Interview with Ä°lker AycÄ±, President, The Republic of Turkey Prime Ministry Investment Support and Promotion Agency

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Currently, what are the main priorities and goals of ISPAT related to the Healthcare and Pharmaceuticals sector, and what are the overall strategies designed to achieve these objectives?

As an agency we aim to attract high quality FDI to Turkey. With â??high qualityâ?• we mean investments that would enable technology transfer, that would fortify and diversify this countryâ??s exports and increase our competitiveness in global markets. High quality FDI would also help decrease the current account deficit, and create employment for an ever-increasing young and dynamic population.

Turkey intends to become one of the 10 top economies of the world by 2023, which is the centennial anniversary of the republic. To accomplish this, the government has decided on a target export volume of $500bn, which currently stands at $135bn (2011).

There is no doubt that the health care and pharmaceuticals sector as well as the medical devices sector are among high priority industries where we would like to see a greater growth of FDI that would bring in new technologies, help domestic products to move up in global value chains, and increase exports. On the other hand, through promoting FDI and providing support to investors ISPAT is responsible for endorsing the national goals of other government agencies and ministries including the health institutions in Turkey. In this context, the pharmaceuticals and healthcare sector is on our radar screen in view of national health policies which make sustainability of health services a key goal.

ISPAT is in accord with the Pharma industryâ??s view that Turkey has all the qualification to be an R & D and manufacturing center for Biotechnology/Biosimilar products as well as a hub for Pharmaceutical Innovation and Development with its highly qualified workforce, attactive regulatory environment and incentive structures. In this regard, ISPATâ??s promotion and support activities focus to improve pharmaceutical industryâ??s international competitiveness, and position the Turkish Pharma Industry, as one of the global R&D and production hubs, a net exporter and a regional management centre.

Could you provide our readers with an overview of the Turkish pharmaceutical market and its potential for growth?

With its 74 million people, Turkey is the 18th largest country in the world by population size. 50% of this population is between 0 and 29 years old and the share of people between 30 and 65 years old is 42%. By 2025 it is expected that the population will increase to 85 million people and the population between the ages of 0 and 29 will decrease from 50% to 44%. With this aging population,

healthcare services will become a more significant budgetary concern for Turkey in light of the fact that the government is the largest provider of healthcare and the only public provider of preventive services in Turkey. The SGK (Social Security Institution) is responsible for public pharmaceutical expenditure, which represents the vast majority of the total market. Therefore access to pharmaceuticals and provision of healthcare services are particularly crucial for the country.

The Turkish pharmaceuticals market, which includes patented, generic and non-prescription drugs, has a turnover of US$10bn; while annual healthcare expenditure is around US$50bn. Turkey was ranked 6th largest market in Europe and 14th in the world by the end of 2010. To put it in perspective, the Turkish pharmaceuticals market is currently larger than the Indian market and close to the South Korean market in terms of size.

With growing demand the Turkish pharmaceuticals market is projected to expand to 55bn while the healthcare market will reach 80bn by 2023 (Boston Consulting Group projection). If you consider that the number of applications to hospitals has increased by 207% and total healthcare expenditure has risen from 18bn to 58bn between 2002 and 2008, the importance of health policies becomes clearer. As GDP per capita (currently at $10,000) grows healthcare spending is expected to follow.

Turkey has the technical capability to produce a wide range of pharmaceuticals, but relies heavily on foreign companies for expensive hi-tech treatments and vaccines, cancer drugs and hormones. Turkey is also dependent on imports for APIs (Active Pharmaceutical Ingredients). On the other hand, the Turkish pharmaceutical industry is mainly centred on the production of non-innovative drugs including antibiotics, anti-rheumatics and analgesics, but also provides contract manufacturing services for multinationals.

Therefore, the Turkish pharmaceutical industry needs to further enhance its innovation capacities. This relates to developing new processes, formulations and combined products while, in the long run, focusing on building a capability to develop new molecules. However, as the industry is still evolving it does not yet have sufficient funds to spend on product development, although the government has launched certain incentives to encourage R&D.

Currently there are approximately 300 pharmaceutical entities operating in Turkey, 53 of which are multinational drug companies. These include leading multinationals such as Pfizer, Novartis, Bayer and Roche which maintain a market share of 4-6%, each. With respect to production, there are 49 manufacturing facilities in country of which 14 are foreign owned. Multinationals with manufacturing facilities include Sanofi-Aventis, Baxter, Bayer, GSK, Novartis, Pfizer and Roche, with EastPharma being the latest to enter the market.

How would you describe Turkeyâ??s current position with respect to pharmaceutical trade and how do you see it developing in the medium term?

In 2010, Turkey imported US$4.24bn and exported around US$560mn worth of pharmaceuticals, resulting in a negative pharmaceutical trade balance of US$3.72bn; making the pharmaceutical industry responsible for 10% of the Turkish trade deficit. In terms of value, imported drugs in 2010 constituted 52% of the Turkish market. Moreover, this deficit is expected to grow in the coming years given continued import dependency and increasing domestic demand.

Looking into the future, however, AIFD (The Association Research-Based Pharmaceutical Companies) has an ambitious yet realistic vision set for the Republic of Turkeyâ??s Centennial â?? Vision 2023. In a little over a decade, AIFD aims to increase total R&D investment to $1.7bn from US$61.4mn in 2010. Moreover, AIFD aims to more than quadruple local pharmaceutical production to US$23.3bn with the production of high value added, innovative and high-tech drugs in Turkey. Through these initiatives, AIFD intends to export pharmaceutical products and services worth

US$8.1bn â?? including a clinical trial services amounting to US$782mn compared to current total exports of US$587mn.

Ultimately, these plans will shape Turkey as a net exporter with a pharmaceutical export surplus of more than US$1bn.

What regulatory reforms and frameworks have the various governmental institutions enacted to support the growth in the industry?

The healthcare system in Turkey is being developed under the 2003-2013 Health Transformation Program. The purpose of this program is to increase the quality and efficiency of the healthcare system and enhance access to healthcare facilities with the introduction of a number of reforms.

Since 2003 Turkey has made structural changes in its health policies by targeting the creation of a sustainable health system that is able to provide high level services for everyone in every part of Turkey. The main aims of these policies are to discipline and standardize service purchases, increase the effectiveness and quality of the existing structure by unifying the management of publicly owned healthcare institutions and expanding the social security systemsâ?? coverage. Also, private investments towards the healthcare system have been encouraged.

Overall, these reforms have shown their effect. This is demonstrated by the ratio of the population that is covered by the social security system, which has increased from 84% in 2004 to 96% by the end of 2011, for instance. Similarly, the number of public hospitals has increased from 1,183 to 1,397 between 2000 and 2010, while the number of privately owned hospitals has also increased from 261 to 489 in the same period. In parallel, the government introduced a new pricing system â?? the Reference Pricing System â?? to sustain public access to drugs with affordable prices.

On the other hand, in an attempt to significantly limit the registration appraisal time for new drugs to 210 working days, the government introduced a new Regulation on the â??Registration of Medicinal Products for Human Useâ?? in January 2005. Although admittedly there are ongoing problems with the time required to register, price and reimburse new medicines the government is keen to actively improve the situation.

With regards to the ensuring a system of intellectual property rights (IPR) that is conducive to the strengthening of the manufacturing basis of the country and create an innovation friendly environment for investors, Turkey has also made significant progress in the area of IPR enforcement. Over the past decade, Turkey has established over 23 specialized civil and criminal IPR courts. In addition to being a signatory to various IPR conventions and treaties, Turkey has also taken further steps to strengthen its IPR regulations to satisfy its EU accession process and has established an EU-Turkey Working Group on Intellectual Property Rights to this end.

As the government is aware of the remaining concerns on the IP enforcement of confidential test data and patent enforcement, it is expected that outstanding issues will be handled with high-level consideration. The Turkish government is keen to attract investment and is developing regulations in line with EU directives in the realm of IPRs and R&D.

Having established the regulatory foundations, how do you aim to incentivize and attract business and R&D investments into Turkey?

With regards to financial incentives, the government has introduced new and soon to be legislated incentive systems. These are based on four pillars which are general, regional, large-scale, and strategic investment schemes.

Broadly speaking, the general incentive systems includes VAT Exemption and Custom Duty Exemption, while the other schemes contain instruments such as corporate tax deduction, government compensation for employerâ??s share for social security premium, as well as, land allocation and interest support.

With regards to the remaining schemes, the rate and level of government contribution in the schemes varies with the location of the investment within the national regions. Therefore, pharmaceutical investments can certainly benefit from these investment incentives depending on the location of the investment and the amount to be invested. Furthermore, specific pharmaceutical investments for oncological medicines and blood products, as well as, biotechnology with minimum investment amount of 20mn will benefit from highly attractive incentives regardless of the location.

Moreover, to benefit from the large scale investment incentive scheme, the minimum required investment for pharmaceutical manufacturers has been reduced to 50mn from 100mn. Finally, if an investment is valued at more than $50mn for products which are currently imported, then they are classified as â??strategicâ?• â?? provided a number of criteria are satisfied. Strategic investments of course benefit from additional incentives.

Another attractive investment feature of Turkey is its well-balanced macroeconomic outlook as well as strict fiscal and budgetary discipline. In fact, Turkey is among the few countries that satisfies the requirements of the Maastricht Treatyâ??s economic criteria with relation to budget gaps and debt issues. This ultimately serves as a shield to all kinds of investments.

On the other hand, considering R&D investments, the Turkish government has been encouraging companies to set up their own R&D centres. Companies with R&D centres can expect to enjoy several benefits. These include, for instance, tax deductible R&D expenditures, income tax deductions of 80% and 90% for employees with PhD and Masterâ??s degrees, respectively, support for social security premiums for five years, no stamp duty for application documents as well as financial grants to new scientists. The increased national R&D expenditure is illustrative of such developments and incetives, having increased from 0.48% of GDP in 2000 to 0.84% of in 2010 â?? a historical high. Moreover, in line with its vision to becoming an R&D center the government aims to increase this amount to 3% by 2023.

In addition to this, R&D activities are further encouraged and supported by Technology Development Zones (TDZ). These are primarily located at the borders of universities and provide ready to work spaces and companies enjoying R&D supports and act as meeting points between industry and the university. As of December 2011, there are 39 TDZâ??s across Turkey boasting over 1,800 companies operating.

Local Manufacturing of biotechnology products by Turkish companies are under progress. Recent government incentives for biotechnology manufacturing facilities is expected to initiate local manufacturing and attract further foreign direct investment in the field of biotechnology; as in the case of the acquistion of Mustafa Nevzat Pharmaceuticals by Amgen for US$700mn.

Moreover, multinationals such as GSK and Roche are increasingly interested in investing in clinical research. For instance, Roche opened its 6th clinical experiments centre in Turkey in 2009.

In addition to this, Turkish companies have already started to invest for Biosmilars. For example, KoÃ§ak Farma started to invest on biosmilars in 2008 and had launched Enoxaparin Sodium as the first biosmilar in Turkey and EU this June.

What would your recommendation be to mid-sized pharmaceutical and biotech companies seeking to take advantage of the opportunities here and enter the Turkish market?

My first recommendation to them would be to cooperate with the variety of SMEâ??s (small medium enterprises) available in Turkey that are also keen to form partnerships and share information with foreign companies as well. If they successfully find the appropriate business partner, they can minimize their risks by quickly gaining an insight into local expertise and business culture. This can serve as an ideal starting point for foreign entrants promoting a win-win situation for both parties.

Moreover, should they require any further assistance, companies are welcome to approach us at the ISPAT. We can coordinate all and any of their activities, meeting, applications and permits with any of the governmental authorities. Similarly, our assistance will also help to shorten their transition into the Turkish market and help to protect their investments.

What is your outlook for the future of Turkeyâ??s pharmaceutical industry and ISPATâ??s role in achieving this?

Turkeyâ??s geographical position plays a central role in its aspirations to become a pharmaceutical production hub for the region. Its proximity to Europe, CIS and MENA, combined with its competitive cost structure and developed production capabilities, will support Turkeyâ??s ambitions described above. Not but least the accession process with EU will improve Turkeyâ??s institutional and business capabilities.

As of today the industry do export to more than 100 countries including EU member states as well as the US. This demonstrates Turkeyâ??s developed installed capacity and the fulfilment of the strictest quality and production standards. In this context, the challenge for Turkey and ISPAT is to further increase FDI to ensure long term sustainability of national healthcare provision with new investments to manufacturing of drugs and R&D.

In order to maximize growth and efficiency within the healthcare industry ISPAT work with relevant bodies such as the Ministry of Health, Scientific and Technological Research Council of Turkey (TUBITAK), research institutes, and universities as well as private stakeholders including both international and domestic firms. As a recent example of a joint effort in promotion of investment opportunities in Turkish pharmaceutical, healthcare and biotechnology industries, ISPAT has organized Turkeyâ??s participation in the 2012 Bio International Convention. In addition to the Ministries of Health and Science, Technology and Industry as well as TUBITAK, industry representatives such as the Association of Research-based Pharmaceutical Companies (AIFD), the Pharmaceutical Manufacturers Association of Turkey (IEIS) and several firms were presented with the opportunity to inform international business and science communities about the potential of Turkey.

Despite certain market access issues in the short run, we would highly recommend it to international investors to take into account the opportunities in Turkey provided by a growing market. It is important to make investment decisions by looking at the opportunities within a longer term perspective taking into account favourable long-term macroeconomic conditions and prospects for growth due to demographic and welfare dynamics.

Turkey has a favourable long-term macroeconomic outlook, reflected in BMIâ??s ten-year forecast which predicts improved access to medical care through the extension of state-funded health insurance towards European-style universal coverage. This positive outlook is further enhanced by various factors, such as increased life expectancy and strong population growth, which combine to give the marketâ??s long-term promise.

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