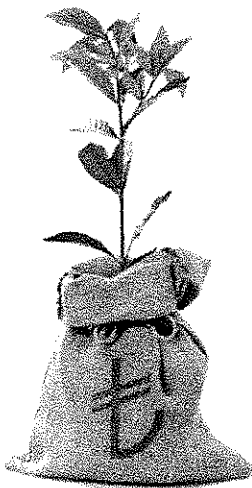




Turkey: A growing pharma market with huge potential

The Turkish biopharma market offers many opportunities - if it can overcome its sustainability challenge



Waiting in line, trying to decipher the 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. A quarter of a million foreign patients come to Turkey each year for medical treatment - and this number is increasing exponentially.

This is only one of the results of the Health Transformation Project, inaugurated by the Turkish Ministry of Health in January 2003. The Project, aiming to ultimately realise universal health coverage and to raise the life quality of Turkish citizens, brought major changes in the organisation of, and access to, healthcare services. To centralise healthcare services, existing state insurance models were merged into the general health insurance programme, with extended coverage, and the newly-established Social Security Institution became its administrator. Structural reforms were carried out in order to increase the capacity of healthcare institutions, enabling better management and more efficient use of healthcare personnel and resources.

The ultimate goal is to provide access to high-quality healthcare services and a series of reforms are being implemented including: the integration of State hospitals, insurance hospitals and institution hospitals, the establishment of new health institutions, construction of new buildings for public hospitals, the modernisation of existing facilities and restrictions on the private working principles of state-employed healthcare professionals.

These reforms have been very effective, as within the first six years of the Project, Turkish life expectancy rose from 71.8 to 74.3 years and the number of primary care facilities increased 230%. Nevertheless, this positive development in health indicators led to a significant increase in the public spending. The government has started seeking ways of realising these projects by minimising the cost to the public budget. Public private partnerships (PPPs) were established to assist the growth of the healthcare industry with the support of the private sector and these projects, based on the PPP model, afford innovative opportunities for private sector players. 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.

On the other hand, the increase in the quality of health services and patients' access to medicines inevitably increased the demand for health services as well as pharmaceuticals.

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While the Turkish government tries to balance increasing public health spending with a rigid pharma pricing policy for pharmaceuticals, in 2012 pharmaceutical spending in Turkey accounted for 1.02 % of GDP. There is also a strong need to invest in local R&D and to incentivise exports in order to reduce foreign dependency and strengthen Turkey's role as a player in the global pharmaceutical arena, where it presently ranks as 36th largest in the world.

This article will focus on developments in the Turkish pharmaceutical sector, which is a rapidly growing market offering many opportunities despite a number of challenges, and on possible solutions to overcome these.

The challenges

The approval process for the marketing of new drugs, which is the first step to entering the market, is slow and problematic in Turkey. Although through national legislation the Ministry of 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.

The 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 is taking a very long time.

The pharma pricing remains one of the most problematic issues. Even though Law 1262, on Pharmaceutical and Medical Preparations, states that the Ministry of Health is empowered to confirm and approve the price of the drugs, the authority of the Ministry of Health is construed to extend to fixing prices. The reference price system has started to lose its rationale as the 'periodic Euro value' to be used in the calculation of referenced drug prices is 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. On the other hand, the Ministry is insisting on applying reference price cuts. In addition to this pressure on the price of pharmaceuticals, 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 those 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 Law 6552, the Social Security Institution has been authorised to develop alternative reimbursement models. Although these alternative reimbursement models can provide a way out, without objective reimbursement decision-making criteria, this provision bears considerable uncertainties.

Suggestions

Turkey holds great potential, as well as motivation, for pharma growth. The government has set very ambitious goals and is working to implement the required legislation. Nevertheless, there are still major challenges that Turkey needs to overcome.

Firstly, and most importantly, domestic production must increase to a level which not only meets the country's needs but also reaches to a good level of export. At a recent meeting with pharma manufacturers, the Minister of Science, Industry and Technology, Fikri Isık, has stated that the government wishes to minimise the foreign-dependency on pharmaceuticals as much as possible. The assistant secretary at the Ministry of Health, Nazım Gümüş, has recently announced that the foundation of the Directorate of Turkish Health Institutions will accelerate studies for the development and domestic production of pharmaceuticals. However, while incentivising local manufacturing and exports, hurdles to the import of critical products and their entering into the market must be avoided.

Secondly, a more sophisticated system must be introduced for the pricing of pharmaceuticals. Innovative products shall be supported, which will decrease the spending on healthcare services and pharmaceuticals in the long term. Alternative methods of payment have been proposed and a healthier relationship shall be established between the Social Security Institution and the

manufacturers of pharmaceuticals.

Furthermore, more emphasis shall be given to R&D and innovation. Fikri Isik has declared that the government is aiming to increase the R&D budget to \$60bn. Emphasising the importance of university 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. Financing by the Social Security Institution itself, which is the biggest buyer in the market, could be an effective solution.

For more innovation and investment in the pharmaceutical market, the strengthening of IP protection is inevitable, 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.

The health reforms of the Turkish government has 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 only a sole cost-oriented approach.

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