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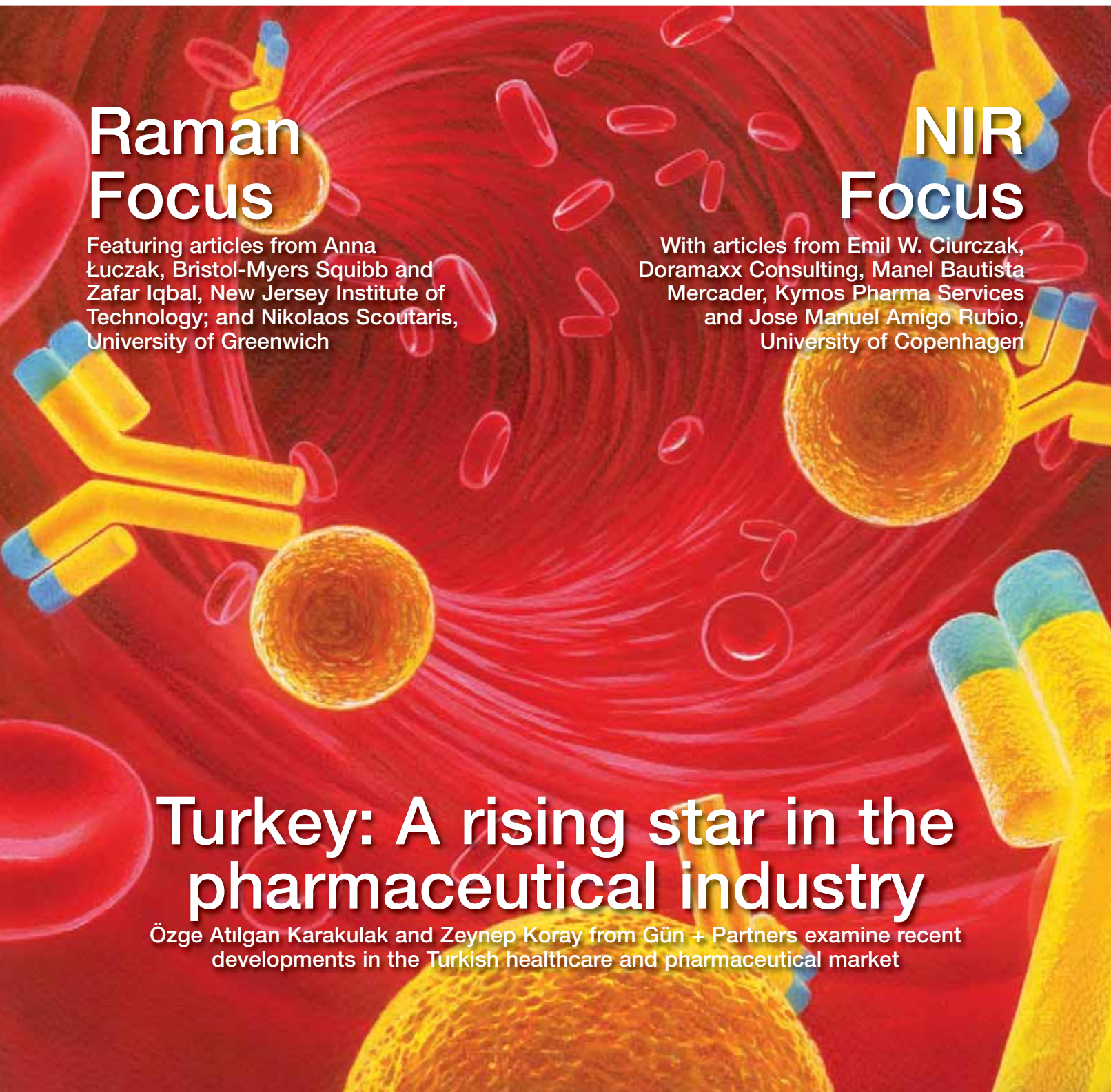

Raman Focus

Featuring articles from Anna Łuczak, Bristol-Myers Squibb and Zafar Iqbal, New Jersey Institute of Technology; and Nikolaos Scoutaris, University of Greenwich

NIR Focus

With articles from Emil W. Ciurczak, Doramaxx Consulting, Manel Bautista Mercader, Kymos Pharma Services and Jose Manuel Amigo Rubio, University of Copenhagen

Turkey: A rising star in the pharmaceutical industry

Özge Atılgan Karakulak and Zeynep Koray from Gün + Partners examine recent developments in the Turkish healthcare and pharmaceutical market

Turkey: A rising star in the pharmaceutical industry

Özge Atılgan Karakulak and Zeynep Koray
Gün + Partners

You are waiting in line, trying to decipher several different languages spoken around you: English, Dutch, German, Arabic, French... This scene is not from an airport but rather from a Turkish hospital: thousands of foreigners, communicating through translators, visit healthcare institutions every day and numbers are increasing exponentially; in the first six months of 2014, 162,445 medical tourists visited Turkey. This is only one of the results of the Health Transformation Project (HTP), inaugurated by the Turkish Ministry of Health in January 2003. The Project, aiming ultimately to enact universal health coverage and to raise the quality of life of Turkish citizens, has brought major reforms in the organisation of, and access to, healthcare services. This article will chart some of the changes that have recently occurred in the Turkish healthcare market, before focusing on developments in the rapidly growing pharmaceutical sector. We will also suggest solutions to some of the challenges facing the bustling Turkish market.

One major reform provided by the HTP was the expansion and amalgamation of health insurance, which gave all citizens, including the poorest people, access to a universal healthcare insurance scheme. Previously existing state insurance models were merged into the general health insurance program, thus extending coverage, and the newly-established Social Security Institution became its administrator, replacing the tripartite organisation scheme of SSK (Social Insurance Institution), BAĞ-KUR (Social Security Organization for Self-Employed) and Emekli Sandığı (Social Security Organization for Civil Servants).

Meanwhile, structural reforms increased the capacity of healthcare institutions, enabling for better management and more efficient use of healthcare personnel and resources. Such reforms included: the integration of state hospitals, insurance hospitals and institution

hospitals, the establishment of new health institutions, the construction of new buildings for public hospitals, the modernisation of existing facilities and restrictions on the private working principles of state-employed healthcare professionals.

The reforms introduced by the HTP have been regarded as very effective, since, within the first six years, Turkish life expectancy rose from 71.8 to 74.3 years, infant mortality declined by 52%, vaccination rates rose from 78% to 96%, hospital rates increased from 124 million to 295 million and the number of primary care facilities increased 230%.

Investment opportunities for pharma

While the healthcare system has improved, Turkey has become a key player in the global pharmaceutical arena, where it presently ranks as 36th largest in the world. The introduction of technology, or 'techno' parks, from the end of 1990's, has helped to achieve this.

These organisations manage and initiate the movement of knowledge and technology amongst universities, R&D institutions, companies and markets and as such are important centres for cooperation between researchers and industry. They sprung from a project coordinated by the State Planning Organization and United Nations Fund for Science and Technology for Development. In 2001, with the enactment of Law on Technology Development Zones (Number 4691), the legal basis for the development of these technology zones was established and to date 39 techno parks have been founded throughout Turkey.

Although companies currently working in the biomedical sector constitute only about 3%, this number is expected to increase significantly in the near future with the foundation of the first biomedical techno parks in Izmir and Çatalca. Thanks to the financial benefits granted by law, these zones continue to attract foreign capital. As recent public policies place an increasing emphasis on the importance of public authority, university and industry cooperation, private companies, universities and research institutions are accelerating their common projects and contributing to the much-needed innovative climate.

> "In addition to drugs pricing pressures, there is a serious discount demand for reimbursements"

The Turkish government has also adopted certain policies to encourage and facilitate investment, while decreasing the weight on public spending. Public private partnerships (PPPs) have started to be established to assist the growth of the healthcare industry with the support of the private sector and these projects, based on the PPP model, and create innovative opportunities for private sector players.

Similarly, planned 'Free Health Zones' will provide foreign investors with cheap infrastructure and investment opportunities, as well as playing an important role in overcoming the lack of staff through the employment of foreign doctors and nurses. Medical tourism, which is already a key strength for Turkey (it presently ranks at seven in the list of the top ten countries for health tourism), will become better regulated and the market enhanced with the help of these Free Health Zones. As the Turkish Minister for Health, Mr. Müezzinoğlu announced, the aim is "to show the brand value of health in Turkey to the neighbouring region comprising a population of one billion and increase healthcare tourism revenue from $2.5 billion to $10 billion in the next five years."

Regulation is aligned with EU standards

Healthcare sector regulation in Turkey is mostly aligned with worldwide standards. Promotional restrictions with respect to pharmaceutical products and medical devices, as well as the rules of ethics and compliance, are in parallel to EU legislation. This makes it easy for European companies to make the transition to investing in Turkey. Furthermore, with a vast population and high number of educated physicians, Turkey has a great potential for clinical trials. For a long time clinical trials lacked effective legislation, but in April 2013 the Regulation on Clinical Trials of Pharmaceuticals and Biological Products was enacted and the necessary legal basis was established. This was completed with the Regulation on Clinical Trials for Medical Devices, which came into force in September 2014.

Besides public hospitals, private hospitals under the control of a governmental body are also allowed to conduct clinical trials, aiming at increasing the number of studies. However, better rewarding the academic researchers who conduct clinical trials would create incentives for more researches to participate. Currently the market is preparing to accept, as an industry standard, to disclose the results of clinical trials, allowing other companies to benefit from the resulting data.

Challenges to entering the Turkish market

The dynamic healthcare market in Turkey, ripe with opportunities for investors, is not without challenges for those wishing to invest. For example, the approval process for the marketing of new drugs, which is the first step for pharmaceutical companies entering the market, is slow and problematic. Although national legislation dictates that the Ministry for Health must authorise the registration of pharmaceuticals within a period of 210 days, in practice this period is almost five times that. The requirement for a Good Manufacturing Practices (GMP) certificate has further slowed down the approval process. This policy, adopted in March 2010, requires Ministry of Health personnel to conduct an inspection at the production site and, due to insufficient resources and long waiting lists, this procedure takes a very long time.

Meanwhile, the increase in the quality of health services and patients' access to medicines has inevitably increased the demand for health services as well as pharmaceuticals, and there has been an associated increase in public spending. This has prompted the government to seek ways of reigning in public expenditure, and one of the ways in which it has approached this is by incorporating a rigid pricing policy for pharmaceuticals.

A Law on Pharmaceutical and Medical Preparations (Number 1262), states that the Ministry for Health is empowered to confirm and approve the price of the drugs, however, it has been criticised for fixing prices. Referenced drug prices are determined by the Price Evaluation Commission, which has the discretion to maintain or change the foreign exchange rate and it has fixed it at the 2009 level. The Ministry has also been insisting on applying reference price cuts.

We believe a more sophisticated system must be introduced for the pricing of pharmaceuticals. Innovative products need to be supported, which will decrease the spending on healthcare services and

pharmaceuticals in the long term. Alternative methods of payment would lead to the establishment of a better relationship between the Social Security Institution and drugs manufacturers.

In addition to drugs pricing pressures, there is a serious discount demand for reimbursements. For innovative drugs, this discount reaches up to 41%. These difficulties in pricing and reimbursement have caused a hindrance in the access to pharmaceutical products. Procurement from abroad of pharmaceuticals that cannot be found on the domestic market has greatly increased, which has led to extra expenditure on the health budget.

With the recent enactment of a new Law (Number 6552), the Social Security Institution has been authorised to develop alternative reimbursement models. However, this Law is ambiguous and does not define what the alternative reimbursement models are, how they will work and from which date they will be applicable, and pharmaceutical companies are concerned that alternative reimbursement models might violate the administrative law principle of equal treatment, if these models are provided only for the entrance of new drugs to the reimbursement list. Overall, without objective reimbursement decision-making criteria, this provision bears considerable uncertainties.

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Imports reliance needs to change

Another challenge in Turkey is the country's reliance on imports. Domestic production must increase to a level which not only meets the country's needs but also delivers a good level of export. At a recent meeting with pharma manufacturers, the Minister of Science, Industry and Technology, Fikri Işık, stated that the government wishes to minimise foreign dependency on pharmaceuticals as much as possible and has underlined that it will be much more aggressive in support of local pharmaceutical production. The assistant secretary at the Ministry of Health, Nazım Gümüş, recently announced the foundation of the Directorate of Turkish Health Institutions which will accelerate studies for the development and domestic production of pharmaceuticals. The primary focus of domestic production will be cancer drugs, antibiotics and blood products, which together constitute the major cost in the budget. In this regard, new factories will be established in the beginning of 2015, the construction encouraged through the build-operate-transfer model.

Whilst announcing the Action Plan for the Structural Transformation Program in Healthcare Industries in the beginning of November 2014, Prime Minister Ahmet Davutoğlu explicitly stated that the government would prioritise domestically-produced medical supplies and medical devices. He added: "Turkey will hopefully be able to produce 20% of the medical devices it needs and meet 60% of its demand for medicines by 2018."

Although decreasing import dependence and taking measures to cover the current deficit are essential, hurdles to the import of critical products and their entrance into the market must be avoided while incentivising local manufacturing and exports.

Sluggish growth in the area of R&D is another challenge in Turkey. However, we believe that the government intends to stimulate R&D and innovation. Minister Fikri Işık has declared that the government is aiming to increase the R&D budget to $60 billion. Emphasising the importance of university and industry cooperation, he has announced that the Ministry of Science, Industry and Technology would cover 85% of the costs arising from these cooperations. R&D financing and state-funded research will also increase, whilst financing by the Social Security Institution itself, which is the biggest buyer in the market, could be an effective solution.

When it comes to intellectual property (IP) in Turkey, the regime here lags behind that in the European Union (EU), with data exclusivity having only come into force in the country in 2005, and Turkey has been under pressure from the EU and United States to improve its IP environment for many years. It has also been criticized for falling short of The Agreement on Trade-Related Aspects of Intellectual Property Rights, the international agreement administered by the World Trade Organization, which sets minimal intellectual property standards for IP regulation.

For greater innovation and investment in the pharmaceutical market, the strengthening of IP protection is imperative, as investors would only be reassured if adequate protection is in place. As Turkey is a signatory to the European Patent Convention, the Patent Decree-Law must be brought fully in line with the EPC. Alongside legislative amendments, the approach of the courts also needs to change and become more patent friendly.

Conclusion

The government's health reforms have brought numerous positive developments to the healthcare sector. However there is a risk that the problems experienced in the access to medicine overshadow these positive developments. There is a need for more focus on how to ensure sustainability in the pharmaceutical sector instead of using soley a cost-oriented approach.

The government has set very ambitious goals and is working to implement the required legislation to stimulate growth in the pharmaceutical arena. Nevertheless, there are still major challenges that the country needs to overcome. In the future, we are optimistic that the obstacles facing foreign investors will be minimised, the issues concerning approval and reimbursement of pharmaceuticals will be overcome and a greater number of incentives will be provided to foreign companies in order to encourage them to conduct more R&D activities and clinical trials in Turkey.

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