Hakkı Gürsöz, President, TiTCK, Turkey

"Turkey is engaged in a two-way transformation process impacting both its health system and its healthcare industry – and TiTCK stands as a key driver behind this dual dynamic"

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Dr. Hakkı Gürsöz, president of the Turkish Medicines and Medical Devices Agency (TiTCK), provides insights into recent localization and pricing policies and delivers strong messages to both domestic and foreign companies operating in Turkey w

hile underlining TiTCK's ambitions to work hand-in-hand with the industry, the world's most respected regulatory authorities and international organizations to further move the Turkish healthcare ecosystem forward.

Founded in November 2011, TITCK is a relatively young regulatory agency. You have been one of TITCK's key executives since the very beginning, first as vice president and then as president since July 2016. Could you give an overview of the structural dynamics and principles that have been guiding the development of TITCK over the past seven years?

As part of Turkey's first Health Transformation Program (2003-2013), the Ministry of Health conducted a comprehensive assessment and came to the conclusion that Turkey should follow the example paved by many developed and developing countries when it comes to handling regulatory and inspections functions. This led to the creation of the Turkish Medicines and Medical Devices Agency (TiTCK) in November 2011, while the agency became fully operational as from March 2012. Since then, TITCK has played a central role in the impressive transformation that has overhauled Turkey's health system over the past decade.

In this regard, I want to highlight that – despite its recent restructuring – TITCK already stands as an experienced and well-established institution, as it was built based on Turkey's pharmaceutical regulatory framework, which was first set up in the early days of the Republic of Turkey in the 1920s.

Having been part of the agency since its beginnings, I am well placed to relate its development and thereby highlight the eye-catching consultation process that has always been at the core of our *modus operandi*. For example, prior to designing the definitive structure of the agency, we engaged with all parts of the Turkish ecosystem – including former and current staff of the MoH, to academia, as well as the industry.

We combined all perspectives into TiTCK's first Strategic Plan (2013-2017), whose main objective was to – transparently – set up strong fundamentals for our agency, with an obvious emphasis on the regulatory and inspection functions of TiTCK. Regarding TiTCK's second Strategic Plan (2018-2022), we first conducted a comprehensive assessment of our processes and activities, and we now aim to leverage the sound basis honed over the past years to bring our agency and the Turkish ecosystem to the next step.

Could you provide insights into the on-going transformation of Turkey's healthcare ecosystem as well as into the role of TiTCK in fostering this crucial process?

Turkey is engaged in a two-way transformation process impacting both its health system and its healthcare industry – and TiTCK stands as a key driver behind this dual dynamic. With regards to our health system, fostering access to medicines for our entire population is first and foremost our priority, while guaranteeing that these medicines meet our standards when it comes to quality, efficacy, and safety also emerges as another crucial responsibility of ours.

The second aspect of Turkey's healthcare transformation relates to the industry. In this regard, we aim to increase the significance of locally produced medicines and medical devices in the Turkish market. We started putting this vision into motion around 18 months ago and our first results are particularly encouraging – although more time and efforts are needed to reach the targets we established.

As a matter of fact, the share of locally produced medicines in the Turkish market increased from 42 percent (in value) in 2016 to 45 percent in 2017, while rising from 15 percent to 18 percent for locally manufactured medtech products. Moving forward, a first satisfactory step would be to reach 60 percent of locally produced medicines and 20 percent of locally manufactured medtech

products in the Turkish market.

What kind of incentives has TiTCK been leveraging to bolster the significance of domestically manufactured products in the Turkish market?

We initiated a localization process; sometimes, the industry refers to it as a “forced localization” process, which seems to be a rather inadequate manner to describe it. As a matter of fact, we held extensive discussions with industry executives of both global and local companies prior to enacting it, in order to convey the philosophy and objectives of our approach to these decision makers.

First of all, the fact that Turkey took steps to bolster its domestic production capacity could hardly come as a surprise: many countries around the world – from Russia to Brazil, and even the United States – set up similar targets and priorities.

As part of the hundreds of meetings we held with industry executives, I personally tried to convince them to further invest in Turkey and increase the scale of their production capacity in the country, with the objective to cater to the needs of both the domestic and international markets. This approach appears even more relevant considering multinational companies have already established a regional or global manufacturing basis in Turkey.

How have these localization policies been received by the industry?

Although some executives were somewhat resistant at first, we truly felt a change of perspective occurred once the localization process started. In this regard, we are glad to see that an increasing number of global pharma executives have understood our ambition to build a win-win relationship which will be a benefit to both Turkey and these companies’ activities.

In the meantime, some foreign companies decided to forge strategic partnerships with Turkish companies, including contract-manufacturing services. Conceptually speaking, we do not want our domestic industry to turn itself into a contract manufacturing basis for foreign companies.

This message has already been conveyed to local companies’ heads, and we expect that the extra-resources gained through manufacturing partnerships will be channeled into R&D projects, the development of these companies’ product portfolios, as well as into the expansion of their own manufacturing capacities. In this regard, the number of R&D staff in Turkey has been soaring over the past two years, while significant investments were implemented in order to increase production capacities – this seems to prove that our message to domestic companies has been well received.

Turkish companies have truly forged a name for themselves with regards to the manufacturing of small molecule generics, and many domestic companies initially planned to further grow the size of their businesses without aiming to climb up the value chain.

We, however, urged them to venture into the biotechnology field and therefore triggered a true paradigm change among the domestic industry. There are plenty of examples in the global pharmaceutical industry – including Israel's TEVA – which proved it is possible for generics companies to move up the innovation chain while becoming a critical size on the global pharma map in the meantime.

At the moment, the domestic industry is seemingly embracing a paradigm change, what should be the role of TiTCK in strengthening this dynamic?

TiTCK is first and foremost a regulatory authority, not a business institution or a government body in charge of development planning. In this regard, we perform all regulatory and inspection activities that one may expect from such authority.

Nevertheless, it is true that the government did add the coordination of the healthcare industries, in which the pharmaceutical and medtech sectors hold a central importance, as one of our responsibilities. With regards to our coordination tasks, we invited industry executives to discuss the role that TITCK could play in fostering the continuous improvement and strengthening of the Turkish ecosystem. In a heavily regulated industry like the pharmaceutical sector, it makes no doubt that the decision process of TITCK holds a critical impact in the planning and progress of companies' activities.

As a result, we jointly established TiTCK's contribution and our tireless efforts to work and operate as transparently as possible (whether a dossier is accepted or rejected), ensure data integrity or while continuously raising the bar when it comes to bringing predictability to our decision-making process.

Furthermore, tremendous progress has already been made over the past years, whether it relates to granting GMP certifications (including both local and international plants) or marketing authorizations. If their products comply with clear, well-defined criteria, companies can moreover benefit from a priority review process set up in 2016.

The price evaluation commission of TiTCK set the Turkish Lira Euro rate for medicine in 2018 at 15 percent above the rate of 2016, while the lira has already lost over 20 percent of its value against the Euro since the beginning of 2018. If you take into

consideration both pricing and localization policies, isn't it a risk that the Turkish pharmaceutical market eventually loses its attractiveness in the eyes of multinational companies?

Turkey's reference pricing system was implemented in 2004. Introduced to contain costs as coverage increased, the system allows prices in Turkey to be determined based on the lowest price amongst France, Spain, Italy, Portugal, and Greece.

On top of this, Turkey also adds mandatory discounts on both innovative and generic drugs. This system has allowed us to exert a strict control on medicines expenditures *[in Turkey, the social security institution SGK covers over 95 percent of all medicine expenditures – Ed.],* while many countries are experiencing increasing difficulties to reimburse medicines whose prices have been soaring year after year.

Although this system is particularly satisfactory from a government perspective, we understand that it also entails complications for the industry. Today, TiTCK's fixed exchange rate revolves around 1 EUR=2.69 TRY, while the current market rate hovers at 1 EUR=5.5 TRY. Over the past years, some companies with relatively small product portfolios in Turkey even posted losses in several product categories, while companies with larger portfolios comparatively faired better thanks to this mixed pricing strategy.

Due to budgetary and inflationary concerns, the price evaluation commission of TiTCK did set the Turkish Lira – Euro rate for medicine for 2018 at only 15 percent above the rate of 2016, therefore creating an eight percent gap between the increase of TiTCK's fixed exchange rate (+15 percent) and the increase of the "real" market exchange rate (+23 percent). A few weeks ago, however, TiTCK, decided to take into account this gap and further increased its fixed exchange rate by 2.5 percent.

This fixed exchange rate still does not meet the expectations of the industry. Nevertheless, important elections were held in Turkey a few days ago and structural changes will be implemented in the coming months. In this context, I am sure that compensation mechanisms will be put into motion.

In this regard, my message to multinational companies is very clear: come and invest in Turkey, we have a lot of opportunities to offer. To Turkish companies, we want to ensure that increasing resources are invested in R&D projects, talent acquisition, and infrastructure building – without ever compromising on the quality, efficacy, and safety of their products. As president of this agency, I will then work in coordination with the Economy Management and Coordination Direction

of the Presidency Office of Turkey and do my best to take steps to the benefit of the industry.

In terms of international cooperation, many eye-catching developments occurred since the beginning of your tenure: in February 2018, TiTCK became a member of PIC/S, while it was approved a few days ago as a new observer of ICH. In June 2018, you signed a collaboration agreement with the Center for Innovation in Regulatory Sciences (CIRS). What are the next steps you envision?

We are trying to heighten our reputation on the international stage. While recently attending a high-level meeting in Washington DC with the heads of the world's main regulatory agencies, we expressed our clear ambitions be increasingly active in the global discussion.

In this regard, we want to become one of the most recognized agencies in the world, as well as a full regulatory member of ICH. We have already reached a great milestone on the inspection side with Turkey's entry into PIC/S, and we are now looking at replicating a similar success for regulatory matters. In this vein, we want to strengthen our collaboration and relationships with leading health organizations such as the WHO as well as with the most respected regulatory authorities in the world, including the US FDA and the EMA.

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