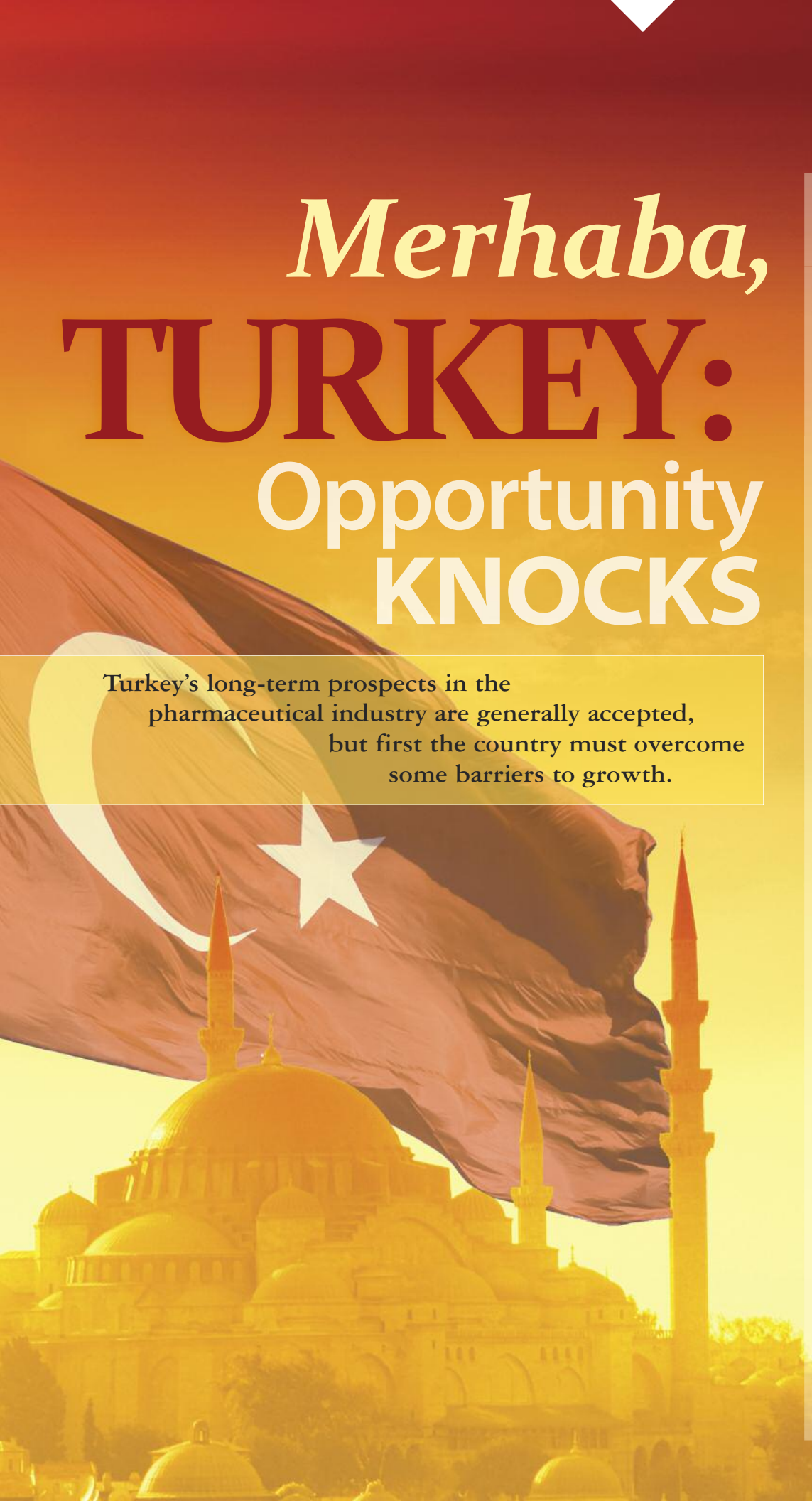
Kim Ribbink

Merhaba, TURKEY: Opportunity KNOCKS

Turkey's long-term prospects in the pharmaceutical industry are generally accepted, but first the country must overcome some barriers to growth.



As the largest pharmaceutical market in the Middle East and the fastest growing in the Mediterranean region, Turkey presents some exciting opportunities for the pharmaceutical market.

Consumption of pharmaceuticals in Turkey totals around $8 billion, with 50% of these drugs being manufactured domestically and about 70% of this manufacturing is done by foreign companies, according to consulting firm Egon Zehnder International.

But companies in Turkey also manufacture products for export and in 2010 the total value of pharmaceutical industry exports to Europe and the United States reached $612 million.

"More than 3,000 drugs are manufactured in Turkey, and the Turkish pharmaceutical industry exports to more than 100 countries," says Dr. Sule Mene of Mene Research.

According to IMS Health, the Turkish healthcare market is expected to grow between 5% and 10% over the next five years.

While in many regards an emerging market, Turkey's healthcare market is relatively mature, says Sven Schmidt, Bayer HealthCare representative and Bayer Pharmaceuticals country division head in Turkey.

About 95% of the Turkish population receives healthcare under the national healthcare system. The healthcare system is governed by the Ministry of Health, while reimbursement is provided by the Social Security Institution. The government is the single payer for medicines in the system with out-of-pocket expenses by the patient being low.

Companies in Turkey

Over the past three decades, the number of foreign pharmaceutical companies in Turkey has been rising significantly. According to Egon Zehnder, U.S.-based companies control about 30% of the market; U.K. companies have about 20%, and Swiss companies account for a 15% market share.

While many global pharmaceutical companies have long histories in Turkey, Murat Yesildere, managing partner at Egon Zehnder International, says global pharma companies tend to use Turkey more as a commercial base, especially after the recent changes in regulatory infrastructure. Ironically the recent changes are intended to promote local manufacturing of products.

Bayer has been present in Turkey for more than 50 years, with its HealthCare, MaterialScience, and CropScience divisions. Bayer HealthCare is ranked No. 2 among pharma

> “As Turkey is a young and high-population growth market, companies aspire to include it in their clinical research plans.”
>
> **MURAT YESILDERE**
> Egon Zehnder International

> “Turkey’s workforce today offers young and excellently trained and qualified scientists, experts, and physicians.”
>
> **SVEN SCHMIDT** / Bayer HealthCare

companies in Turkey in volume and a top 10 player in value, with leading positions in both the Turkish prescription and nonprescription pharmaceuticals market, Mr. Schmidt says.

“The pharmaceutical division’s general medicines portfolio, encompassing anti-infectives, cardiovascular risk management, as well as women’s and men’s health drugs, is well-suited to address the medical need arising from demographic challenges,” he says. “Furthermore, the division is a leader in the specialty pharmaceuticals market in Turkey with its portfolio of therapies for multiple sclerosis (MS), cancer, and rare diseases, such as hemophilia and PAH as well as its strength in diagnostic imaging.”

Another company strong in the Turkish pharmaceutical market is Pfizer, which started its operations in the country in 1957. According to the Republic of Turkey Prime Ministry Investment Support and Promotion Agency of Turkey (ISPAT), Pfizer Turkey produces 77% of the products marketed to the medical sector and employs more than 1,400 people in Turkey. Pfizer Turkey exports its production to 22 countries in Central and Eastern Europe, including EU countries, the Middle East, and Far East.

Pfizer also conducts R&D projects in Turkey and has opened a research office in Hacettepe Technopolis, Hacettepe University, Beytepe/Ankara. The company also signed a memorandum of understanding with ISPAT to deepen its R&D activities in Turkey.

Clinical Perspective

One draw for pharmaceutical companies is a highly qualified scientific community.

Egon Zehnder says about 900 pharmacists graduate from universities each year and most move into the pharma sector. On top of this, there are more than 80,000 doctors, 77,000 nurses, and 15,000 dentists, but because of limited private health institutions these professionals tend to choose jobs with multinational pharmaceutical companies.

Turkey’s young and growing population makes it a popular destination for clinical research, although efforts by the Ministry of Health to regulate research activities pose obstacles for global companies, Mr.

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FAST FACTS

Turkey: Healthcare System Fast Facts

- Population: 74 million (2010)
- No. 1 cause of death: Ischemic heart disease
- Total Healthcare Spending: $44 billion (2008)
- Healthcare Spending per Capita: $645 million
- Life expectancy: 72.9 years (2007)
- Physician Density (per 10,000 people): 14.5

Source: World Health Organization and Health of Nations. For more information, visit who.int and healthofnations.com.

Yesildere says.

Since the issuance of the first good clinical practice guidelines compliant with international regulations in 1993, Turkey has participated in numerous national and international clinical research activities, Dr. Mene says. Those regulations lift the number of qualified investigators each year.

Between 2008 and 2009, Turkey adopted the EU Directive on implementing GCP guidelines. An increase in GCP training and adoption of the EU guidelines have helped to reduce past regulatory issues and resulted in growth in the clinical research sector. In April 2011, the Ministry of Health implemented a new law aimed at overcoming the challenges presented by the bylaws and guidelines, especially in terms of ethical committees.

Specialist therapeutic areas are gaining a larger share in the Turkish market, including cardiovascular, CNS, respiratory, and oncology.

While there are no data on patient rates of recruitment and completion in clinical trials, Dr. Mene says her company's experience shows the clinical trial initiation timeline, including all approvals, is around two to four months.

Turkey is a very exciting market for clinical trials and could be the next best place to do FDA and EMA trials, yet the Turkish government is doing nothing to incentivize pharmaceutical firms to do this, says Peter Pitts, senior partner, director of regulatory affairs and health policy, Porter Novelli and president of the Center for Medicine in the Public Interest.

"In fact, Turkish authorities are actively discouraging pharmaceutical partnerships; they are demanding that any new drug have trials done in-country as a prerequisite for licensing," Mr. Pitts says. "This isn't a partnership it's a threat."

Illustrating this point, Mr. Schmidt says there are a limited number of Phase II-IV trials in Turkey.

"R&D activities and expenditures, and the number of R&D personnel remain behind the world average," he says. "In 2009, only 521 of a total 72,615 clinical trials in the world were carried out in Turkey. The number of clinical trials — per million in population — was only four in Turkey, while there were 191 in the U.S., 86 in Western Europe, and 22 in Eastern Europe."

This is starting to change, Mr. Schmidt adds, helped in part by a new R&D law introduced in April 2008 to boost local R&D and increase investments from global companies through tax incentives.

"Local R&D activity is gaining higher priority and is resulting in a higher volume of clinical trials conducted in Turkey," he says. "Local and multinational companies are opening more R&D centers and engaging in scientific research partnerships."

Healthcare in Turkey

Turkey's healthcare system is undergoing a prolonged period of transition under the 2003-13 Health Transformation Programme.

The aim is to control public healthcare expenditure and restructure the health ministry to enhance its core functions of developing policies, setting standards, and ensuring quality; introduce compulsory health insurance for the entire population; increase access to healthcare facilities previously reserved exclusively for members of the various social security institutions and their dependants; improve training for doctors, nurses, and administrators; and provide incentives for a more even distribution of personnel nationwide.

A family practitioner service, which should improve primary care, is also being rolled out across the country, but it will take time to implement in full because of the shortage of trained general practitioners (GPs).

One aspect that has been burdensome for the pharmaceutical industry is a new regulation that only allows drugs to be launched in Turkey within two to three years following their Europe launch. Since the period of data exclusivity in Europe is six years, this means a very short exclusive marketing period in Turkey before a brand faces generic threat.

Tackling Barriers

While pharma companies do seek to work with local CROs, there are several barriers, Mr. Yesildere says.

"First, most local CROs are still at an emerging phase, and second, decreasing prices, increased regulations, and tighter controls on commercial — both sales and marketing — activities definitely do not appeal to multinational players," he says. "The pharma sector is one of the few industrial sectors in Turkey where the government has tight controls.

"The most direct form of this control is the Ministry of Health's authority to determine the rates by which pharma companies can increase their prices," he adds. "Less direct, but equally effective, has been the Social Security Institution's policy of purchasing, i.e. reimbursing, the cheapest alternative among pharmaceuticals comprising the same molecular structure."

This is effective because about 80% of pharmaceuticals are reimbursed by the state. In addition, a tightening of the regulations Regarding the Promotional Activities of Medicinal Products for Human Use, expected to come into effect later in 2011, pose a threat to access to doctors and indirectly to patients as well.

This is exacerbated by the fact that lower prices and tighter margins have forced companies to consolidate their field forces.

"Turkey's recent healthcare reforms, centered on price cost containment, remain a chal-

> "When a nation does not recognize or reward innovation it becomes very difficult to do business in that location."
>
> **PETER PITTS**
> Center for Medicine in the Public Interest

> "In Turkey, patients have access to a less expensive healthcare system than patients in Europe."
>
> **DR. SULE MENE** / Mene Research

lenge," Mr. Schmidt says. "Turkey has now by far the lowest prices in Europe, which will be unsustainable over the long term. Fair pricing for innovative medicine will be key to further develop the healthcare system in Turkey."

Companies are also challenged by delays in regulatory approval times. Dr. Mene says a survey of 33 members of the Association of Research-Based Pharmaceutical Companies (AIFD) in February 2011 states that new drug regulatory approval timelines differ from around two to four years.

On top of that, a new regulation from the Ministry of Health, the Good Manufacturing Practice Certification, threatens further delays in new drug regulatory approval times.

Under the new GMP, manufacturing facilities that do not hold a certificate issued by the Ministry of Health, must undergo inspection. This requirement is equally applied to medicines that hold an approval from agencies such as the FDA and the EMA.

"According to figures from AIFD, the number of dosage forms and new medicines withheld from patients and doctors is heading toward 500 applications, despite pleas from industry, doctors, and patient societies," Mr. Pitts says. "And there is no relief in sight, as the MOH lacks the capacity and resources today to meet the expanding, self-imposed burdens that are a direct consequence of this regulation."

No new medicines have been approved for use in Turkey since January 2010, representing a significant slowing of medicines licensing, Mr. Pitts says.

"The treatment gap between Turkish and European patients continues to grow, with experts now calculating that Turkish patients lag European and North American patients by three to five years following approval of new medicines in those countries," he says.

However, Dr. Mene says significant improvements have been realized in healthcare services, and today access to drugs has improved significantly for around 44 million people. PV

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EXPERTS

DR. SULE MENE. CEO, Mene Research, which was the first approved CRO in Turkey by the Turkish Ministry of Health and conducts studies ranging from Phase I to Phase IV. For more information, visit meneresearch.com.

PETER J. PITTS. President of the Center for Medicine in the Public Interest and Senior Partner, Director of Regulatory Affairs and Health Policy, Porter Novelli. The Center for Medicine in the Public Interest is a nonprofit medical issues research group that is partially funded by the pharma industry. For more information, visit cmpi.org. Porter Novelli is a global public relations firm. For more information visit porternovelli.com.

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Peter Pitts

Protectionism VS. The Public Health: A Losing BATTLE

If you search the FDA online database for "Turkey," what you get are many references to listeria-related recalls, but none on any pending Turkish ANDAs — applications for generic drug approvals.

There are many reasons for this, but none of them has to do with the American regulatory agency's unwillingness to consider approval for Turkish pharmaceutical products. Why, then, does the Turkish Ministry of Health continue to use "mutual recognition" as a rallying cry?

Officially the rationale is that the MOH is concerned about health and safety. In other words, the agency is not sure it can "trust" FDA assessments. The result is that many pharmaceutical products that are available in the United States and the European Union remain unapproved in Turkey and unavailable to its citizens.

The ministry's call for "mutual recognition" one day and its "concern" about health and safety the next is confusing since these almost seem entirely contradictory. (After all, why would the ministry want mutual recognition if its "mutual" partner's regulatory system is suspect?)

Should the Turkish Ministry of Health Trust the FDA? That's an excellent policy question. And the answer is a resounding "yes" — just like the rest of the developed world. The FDA is the global gold standard. And what of the EMA? Somehow the mandarins in Ankara don't trust its quality standards either.

What's wrong with this picture? There's no logic to it, so there must be something else, some subtext driving this quixotic policy. It isn't difficult to figure out. It's protectionism. And worse, it's protectionism trumping the public health. As the saying goes: "Insolent ones are never without wounds."

> **"Turkish pharmaceutical products haven't succeeded in penetrating the American market because it seems they don't want to go through the rigor of seeking FDA approval."**
>
> PETER PITTS / Center for Medicine in Public Interest

This was made very clear last March when members of the Ministry of Health spoke about how a blunt trade barrier — disguised as a regulatory GMP dispute — would somehow compel and enhance more local manufacture, magically transforming Turkey into a pharmaceutical export hub for the Balkans and helping to positively adjust Ankara's balance of payment problems by even further lowering the amount of foreign medicines available to Turkish patients. But in recent months, the MOH has refrained from making those arguments in public.

One wonders whether the MOH got a terse memo from the Foreign Office reminding them that arguments about health and safety were okay, but that openly embracing trade barriers was beyond its ministerial portfolio.

The fact is that Turkish pharmaceutical products haven't succeeded in penetrating the American market because, it seems, the ministry doesn't want to go through the rigor of seeking FDA approval. For the most part, Turkish pharmaceutical companies are not making a concerted effort to penetrate the highly competitive American market because their profits and margins are substantial at

home, and they want to protect their near-monopoly.

Why do regulators in Ankara believe that Turkish generic drugs shouldn't have to follow the same pathway as products from Indiana, or those from China and Israel? There is no shortage of approved foreign medical products in the United States. This is common knowledge. It reveals the truth: the goal of the MOH is to keep innovative and important, safe and effective new medicines off the Turkish market so that local firms maintain a monopoly. When protectionism trumps the public health, Anatolia weeps.

This is particularly surprising — and highly concerning — considering the delicate state of negotiations relative to Turkey's accession into the European Union. Turkey's commitment to remove technical barriers to trade — import/export licensing, enforcement of intellectual property rights, and requirements for the registration of new pharmaceutical products — remain not only unfulfilled, but seem to be going in the completely opposite direction. In other words, not only is the Ministry of Health causing an ever-increasing "medicines gap" between Turkey, the United States, and the European Union, it's creating a potential foreign policy crisis.

Another unfortunately increasing disparity between Turkey and the West is in the area of intellectual property protection. Intellectual property rights are the fertile soil that facilitates the tree of pharmaceutical innovation to grow in the first place. To borrow an over-used adjective from the world of global climate change, we must protect "sustainable" innovation. And, on a related issue of relevance in Turkey, intellectual property protection and valid patent rights are a crucial weapon in the fight against counterfeit and substandard medicines.

To quote directly from the World Health Organization report (March 2008): "A competitive marketplace is the best way to ensure low prices for medicines. Proper organization of the market and application of anti-trust (monopoly) laws should facilitate price competition."

Alas, according to the European Commission's 2010 progress report on Turkey's progress toward joining the EU: "No progress can be reported in the legislative framework for industrial property rights. A constructive and structured dialogue should be established between the Turkish Patent Institute (TPI) and IPR-holders. Issues linked to bad faith and similar trademarks and industrial designs remain unresolved. The re-examination board needs more legal experts. The search and examination capacity of the patent department needs to be improved. The draft laws regulating industrial design and patent and geographical indication rights, including deterrent criminal sanctions, prepared by the TPI in consultation with other stakeholders need to be urgently adopted by parliament as the deadline for the adoption of new legislation expired on 10 June 2010."

There is a reason why virtually all the world's "miracle drugs" have been developed in Western countries. It's called incentive. Because innovation is honored and protected, inventors are rewarded for their work.

Unfortunately, once a life-saving drug or treatment exists, it's seductively easy to take it for granted. We sometimes forget the years of toil these things take to develop; the millions spent to bring a new drug or treatment from theory to actuality.

And because we need it, we expect it to be free. But if we allow our emotions to trump reason and cloud our minds to the realities of human nature and economics 101, we'll end up with a lot less innovation.

And fewer lifesaving drugs to take for granted. And that is a conclusion that must be unacceptable in Turkey.

Robust protection of intellectual property, to quote Abraham Lincoln, adds "the fuel of interest to the passion of genius."

Turkey has an important role to play in the world of both innovative and generic medicines. But, to alter the Turkish proverb, a sheik's miracles must not be of his own telling. PV

Source: Peter J. Pitts, former FDA Associate Commissioner, Senior Partner, Director of Regulatory Affairs, Porter Novelli, and President of the Center for Medicine in the Public Interest. For more information, visit cmpi.org.

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