

## **US-Turkey Business Council, Session III**

### **Topic 7.**

#### **Life Sciences**

##### Background:

The Life Sciences sector, comprising technologies for the advancement of crop, animal and human life, including specifically biotechnology and pharmaceuticals (including the generics and innovative segments), represents one of the fastest growing, dynamic and high value-added strategic sectors in the global economy.

The U.S. is acknowledged as the global leader today in biotechnology, research-based pharmaceuticals, medical devices and diagnostics. A very high percentage of novel products and devices originate from the U.S., which has established a strong and stable eco-system to support innovation in Life Sciences. Forward-looking policies, built on years of private-public sector consultation and collaboration, form the building blocks of this success.

In recent years, senior Turkish policy-makers have expressed their ambition to evolve as a global competitor in Life Sciences, with a specific focus on biotechnology, medical devices, and establish a manufacturing base for the export of generics and innovative medicines.

The Government of Turkey has made significant investments in its healthcare sector over the past decade, resulting in impressive improvements in health outcomes. However, it's ranking on key pharmaceutical and healthcare indicators still barely meets the global average. Turkey is the 16th largest pharmaceutical market in the world, but ranks only 35th in share of pharmaceutical R&D and manufacturing; it also lags compared to other similar sized markets in FDI for R&D and manufacturing.

To position itself as a major player in the life sciences, especially in pharmaceuticals, and to secure a greater share of global pharmaceutical investments, Turkey should consider recalibrating its policies to create the eco-system of innovation needed to create and support the life sciences industry.

These policies that comprise the eco-system include a high degree of free market competition, recognition and reward for innovation, consistent public support for basic research, close collaboration between the private sector and academia, a world-class intellectual property rights system to support investment and commercialization, and a globally-recognized standards-setting regulatory authority.

Industry has been working with the government for a number of years with the goal for the Government to develop a well-articulated, detailed vision, strategy and policy road map that would support a vibrant medical devices, generics and innovative medicines sector. More work is needed to develop and implement policies that will allow Turkey to compete with other countries seeking to develop the life sciences sector. Based on the data from a recent Putgatch Report released at the Annual International Biotechnology Conference, Turkey has yet to create the eco-system that will allow it to compete with other countries seeking the same investments.

### Opportunity

The U.S.-Turkey Business Council, aware of Turkey's as yet mostly untapped but very high potential for R&D, manufacturing and exports in this sector, is encouraged by outreach by the new government to external stakeholders and across relevant ministries and government agencies to develop a new Vision and Strategy to rejuvenate the sector. Industry believes the creation of the new Health Care Steering Committee to oversee the transformational change in the healthcare sector is an important start.

As an established powerhouse in the Life Sciences, the U.S. is in a strong position to provide benchmarks, modeling and counseling on best practices. It's globally leading Life Sciences companies are in a strong position to increase their investment, employment and operations in Turkey. As a country possessing rich human potential and other competitive advantages, including a well-established healthcare and university system, Turkey can reasonably expect to achieve its ambition to become a global top 10 player in the Life Sciences sector by 2023. In a globally-competitive world, however, this will necessitate adopting world class

standards and practices, including supporting the young researchers in universities in Turkey, as well as predictability and transparency in this sector.

The U.S-Turkey Business Council urges that the governments would prioritize their collaboration in this sector, particularly in the area of harmonizing regulatory standards and best practice sharing to incentivize investment. Upgrading and harmonizing standards in these areas will strengthen the prospects for the sector in both countries. It will also fortify the case for moving toward an FTA and ensuring that Turkey will be among equals at the U.S.-E.U. Trans-Atlantic Trade and Investment Partnership.

### **Recommendations:**

U.S. and Turkish policy-makers should agree to provide the necessary technical assistance and demonstrate strong political will to support the advancement of the Life Sciences sectors in both countries.

- This includes cooperation in the regulatory sphere that would assist Turkish companies aiming to increase exports to the USA and find new partners there, and policy assistance that would help U.S. companies to benefit from a secure and predictable investment and operating environment in Turkey. Explore ways to connect possible partners as a means to increase exports to the USA.
- Given the size of the Life Sciences sector, it is important that the two countries accelerate harmonization of standards (e.g. regulatory, market access including pricing and market-based exchange rates) in a manner that would provide a stronger foundation for FTA discussions or Turkey's close involvement in the US-EU TTIP. Specifically,
  - **Ensure local market price of products is not barrier to exports.**  
**Confirm timetable** to move to 100% of FX rate by 2019.
  - **Promote industry dialogue with government** to:
    - 1) Ensure fair and transparent public tender procedures
    - 2) Review opportunities for incentives for investments in manufacturing and other R&D and pharma-related investments

- **Extend concurrent GMP and registration applications to Category II** to expedite patient access.
  - **Implement risk-based assessments on-file** by relevant experts **for an expedited review of sites** approved by **FDA or EMA**.
  - **Finalize membership by Turkish Pharmaceutical and Medical Devices Agency (TITCK) in PIC/S** including FDA and other EU authorities.
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- The US Government should direct the FDA to conduct 2-3 technical workshops in Turkey in 2017-18 focusing on the regulatory process and requirements for approving exports of pharmaceuticals, food and agricultural products.
  - Create a formal role of private sector engagement and input with and into the new Health Care Steering Committee
  - Leverage Turkish expertise especially on phytotherapy and conventional methods for R&D of innovative products.
  - Ensure an attractive investment climate by refraining from implementing preferential reimbursement arrangements for healthcare products produced domestically and the delisting of imported products from the reimbursement list as such measures appear to be inconsistent with the WTO's national treatment requirements.