HEALTHCARE & LIFE SCIENCES REVIEW

PHARMA BOARDROOM

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TURKEY

FEBRUARY 2016

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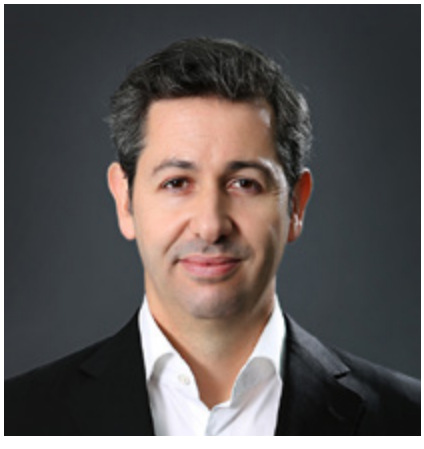

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Project Director: Alina Manac
Editorial Coordinators: Alexander Ackerman, Jun Wakabayashi
Project Assistants: Simona Simeonova, Roxane Hock, Nicholas Laane
Report Publisher: Mariuca Georgescu
Editorial support: Patrick Burton
Graphic design: Carmen Reyes

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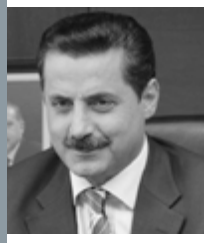

To the healthcare and life science community worldwide,

It is my pleasure to introduce this special report titled “Healthcare and Life Science Review on Turkey” and I am proud to share Turkey’s healthcare and life science capacity and capabilities with you through this publication.

During the last decade, Turkey has prioritized the modernization and improvement of the healthcare industry, establishing universal public healthcare, improving access to healthcare providers across the country and transforming the structure of the healthcare system by giving the private sector an integral role in the provision of healthcare services.

Today, the pharmaceutical industry in Turkey is positioned to develop into a major exporter and regional hub for the global pharmaceutical business and achieving significant growth in this sector is a national objective as a part of Turkey’s Vision 2023 that is developed for the centenary of the Republic of Turkey.

Coordination and collaboration between all stakeholders, including government, the Turkish healthcare industry and global big pharma will help us to improve Turkey’s competitiveness globally and to secure a leadership position in its region.

With this special review, I invite all members of the global healthcare and life science community to take a look at the exciting opportunities that Turkey has to offer, and the significant achievements that our country has made, and will continue to make, within the field of healthcare and life science.

Thank you.

Faruk ÇELİK
Minister of Labour and Social Security, Republic of Turkey

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TURKEY IS THE LARGEST MARKET IN MIDDLE EAST & EASTERN EUROPE REGION IN 2014 SALES

Source: IMS Dataview Retail Hospital Database, December 2014.

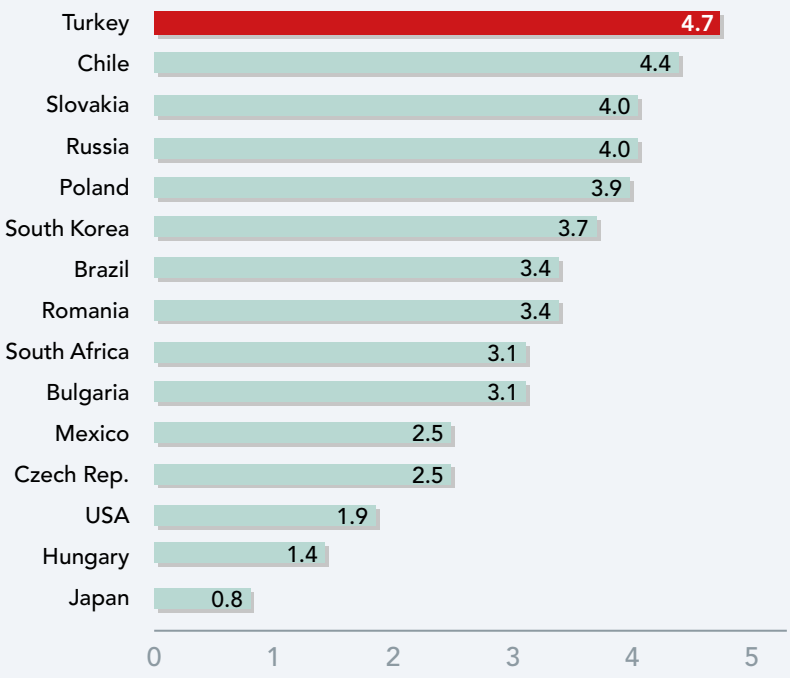
Preface

The Turkish pharmaceutical industry has a rich heritage, with several of the oldest manufacturers having more than 100 years of history in this challenging industry. Today, the sector is one of the country's leading industry's, employing many of the best and brightest from across the country, and holds significant potential as an engine of economic growth for this regional leader. Arguably the most politically stable country in a tumultuous region, long touted as a crossroads between civilizations, and with pharmaceutical manufacturing to spare Turkey is well positioned to supply populations across North Africa, the Middle East, the Balkan, and parts of western and central Asia.

In line with global trends, the industry has faced significant pricing pressure in recent years, motivating the industry to restructure to improve efficiency, while developing new goals and targets in collaboration with the government. With pharmaceutical imports ranking as the fifth largest cause of Turkey's growing current account deficit, import substitution is a top government priority, and thus a number of initiatives are underway to develop domestic production for vaccines, biotech products, and other high cost treatments.

At the same time, the innovative pharmaceutical sector is quick to point out that Turkey has much to gain by working with the global industry, increasing participation globalized production of innovative products, and playing a role in the R&D process for new medicines. Can Turkey find the balance between fostering the growth the domestic industry and building stronger partnerships?

AVERAGE ANNUAL REAL GDP GROWTH (%) 2003-2014



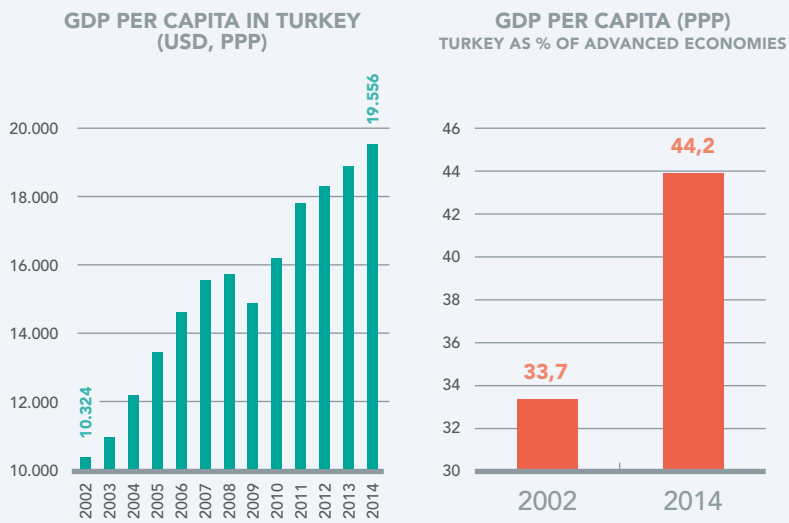
Source: IMF World Economic Outlook April 2015, Turkish Statistical Institute (TurkStat)

DID YOU KNOW THAT?

- Turkey's economy has more than tripled its GDP, reaching USD 800 billion in 2014, up from USD 231 billion in 2002 *(TurkStat)*
- The country has a stable economic growth with an average annual real GDP growth rate of 4.7 percent between 2002 and 2014 *(TurkStat)*
- It is a promising economy with a bright future as it is expected to become one of the fastest growing economies among the OECD members during 2014-2016 with an average annual real GDP growth rate of 3.6 percent *(OECD, February 2015)*
- 16th largest economy in the world and 6th largest economy compared with the EU in 2013 *(GDP at PPP, IMF WEO)*
- Institutionalized economy fueled by USD 144 billion of FDI in the last decade *(CBRT)*
- A dynamic and mature private sector with USD 158 billion worth of exports and an increase of 250 percent between 2004 and 2014 *(TurkStat)*

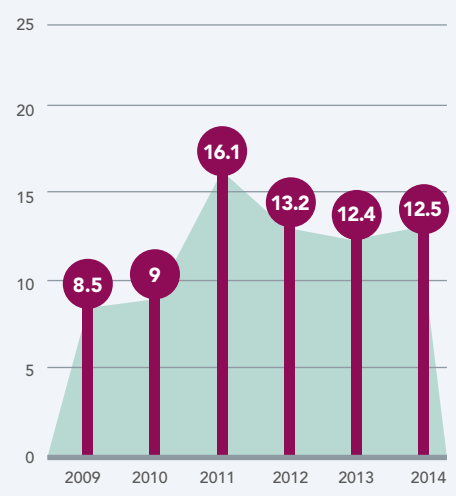
Source: Invest in Turkey http://www.invest.gov.tr/en-US/investmentguide/Pages/10Reasons.aspx

GDP PER CAPITA & TURKEY AS % OF ADVANCED ECONOMIES



Source: IMS

FDI INFLOW TO TURKEY (USD BILLION)



Source: Central Bank of the Republic of Turkey

THE FOUNDATIONS OF A GLOBAL HEALTHCARE COMPETITOR

Preface: Turkey's minister of health discusses the major achievements of his party in the area of healthcare since 2003 and the key priorities for the country's healthcare system moving forward.

HCLS: During AKP's (Justice and Development Party) incumbency, what were the main policies in health, and what are your priorities for future healthcare policy?

MEHMET MÜEZZINOĞLU: Upon the AKP's assumption of power, we initiated the 'Health Transformation Program' in 2002, which was a very extensive program of reforms and developments in healthcare. In brief, this program involved establishing a well-organized and empowered Ministry of Health, creating a general health insurance system that covers every citizen, and ensuring that patients have easy access to healthcare services. Primary healthcare services were strengthened, a family doctor system was created, and regulations were reformed to improve the productivity of healthcare institutions.

As a result of this program, all citizens can now obtain reimbursed-medicines from every pharmacy, every citizen can build a relationship with a family doctor, and we have reached high standards for emergency healthcare services. Also, ambulatory services now reach every region in Turkey, as we have introduced the use of planes and helicopters.

Going forward, we will be prioritizing R&D initiatives, including health studies and medical innovation. It is for this purpose that we founded the 'Department of Health Institutions of Turkey', which will follow the developments in medicine closely. The Ministry of Health is encouraging the production of medical devices and medications in Turkey, and we will be supporting the development of vaccines and high value added medicines in Turkey. Our ultimate goal is for Turkey to be a globally important R&D center for pharmaceutical production, and we will improve Turkey's competitiveness in the pharmaceutical and medical devices sectors.

The Ministry of Health's priorities also include developing medical tourism, building more city hospitals to create more comprehensive health services, and accelerating awareness initiatives that encourage healthy living.

HCLS: Given the growth of medical tourism in Turkey, what are the ministry's objectives in this regard?

MM: Turkey has a well-developed economy, and strong human resources due to our young and well educated population, and these factors, along with cultural and historical factors, have made Turkey one of the most popular destinations for tourism, with over 40 million people visiting our country each year. Since we began to invest heavily in the healthcare sector ten years ago, many healthcare institutions in Turkey are now competitive at the international level in terms of quality. As a well-connected and attractive tourism destination with good infrastructure, as well as high quality and good value medical services, Turkey is becoming an increasingly popular medical tourism destination. The number of visiting patients has been increasing by about 20 percent per year for several years, and in 2014 there were 496,324 people who visited Turkey for the purpose of receiving healthcare services. There are many reasons behind Turkey's growth as a medical tourism destination; the high standard of health services, doctors with strong global reputations and experience, fair payment policies, and immediately available services. Furthermore, our country is positioned such that one billion people live within a four hour flight of Turkey.

Due to the experience and knowledge required to provide quality medical care, these services can be considered to be high value added services, and as such we have added medical tourism to our tenth Development Plan as a strategic industry. If Turkey can make some small improvements in this field, we are within reach of becoming a leading country in the world for medical tourism.

> "All citizens can now obtain reimbursed-medicines from every pharmacy, every citizen can build a relationship with a family doctor, and we have reached high standards for emergency healthcare services"

HCLS: Considering the 2023 Vision healthcare targets, what is the Ministry of Health doing in order to increase medicine exports?

MM: The Tenth Development Plan comprises four years between 2014 and 2018. In its action plan the article 1.16, 'Structural Transformation Program within the Health Industry' aims to develop a structure that is able to produce high value added medicines. In that context, in order to increase the exportation, these actions will take place:

- Bilateral negotiations and protocols will be made in order to ease the technical controls and to simplify the processes of obtaining licenses in export markets.
- Target countries' non-tariff barriers that impede Turkish exporters will be taken into consideration and studies will be made.
- We will prioritize the advertisement of Turkish medicines and medical devices in target countries.
- We will provide medicine and medical device producers' efficient support for exportation.
- Studies will be done in order to add the licensed products – produced for exportation – to the reimbursement list.

Another target for improving the exportation is to make Turkey a member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation

Scheme (PIC/S). This will speed up and ease the process so that medicines made in Turkey can be easily exported to other countries that are also members of PIC/S and in that case, this situation will increase the exportation in a positive way and this will change the import-export balance in favour of Turkey.

HCLS: What is your ministry doing to make the medicine sector grow, and to define its role in the market?

MM: For all the medicines produced in Turkey, in the Tenth Development Plan's article 1.16, 'Structural Transformation Program within the Health Industry':

- All of the medicines that apply for manufacturing in Turkey will be quickly provided a license by the Ministry of Health.
- Social Security Institutions will accelerate the process of adding a medicine into the reimbursement list for the medicines produced in Turkey by making necessary arrangements.
- Investments will be encouraged for medicines and devices (diagnostics and imaging devices) which are not produced in Turkey or which are difficult to obtain and for the electric devices (diagnostic medical device, imaging device etc.) with high added value which are not produced in Turkey or which are not produced enough.
- R&D studies and production will be encouraged in the frame of advanced treatment which includes Advanced Medical Treatment Productions.

HCLS: In Turkey, can patients reach innovative products? What are the potential reforms, pricing and registry systems?

MM: In the case of a treatment choice that is more favourable, patients – in some specific conditions - can access the innovative medicines even if they are still not licensed. In that case, they just need some special approval. In the matter of pricing the medicines for human use, there are discussions regarding

new pricing arrangements, studies are still continuing. For both of the regulations – ongoing or finished - in every step of work, expert opinion is being taken and new decisions are announced to the sector.

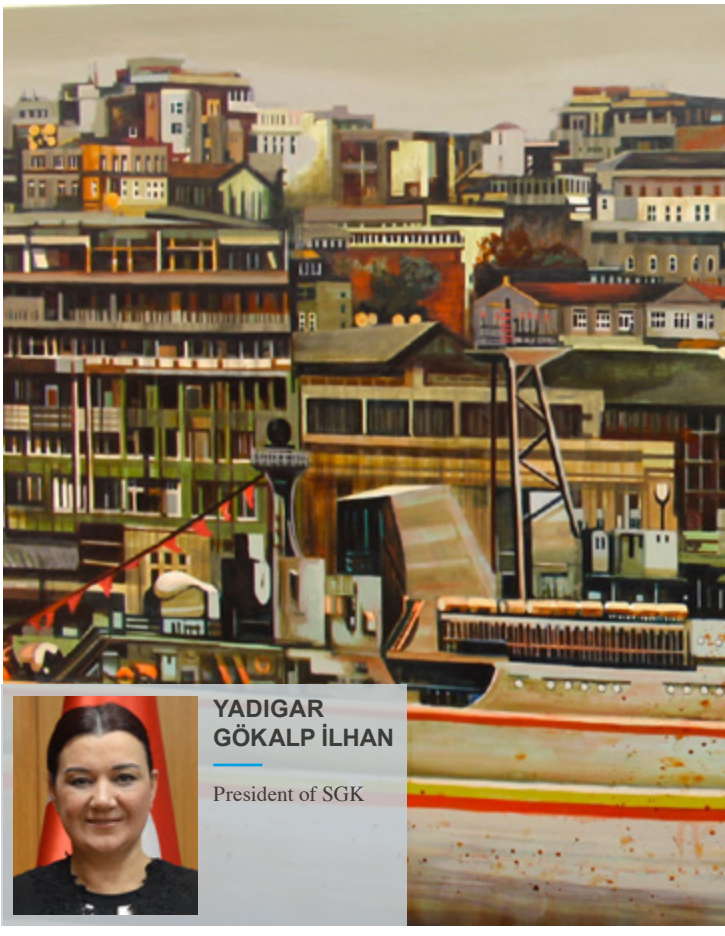
In order to provide patients' trust in the medicines, we set up a new system called *İlaç Takip Sistemi* (Medicine Tracking System). This innovative system is unique and is being applied successfully only in Turkey. With MTS, we ensure the entire process that medicine passes through; from production to consumption. With that system, our target is prohibiting the use of counterfeit drugs and illegal drugs; prohibiting the forgery of packaging; supporting rational drug use and collecting data about drugs for market control.

HCLS: What is the Ministry of Health doing to incentivize investment from foreign investors?

MM: It is important that we increase the amount of production with high technology by attracting foreign investors to our country. So, in our Tenth Development Plan, we placed emphasis on the following subjects:

- In the reimbursement and pricing policies and in the authorization process, we will make some regulations and put some implementations in order to value Turkish products (medicine and medical devices) prior to others.
- As part of advanced treatment, medicines for advanced medical treatment will be encouraged in terms of production and R&D studies The pricing and reimbursement process will be encouraged for sponsors of R&D studies that consider the needs of our country.
- We will support investments to medical products that are not produced in Turkey or that are not produced enough.
- We will transform Turkey into a regional administration in the medical sector and into a service center in the healthcare services.
- We will provide an efficient use of exportation support to medicine and medical device companies.

THE EVOLUTION OF HEALTHCARE SPENDING



YADIGAR GÖKALP İLHAN
President of SGK

Preface: The president of Turkey's social security institution, the SGK, discusses the evolution of healthcare spending over the past three years, and the underpinning principles guiding their drug reimbursement policy decisions.

HCLS: With increasing demand for and access to healthcare, how has the SGK controlled growth in healthcare expenditures, particularly on pharmaceuticals?

YADIGAR GÖKALP İLHAN: Since 2006, the 'Sosyal *Güvenlik Kurumu*' (SGK), or Social Security Institution, has been the institution responsible for reimbursing organizations for health care expenditures. It was created through the integration of three different social security institutions in 2006, and by 2008 the SGK had established a new health insurance system that covered nearly all citizens. At the end of 2014, 98 percent of Turkey's population was covered by the SGK. In 2009, public expenditures on pharmaceuticals accounted for 1.7 percent of gross national product, and began to rise further. In order to maintain financial stability, some precautions were taken between 2010 and 2012 including the passing of a global budget, increasing public medical discounts and taking consideration of demand-side practices. These policies were successful, and by 2012 public expenditures for medicines regressed back to the level of 2009.

Although this rate did not change in 2013 and in 2014, nominal expenditures did increase. Between 2012 and 2014, health expenditures increased nominally 21 percent, roughly 10 percent annually. Over the same period, expenses for biotech drugs – which are expensive and innovative – increased about 60 percent, or 27 percent annually. Each year, health insurance is extended to cover more medicines, and patient access to these medications increased overall, which drove this spending growth. Biotech drugs accounted for 13 percent of the total medicines expense in 2012, and by 2014 this share had increased to 17.4 percent; oncology drugs and insulin took up the largest share of this expense.

HCLS: With regards to drug pricing policy, what are the primary objectives of the SGK?

YGİ: The directive for working principals and procedures of the payment commission, which came into effect on July 3rd 2014, plays a major role in defining the medical policy and shapes the SGK's future policies. With this new directive, we have several targets including: improving patients' access to medicines, supporting the repayment of the products made in Turkey, renovating payment commissions, prioritizing pre-

ventative healthcare, and creating alternative payment policies.As of March 2015, the SGK will reimburse the costs of 7934 different medicines. For a medicine to be placed on this repayment list, firms must submit an application for analysis and evaluation, following which a decision is made. This procedure allows for the easy addition of products to the reimbursement list, although there may be some products that cannot be found on the market or which are removed from the list because the Ministry of Health determines them to be inactive.

In general, when determining drug reimbursement policy the SGK aims to promote financial sustainability, easy access to medicine, rational drug use, and to prioritize the use of domestically produced products.

HCLS: In general, what are the key aims of the SGK for the Turkish healthcare and life science sector today?

YGİ: We encourage companies to produce medications in Turkey instead of importing by providing an easier payment system. With respect to incentivizing local manufacturing, some arrangements were made for adding locally produced products to the SGK's reimbursement list, and these products will have the privilege of getting reimbursement first.

Medical technologies have progressed greatly in recent years, and accordingly the share of reimbursement going to biotechnology products has increased. As such, our 10th development plan has the goal of improving our industry's ability to export, and to support a high standard of technology in the industry with R&D studies and funding. We are encouraging pharmaceutical manufacturers to take the necessary steps to develop capabilities in molecular medicine over the long run, and are trying to transform the industry into one that produces medicines with high added value, including biotechnical and biosimilar products.

In this context, the Ministry of Science, Industry and Technology prepared a 'Strategy Plan for the Pharmaceutical Industry'. According to this plan, it is necessary to carry out reforms to provide more predictability about the national market access conditions. The plan has also aims to prepare legislation on orphan drugs to ensure prevention and diagnosis of rare disease in accordance with international standards. For the new drugs, which are the results of R&D studies, easy repayment procedure will be provided. As such the SGK is aiming to support these goals through the improvement of the repayment system.

SGK's first aim is to provide necessary healthcare services on time and in a correct way. In terms of the access to drugs, the SGK is protecting the public's rights of reaching the correct drugs, and other alternatives are always being produced. Certain drugs can not be found on the market Turkey but it is inevitable that they will be needed to cure some diseases or treat some illnesses, so the Turkish Pharmacists' Organization (TEB) authorized to import them from other countries when necessary, and our institution reimburses them. The SGK also has the aim of developing alternative repayment models.

IS THERE ANOTHER WAY?

Preface: The chairman of AIFD analyses the Turkish government's plan to reduce the trade deficit in pharmaceuticals. He suggests that pricing reform, rewarding investment in the country, and working to increase competitiveness are all needed to increase the value of Turkey's pharmaceutical exports.

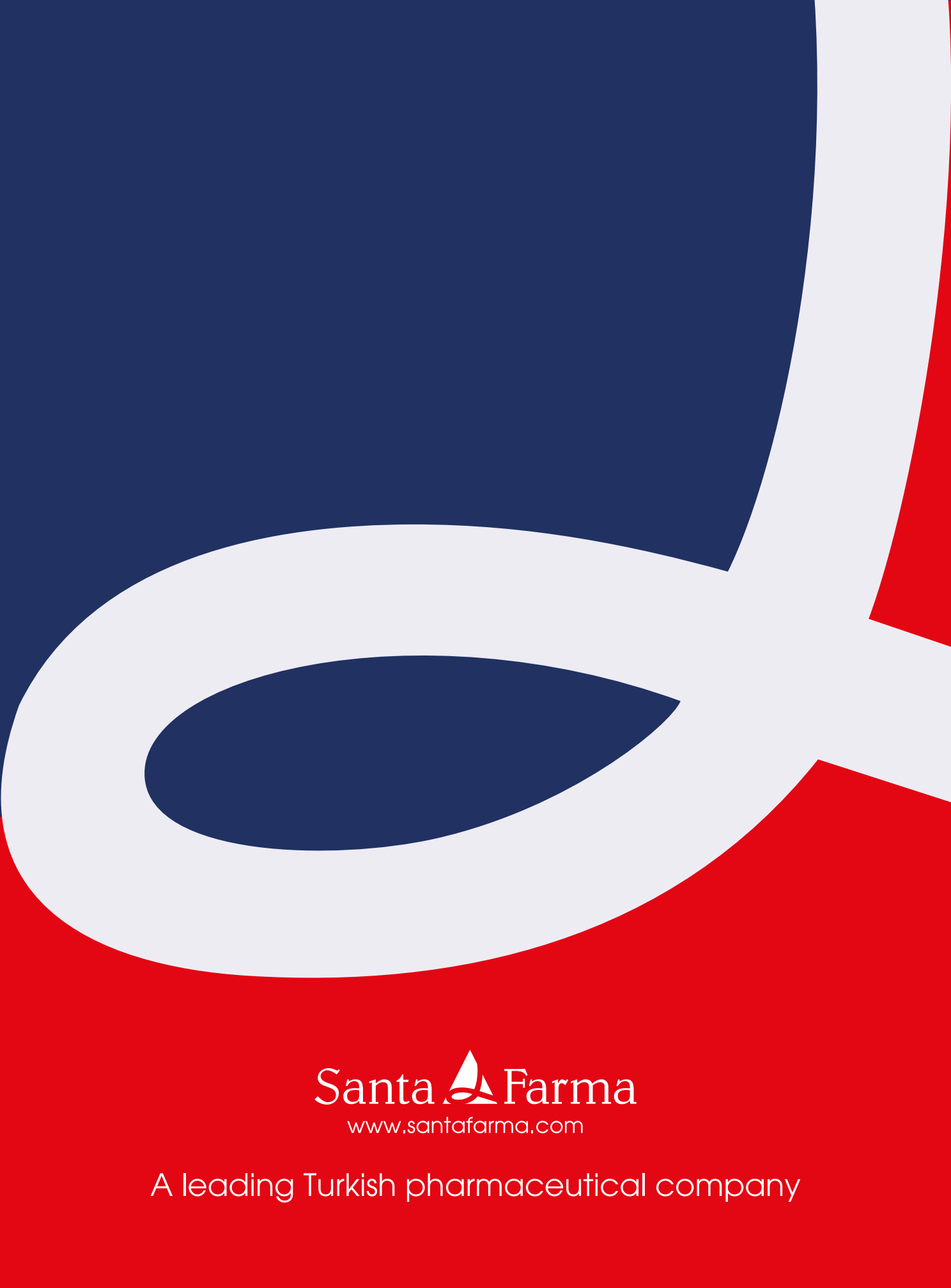
EMIN FADILLIOĞLU

Chairman of Turkey's Association of Research-Based Pharmaceutical Companies (AIFD)

"From the government's point of view," explains Emin Fadıllıoğlu, the chairman of Turkey's Association of Research-Based Pharmaceutical Companies (AIFD) and GSK's VP and Area GM Pharmaceuticals, "they made a very successful transformation project in healthcare, which of course caused pharmaceutical imports to increase, increasing the deficit. As a result, they have implemented two policies; containment of pharmaceutical expenditures, and incentivizing investments to increase local production to substitute imported products."

Regarding the government's goals, Fadıllıoğlu believes that "the methodology behind their approach may benefit from some fine-tuning… [and] the targets the government has set should be reconsidered." Highlighting the fact that a major motivating factor behind the pharmaceutical spending containment policies is that "pharmaceutical products are the fifth largest cause of Turkey's foreign trade deficit," he argues that "the real problem is that Turkey exports too little in terms of both goods and services… pharmaceutical exports are just a fraction of imports [USD 828 million], under 20 percent." Instead of trying to minimize pharmaceutical imports, worth USD 4.347 billion in 2014 according to TurkStat, if Turkey were to heavily incentivize companies to bring "manufacturing for global top 20 products, potentially only a single blockbuster product, it would bring more value to Turkey than localizing production of hundreds of generic products." Fadıllıoğlu concludes, "I fully understand and support the government's overall goal of reducing the trade deficit in pharmaceuticals, but it can be achieved more readily by adjusting prices to reflect the value of pharmaceutical products, rewarding companies that invest in Turkey, and working to improve Turkey's competitiveness relative to other countries."

The repercussions of the government's current policies illustrate the costs associated with this approach. For multinationals and domestic companies alike, the primary issue is that the government has not implemented the reference pricing system in the way that it was initially outlined to the industry; discounts were introduced arbitrarily, and the exchange rate was not updated to reflect market prices as originally promised. As such, "there are two court cases regarding the pharmaceutical prices against the government at present, one of them on behalf of the industry, and the response so far, raising the exchange rate used to calculate the reference prices from 1.9595 to 2.0 TRY [and then TRY 2.0787] per EUR was relatively insignificant," according to GSK VP and AIFD chairman Emin Fadıllıoğlu. For AIFD members, "a sustainable pricing model must be introduced, which will start by adjusting the exchange rate to reflect the market rate, before we can have any meaningful discussions about increasing investment in Turkey substantially." Without significant pricing reform, attracting investment will remain difficult, and without large-scale investment, increasing the value of Turkey's pharmaceutical exports will remain a slow and uncertain process.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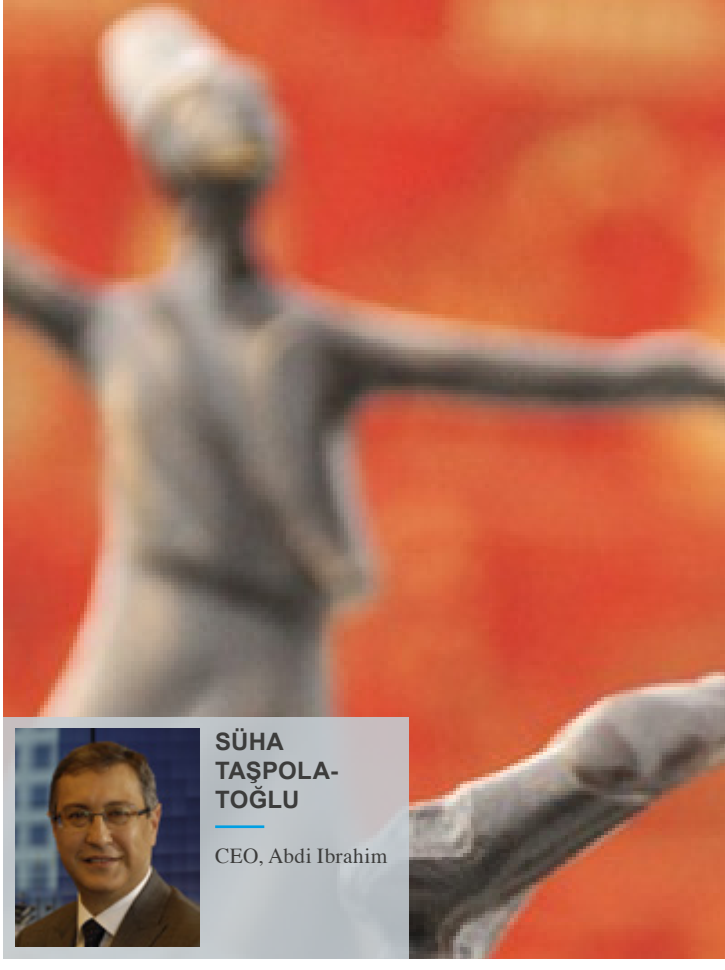
TAKING THE TURKISH FLAGSHIP GLOBAL



SÜHA TAŞPOLA-TOĞLU

CEO, Abdi Ibrahim

Preface: Turkey's leading pharmaceutical company is in the process of developing production facilities abroad, and it has just begun construction of a USD 100 million biotech facility; CEO Süha Taşpolatoğlu believes that these two steps will help bring the company closer to its aspiration of becoming a pharmaceutical player on the global stage.

HCLS: Abdi Ibrahim is the leading Turkish pharmaceutical company; what unique traits have allowed the company to be so successful in Turkey?

SÜHA TAŞPOLATOĞLU: Abdi Ibrahim is one of the oldest companies in Turkey, at 103 years of age, and it is still a family owned company. If you look at Abdi Ibrahim's existing model, which the company has been using successfully for many years, it is quite unique. Abdi Ibrahim is a local company, but nearly 50 percent of our revenue comes from original products of which Abdi Ibrahim is the licensee. Working with originators has not only contributed to Abdi Ibrahim's success in the past, but has also allowed our people to develop and learn through collaborating with our partner companies. Over the years, we have taken the competencies learned in this process and implemented them in our business in Turkey, which has differentiated us from the other Turkish pharmaceutical companies.

As for our entrance into the biotech business, we are planning to become involved in all of the fields where there are already biological products on the global market, primarily oncology, rheumatoid arthritis, diabetes mellitus, and hematology. Our objective is to effectively bring existing biosimilar products to Turkey by collaborating with foreign manufactures to develop local production, and with these partners we will hopefully be able to produce our own versions of almost all of the biological products currently available on the market. Most important effect of bringing biosimilar versions of original products to Turkey, will be that the trade deficit is going to decrease substantially.

HCLS: In terms of size and scale, Abdi Ibrahim has a very large facility in Esenyurt with a capacity of 350 million units, which is fully EU GMP and cGMP approved. How much of the capacity distributed between production for local sales, exports, and toll manufacturing?

ST: In 2015, we expect to produce a total of 220 million packs by the end of the year, with approximately 25 percent of this volume produced on behalf of our toll-manufacturing clients.

Our total business outside of Turkey will be about USD 50 million this year, which includes exports to countries where we have partnerships and affiliates like Algeria, Kazakhstan, Georgia, and Azerbaijan, as well as exports to our partners mainly in Europe. With regard to our partnerships with European companies,

many of these are for products that we co-developed with them and now produce, while they commercialize these products globally. We currently produce a number of products for many multinational generic companies for Germany, the UK, Holland, Canada, and other developed countries.

HCLS: Abdi Ibrahim is developing new production facilities in Kazakhstan and Algeria; going forward, what role will Turkey play as a manufacturing base, relative to foreign production at your new sites?

ST: Turkey will continue to be the primary center for production; although there may of course be some opportunities to export from Kazakhstan and Algeria to other countries in their regions, this was not something that we factored into our decision to make these investments. Our decisions were motivated by the incentives offered by the respective governments, and our P&L and feasibility studies were based purely on sales potential with the local markets. In Kazakhstan, we have signed an off-take agreement with the government, and will be the exclusive provider of certain products to hospitals in Kazakhstan for several years. The situation in Algeria is a bit different. We exported approximately USD 25 million to the Algerian market in 2008, however, after the localization rules were introduced, we lost much of this business; building a facility will allow us to sell our products in Algeria once again.

Of course, once complete, we will explore what export opportunities are available. Algeria will likely become a minor-hub for exports to Tunisia and other Maghreb countries, while Kazakhzstan will be well positioned to reach other central Asian markets and potentially Russia. However, we were recently made aware that the regulatory agreements between Kazakhstan and Russia are likely to change, but the nature of this potential change is unknown.

HCLS: Germany has Bayer, France has Sanofi, the UK has GSK, while other countries like South Africa have companies like ASPEN; what needs to change or be adapted in Turkey for Abdi Ibrahim to become a global brand?

ST: I agree that if there is a Turkish company that can do this, it is Abdi Ibrahim. I say this primarily because of the company's ownership; while many of the owners of Turkish pharmaceutical companies have already or are trying to sell their companies and get out of the industry, Abdi Ibrahim's board is still pushing their business forward, and willing to take risks and invest to take the business in new directions. Furthermore, our current investment strategy will certainly help increase Abdi Ibrahim's presence on the global market. It is also worth noting that we have the moral support of the government in Ankara as well; many officials have openly told us that Abdi Ibrahim is the company with the potential to become a Turkish multinational pharmaceutical company.

MIND THE GAP!

Preface: Turkish pharmaceutical companies are working hard to ensure the quality of raw materials; both domestic and imported. However, compared to EU standards, a regulatory gap exists which makes ensuring sustainable product quality a difficult task.

PERVIN EJDER
Managing director of Ejder Kimya

HASAN ULUSOY
Chairman of Nobel

In total, there are 12 raw material manufacturing facilities in Turkey according to the IEIS, nine owned by Turkish manufacturers such as Deva, Atabay and Nobel, and the strategies behind their use vary considerably. Hasan Ulusoy, chairman of Nobel, explains that "European authorities appreciate that we produce some of our APIs ourselves, in facilities that they have approved, because this ensures the quality of the API. For Atabay, who focus primarily on primary care products, producing their own APIs allows them to keep costs down while ensuring consistent high quality, while, according to Haas, Deva uses their capabilities "to produce products where the APIs are difficult to purchase. For example, we produce the active ingredient for imatinib… and our product was the first generic to reach the market." As such, the vast majority of raw materials are imported, with a growing proportion coming from lower-cost suppliers in India and China.

Relative to European standards, a gap exists in Turkish regulations regarding these imported inputs. "Currently, in Turkey it is solely the responsibility and challenge of the manufacturing company to procure good quality and safe raw materials," explains Murat Çıtıroğlu, business development director at Ekin Kimya. While the majority of Turkish manufacturers can uphold this responsibility effectively, he argues that "if the procuring company does not have substantial experience and a reliable network in markets like India and China, it is very difficult, almost impossible, to ensure a sustainable product quality," when importing from the thousands of API producers in these countries. Furthermore, Ümit Yaldiz, head of the Merck Millipore business in Turkey, warns that "we cannot ignore the fact that there is heavy and severe price pressure, and for some companies with weaker internal ethical and quality controls, this means they may find cheaper sources for inputs which are of doubtful quality and don't have the best documentations."

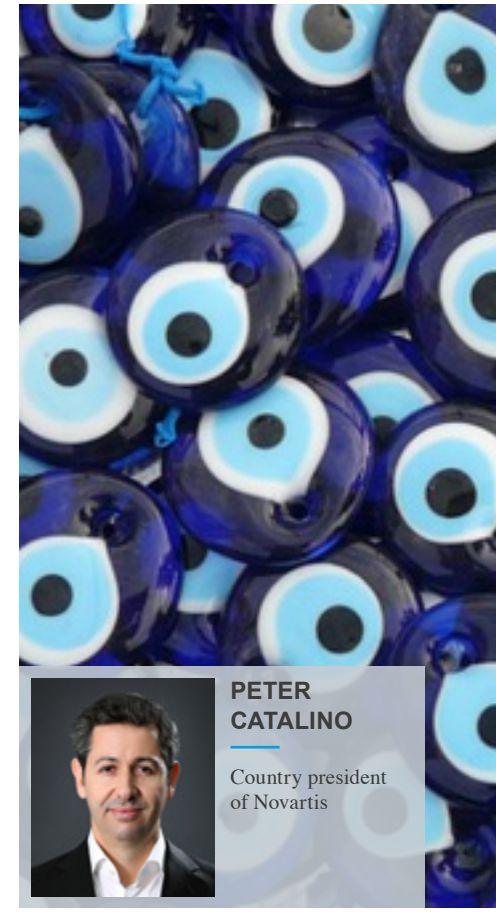
Distributors such as Ekin Kimya and Ejder Kimya have gone to great lengths to ensure that they

can provide clients with well priced products of reliable quality, eliminating the risks that companies might face in trying to select their own Indian or Chinese supplier. Pervin Ejder, managing director of Ejder Kimya, explains that when working with suppliers from low cost markets "quality assurance can certainly be found simply by performing enough due diligence and selecting the right partner that seamlessly aligns with a company's own standards." As a distributor, Ejder Kimya carries out much of this due diligence, and manufacturers are generally glad to work with them because "all of our multinational and local customers, especially when it comes to APIs, are aware of the detrimental implications of valuing price over quality."

Ekin Kimya has gone one step further, and "opened a sourcing office in Mumbai two and a half years ago," according to Çıtıroğlu. "Through this office we are able to audit, inspect and monitor our suppliers to ensure that the products we are importing to Turkey are of quality that we are comfortable bringing to our customers. This way we are able to provide different grade products at different price points, but of tightly monitored consistency, to our clients."

That said, a regulatory gap still exists as there is no government oversight of the quality of raw materials used, and it is possible that a company could utilize products of unknown quality; "there needs to be tighter controls on the quality of chemical supplies and raw materials, both legally and from the companies themselves," according to Yaldiz. Due to this gap, many in the industry believe the government should follow the lead of the European directorate for the quality of medicines (EDQM), and require a "written confirmation." "The written confirmation is a document demanded for each active substance. It has to be issued by a competent authority of the exporting country and confirms that the standards of good manufacturing practice and control of the manufacturing plant are equivalent to those in the European Union," explains Çıtıroğlu. He continues "The government is responsible for public health, and must set the rules for the market to ensure that all the products produced and sold in the country are safe, which means introducing policies to ensure that producers are using good quality excipients and APIs. We have discussed this issue with the industry leaders in Turkey, and they agree that in Turkey it will be to the benefit of the public and the industry to follow the EU's regulations."

STIMULATING INVESTMENT THROUGH R&D



PETER CATALINO
Country president of Novartis

Preface: Novartis country president Peter Catalino discusses the need for Turkey to introduce financial investment incentives to compete more effectively with other countries for investments in R&D and manufacturing.

HCLS: Despite the lack of R&D incentives, companies are bringing R&D to Turkey, ranging from clinical trials to basic pharmaceutical research. What is on Novartis's R&D agenda for Turkey?

PETER CATALINO: Novartis is doing about a quarter ¬of the clinical trials in the country at present, making us the largest sponsor of clinical trials in Turkey. We're working very closely with a number of university medical centers to look at diseases that are of interest globally, as well as some that are specific to Turkey. There are several diseases with high prevalence rates in Turkey, such as Behcet's disease and the colchicine resistant strain or Familial Mediterranean Fever (FMF), a hereditary inflammatory disorder, being areas with unmet medical needs.

Our R&D efforts in Turkey have been focused on the development side so far, with particular emphasis on these areas that are prevalent in Turkey, so that Turkish patients can get access as early as possible. Moving into research is on the next horizon, however our first priority will be to get true incentives for clinical trials, before moving towards earlier research.

HCLS: Turkey is encouraging the development of biotech production in Turkey; as a leading biopharmaceutical company, what is your outlook on the role biosimilars can play in the Turkish market, and do you have any plans to support the development of this side of the sector?

PC: With regards to local production, we do have plants here working in small molecule production. Before we expand into large molecule production and the investment that entails, we would like to see some real return on our investments in small molecule manufacturing. Very few multinationals still have manufacturing plants in Turkey, and several of those that do are looking to divest instead of investing more; it one of the key challenges for the industry. Before we would be able to consider an investment on the scale of a biologics plant, we would need to see much stronger investment incentives that were more competitive with those offered in other countries.

HCLS: Based on your recent discussions with the government, what are you expectations in terms of introducing well-defined incentives, or reforming the current pricing system?

PC: Our recent discussions have been quite positive and productive, and our main goals are fully aligned with the government; to provide healthcare for more as

much of the population as possible, meaning more than 98 percent of Turkish people. The coverage here is very good, especially for an emerging market, and the counterbalance is the low pharmaceutical pricing environment, with prices among the lowest in the world. We are now focusing on finding ways to ensure that this excellent coverage is sustainable, from both the industry's side as well as the government's, and to do so in a way that is local, helps with the current account deficit and brings R&D activities to Turkey.

We are hopeful that we can come to an agreement that will make sense from the government perspective, and make it attractive for multinational pharmaceutical companies to invest in Turkey, as current incentives are not adequate. Strategically, the government should incentivize local production, not just to substitute for imports, but to attract more valuable production on a larger scale; technologically demanding or innovative products with strong export potential. Turkey has the resources needed for this to be possible, with a lot of very talented people with experience in pharmaceutical production, but there has to be a reason to invest in Turkey instead of another county. If you look to other countries where Novartis has made large R&D investments, it is clear that Turkey has much room for progress. One of Novartis's three global headquarters for R&D is in Shanghai; we worked closely with the Chinese government who had a strong desire to attract R&D investments to the country, and they were willing to offer significant financial incentives to make it happen. This is an example that Turkey could learn from, as investment incentives are inadequate; further contributions from the government could take a variety of forms, the most evident being adjusting pharmaceutical prices to a reasonable level, giving VAT discounts or rebates, or a variety of other mechanisms.

HCLS: How would you define success for the pharmaceutical industry in Turkey over the next five years?

PC: Success could mean closing the gap between Turkey and more developed markets in Western Europe and the US, where patients get access to medicines years earlier than they do here in Turkey. On average, medicines reach the Turkish market three years after they do in the US and EU. Improving the market access situation to reduce this three year delay will make a difference for everyone involved in the healthcare sector, most importantly the patients who's lives can be saved by innovative medicines that can be stuck in the lengthy approval process.

TURKEY

NAVIGATING THE CROSSROADS

The 21st century has brought much change to Turkey. GDP tripled from under USD 267 billion in 2000 to over USD 822 billion in 2013. Massive infrastructure projects created over 13,000 km of roads, 24 new airports, 88 new universities, and 650 hospitals. For the healthcare and pharmaceutical industry, this period was defined by the Healthcare Transformation Program (HTP), which saw the complete overhaul and expansion of the Turkish Healthcare system between 2003 and 2013, with three separate social security agencies combined into a unified social security institution (SGK). During the same period the private sector was expanded and brought into the national reimbursement system, and more than 98 percent of Turkey's population were brought under national insurance coverage.

THE END OF AN ERA

This transformation caused pharmaceutical sales volumes to skyrocket at a 9.6 percent CAGR between 2003 and 2013, according to the Turkish Drug and Medical Devices Agency (TITCK). The reimbursement rate increased to more than 95 percent, and patient access to healthcare services and general healthcare awareness improved each year. Of course, achieving this status quo came at a price, and after seeing healthcare expenditure begin to rise rapidly in the late 2000s, the government instituted aggressive public discounts in 2009 and 2011 to contain spending. As such, pharmaceutical expenditure grew by just three percent in real terms over the same period.

"At the time we took office in 2002, Turkey was not in a good position with regards to the economy, various social issues, and of course the state of the public health system," explains the former minister of health Recep Akdağ, who led the transformation program. "The entire country was waiting and hoping for change, and the expectations for this change to happen were very high. This was both an advantage and disadvantage for us; we were able to gain strong political commitment and public support which were essential for reforms of the magnitude that were required… We were able to achieve real progress through our efforts, and together the changes that were made transformed the healthcare system in Turkey to the extent that it is now being used as a model for many developing countries." Minister of Labor and Social Security Faruk Çelik states that the Healthcare Transformation program is "now used as an example of good practice in healthcare systems around the world," and that due to the reforms Turkey has "a new social security system, which is more compatible with international standards, offers high quality services, covers the entire population, and is financially stronger than before."

Since the transformation program's reforms ended in 2013, and with it Akdağ's ten year mandate as minister of health, the driving force for change and progress in the sector

MEHMET MÜEZZINOĞLU
Minister of health

RECEP AKDAĞ
Former minister of health

YADIGAR GÖKALP İLHAN
President, Social Security Institution (SGK)

CEM BAYDAR
Lead Consultant, IMS

NEZIH BARUT
Chairman, Abdi Ibrahim

SÜHA TAŞPO-LATOĞLU
CEO, Abdi Ibrahim

faded away. The need for a new vision for the sector arose, as well as the opportunity for the industry associations to play a role in developing the government's new strategic plans, particularly in the pharmaceutical industry. Murat Barlas, chairman of Liba Laboratories and the senior board member of the Pharmaceutical Manufacturers Association of Turkey (IEIS), explains that "the current plan for the pharma sector until 2023 was prepared by the industry and delivered to the government." This plan was published by the association in November 2011, in a report entitled 'Partnering with the Government to Globalize the Turkish Pharmaceutical Industry,' while the AIFD published a similar strategy document in 2012 titled 'Turkey's Pharmaceutical Sector Vision 2023 Report', and the two garnered enough attention that several items from their action plan surfaced in the government's own plans, including the national Tenth Development Plan.

"Going forward, we will be prioritizing R&D initiatives, including health studies and medical innovation," details Akdağ's successor, minister of health Mehmet Müezzinoğlu. "It is for this purpose that we founded the 'Department of Health Institutions of Turkey', which will follow developments in medicine closely. The Ministry of Health is encouraging the production of medical devices and medications in Turkey, and we will be supporting the development of vaccines, biosimilars, and other high value added medicines in Turkey." Article 1.16 of the Tenth Development Plan outlines a 'structural transformation program within the health industry,' and includes the target for 60 percent of pharmaceutical products and 20 percent of medical devices consumed in Turkey to be produced domestically by 2018. Other targets for the healthcare and pharmaceutical industries have been set under the auspices of President Recep Tayyip Erdoğ an's '2023 Vision', a set of goals for the country to achieve by the 100th anniversary of the Republic of Turkey's foundation in 1923, which include aggressive targets for increasing exports and improving competitiveness for R&D investment.

While much progress is being made, questions remain regarding the feasibility of achieving these goals, and the effectiveness of the initiatives that have been introduced thus far. "The vision that the government has for the pharma sector will be achievable only if it changes its perspective on the industry as it stands," argues Barlas. He explains that "today, for our government, the most important issue is the cost of healthcare and pharmaceuticals… if this perspective shifts and we are able

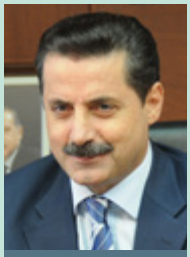
SELECTED KPI TARGETS FROM VISION 2023 ACTION PLAN

	2014	2023
Innovation Capacity	71st	Top 20
Quality of Scientific Research Centers	89th	Top 30
Retaining Scientists and Engineers	35th	Top 20
Number of new local molecules	0	At least 1
Number of clinical trials condusted in a year (2013)	1.267	Approx 3.600
Export/Import ratio	10%	107%

Source: AIFD, Vision 2023 Report; Ministry of Science, Industry and Technology, TurkStat, Deloitte Analysis.
Compiled by Investment Support and Promotion Agency of Turkey.

ERSIN ERFA
General manager, Centurion

BERK ÖZDEMIR
General manager, Omega CRO



FARUK ÇELIK
Minister of labor and social security

FATMA TAMAN
Chair, ISPE

to communicate our needs better to the government, then achieving this vision may yet be attainable." Yet, much progress is being made across the industry with numerous biosimilar development projects underway, and other investments in higher value manufacturing activities taking place. In fact, while "some existing policies are still contradictory to this 2023 vision," Pfizer country manager Elif Aral alleges that "the government has made it clear that they will support the industry moving forward, and not continue to treat it as a cost that must be contained."

METAMORPHOSIS UNDER PRESSURE

In terms of Turkish Lira, pharmaceutical spending returned to above inflation growth in 2014, rising 10.1 percent to TRY 16.3 billion (USD 7.45 billion) in 2014, after actually falling 4.1 percent in 2012, according to IMS and TurkStat. However, local manufacturers are quick to point out that this growth is not distributed evenly across the industry. Cengiz Celayir, president of the Pharmaceutical Industry Association of Turkey (TISD), points out that "original imported products make up only three percent of the market by volume, but have a market share of 27 percent in terms of value, and this is the segment that is seeing some revenue growth at present."

Santa Farma chairman and CEO Erol Kiresepi argues "this is the problem faced by the local industry today. Our prices are low, and the products we're offering on the market are primarily generics…the market increase last

World Medicine: an emerging giant

ROVSAN TAGIYEV
—
Founder & chairman, World Medicine

World Medicine, the Turkish member of World Medicine group of companies, has turned heads with their strong entrance into the industry since 2011. Thus far the company has built two facilities in Turkey; a modern R&D center and an EU GMP certified pharmaceutical plant with a production capacity of 70 million units in a wide range of dosage forms. Moreover, the group has plans to build three more plants in the country within the next five years. As a strongly export oriented company, they currently export 95 percent of the pharmaceuticals that they manufacture in Turkey, although they aim to increase local sales to 30 percent in the coming years as they further penetrate the competitive Turkish market. The company has also been quick to throw its support behind the government backed initiatives for the pharmaceutical industry, as outlined in the context of President Erdoğan's 'Vision 2023' for Turkey. "World Medicine operates in order to realize the plan of our president," explains Rovshan Tagiyev, its founder and chairman. "We have worked hard to expand our global footprint in recent years, registering products around the world, and developing new products. In recognition of our efforts, World Medicine received a prize directly from President Erdoğan in April 2015, specifically for being the Turkish company with the greatest number of trademark applications globally." The company's willingness to collaborate and align itself with the government priorities has already generated strong returns; Tagiyev explains, "With the support the Turkish government in general, and specific investment incentives, we have begun developing our own biotech laboratory which will be complete in 2016."

> "The future of local producers will lie in specialty products, OTC, and exports"
>
> **Erol Kiresepi, Santa Farma**

year has primarily been a result of high value, low volume products coming from multinationals." In line with the government's heavy emphasis on R&D and producing more value added pharmaceutical products, Kiresepi asserts that "companies need to focus on building up exports, reinforcing R&D, and restructuring portfolios to account for changing market dynamics. As such, he contends "the future of local producers will lie in specialty products, OTC, and exports, all of which we're currently building up our capabilities in."

"The pricing situation is now a fact of life," says Cem Baydar, senior principal consultant for IMS in the Turkey and Near East region. Reference prices in Turkey are constructed from the lowest price in France, Greece, Italy, Spain or Portugal, converted to Turkish Lira at a rate of TRY 1.9595 per EUR, and then the public payer, the SGK, pays a discounted price, which was set in agreement with the industry consensus in 2009 at 11 percent. In December 2009 the government arbitrarily raised the discount rate to 23 percent, then to 31.5 percent in December 2010, and again to 41 percent in November 2011; the conversion rate was not changed at all until June 2015, when it was raised by 2.07 percent to TRY 2.00 per EUR, and in July it was increased by another 3.9 percent to TRY 2.0787

WORLD MEDICINE

Pharmaceutical Company

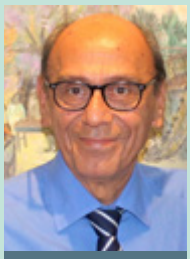
Health is a treasure we share

WORLD MEDICINE İLAÇ SAN. VE TİC. A.Ş.
Evren Mahallesi, Camiyolu Caddesi No:50 Güneşli / İstanbul
+90 212 474 70 50 +90 212 474 09 01 www. worldmedicine.com.tr

ÜMIT DERELI
General secretary, AIFD

EMIN FADILLIOĞLU
VP and Area GM, GSK Pharmaceuticals, Turkey and Caucasus region

CENK SOKMEN
General manager, Genzyme



MURAT BARLAS
CEO, Liba Laboratories

per EUR, at which point the market exchange rate was approximately TRY 3 per EUR. As a result, Turkish pharmaceutical prices are now at approximately 38 percent of the lowest prices in Europe, save in a few special circumstances where alternative pricing arrangements are in place.

Ümit Yaldiz, head of Greater Turkey for Merck Millipore, argues that "with the change in the pricing model… companies were forced to restructure their businesses and overhaul their operating models; as such, the industry has become much more efficient, and much more competitive in the global arena, and from this perspective cutting prices was the right move and the policies have had a positive impact." Cem Baydar of IMS explains that "companies had to adapt and implemented change management programs that are now mostly completed," detailing how the top ten companies have reduced their sales forces by 44 percent over the last five years.

On the topic of spending growth, Baydar says that "the market has changed and is going in a new direction… specialty care is on the rise… and the hospital channel is outpacing the retail channel; sales in the hospital channel increased by 20 percent last year, while retail only increased by 8 percent," and will continue to grow with the "growth of private hospital chains and the opening of new public hospitals."

The healthcare system itself is growing rapidly, including the private hospital sector, which is tied closely to the public system. "70 percent of patients in private hospitals are referred from the public system and are covered [at least partially] by social security," explains Cevat Sengül, secretary general of the Association of Private Hospitals and Health Institutions (OHSAD). "18.9 percent of Turkish hospital beds and 23.8 percent of specialist physicians are in private institutions," according to Sengül, yet private hospitals "have 38.3 percent of the ICU beds and perform 53 percent of class A1 surgeries,

the most complex category of procedures." Furthermore, the private sector is expected to grow significantly: Sengül expects "that by 2020, the sector's revenue will double to USD 20 billion."

For the pharmaceutical industry, this means that the private hospital system represents a large and fast growing market. Ufuk Kumrulu, chairman of IV solutions manufacturer Polifarma, explains that "the private healthcare sector has been growing strongly since the early 2000s, and Polifarma identified this trend early on, so we have sold and marketed to private hospitals for many years now." According to Kumrulu, "today 30 percent of the total [parenteral solution] product consumption is in the private system, and we think the private sector's share of the market will continue to grow over the next several years."

The public sector also continues to grow, with new hospitals being opened across the country and occupancy rates rising. "In public hospitals, the system is based on tenders," explains Kumrulu, and this tender process began to change in the last year, "as in all cities' hospital management systems, purchasing, and stock management have been consolidated underneath a single institution, which has raised the size of tenders and depressed prices."

While it is critical that Turkey invests in expanding its healthcare system to ensure that infrastructure is able to support the growing demand for healthcare services as Turkey's population ages, the country must also invest in physicians to get the best value out of those investments. "The current defining circumstance in Turkey is that we have limited human resources in healthcare and have the lowest number of doctors per capita in Europe," explains

> "By 2020, the [private healthcare] sector's revenue will double to USD 20 billion"
>
> **Cevat Sengül, OHSAD**

former minister of health Akdağ . UCB's managing director, Özdemir Şengören, indicates that this shortage creates significant access problems for patients. "When you drill down," she says, "you discover that in Turkey there are patients that have had an epilepsy diagnosis for many years… who still complain that they can't find … an epileptologist, to treat them. Patients also complain that when visiting hospitals, they can't ask their physicians the questions they have because each patient has very limited time with the doctor," due to the incredible number of patients each physician must see each day.

Murat Uslu, general manager for Actelion Turkey, echoes Şengören's comments. "The Turkish healthcare system has a lot of excellent facilities, while some others have quite a way to go in terms of equipment and workload, and this of course affects physicians' ability to efficiently diagnose patients. The number of physicians, and the number of specialists per capita is very low in Turkey, making it difficult for physicians to dedicate sufficient time to each patient."

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

RECORDATI

RECORDATI İLAÇ
GROUP

TOP 20 LEADING CORPORATIONS* SALES GROWTH

SALES GROWTH BY VALUE

		VALUE GROWTH '13 - '14	COMPOUND ANNUAL GROWTH RATE '10 - '14
1	NOVARTIS	10.6%	-0.4%
2	SANOFI	10%	-1.1%
3	IBRAHIM	9.9%	-0.6%
4	PFIZER	2.6%	-1.5%
5	ROCHE	19.8%	11.1%
6	BAYER	5.6%	2.6%
7	GSK	5.2%	-2.3%
8	BILLIM	-2.2%	-2.1%
9	AZ	-0.1%	-1.9%
10	MSD	8.9%	-2.9%
11	EAST PHARMA	10.1%	3.5%
12	NEUTEC İLAÇ	8.7%	17.2%
13	NOVO NORDISK	15.5%	12.8%
14	SANOVEL	2%	-2.4%
15	ABBOTT	20.2%	7.1%
16	ECZACIBAŞI-BAXTER	25,8%	22,1%
17	NUMIL	18,5%	27,3%
18	BOEHRINGER INGELHEIM	4,9%	0,6%
19	JANSSEN	-2,1%	6,5%
20	IBRAHIM ETHEM	4,9%	-4,9%

Multinationals continue to dominate the top 20; with Eczacıbaşı-Baxter leading in value growth

SALES GROWTH BY VOLUME (BN SU)**

		VOLUME GROWTH '13 - '14	COMPOUND ANNUAL VOLUME GROWTH RATE '10 - '14
1	NOVARTIS	1.8%	2%
2	IBRAHIM	4.7%	-0.7%
3	BILLIM	-3.7%	3.7%
4	GSK	0.9%	6.4%
5	BAYER	-5.8%	-2.3%
6	SANTA FARMA	8.3%	6.5%
7	SANOFI	3.2%	1.6%
8	EAST PHARMA	4.5%	3.8%
9	SANOVEL	4.5%	15.4%
10	IBRAHIM ETHEM	-5.6%	-0.4%
11	PFIZER	-6.8%	1.2%
12	ALI RAIF	0.2%	3.3%
13	ASTRAZENECA	2.2%	6.5%
14	NEUTEC İLAÇ	26.4%	28.2%
15	RECORDATI	6.5%	8.9%
16	SERVIER	6,5%	8,9%
17	ATABAY	2,3%	13,8%
18	BOEHRINGER INGELHEIM	-7,5%	-0,3%
19	ABBOTT	10,7%	7,2%
20	PHARMACTIVE	84,6%	16,1%

Neutec İlaç and Pharmactive stand out with high long-term and short-term volume growth

*Novartis includes Sandoz and Alcon; Sanofi includes Zentiva, Genzyme and Sanofi Pasteur. **One Standard Unit is equal to one dose.

Source: IMS Dataview Retail Hospital Database, December 2014.

International Turkish brand in pharma

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

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

NOBEL

ULKAR HOLDİNG

ULKAR KİMYA

NOBEL AFF Kazakhstan

NOBEL PHARMSANOAT Uzbekistan

GeneriNobel

Nobel: the global Turkish brand

HASAN ULUSOY
Chairman, Nobel

Nobel is Turkey's most internationalized pharmaceutical producer, having begun the process of developing international operations in the early 2000s, when they "established subsidiaries outside of Turkey, and then built two foreign production facilities in Uzbekistan and Kazakhstan," according to the company's chairman, Hasan Ulusoy. "In 15 years, we have established offices with our own marketing teams in 24 countries, and our products are marketed and sold in nearly 50 countries in total," he explains, pointing out that in 2014 "our turnover outside of Turkey reached a value of USD 120 million, while our export volume from Turkey grew to USD 60 million, which represents more than 1/14th of all Turkish pharmaceutical exports." More than just establishing a strong international presence, Nobel is the only Turkish company to have established a pharmaceutical brand on a global scale. The firm's Tylol Hot brand "has become one of our flagship products, which we are marketing in 20 different countries under the Tylol Hot brand, and this makes it the only Turkish pharmaceutical brand with significant international recognition at present." Regarding the future, Ulusoy hopes "that the company can continue to expand in an international way, and become a truly global company. Competition abroad is tough, but so is it in Turkey, and we have developed excellent quality standards and a large, strong portfolio over the years, so we are well prepared to compete with international and local companies in other markets."

WHY INVEST IN TURKEY?

ŞEBNEM AVŞAR TUNA
General manager, Novo Nordisk

AHU YAZICI
General manager, BMS

ASGAR RAGOONWALA
Managing director, Janssen

PROF. DR. ÖZKAN ÜNAL
Turkish Drug and Medical Devices Agency (TITCK)

"Turkey is already an attractive investment destination for multinational pharma companies for a variety of reasons, including geographic location, market size and composition, the aging population of 75 million people and likely healthcare spending escalation in the future," explains Ümit Dereli, secretary general of the AIFD. "More importantly, the timing is right as Turkey is still in a phase of fast economic growth relative to developed economies. The timing will not remain this favorable for long, and there are a number of factors that are discouraging investment in the industry, from Turkey or abroad, at present." Dilek Bayraktar, secretary general of the innovative medical devices industry association (ARTED), adds that "the average Turkish person is still getting used to having access to publicly reimbursed healthcare services, so healthcare demand will certainly rise on both a per capita and aggregate basis. Economic growth is also expected to continue at a rate above that

Polifarma: from parenteral to hospital solutions

Polifarma has manufactured parenteral solutions for two decades, but after investing in a new facility, the company started to expand into hospital IV products. "We saw there was a need for locally produced IV solutions since most of these products were being imported," according to the company's chairman, Ufuk Kumrulu. With the capability to produce "a range of basic IV parenteral solutions and hospital IV solutions in a variety of forms and volumes, including polypropylene (PP) bags, PP bottles, polyvinyl chloride (PVC) bags, and glass bottles," Polifarma is the most versatile parenteral solutions manufacturer in Turkey, and has a strong position in the market, having achieved a market share of 41 percent in 2014. With a new aseptic production line currently in development that will support the expansion into hospital IV products, Polifarma is well positioned to grow within Turkey, and to begin expanding abroad more aggressively. So far, Polifarma's product development strategy has been driven by "our ability to produce a variety of products in terms of volume and form to change the demand of our customers by offering them new options that are currently unavailable on the market… to offer our clients the products they want in the size and form they want," according to Kumrulu. Going forward, the same principle will be applied to the hospital solutions business, where Polifarma will offer "pre-mixed products that fit the precise needs of our clients." As an example, Kumrulu explains that "all moxifloxacin products on the market were in glass vials [that had to be mixed into a solution] prior to our to our launch of Moksilox, our pre-mixed PP IV bag solution… hospitals liked this product and strongly adopted it, and we established a 70 percent market share in the first year." As a long term objective, Kumrulu's "goal is to transform Polifarma's image in hospitals, and to become a market leader not just in basic IV solutions but in hospitals in general… While we are now known in hospitals as a basic IV producer, hopefully they will start to say 'hospital solutions producer' in the near future."

> "Economic growth is expected to continue … and Turkey continues to be the most stable country in the region .... investing in Turkey makes sense"
>
> **Dilek Bayraktar, ARTED**

of the developed economies… and Turkey continues to be the most stable country in the region. On the whole, investing in Turkey makes sense; the remaining challenges are making it attractive for medical device manufacturers specifically." This situation is the same for the pharmaceutical industry, with Novartis country president Peter Catalino saying that despite the attractive economic factors, Novartis "would need to see much stronger investment incentives that were more competitive with those offered in other countries," before considering large scale investments in Turkey.

In fact, some companies have recently chosen to invest in Turkey on these macroeconomic factors alone, despite the lack of competitive pharmaceutical investment incentives. Recordati recently made the decision to develop a second production plant in Turkey, with a planned investment of USD 50 million. "Turkey's entrepreneurship friendly environment is one of the two main reasons why it is the right time for Recordati to invest here," explains

İsmail Yormaz, VP and regional director for Recordati's southeast region. "The other reason is the demand, the need that currently exists in Turkey and will grow in the coming years." He continues, saying "I do not know what will happen in the short term for the Turkish pharmaceutical environment, but I am quite certain of what will happen in the mid to long-term; the Turkish pharmaceutical market will continue to grow, because Turkey has a growing population, one of the youngest populations in Europe, and as this population ages its medical needs will increase, particularly in chronic areas. For the last 12 months Turkish pharmaceutical consumption has grown in the double digits. Furthermore, Turkey has strong human resources for pharmaceutical production with a lot of expertise, experience, and knowhow. Lastly, the surrounding region also has growing needs for medication, and given the political situation in some nearby countries, Turkey is optimally positioned to supply these markets."

ŞEBNEM GIRGIN

Managing director, Lundbeck

CENGIZ CELAYIR

President, TISD

MEHMET N. PISAK

Vice chairman & CEO, Imuneks Farma

Feliz Balcay, general manager for Chiesi Turkey, echoes Yormaz, explaining that Chiesi's "aspiration is

Pharmactive: adapting to demand

HALUK SANCAK
—
Chairman,
Pharmactive

The low pharmaceutical pricing environment and demand for cost effective contract manufacturing services in Turkey has clearly influenced the design and vision behind the newest Turkish pharmaceutical manufacturer, Pharmactive. With a new facility with a capacity of 330 million units per year, built at a cost of USD 200 million, the company's first concern was "minimizing production costs to have a competitive edge," according to president Haluk Sancak. "It is a burden now but in time it will be an advantage for us, as we will benefit from significant economies of scale." While Pharmactive has its own product portfolio, and is planning on launching its first generics in the EU in 2017 and the USA by 2018 under its own name, the company's long term strategy is geared towards generating a large proportion of revenue from contract manufacturing, with the target of reaching 12 percent by the end of 2015, and 40 percent by 2020. Sancak contends that Pharmactive can bring unique value to clients as a contract manufacturer, "since our operations are still expanding and being developed, the course of this development can be influenced or molded by a third party." He continues, saying Pharmactive is "happy to accept the guidance, advice, and support of global pharmaceutical players who would like us to develop specific capabilities and technologies so we can produce their products for them, as we are seeking to establish long-term relationships with them. In this regard, Pharmactive is a production platform for the global pharmaceutical business that can be adapted to fit their specific needs."

Courtesy of Pharmactive

to position Turkey as a hub for management and manufacturing; Turkey is already positioned as a regional management center for many multinational pharmaceutical companies. However, there is still a need for a better framework for potential investors in manufacturing in the country." These multinationals include GSK, who relocated their regional management hub for their pharma business for the Middle East, North Africa and CIS regions to Istanbul in 2012. Other companies have since followed. Ilker Özbay, general manager for Daiichi Sankyo Turkey, explains that "since 2012, we have expanded our business to cover markets such as Azerbaijan, Kazakhstan, Algeria, and soon Ukraine and Nigeria… We prioritized this geographic expansion in 2012 because it was apparent that the Turkish market was unlikely to grow… [and this strategy] helped us achieve revenue growth in a stagnant market, and increase our profitability."

Thus far, the Turkish government has not introduced any meaningful incentives to encourage such investments, but due to the current market access situation in Turkey, there are certain advantages to developing local

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SAYA GRUP

UĞUR BINGÖL

Managing director Ibrahim Etem Menarini

production. Products manufactured in Turkey are given significant advantages at the reimbursement stage, strongly demonstrating the government's aim to achieve a local production rate of 60 percent by 2023. Yadigar Gökalp İlhan, president of the Social Security Institution (SGK), explains that the institution encourages "companies to produce medications in Turkey instead of importing by providing an easier payment system… With respect to incentivizing local manufacturing, some arrangements were made for adding locally produced products to the SGK's reimbursement list, and these products will have the privilege of getting reimbursement first."

HATICE DEMIRAY

Managing director, MSD

The standard of pharmaceutical reimbursement is quite high, as Novo Nordisk Turkey's general manager Şebnem Avşar Tuna affirms. "Turkish universal health insurance provides a very strong foundation for healthcare treatment in general; … we are able to provide modern insulins for the treatment of people with diabetes; established insulin products are fully reimbursed." Yet, for highly innovative products, "market access is the main barrier of growth for innovators, to the extent that one of our combination products was submitted for reimbursement 960 days ago and still hasn't been approved," says Ilker Özbay, general manager of Daiichi Sankyo Turkey. Under this incentive

structure, of strong reimbursement but sometimes slow and limited market access, the Turkish Pharmacists Association (TEB) has become the country's largest importer of registered and unregistered drugs from abroad. However, in hope of creating a more favorable appeal for foreign companies operating in Turkey, the government has begun implementing new channels that will allow these companies to play a more active role in addressing the clinical needs of Turkish citizens. "Recently, SGK commenced an initiative to involve more Turkish affiliates of multinational pharmaceutical companies [to import]," says Gökhan Gökçe, one of YükselKarkınKüçük's founding partners. "Currently, although more so in the past, trading companies have been supplying products to TEB, after which point TEB would sell to SGK. Now, the subsidiaries of those large manufacturers in Turkey will be the ones interacting with SGK and adopting alternative reimbursement models." Such an initiative will help create a shared platform for foreign companies to expand their current commercial activities in Turkey through imports, while also expanding the range of medicinal treatments available for the local population and alleviating any supply shortages for certain medications.

Under the leadership of Nezih Barut, the third generation of the family to run the company, Abdi Ibrahim has sought to become and be seen as increasingly innovative, and as such, the company embarked on a 50-50 joint venture with leading Japanese innovator Otsuka in 2012. Tuna Yavuz, general manager of the joint venture, called Abdi Ibrahim Otsuka, argues that this strong "reimbursement system poses other challenges, as reimbursement payments are currently made according to the product class, meaning that the social security institution will buy and pay for illegal generic copies of patented drugs; the responsibility of enforcing a patent falls on the patent holder, who must sue the patent violator, resulting in costly and extended legal battles."

GMP requirements and inspection timelines also indirectly encourage local production. Daniel Lucas, managing director of Lilly Turkey, explains "that since 2009, a Turkish GMP certifi cate is required prior to an application

ÖZDEMIR ŞENGÖREN
Managing director
UCB

ELIF CELIK
General manager,
Eczacibasi Baxter

MURAT USLU
General
manager, Actelion

for marketing approval, which requires an onsite inspection and thus has signifi cantly delayed the registration process." Yavuz claims that "to expedite product approvals, we decided to establish local production of our products using Abdi Ibrahim's facilities; this accelerated the GMP certification process significantly."

Many other firms have and are utilizing the option to localize production through toll-manufacturing agreements with local manufacturers. "Lundbeck is very proud to have taken action, and has transferred technology and brought innovative manufacturing activities to Turkey," affirms Şebnem Girgin, the managing director of the company's Turkish affiliate. "With our local manufacturing partner, Pharmavision, we have completed the technology transfer necessary to produce our innovative antidepressant product and we obtained marketing authorization for this molecule as a locally manufactured product at the end of 2014." According to UCB Turkey's managing director Özdemir Şengören, "93 percent of our sales by volume are produced in Turkey, mostly in our established brands. This is very critical for a small company like UCB, and for our size we have made some very effective investments in partnerships with Pharmavision, Bilim, and Adeka. In terms of 2023 objectives, we have efficiently localized production and helped to increase the Turkish manufacturing capacity utilization rate."

However, it is important to recognize that Turkey does recognize foreign GMP certificates in theory, if there is mutual recognition of Turkish GMP certificates in the country in question. At present, Turkish GMP standards

Atabay: meeting global needs with low costs

Atabay's president, Bulent Atabay, discusses his company's dedication to producing high quality life saving primary care products at accessible prices.

BÜLENT ATABAY
—
President,
Atabay

ZEYNEP ATABAY TAŞKENT
—
Owner, Atabay

What is the most important decision you have made on behalf of Atabay?

The most important decision we ever made at Atabay was in defi ning the mentality of our business and the types of products we seek to develop. Our goal is to produce and sell high quality pharmaceutical products at a reasonable price, and to select products that have a substantial impact on global public health. For us, paracetamol is the best example, as this is a cheap product that can save the lives of patients, and it can still be considered best in class. For the millions of patients worldwide suffering from diseases like malaria, paracetamol can reduce potentially fatal fevers; this is why we are proud to export paracetamol worldwide, in volumes that reach approximately 300 million people.

How is Turkey positioned to be a competitive API producer?

Today, chemistry related industries are slowly disappearing from the western world due to environmental concerns and expenses. China has become the biggest global player in fi ne chemicals, with India close behind. At the same time, multinational pharmaceutical companies have pulled out of low-cost products to a large extent; we competed directly with Bayer and Roche's primary care products 20 years ago, but no longer. This has created a potential export market for players like us that can synthesize the APIs using chemical intermediates, instead of buying them from Chinese or Indian producers, and provides benefi ts in terms of reliability, quality, and cost.

What is your long-term vision for Atabay?

Our mission should be to develop high-quality, relatively lowcost products that require advanced technological capabilities, and for which there is a strong global need. Furthermore, we will seek to fi nd opportunities to develop fi rst equivalent generics and biosimilars, and in doing so will bring down the market price of these treatments to levels that are more sustainable for public payers.

are not widely recognized, and this is limiting the export potential of the Turkish industry, for both Turkish producers and multinationals considering investing in the country. According to Özkan Ünal, president of the Turkish Drug and Medical Devices Agency (TITCK), this situation is in the process of being resolved. "Turkey applied to become a full member of PIC/S in 2013… At present, we are aiming to become a full member of PIC/S in one year." The expectation is that as a fully accredited PIC/S member, Turkey will be able to establish mutual recognition agreements with other members more easily, and in Ünal's words, "once this accreditation comes through it will bring many new opportunities to our pharmaceutical manufacturers in export markets."







HEALTH FROM THE PAST INTO THE FUTURE WITH CHEMISTRY AND BIOTECHNOLOGY

Atabay Pharmaceutical Fine Chemicals Inc. was started by organic chemist Bülent Atabay in 1970 at Atabay Gebze plant.

Since then, many pharmaceutical fine chemicals like ampicillin, amoxicillin, ipubrofen, trimethoprim, sulfamethoxadole, ethambutol, rifampicine and most important Paracetamol (Acetaminophen) were produced by Atabay Fine Chemicals Inc.

For Paracetamol (Acetaminophen) precursor paraaminophenol, Atabay has developed a very clean process using hydrogen gas and platinum catalyst to reduce nitrobenzene to paraaminophenol (Bamberger reaction). Then Paraaminophenol is acetylated to Paracetamol (Acetaminophen) using acetic anhydrate.

Atabay's Paracetamol (Acetaminophen) plant is FDA approved since 1986. Atabay is the sole manufacturer of Paracetamol (Acetaminophen) in Europe. Atabay has been exporting Paracetamol (Acetaminophen) to Europe and America in the last thirty years.

In the recent years Atabay has been developing APIs for antiviral, antithrombotic and gastrointestinal finished dosage forms.

www.atabay.com

ATABAY
PHARMACEUTICAL FINE CHEMICALS INC.

HEADQUARTERS
Köftüncü Sok. No:1 Acı-
badem 34718 Kadıköy /
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ILKER ÖZBAY
—
General manager, Daiichi Sankyo

In Turkey, one pharmaceutical company has led the way in terms of talent recruitment and retention through their excellent workplace culture, winning an assortment of 'Great Place to Work' and 'Respect for Human Life' awards over the last five years: Daiichi Sankyo Turkey. Daiichi Sankyo was ranked the seventh best place to work in Turkey in May 2015, the highest ranking achieved by a pharmaceutical company, and in 2010 the company was selected as the best employer in the entire country. General manager Ilker Özbay believes that the company's open communication policy lies at the heart of their great workplace culture, explaining that "when employees want to reach me I am always available whatever the time. We communicate positive and negative things in the same manner, honestly and respectfully," and "our people are respected as humans as well as employees, as mothers and fathers who have family lives, and we try to always see things and make decisions from this frame of reference." The time and resources invested in maintaining this company culture has benefited the business' bottom line. It has also made them one of the most desired employers in the country. Özbay sees these awards as key indicators of the "emphasis that we place on the human aspect of business, and the value that we place in relationships," which is of key importance for a firm that competes against industry giants such as Astra-Zeneca and Pfizer in cardiology, with just 35 sales representatives for the entire country. As he explains, "our strategy relies upon the quality of relationships, as our small teams must create strong effects with stakeholders to compete with larger companies that can visit them more frequently, and cover more prescribers"; to do this, Daiichi Sankyo has "made the choice to only focus on high potential regions and prescribers, maximizing the impact we can achieve with limited resources." Such a strategy can work very well when implemented as Daiichi Sankyo Turkey has, allowing this small affiliate to match the level of sales achieved by a competitor with a sales force more than four times larger.

QUALITY AND CAPACITY

With 78 pharmaceutical manufacturing plants registered in Turkey in 2013, owned by 74 separate companies, 16 of them multinationals, the number is continuing to grow with investments in greenfi eld facilities from both Turkish and multinational players continuing.

Yet, according to Cengiz Celayir, president of the Pharmaceutical Industry Association of Turkey (TISD), "roughly 30 percent of conventional dosage form manufacturing capacity is idle." Thus, "we have the capacity to export… and there are many companies that do some contract manufacturing on the side," which has in effect prevented the establishment of pure contract manufacturing organizations in Turkey, apart from a single example, Pharmavision. As Murat Barlas, chairman of Liba recounts, this is not a new situation. "It started in the 1990s… at that time we realized that there is a huge unfilled capacity in Turkey. In competitive areas, there were so many similar products that most of them did not bring any added value,

and instead, many pharmaceutical products were becoming more like commodities."

The distribution of this excess capacity is far from uniform. Menarini's Turkish subsidiary, Ibrahim Etem Menarini, "would like to be a source for Menarini affiliate in the region," according to managing director Uğur Bingöl, but "due to our very high utilization rate of our facilities we do not have the capacity to become a true manufacturing hub." Currently the affiliate "exports a small number of products to countries like Azerbaijan, Afghanistan, Kosovo and Somalia." Bingöl continues, saying "having a very high level of utilization, one of the highest in Turkey, also means that we are constrained in terms of developing domestic business as well, as we have very minimal excess capacity to use for new products or to contract out as a toll manufacturer. However, this is of course a positive situation in terms of efficiency, and we are proud to be working two or even three shifts for some production lines."

One of the most sophisticated and technically advanced manufacturers in Turkey, Deva, shows that demand for manufacturing varies significantly across different dosage forms. "We can produce nearly all pharmaceutical forms, from tablets and capsules, to inhalation products, sterile injectables, creams, suppositories, etc,"

> "There is a huge unfilled capacity in Turkey"
>
> **Murat Barlas, Liba**

says CEO Philipp Haas. He explains that Deva's utilization rate "varies significantly from one area to another; in some production lines we are quite full, while in others we have a lot of capacity left… on average we're at about 50 percent capacity across the board… however, in some key areas… we will soon be reaching the limit." Deva's technical capabilities and versatility has been critical to the firm's recent success, as "this has allowed

KÖKSAL ÜLGEN
General manager, Pharmactive, Turkey

PHILIPP HAAS
CEO, Deva


Courtesy of World Medicine

us to take on business opportunities that other Turkish firms are unable to, as we have licensed product portfolios from Roche and BMS, in 2008 and 2010 respectively, that contained a wide variety of individual products… We were able to do these deals because we can produce all of the products."

Manufacturers who have entered the Turkish pharma sector more recently, such as Pharmactive and World Medicine, have significant excess capacity, with which they can develop exports. World Medicine recently "made the decision to build factories in Turkey," due to "Turkey's geographical position and the political situation in the surrounding region, as well as the support from the Turkish government for the development of pharmaceutical production," according to founder and chairman Rovshan Tagiyev. "One production facility has now been finished (with plans for another three to be built in Turkey), which has a production capacity of 70 million units in various dosage forms that produce a range of solids, liquids, softgelatin capsules, semiliquids, sterile eye drops, and antiasthmatic inhalers," explains Tagiyev, and "despite the fact that World Medicine has strong sales in the countries that we export to, because our Turkish production facility is quite new we still have excess capacity to support our expansion." Pharmactive's facility is significantly larger, "with a production capacity of 330 million units per year, of which we are utilizing approximately 15 percent at present, and hope to increase this to 18 to 20 percent by the end of the year if things go well," general manager Köksal Ülgen details. Erol Kiresepti, chairman and CEO of Santa Farma, also introduces his firm's new facility, saying that the new plant will be located in an 80,000 sq meter area outside of the city, with a closed area of 42,000 sq meters… [and upon completion] "it will have a capacity of 150 million units per year. This is, by definition, the newest and most modern facility in Turkey."

In addition to facilitating trade with the CIS and MENA regions, this new asset was meticulously

Ejder Kimya: turning towards Europe

PERVIN EJDER
Managing director,
Ejder Kimya, Turkey

Although pricing constraints have placed downward pressure on all players across the pharmaceutical value chain, API and raw materials supplier Ejder Kimya has managed to find opportunity in the face of this challenge. "Our success so far has been a function of the industry's emphasis on quality," argues the supplier's managing director, Pervin Ejder. "That's mainly because sourcing cheap raw materials with poor quality often leads to a higher total cost of ownership." The Turkish supplier has not only managed to capitalize on this industry-wide mindset domestically, but also abroad, with foreign markets now accounting for roughly 50% of their business. "We've been exporting to countries such as Iran, Lebanon, Algeria, UAE. Now, we're really focused on selling our laboratory services to European countries including Italy and Spain." Ejder Kimya's overarching emphasis on quality service and competitive pricing has allowed the supplier to develop long-term partnerships with several multinational companies, including Kerry and Ajinomoto. But, perhaps in line with industry trends, Ejder Kimya has striven to go beyond the status of a simple supplier, and offer more value-added services covering their clients' entire supply lifecycle. "For instance, three years ago, we partnered with MNC to establish a microbiology lab, intended for developing our competencies within food supplements. Last year, we bought out our partner's shares, and have since used the facility to supply test services for the global cosmetic industry," says Pervin.

designed in such a way to allow the company to eventually penetrate a developed market where many Turkish brands have dreamed of going, but few have actually gone—the United States. "We've been working with two international advisors to design the production facility in compliance with the anticipated changes to the FDA and EU GMP changes coming in the next few years," highlights Kiresepi. Ultimately, the aim of "this new plant will be to attract business not only from Turkish companies operating in the local market, but also international companies looking for superior and costeffective manufacturing capabilities combined However, Muzzaffer Bal, general manager of Ali Raif, highlights the importance of current export developments explaining that "until only a few decades [earlier], Turkey paled in comparison to other emerging countries with regards to export

MUZAFFER BAL
General manager,
Ali Raif

UFUK KUMRULU
Chairman,
Polifarma

CEVAT ŞENGÜL
Secretary general,
OHSAD

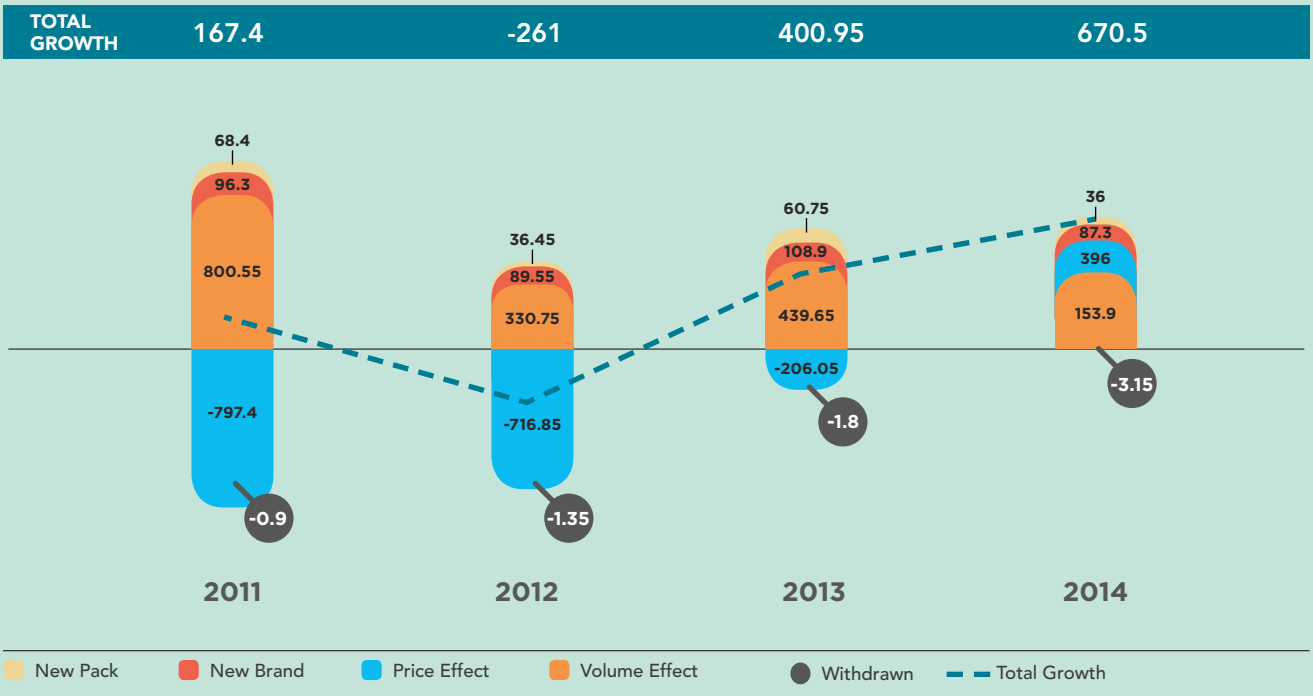
DILEK BAYRAKTAR
Secretary general,
ARTED

volume… The economy was still in its early onset of globalization and exhibited more closedborder commerce—and the pharmaceutical industry was no exception.

The effects of globalization on Turkey's economy have been self-evident— increased trade activity, and in turn GDP, multicultural exchange of skills and labor, and an accelerated rate of industrialization. But, perhaps less obvious, are the effects on local Turkish pharmaceutical players and their strategies to drive commercial success. "Traditionally it's been 50% in-licensing and 50% proprietary production. But as the local environment became increasingly accessible, with less stringent import controls and more favorable incentives for FDI, many of our former licensors either acquired their own Turkish distributors or established an affiliate office in Turkey," recounts Bal.

Founding partner of Yüksel KarkınKüçük, Gökhan Gökçe agrees. "In the interest of profitability, efficiency, and long-term sustainability, many of these pharmaceutical and medical device companies are [now] contemplating going direct to market," leaving domestic pharmaceutical players such as Ali Raif to shift from primarily licensors to proprietary manufacturers—strictly to maintain a competitive positioning in the market. "We had the opportunity to work with upwards of 20 MNCs at one point—enabling us to obtain several market leading positions across Europe over the years. Now we've extensively pursued our own

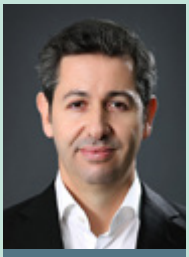
VOLUME DRIVING GROWTH OVER THE LAST FIVE YEARS, VOLUME HAS BEEN THE BIGGEST GROWTH DRIVER IN THE TURKISH MARKET. SOURCE OF GROWTH ANALYSIS, NET GROWTH - VALUE, Mn USD



Source: IMS Dataview Retail Hospital Database, December 2014. Growth is calculated vs previous year.

> "There is certainly the political will, the technical knowhow, and overall capability to accelerate [biotech manufacturing] to the top ten"
>
> **Cenk Sokmen, Genzyme Turkey**

TUNA YAVUZ
Managing director, Abdi Ibrahim Otsuka, Turkey



PETER CATALINO
Country president, Novartis, Turkey

ELIF ARAL
Country manager, Pfizer, Turkey

R&D and production initiatives—producing approximately 75 percent of our own generics, with the remaining portion of our portfolio attributed to in-licensing," details Bal. with the geostrategic advantages of Turkey based operations."

MOVING UP THE VALUE CHAIN

With the Tenth Development Plan specifically aiming to encourage the production of medicines with "high value added," Turkey's government is seeking to create production of several categories of products, including vaccines, blood products, and biosimilars in Turkey. In pursuit of this goal, a few subsidy programs and public private partnership projects have emerged, and several multinationals have made significant investments to support the achievement of this goal.

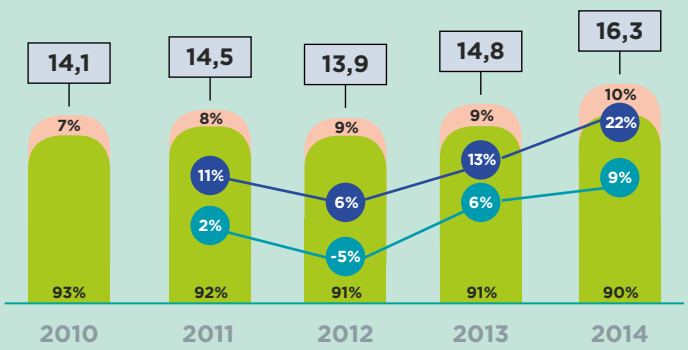
Partnerships between Turkish pharmaceutical producers and multinationals are also on the rise under a variety of structures, but general manager Tuna Yavuz explains that Abdi Ibrahim Otsuka will be the only joint venture offering "the opportunity to manufacture several products within Otsuka's portfolio of highly demanded, blockbuster drugs such as Samsca, Pletal, and Abilify, which brings high 'value added' activities to Turkey, and will help to build pharmaceutical exports."

On the vaccine front, Pfizer has taken the lead. As Elif Aral, country manager for Pfizer Turkey explains, "in the last five years we developed a new, much more advanced facility to manufacture Prevnar, a vaccine that won the US Prix Galien in 2011. The new Prevnar manufacturing facility, developed in partnership with Mefar, is only the third manufacturing site for Prevenar in the world after sites in the US and Ireland, and is the first locally manufactured vaccine in Turkey," with the first commercial batches completed in 2012.

As for biotech and biosimilars, Genzyme Turkey's general manager Cenk Sokmen explains that "at the moment, Turkey does not have the necessary infrastructure for biotech manufacturing, however, looking at the president's 'Vision 2023' strategies and relevant development plans it is clear that there is certainly the political will, the technical knowhow, and overall capability to accelerate our industry to the top ten." The government entities directly engaged in biotech and biosimilar development projects include the Scientific and Technological Research Council of Turkey (Tubitak) and several ministries. Ersin Erfa, CEO of Centurion, says "the government has been very supportive of companies developing biotech manufacturing, providing some fi nancial support and cooperating in the regulatory environment. Of course there are other countries with more robust incentive programs, but overall Turkey has offered an effective set of incentives, and clarity as to

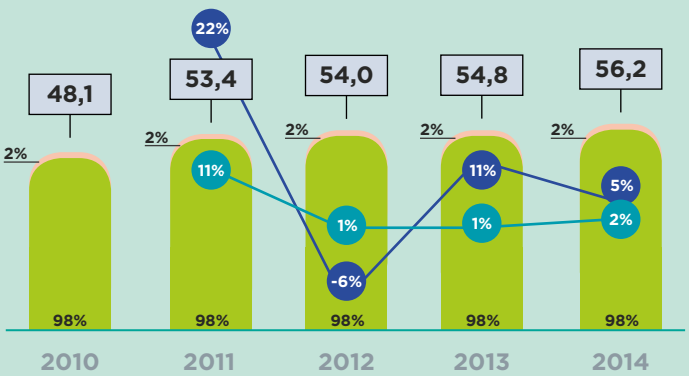
PHARMA SALES ON THE UP TURKISH PHARMA MARKET HAS REACHED 16.3BN TL NET SALES WITH 3.6% GROWTH OVER THE LAST FIVE YEARS

Pharmaceutical Market Sales and Growth VALUE, BN TL



Sales Value	CAGR ('10-'14)	PPG ('13-'14)
HOSPITAL	12.7%	22.2%
RETAIL	2.8%	8.8%
TOTAL MARKET	3.6%	10.1%

Pharmaceutical Market Sales and Growth SU*, BN (* 1 Standard Unit is equal to 1 dose)



Sales Volume	CAGR ('10-'14)	PPG ('13-'14)
HOSPITAL	7.5%	5.2%
RETAIL	3.9%	2.4%
TOTAL MARKET	3.9%	2.5%

Source: IMS Dataview Retail Hospital Database, December 2014.

their policy agenda to minimize uncertainty, which is much more than we could have said a few years ago. As a Turkish company that wants to invest in Turkey, they've done more than enough to encourage us to do so." Furthermore, the Turkish Drug and Medical Device Agency (TITCK) "is supporting the development of the Turkish biosimliar sector by developing an appropriate regulatory access approach that will allow biosimilar products to be evaluated more quickly and effectively," according to the agency's president, Özkan Ünal.

"Another program was created with the purpose of providing fi nancial support to promising biotech projects," explains Hasan Ulusoy, chairman of Nobel,

ORHAN MUTLU TOPAL
Managing director, Keymen, Turkey

EROL KIRESEPI
Chairman & CEO, Santa Farma, Turkey

"and after a competition in which 23 companies submitted 28 projects, Nobel's submission was selected as the only project worthy of this support." As of June 2015, a second project was approved under this program, submitted by Atabay. "We signed the agreement and have already started work on the development of an oncological biosimilar product from scratch, with Tubitak as a partner." Ulusoy's goal is to "bring the product to market by 2023, which means beginning phase II trials by 2019."

For Atabay, assistant vice president Zeynep Atabay explains that "for this project we will be working with Marmara University, Boğaziçi University, and Istanbul Technical University and their molecular biology and biotechnology research center, Mobgam. 50 percent of our R&D expenses will be reimbursed… through Tubitak, who is also a partner for this project, and overall the expected timeline is 48 months, but we will be eligible for government support for an additional 12 months, which we will likely need."

On the production side, several companies are already developing biosimilar manufacturing facilities, to be used for manufacturing products in conjunction with foreign partners. Erfa explains that Centurion, currently the market leader in many plasma derivative categories, is now "working with a strong and reliable partner, Amega Biotech from Argentina, to develop a new biotechnology manufacturing plant." This facility "will produce, fill, and finish injectable biosimilar products, and we hope that its development will be finished in about 30 months."

Abdi Ibrahim, the leading Turkish pharma company by revenue, began construction of AbdiBio, a greenfield biotech manufacturing and R&D facility with a planned cost of USD 100 million, in June 2015. "The facility we are building will be capable of carrying out the full biosimilar production process, from cell culture growth or fermentation to purification, then fill and finish processes," explains CEO Süha Taşpolatoğlu. "The facility will likely also perform a toll manufacturing function for some clients at the fill and finish stage." He continues by saying that the primary goal is "to be able to work with biotechnology companies from all over the world to codevelop new biologicals, and to carry out the full production process."

Winalite: bringing innovative consumer healthcare to Turkey

ARAFAT YADIGAR
—
General manager, Winalite

For Chinese consumer healthcare manufacturer Winalite, Turkey is a key market in their global and European expansion strategy. "At present, we already rank sixth or seventh for Winalite globally, behind a few countries like Korea, Malaysia, Russia, Japan, Singapore, and of course our home market China," explains general manager Arafat Yadigar. "My target is to eventually control a large segment of the European market from Turkey, as well as countries in the region like the GCC states, Saudi Arabia, Iran and Iraq," asserts Yadigar, clarifying that "due to Turkey's excellent geostrategic position, our HQ is very supportive of this idea, and wants Turkey to be a regional HQ in the future."

Winalite has just nine products in Turkey, "including our leading Winion sanitary napkin product, as well as our Winskin line of skin care products, nourishing Winalite lipstick, WelSmile toothpaste, and our line of Winwave thermotherapy products, which also incorporate magnets for magnetic flux therapy and our anion therapy technology." All Winalite products are "100 percent natural and free of chemicals, and… we regularly test our input materials and audit our suppliers, and have very high quality control standards." In the case of Winalite's flagship Winion sanitary napkin product, its quality and efficacy was "was recognized by the Urogynecological and Pelvic Reconstructive Surgery Association of Turkey due to the positive health benefits it offers women."

With aggressive long-term targets and the support of the global Winalite organization, Yadigar must first focus on building up Winalite's portfolio in Turkey. While "in China, Winalite has over 500 different products, in categories such as nutritional products, sanitary products, personal care and hygiene, and household products," regulatory requirements make bringing them to Turkey rather difficult. Instead, Yadigar is "searching for products produced in Turkey to complement our portfolio that feature some advanced technological features to distinguish them from similar products, enhance their efficacy and improve the health of our customers, while being made of all natural materials and components." Furthermore, Winalite requires any unique technological features of to be covered by patents.

THE INDUSTRY'S CRITIQUE

Despite the progress the Turkish pharmaceutical industry is making in terms of producing higher value products, developing biosimilar production, and the exciting advancements in R&D, there are still clearly many issues to be solved in Turkey. The government is taking effective steps to support the industry in achieving many of its targets, but they have done little so far to improve other aspects of the environment for investment and innovation, particularly with respect to pricing. Of course, the industry recognizes that the government introduced mandatory public discounts for good reasons, as Feliz Balcay, general manager of Chiesi Turkey, explains. "The expansion of healthcare services [under the healthcare transformation program] had an impact on total healthcare expenditures; pharma spending soared and

TOP 10 PHARMACEUTICAL MANUFACTURING COMPANIES IN TURKEY

	Company	Market Share (2012)
1	ABDI İBRAHIM	7.5%
2	NOVARTIS	7.0%
3	SANOFI	5.8%
4	BILIM	4.9%
5	PFIZER	4.3%
6	BAYER	4.3%
7	EASTPHARMA	3.8%
8	GLAXO	3.7%
9	ROCHE	3.4%
10	ASTRAZENECA	3.0%
TOP TEN TOTAL		**47.6%**

austerity measures were introduced to manage the total pharma budget."

Containing spending has become particularly important in the context of healthcare sustainability, due to Turkey's aging demographic structure. BMS Turkey general manager Ahu Yazici claims that "the system has spread itself very thin by trying to invest in all areas of healthcare, and therefore is not able to invest meaningfully in any area. Ideally, all healthcare costs must be controlled and balanced, including hospital costs, treatment costs, and other categories, with drug costs as only one component." Balcay agrees that the Turkish "healthcare system is in need of better budget allocation in order to sustain their services. Innovative medicines and solutions should be assessed using a valuebased pricing approach, as well as based on clinical outcome and safety."

> "The system has spread itself very thin by trying to invest in all areas of healthcare"
>
> **Ahu Yazici, BMS Turkey**

While the industry does see some progress on reforming pricing practices, there are still doubts as to the government's true intentions. Yazici explains that "we are also seeing the possibility of change for the pricing of certain product types, as the SGK is now discussing [various] alternative reimbursement models with the industry and other government stakeholders." Pfizer Turkey's GM Elif Aral clarifies: "they invited the industry to develop proposals for alternative payment systems, and while there are no concrete examples yet, discussions are moving forward." While some are quite hopeful that these discussion may represent progress, and that these 'alternative models' could be designed to include value-driven pricing mechanisms, others such as Raf Vrints, Celgene Turkey's general manager, maintain that "it is very important that we ensure these discussions do not become another cost containment exercise, and this may be difficult because we have seen this is still the SGK's mentality."

Making progress on any of these points may be difficult due to various communication challenges, and a lack of clarity surrounding who in government should take the lead on various issues. Incesu notes that "it is very important to work closely with the key decision makers, to build real and strong partnerships with stakeholders, as well as to maximize the level of investment for our patients… We are in constant contact with not only the ministry of health, but also

the ministry of labor and social security, the ministry of development, ministry of industry, the treasury, and many other government stakeholders. The challenge is addressing the right need to bring all parties together and create a valuable program for our patients." For Şebnem Avşar Tuna, general manager of Novo Nordisk Turkey, "my most important responsibility is to continue to communicate with regulators and public servants… and to help find solutions that allow us to bring innovative products to patients in Turkey, while achieving a sustainable financial outcome."

Ultimately, the Turkish government and its relevant stakeholders strive to keep its citizens' best interests in mind when reforming existing regulations and introducing new policies. "The Turkish life sciences industry is not so different from other developing countries' markets," says Sevi Firat, founding partner of Firat Izgi. "The Turkish government has made R&D in pharmaceuticals a priority and we see this as a way to break from the past difficulties the pharmaceutical market faced here. This is an area which generates jobs and income, while showing that Turkey is strong in terms of R&D globally and [that it] will become a rising star in its region."

FRAMEWORK FOR R&D INVESTMENT

PHILIPPE MÉA
General manager, Servier, Turkey

FILIZ BALCAY
General manager, Chiesi, Turkey

Multinational R&D investment in Turkey, particularly investment in clinical trials, has been quite limited relative to the size of the Turkish pharmaceutical market. Turkish R&D spending totaled TRY 14.8 billion (USD 7.77 billion) in 2013, just 0.95 percent of GDP according to TurkStat; President Erdogan's 'Vision 2023' includes the target to increase this ratio to three percent of GDP by 2023. R&D spending on all healthcare related topics has grown at a CAGR of 8.3 percent per year since 2009, reaching TRY 2.217 billion (USD 1.16 billion) in 2013, with pharmaceutical investment on pharmaceutical clinical trials accounting for only TRY 85 million (USD 45 million).

One of the major limiting factors for pharmaceutical R&D investment in Turkey is the small number of certifi ed clinical trial research centers capable of carrying out early phase trials; in a country of 75 million, there are only six such centers, with one of which only opened in May 2015. As such, Turkey is not particularly competitive in R&D when compared to countries with

robust, often government funded, research infrastructure, and as such the ratio of pharmaceutical R&D spending to pharmaceutical expenditures in Turkey is low relative to many other countries. According to AIFD chairman and GSK VP and Area GM Emin Fadıllıoğlu, "our level of investment in R&D is USD one billion lower than it would be if our R&D share matched our share of [global] expenditures." At present, the Tenth Development Plan includes targets to increase the number of clinical trial centers to 13 by 2018, and "to increase the number of clinical trials by 25 percent each year until 2023," according to TITCK president Özkan Ünal.

Lundbeck Turkey general manager Şebnem Girgin indicates that the company has "been extremely satisfied with the quality of the neurology and psychiatry centers in Turkey when it comes to R&D cooperation, and we have identified a few as key centers for future global studies in this area," demonstrating that expertise and capabilities do exist to support more investment in clinical trials. Founded in 1997, the key player in the Turkish clinical trial industry is Omega CRO, the first Turkish CRO, and according to

> "Our level of investment in R&D is 1 billion USD lower than it would be if our R&D share matched our share of [global] expenditures"
>
> **Emin Fadıllıoğlu, AIFD**

ISMAIL YORMAZ

VP and regional director South East, Recordati, Turkey

CEO Berk Özdemir, "the only truly full service CRO in Turkey; other local CROs have limited services and outsource work to us." As he explains, "the Turkish clinical trial area has changed a lot since Omega CRO was founded; at the beginning we didn't have a solid regulatory framework, then we had solid regulations but the timelines became too slow, and now we have optimal regulation with optimal timelines." Regarding the current clinical trial environment, Özdemir admits Turkey is "still not very competitive, it is difficult for us to substantially increase the number of global trials we can attract… [However], there are some very good projects underway in line with the Vision 2023 goals, and the Ministry of Health recently hosted a workshop in Izmir on how to attract more clinical trials."

SVEN SCHMIDT

Country division head, Bayer, Turkey

Yet, one multinational has taken a strong interest in bringing high value R&D activities to Turkey, going beyond clinical trials and bringing basic drug research to Turkey. "AstraZeneca has signed a collaboration agreement with Koç University, that gave us responsibility for preclinical testing and research for a few candidate molecules, as well as access to their broader open innovation chemical library," according

> "The Turkish clinical trial area has changed a lot ... now we have optimal regulation with optimal timelines"
>
> **Berk Özdemir, Omega CRO**

to Burak Erman, head of the Drug Research Center at Koç University. AstraZeneca Turkey's country president Pelin Eriştiren Incesu explains that "some of the projects have progressed very well, and the Turkish scientists involved have travelled to AstraZeneca HQ in Cambridge to present their findings, and we remain confident that one or two of these projects will proceed to the clinical development phase, and maybe become the first drug of Turkish origin in the coming years." AstraZeneca's support of this project demonstrates that the company is "on the right track to building scientific leadership," one of the three pillars of AstraZeneca's current global strategy, according to Incesu.

TURKISH INNOVATION

Apart from R&D efforts in the field of biosimilars, several locals and multinationals are taking strong innovative steps. Mehmet Pisak, one of the former owners of Mustafa Nevzat, which was sold to Amgen in 2012, and now CEO of Imuneks Farma, contends "supergeneric product development makes a lot of sense for Turkish companies. Combination products are the starting point, which are very popular in Turkey right now, and we as Imuneks Farma have three of them with marketing authorization in Turkey. Further down the road, a few of the larger Turkish players might be able to develop a molecule from scratch." Imuneks has four patents, two approved and two pending, for "a rare disease product… another is in ophthalmology, and two others are for antiviral products. The first two were just approved in the US and EU." Pisak continues, "These are drug repositioning projects, where we took an existing molecule and targeted a new indication with a new formulation… We're maybe three years away from bringing at least one of these products to market."

Larger Turkish companies like Abdi Ibrahim and Nobel are also investing in innovation, with combination products being the best example of value added products that have reached the market; as Hasan Ulusoy, chairman of Nobel describes, "most R&D in Turkey is done in the context of generic development, while there is some product innovation in terms of combination products and improved formulations." Abdi Ibrahim fits this description.

PELIN INCESU

President, AstraZeneca, Turkey

CEO Süha Taşpolatoğlu recounts that the company's R&D unit has "developed several generic products which are the first generic versions of the molecule worldwide, and several of the products developed by our team are sold in Europe by our [multinational] partner companies," and is beginning to make headway in "value-added product development, specifically in combination products; we have already launched our first [combination product] on the Turkish market and have others in development."

Nobel is working to innovate on a higher level, as Ulusoy explains. "Nobel has started some elementary research for an original product, and in this respect I believe we are the only Turkish company to have invested so much in R&D. Currently this product is in a phase I clinical trial."

According to CEO Ersin Erfa, Centurion is also working on "the development of a new orphan drug, a new molecule to treat pulmonary sarcoidosis… This new molecule is currently in phase III of clinical development, and we hope that it will become the first molecule to be developed by a Turkish company to reach the market, which should occur within the next two years."

DANIEL LUCAS

General manager, Lilly, Turkey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PHARMA BOARDROOM

Top 100 Pharma Companies In Turkey

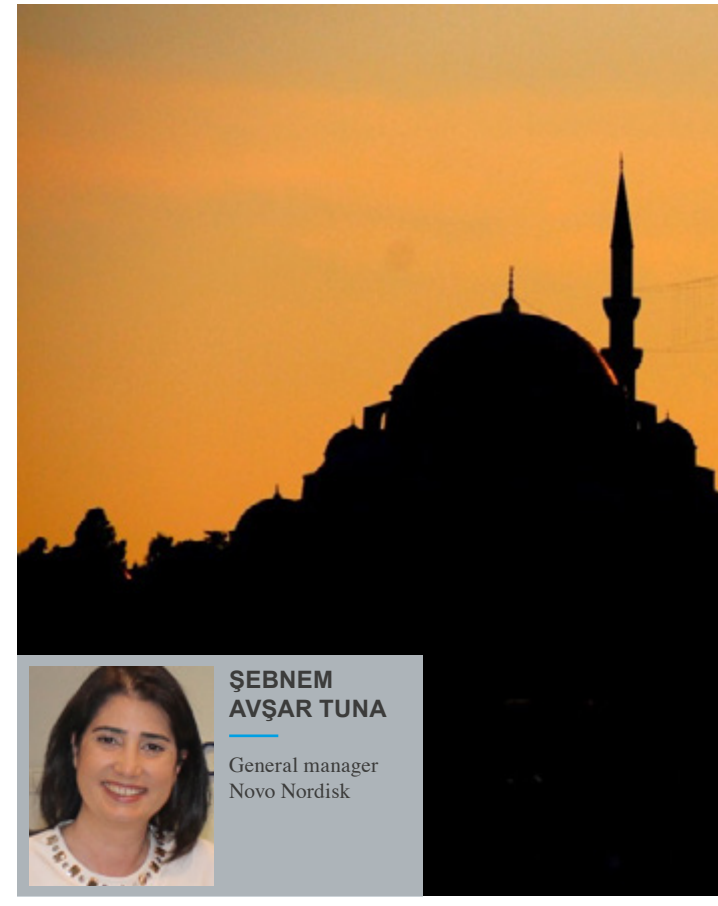
2014 VALUE SALES (USD)

1	NOVARTIS	495,615,358
2	SANOFI	401,264,940
3	IBRAHIM	385,316,088
4	PFIZER	310,282,135
5	ROCHE	290,013,976
6	BAYER	274,327,472
7	GLAXOSMITHKLINE	242,406,434
8	BILIM	224,495,068
9	ASTRAZENECA	202,300,596
10	M.S.D.	197,793,627
11	EASTPHARMA	193,056,784
12	NEUTEC ILAC	170,390,370
13	NOVO NORDISK	156,275,830
14	SANOVEL	153,075,361
15	ABBOTT	126,403,116
16	ECZACIBASI-BAXTER	126,043,368
17	NUMIL	123,632,755
18	BOEHRINGER ING.	122,528,373
19	JOHNSON & JOHNSON	119,028,945
20	IBRAHIM ETEM-M.	115,815,351
21	SANTA FARMA	107,604,454
22	LILLY	107,169,834
23	NEVZAT	102,270,996
24	KOCAK FARMA	100,807,416
25	NOBEL	92,876,376
26	ALI RAIF	90,005,474
27	ABBVIE	89,039,805
28	SERVIER	80,643,763
29	MERCK SERONO	79,962,970
30	RECORDATI	79,769,159
31	DEM ILAC	65,874,875
32	ECZACIBASI ILAC PA	54,163,815
33	ADEKA	53,199,813
34	AMGEN	48,737,624
35	NESTLE	47,782,298
36	ACTAVIS	46,979,096
37	GILEAD SCIENCES	46,283,623
38	BERK	44,420,014
39	ONKO-KOCSEL	43,817,383
40	BIOFARMA	42,264,014
41	RECKITT BENCKISER	40,169,140
42	GEN ILAC	40,025,866
43	U.C.B.	38,525,493
44	ATABAY	38,377,851
45	ASSOS ILAC	37,735,220
46	CELGENE	36,381,972
47	BERKO	36,211,755
48	ER-KIM	36,184,241
49	MEDA PHARMA	34,041,585
50	CHIESI	33,742,970

51	FARMA TEK	33,288,273
52	B.M.S.	32,872,966
53	LUNDBECK	32,095,150
54	MED ILAC (TEVA)	31,383,830
55	CENTURION PHARMA	28,763,731
56	BASEL KIMYA	28,289,935
57	VEM ILAC	24,615,185
58	ASTELLAS PHARMA	24,141,217
59	KANSUK	23,706,692
60	DROGSAN	23,664,792
61	SOLGAR	22,348,668
62	PHARMACTIVE	21,976,463
63	POLIFARMA	21,410,637
64	TAKEDA	18,994,534
65	FERRING	18,262,947
66	DAIICHI SANKYO	17,827,851
67	TUM EKIP ILAC	16,355,097
68	ROCHE DIAGNOSTIC	16,239,070
69	OPAKIM	15,881,362
70	BAUSCH & LOMB	14,405,649
71	GENERICA	14,372,919
72	ACTELION	13,863,883
73	ORVA	13,769,572
74	ARVEN	13,023,155
75	ILKO ILAC	12,930,539
76	EMBIL	12,911,934
77	LIBA	12,543,763
78	KURTSAN	12,371,399
79	FRESENIUS KABI	11,494,541
80	TEKA	10,531,380
81	ORNA	10,485,174
82	UNIDENT MFR	10,460,917
83	2B DIAGNOSTIC	10,035,697
84	PENSA ILAC	9,705,707
85	MAMSEL	9,571,859
86	AVIS ILAC	9,422,693
87	YENISEHIR	8,597,231
88	MT SAGLIK	8,531,224
89	GUERBET	8,346,413
90	DG FARMA	7,797,015
91	TURKTIPSAN	7,787,510
92	THEA PHARMA	7,584,884
93	BIOCODEX	7,354,391
94	KEYMEN ILAC	7,289,093
95	SMF ILAC	7,166,132
96	IRMAK MEDIKAL	6,414,792
97	EGIS	6,087,458
98	SHIRE	5,969,012
99	CELTIS ILAC	5,889,562
100	ITF ILAC	5,713,674

Total Pharma Market **7,150,262,136**

BUILDING THE ISTANBUL DIABETES ROADMAP



ŞEBNEM AVŞAR TUNA

General manager
Novo Nordisk

Preface: Novo Nordisk Turkey has taken a degree of leadership by working to facilitate and encourage cooperation and collaboration between different stakeholders in the diabetes management ecosystem. For general manager Şebnem Avşar Tuna, developing stronger lines of communication with regulators and payers is the top priority going forward.

HCLS: What steps have you taken to address currently unmet medical needs of diabetes patients?

ŞEBNEM AVŞAR TUNA: In 2013, we partnered with Ministry of Labor and Social Security and the Social Security Institution (SGK) to bring together 300 executives from Turkey for an "International Diabetes Leadership Forum", which featured a keynote speech from former UN Secretary General Kofi Annan and a special address via teleconference from former US President Bill Clinton. This forum brought together executives from the industry, payers, policy makers, healthcare professionals, patient organizations, and representatives from key international diabetes medical associations, from a wide range of countries across the region to discuss the current unmet needs of patients, potential strategies for addressing these needs, as well as defining the responsibilities of different stakeholders within the system.

The results of these discussions were published in a "Istanbul Diabetes Roadmap", under which each stakeholder agreed to take on certain responsibilities to improve diabetes treatment here in Turkey, such as the Ministry of Health agreeing to train physicians in primary care, and the social security institution (SGK) committing to increase coverage for diabetes related health expenses such as eye care and food for patients, as well as coverage in the early and preventative phases.

At the regional level, this event also had strong impacts on neighbouring countries. For example, after this meeting Iran updated the reimbursement status of the most innovative diabetes products on the Iranian market, and now diabetes products are reimbursed to a very high standard in Iran. In Pakistan, insulin is now being distributed for free to children and adolescents under the age of 18 in certain provinces, and in Jordan 15 diabetes healthcare units were established by the Jordanian Ministry of Health.

We are very pleased with the positive results of this forum, and Novo Nordisk will continue to exercise a degree of leadership in the diabetes ecosystem by organizing awareness initiatives, and facilitating collaboration. Diabetes is a key healthcare issue worldwide, with nearly ten million diabetic patients in Turkey, and to properly address a healthcare issue of this magnitude all of the relevant stakeholders must cooperate to develop coordinated healthcare solutions for this large patient population. Novo Nordisk's commitment in this respect

> "To properly address [diabetes], all of the relevant stakeholders must cooperate to develop coordinated healthcare solutions"

is to secure the resources for R&D so we can bring more value and innovation to patients and payers in the future, as well as the healthcare economics data to justify the cost of these treatments, which can prevent major medical complications in the future.

HCLS: In many countries Novo Nordisk seeks to facilitate patient access to medicines by providing non-innovative generic insulin as well; how has this initiative been implemented in Turkey?

SAT: As the universal healthcare insurance provides a very strong foundation for healthcare treatment in general, and in diabetes, we are able to provide modern insulins for the treatment to people with diabetes. Established insulin products are fully reimbursed in Turkey, so all diabetes patients have access to good quality and effective medicine. Globally, we continue to develop further medicines and treatments which are highly innovative and in Turkey we work hard and negotiate with the government institutes to get marketing approvals and reimbursement for our highly innovative products so that the patients nation-wide have access to the products that allow them to effectively treat their condition.

HCLS: How will Novo Nordisk Turkey's portfolio evolve over the next five years?

SAT: At present, our portfolio is made up of highly innovative products and we are constantly developing new and improved innovative medicines. In Turkey, we struggle with the launch of new products but we work hard to get them in Turkey at the same time with other European countries.

Today, market access is a bit more challenging in general going forward. The SGK has made it very clear that increased costs in healthcare budget require cost containment measures for existing products as well as the innovative new drugs. This of course is a barrier in the industry to bring new innovative products to Turkey. For patients to have access to these new innovative products, it is essential that the different stakeholders in the public sector and industry communicate openly, seek to understand each other, and continue to prioritize patient wellbeing to ensure that fair and effective solutions can be found.

As Novo Nordisk Turkey, we are currently adapting our business model to better fit the needs of the public healthcare sector and the SGK, so that we are able to collaborate with them more effectively as a partner for the treatment of diabetes. The key aspect of this type of collaboration is effective communication, and from our side we are working to improve our ability to communicate and explain the incremental-value of innovation and our innovative products over existing treatments to the authorities and the public.

THE NEW KID ON THE BLOCK

Preface: The leadership of Turkey's newest major pharmaceutical player, Pharmactive, discuss the firm's two pronged growth strategy, detailing their own sales objectives and prospects, as well as the opportunities that they can bring to multinational pharmaceutical companies as a flexible, top-quality pharmaceutical company.

KÖKSAL ÜLGEN
General manager,
Pharmactive

HALUK SANCAK
President,
Pharmactive

HCLS: As a new pharmaceutical company, how have you designed Pharmactive to succeed in the 'new' Turkish pharmaceutical market?

KÖKSAL ÜLGEN: Developing this company, our first concern was minimizing production costs to have a competitive edge, so we have built a very large facility with a USD 200 million investment; it is a burden now, but we will benefit from significant economies of scale in the future. The second issue is sales and marketing expenses, which most of the industry had to reconsider as prices fell. We have established all of our strategies and team structures to avoid this scenario by being very cautious about the organization matrix at all departments, and monitor sales and marketing expenses closely, so we are confident that we can control these costs. Also, our second major goal is creating 25 percent of our sales from international markets, to avoid depending solely on the Turkish market.

HCLS: You started with some very ambitious goals, including reaching the top five in generics sales for Turkey. Now in your third year on the market, how much progress have you made towards these goals?

ÜMIT CEYLAN: We are very young company, but one with a very strong R&D group and a top quality R&D facility. This has allowed us to develop a strong portfolio of products over the last two years, and can serve as a source of revenue and growth as service center for third parties interested in outsourcing product development to us. This facility has been recognized as an R&D Center by the Turkish government, certifying the quality, capability and capacity of the facility.

In the local market we have the expectation of reaching the top five in terms of generic manufacturers, and this is a goal that we should be able to easily achieve, equivalent to roughly USD 200 million in sales per year. We currently have a production capacity of 330 million units per year, of which we are utilizing approximately 15 percent of this capacity at present and hope to increase this 18 to 20 percent by the end of the year if things go well. Our five-year plan aims to generate 40 percent of our total turnover from contract manufacturing, and by the end of this year that number will be between 10 and 12 percent.

KU: In line with this goal, our production facilities recently received EU GMP certification from the Germany Ministry of Health, BfArM, which came much earlier than expected, and is a huge

achievement given how recently Pharmactive was founded. This approval brings many opportunities for us to work with companies in the EU and other countries where EU GMP is well accepted as a CMO, and with co-development and sales and marketing partnerships. We will be launching our first generic products in the EU by 2017, and are currently working on strategies to enter the US pharmaceutical market. Our ultimate goal is to get FDA approval, and then launch our own products under our own brand with our own team in the US within three years.

HALUK SANCAK: Our plan, which is ambitious by some measures, is to start with EU and US, the two toughest markets. We have decided to target these markets because there is a much greater reward to doing so, despite the higher required investment and associated risks. We also have different market entry strategies for different regions and countries, such as Gulf Region, CIS region and MENA region.

HCLS: What is Pharmactive's unique value proposition?

HS: Perhaps most importantly, we are a very new company with a lot of excess capacity and room to expand, a major advantage as many of the other top-quality contract manufacturers in Turkey are operating at or near capacity. The course of our development can also be influenced or moulded by third parties, depending on their specific needs, and this is something that we invite. We are happy to accept the guidance, advice, and support of global pharmaceutical players who would like us to develop specific capabilities, and we are seeking to establish long-term relationships with them; we are even open to allowing partner companies to help design aspects of our facilities that have yet to be established. In this regard, Pharmactive is a production platform for the global pharmaceutical business that can be adapted to fit their specific needs.

HCLS: What would you like Pharmactive to achieve in the next five years, Koksal?

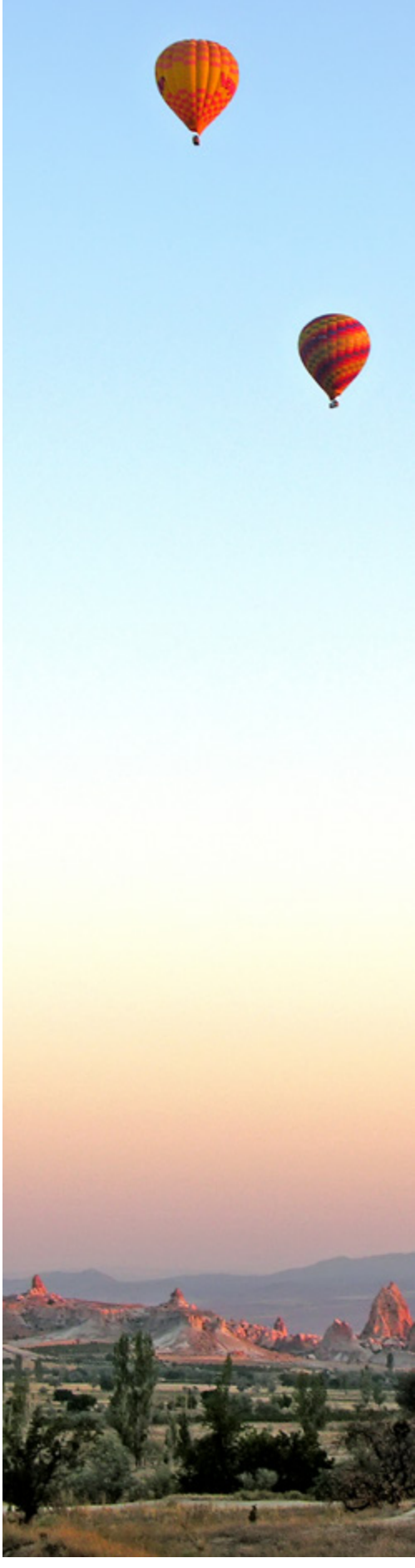
KU: By 2020, we will be a top five generics manufacturer in Turkey, and hopefully this will happen in less than five years. By then we will be the largest CMO in Turkey in terms of output and the number of client companies, and will be able to create 25 to 30 percent of our sales from exports with the potential to grow further. We will also be the only Turkish pharmaceutical company to have a solid presence on the US pharmaceutical market, with our own team on the ground. To accomplish these goals, we will have to hire significantly more employees, as we have only 800 at present, and by 2020 we will need at least 2000.

CLUSTERING FOR A SUSTAINABLE FUTURE

Preface: Biotechnology is crucial to the future of the pharmaceutical and healthcare industries in Turkey. The coastal city of Izmir is fast becoming a center for biotech; full of high-tech start-up clusters and now the recipient of significant international investment.

The potential implications of biotechnology on the sustainable growth of Turkey's pharmaceutical and broader healthcare sector are self-evident: increased investments in R&D, introduction of more high value-added products, improved patient outcomes, and a boost in pharmaceutical exports and subsequent reduction of the country's current account deficit. That being said, however, according to Scientific American's annual Worldview Bio-Innovation scorecard, Turkey has been consistently ranked in the bottom quartile of the 48 different countries that were assessed in the last few years. As Prof. Dr. Mehmet ÖzTürk, Director of iBG-Izmir, exclaims, "the problem is that [companies] have the ideas, they have the money, but qualified manpower is missing, quality control facilities are missing, pilot production facilities are missing, and R&D facilities are missing." For these reasons, organizations such as the Izmir Development Agency (IZKA) have prioritized projects in the health technologies arena. "We made a roadmap as part of a 2-year study," Dr. Saygin Can Oguz of IZKA details, "which shows how to increase Izmir's capacity for R&D, how to encourage innovation and how to bring universities and the industry together for collaborations."

This roadmap eventually led the agency to provide a 9 million TRY grant to Bio-Izmir, a jointly funded collaboration with Dokuz Eylül University that acts as an accelerator for health technologies. Traditionally, pharmaceutical companies have received avid support from stakeholders for exploration and displayed exceedingly exuberant competence when it comes to marketing their products. The objective of this project circumvents these aspects of the pharmaceutical value chain and aim to tackle inefficiencies specifically



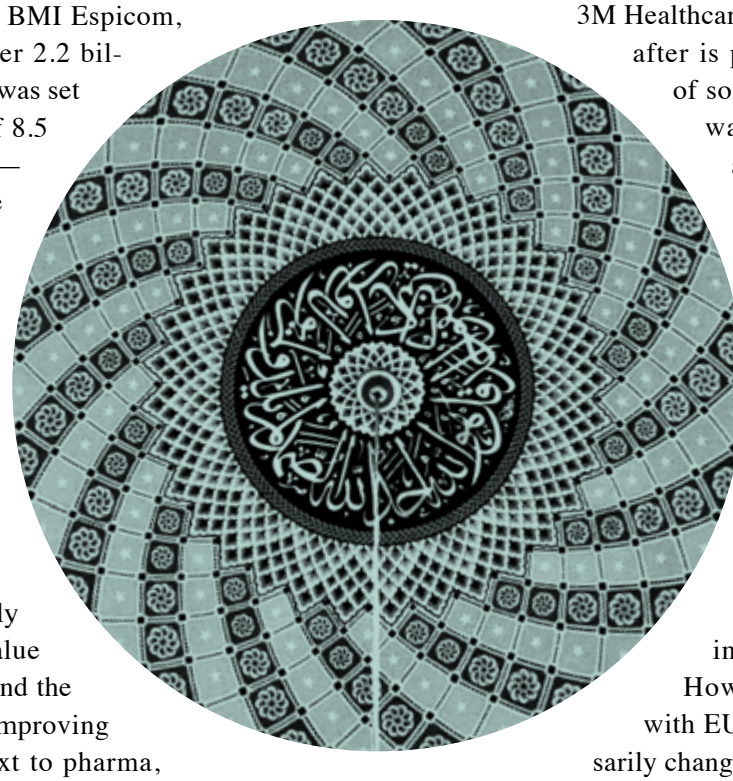
within the research and developmental pipeline, which can take upwards of 20 years and two billion dollars. Prof. Dr. Murat Özgören, VP of Dokuz Eylûl University explains further, "we have a unique cluster of expertise here not found anywhere else, and we hope that having these people work closely together will bring great benefits to us all." Already receiving interest from big pharma players including Baxter and Bayer, Bio-Izmir brings together a community of researchers, scientists, and industry leaders—creating a shared platform for effective knowledge transfer and pushing the frontier on health innovation.

But, let us not forget, at the center of this ecosystem is Izmir—a burgeoning hub of high-tech start-ups, biotech clusters, and international commerce. In line with this characterization, even medical device companies have centralized operations in this coastal city. "Now with well-educated resources, significant export potential, and a favorable investment climate, Izmir has become the ideal environment for domestic and multinational companies to cultivate their operations," highlights Atilla Sevinçli, GM of Meditera. Especially considering the material developments for biotech, it seems the less commercial-centric Izmir is stepping out of Istanbul's shadow and gradually establishing a name for itself, even among international peers.

ALLEVIATING PAINS IN TURKISH MEDTECH

Preface: The Turkish medical devices market has grown significantly in recent years and is now among the world's top 30 in terms of value. However, regulatory reform and greater government support is needed to incentivise success, reprimand failure, and ensure the future sustainability of this important sector.

Looking at the other branch of Turkey's healthcare reform, the medical device sector has also become an inherent component of advancing patient care in the country. According to BMI Espicom, the sector reached over 2.2 billion USD in 2012 and was set to grow at a CAGR of 8.5 percent through 2018—placing it among the world's top 30 medical device markets in terms of value. Although a completely different ball game, Turkey's medical device industry exhibits several dynamics that run in parallel to pharmaceuticals—especially with regards to the value of R&D investments and the overall emphasis on improving patient outcomes. Next to pharma, global medtech boasts the second-highest R&D to revenue ratio—ranging roughly from 9 – 11 percent; needless to say, innovation lies at the core of many industry players' strategic directions. "Healthcare's aim is not just selling isolated products, but also providing solutions for the entire care pathway," Ebru Erden, Country Business Leader of 3M Healthcare, exclaims. "What we are after is providing a full portfolio of solutions in these care pathways. All the investments and new R&D development products are based around this one-stop-shop concept."



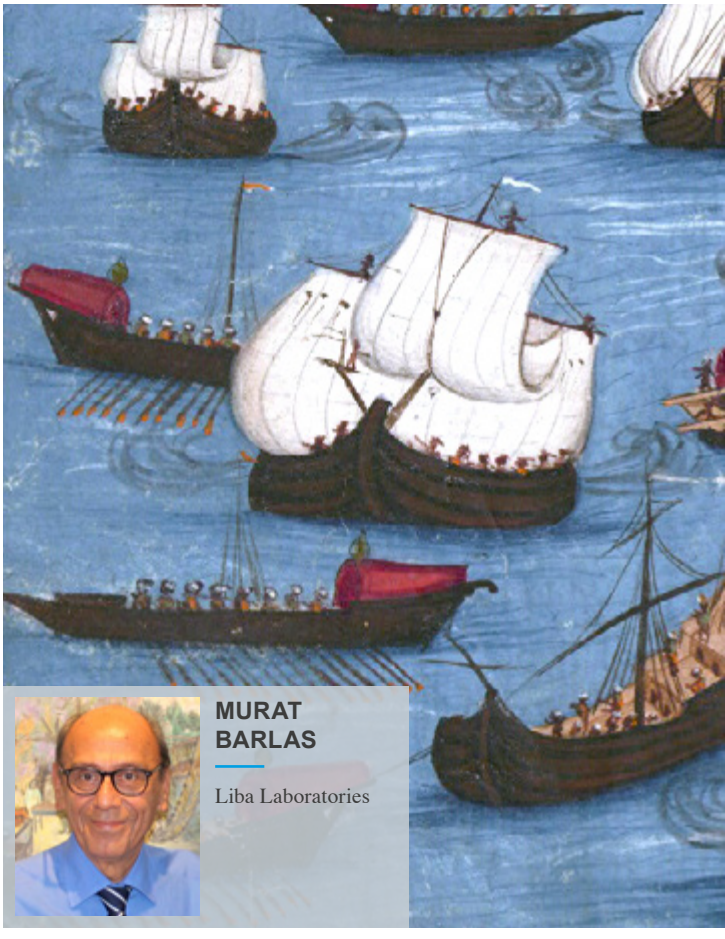
Given the sector's immense growth over the past decade, the Turkish Medicines and Medical Devices Agency (TiTCK) has developed regulations regarding the management of medical devices in line with EU standards. However, the harmonization with EU directives has not necessarily changed the industry for the better. "In the current regulatory environment, the companies that produce good services and products are not adequately incentivized, and the ones that

pursue poor quality assurance standards are not reprimanded," asserts Erdinc Eroğlu, GM of Beckman Coulter Turkey. After obtaining a CE mark, which is often mistakenly viewed as an indication of quality, importers can easily access the market with minimum hurdles. "The lack of control mechanisms regulating the quality level of new products entering the market ultimately increases the total cost of ownership for medical devices," details Murat Erboz of Becton Dickinson, "especially when considering the added level of treatment costs for complications arising from subpar and faulty products."

Adding to the lack of regulatory governance is the thinning profit margins for medical device players. "This is the largest challenge we face because we have a central decision-making body (SGK) which has enormous decision-making power that allows them to negotiate heavily on prices," highlights Ozgur Tomruk of J&J Global Surgery."

Ultimately, if the government can pursue a greater interest in developing greater support structures and more robust regulatory regimes for the medical device industry, then providers can focus on "inject[ing] savings into the global healthcare environment—affecting all parties including reimbursement agencies, insurance companies, private enterprises, and a country's overall economy," stresses Ayhan Ozturk of Medtronic Turkey.

NAVIGATING A CHANGING ENVIRONMENT



Preface: Murat Barlas, the longest serving board member for the Turkish Pharmaceutical Manufacturers Association, discusses the need for a new perspective in government-industry relations in the Turkish pharmaceutical industry, and the steps his firm has taken to find success in the meantime.

HCLS: What is the role of companies like Liba in achieving the Turkish government's vision for the pharma sector, and how achievable is that vision today?

MURAT BARLAS: The vision the government has for the pharma sector will be achievable only if it changes its perspective on the industry as it stands. Today, for our government, the most important issue is the cost of healthcare and pharmaceuticals. Because of this, they put so much pressure on prices that we have no idea where the market will be in the next five or ten years: we don't even know right now what will happen next month.

However, if this perspective shifts, and we are able to communicate our needs better to the government, achieving this vision may yet be attainable. One of the biggest challenges we face as a sector is that we don't have good lines of communication to legislators. In fact, the current plan for the pharma sector until 2023 was prepared by the industry and delivered to the government, but so far we have had limited opportunities to discuss the challenges brought up in that plan.

Liba is an example of a local company that is doing its utmost in the market at present: we have focused on specialty products in order to carve out a niche for ourselves and become successful in that way. Until the conversation changes, we have to use all possible means.

HCLS: Can you please tell us about some of the most important decisions that you have made on behalf of Liba in the last ten years?

MB: In the last ten years we have continued with our strategy of moving in niche fields, being a reliable partner to specialists, and trying to serve all their needs from one source.

What has changed in this time is the industry environment: the new pricing system and reimbursement system. You have to be very careful calculating your costs and margins to be able to survive. Therefore we had to decide to exclude some groups of products from our pipeline. Once, for example, we were very active in oncology

– but because it is no longer a niche field, and because the pricing system does not make the products in our pipeline an attractive field any more, we decided to step out.

On the other hand, we are always looking for new therapy areas in niche fields, and today, for instance, we are very active in addiction therapy. And whenever we enter a new field, we not only bring new products onto the market, but try to shape the system and the infrastructure too.

HCLS: In these specific fields like addiction therapy and ophthalmology, as you build relationships with specialists, what are some of the initiatives that you are carrying out to improve the environment?

MB: First of all, we listen well and try to understand what kind of demands the specialists in those areas have.

> "The vision the government has for the pharma sector will be achievable only if it changes its perspective on the industry as it stands"

Then we try to cooperate with the international experts in that field – we try to find out what is missing and what kind of innovation we can bring to Turkey.

In addiction therapy, everything was missing, so we had to work closely and find the stakeholders, whom we didn't even know when we started working in this area. There was no drug therapy for addiction before 2009. Now, from zero treatment in 2009 there is a treatment center in almost every Turkish city today: 80 cities, 50 to 60 treatment centers, this is a drastic change.

This is something very positive the government did, but there is still a long way to go. The approach of the Ministry of Health is very constructive, but overall the legal structure has to be adapted much more to standards determined by research.

HCLS: How would you describe the value proposition that Liba brings to its partners today?

MB: We are cooperating with leading companies in our chosen areas, bringing their innovations to the Turkish market. Having a profound knowledge of the characteristics of the area we can build up the optimum strategy. Being a very flexible team we adapt to any change in the environment easily and fast.

HCLS: In the future, what niches and partners will you be looking at?

MB: First of all, new partners in the fields where we are active are always welcome. Of course we are looking for them, there are always new discussions, and we are trying to follow the needs of the market and the specialists, and whenever there is a new field, we try to enter.

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