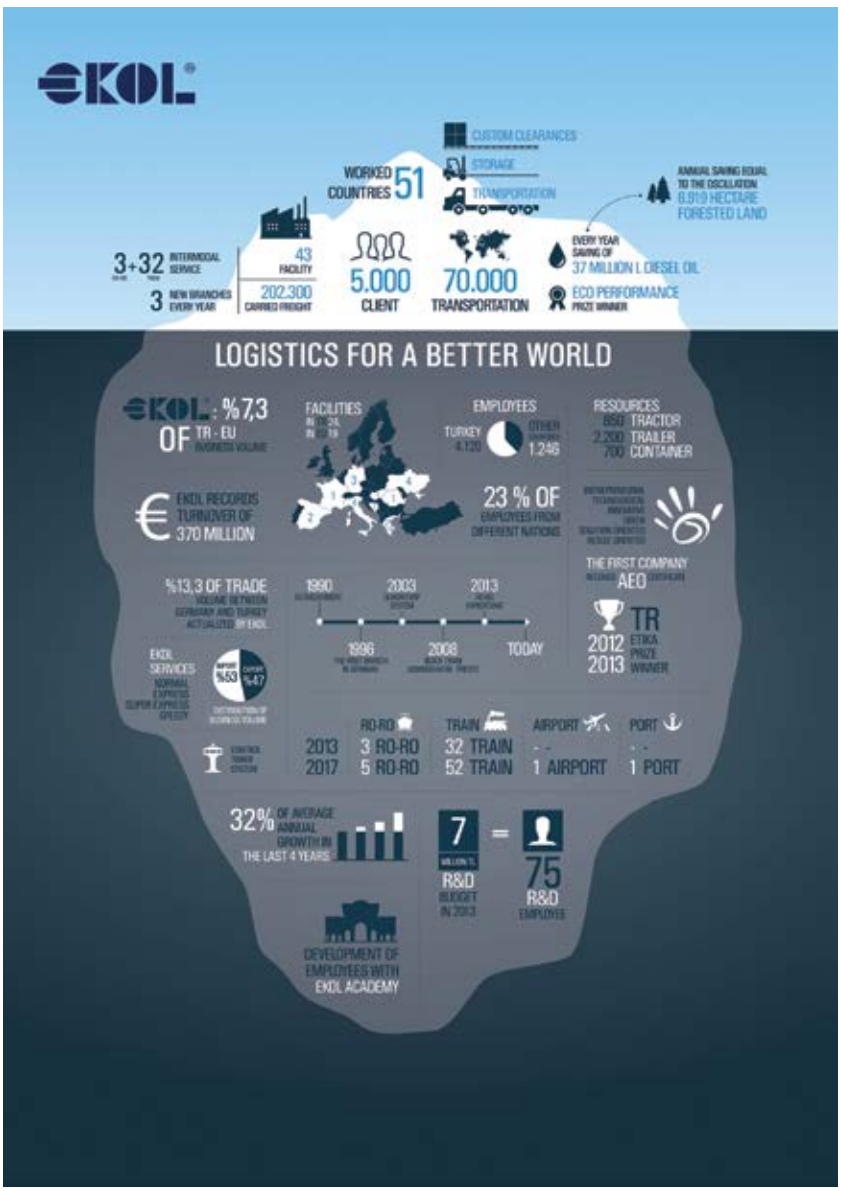
Cold chain management is critical for the effective provision of logistical services to the pharmaceutical industry. An ineffective cold chain management system compromises product quality. Ekol has invested heavily in the development of its cold chain management system;we provide international transport, bonded warehousing, warehousing and national distribution services to our several customers requiring ambient and cold chain systems. Our solutions within both of these areas are tailor made to the industry, based off of the understanding that we have gathered on a company's needs as specified by their SOP. Today,Ekol has several cold chain bonded warehouses as well as a fleet of vehicles dedicated to the healthcare sector.

**What do the next five years have in store for Ekol's healthcare division?**

Today, Ekol stands as the market leader for the provision of logistics services dedicated to the healthcare industry, both with regard to product diversity and volume. We strive to increase our market share in the short-term to 30%. The implementation of Good Distribution Practices (GDP) standards will aid in this as many operations that do not employ the same quality standards that Ekol does will face greater difficulty in competing within Turkey's logistics industry.

Soon we will also introduce several new services to the industry and expand our presence within the European market. Ekol is already well established in Europe. The Turkish pharmaceutical industry is becoming more global. We believe that we can support these businesses in expanding into the European market. Also, as two-dimension barcoding become standard place within European nations, Ekol, through already understanding the requirements of this system, will be prepared to lead in these markets.

Ekol is on its way to becoming a global brand. Within this scope, we are actively seeking to develop a presence within other markets. We now lead within healthcare logistics in Turkey; our objective is to achieve this in other countries as well.•



# Into the Future: Final Thoughts, Index and Credits


Image: Drogsan
Drogsan's modern production facilities are comprised of 3 sites, which focus on the production of pharmaceuticals in solid, liquid and nasal spray forms. These plants also include state-of-the-art R&D laboratories.

"The quality of Turkish pharmaceuticals is well understood. Those companies that have expanded aggressively into external markets from the industry, such as Bilim Pharmaceuticals, have developed a reputation for the quality of their products in emerging healthcare markets like Ethiopia. The products of Bilim Pharmaceuticals are now regarded as among the most reputed pharmaceutical manufacturers serving this region. Their products are recognised and requested for -- above the products of other pharmaceutical manufacturing regions such as India and China. This strengthens the reputation of the entire industry. It is for this reason that Keyman Pharmaceuticals has invested in establishing a presence in Azerbaijan, and also the Ukraine. Currently we have registered five products within Azerbaijan. The future of Turkish pharmaceuticals lays overseas, in markets such as these."

- Dr.O.Mutlu Topal, Managing Director, Keymen

"Turkey is a huge country and its pharmaceutical market will be one of the world's biggest pharmaceutical markets in the future. While the country has currently its challenges, those who invest in Turkey today will earn."

- Süha Taşpolatoğlu, CEO, Abdi Ibrahim

"AT Kearney sees interesting players in the market who need to devise strong plans for the next five years. We believe strongly if there is not more innovation drive, teaming up, partnering and consolidation, then the pure generic model or contract manufacturing will not be lucrative enough for the industry. On the other hand, healthcare is moving up, hospital chains are growing and there are enough opportunities to attack this market. We need internationalization and innovation."

- Michael Weiss, Head for Health, AT Kearney

"The growth rate of the market will decrease year by year but still we have a good potential compared to Europe. Turkey is a regulated market, so many multinational companies are setting up their regional headquarters here and we expect multinational companies to continue making acquisitions in Turkey. Turkey can also be an important site for production for Europe; labor costs are lower and our manufacturing sites are of good quality. We can also be a center for R&D and a site for clinical studies."

- Dr. Erhan Baş, General Manager, Bilim Pharmaceuticals

"When life is relatively easy, one does not need to develop strategy. But, when the market conditions deteriorate and margins start to suffer, one cannot afford not to have a clear cut strategy. Strategy firstly means making sound choices and sticking to them decisively. Besides the turbulence of the market conditions, we are also suffering from not having proactively developed focusing, development and export strategies. Differentiation of products and technology is key to the creation of a sustainable industry."

- Serdar Sözeri, General Manager, Biofarma

"We would like to see Turkey grow as an access point to near markets and, through this, expand Ejder Kimya. Turkey's geographical position as a nexus between Middle East and Europe, but especially, its proximity to MENA and the Balkans, provides us with a strategic advantage. We understand these markets. Through this understanding we will be able to penetrate them."

- Pervin Ejder, Managing Director, Ejder Kimya

"The place of the Turkish manufacturer in the domestic pharmaceutical industry is shrinking. Their profitability is in decline. Small- to mid-sized companies will not survive in the long-term. These companies have now reached a juncture: they must grow and transform themselves into global companies, or they will be swallowed. Those that do survive will be in a very good position. It is a decisive moment for Turkish pharmaceuticals industry."

- Ersin M. Erfa, General Manager, Centurion

**This list contains those companies interviewed during the course of research for this publication and as such represents only a limited selection of the companies operating in the pharmaceutical industry of Turkey. It should not be considered a comprehensive guide. GBR holds an exclusive and extensive pharmaceutical database for Turkey and the wider region. For further information on database access packages, please contact info@gbreports.com or call +44 20 7812 4511.**

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**Turkish Medicines and Medical Devices Agency - TITCK**
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**Pharmaceutical Manufacturers Association of Turkey**
www.ieis.org.tr

**Turkish Pharmaceutical Exporters**
www.trpharmaexporters.org

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www.ubm.com
www.cphi.com/istanbul/home

Finally, we sincerely thank all the companies that took the time to give their insights on the market and share their experience and knowledge.

# WORLD MEDICINE

Pharmaceutical Company

| | | |
|---|---|---|
| | Film-coated and enteric-coated tablets | 1.500.000 tablets/day |
| | Soft gelatin capsules | 1.500.000 capsules/day |
| | Hard gelatin capsules | 1.500.000 capsules/day |
| | Micro dose capsule antiasthmatic drugs | 800.000 capsules/day |
| | Dry powder for suspension | 23.000 bottles/day |
| | Oral solutions | 20.000 bottles/day |
| | Nasal spray | 20.000 bottles/day |
| | Ear & Eye drops | 80.000 bottles/day |
| | Inhalation aerosol | 10.000 containers/day |
| | Sachet | 180.000 Sachets/day |
| | Granules | 10.000 bottles/day |
| | Syrups | 20.000 bottles/day |



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