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Dr. Ã?mit Dereli and Cengiz AydÄ±n of the Association of Research-Based Pharmaceutical Companies (AIFD) inTurkey discuss significant recent changes in the Turkish ecosystem, including the improving recognition of the countryâ??s regulatory agency, new pricing and localization policies, AIFDâ??s contribution to Turkeyâ??s 11th Development Plan, and the ambition to make Turkey â??a globally competitive power in the pharma industry and across all parts of the value chain.â?•

What would you highlight to our international readers as the most significant changes that have been shaping the Turkish pharmaceutical ecosystem over the past years?

Dr. Ã?mit Dereli (UD): One must highlight the significant efforts of the Turkish Medicines and Medical Devices Agency (TITCK) to become a globally recognized reference regulatory authority. In this vein, the agency has carried out over the past years a thorough assessment of its processes and regulations, while looking more closely to integrating leading international networks and

organizations.

A remarkable milestone was reached with the accession of Turkey to the Pharmaceutical Inspection Co-operation Scheme (PIC/S), as it will enable our country to engage in bilateral talks with advanced pharmaceutical ecosystems and eventually forge mutual recognition agreements. The entry of Turkey into PIC/S goes hand in hand with the full implementation of the existing EU-Turkey Customs Union *[signed in 1995 â?? Ed.]*, which entails harmonization of technical regulations including pharmaceuticals and hence mutual acceptance as for GMP inspections carried out by both sides. Although Turkey has already harmonized its technical regulations mutual acceptance is yet to be in place.

In the meantime, TITCK was recently accepted as an Observer of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The Turkish agency also signed an agreement with the Center for Innovation in Regulatory Sciences (CIRS) with the objective to upgrade TITCKâ??s standards by integrating academic knowledge from all around the world.

We can already feel that TITCKâ??s improvements have had a positive impact on the Turkish ecosystem at large and could usher in evermore-promising outcomes for the future of Turkeyâ??s pharmaceutical industry, as well as from a patient safety perspective.

Since its introduction in 2004, Turkeyâ??s pricing system and its fixed exchange rate has been the source of many woes for the industry, in a country where imports moreover account for over 55 percent of the market (in value). How has the situation been evolving recently?

UD: Pricing is definitely an issue in Turkey, and no one can say the contrary â?? From the perspective of pharmaceutical companies, the current pricing system is unsustainable, while the gap between TITCKâ??s fixed EUR/TYR exchange rate and the â??realâ?? market exchange rate has almost reached 50 percent.

The current legislation clearly states the method of fixed exchange rateâ??s adjustments to be conducted by TITCKâ??s price commission, and the required adjustments were carried out in 2016 and 2017. However, in 2018, as a consequence of some economic and fiscal concerns, the exchange rate adjustment that should have been around 23 percent was capped at 15 percent with the introduction of a temporary provision to the related Degree. On a side note, the impact of this 15 percent adjustment was completely eroded by the on-going depreciation of the Turkish Lira since the beginning of the year *[devaluation of around 20 percent against the Euro since the beginning of 2018 â?? Ed.]*.

A month ago, TITCK and the Universal Health Care department of the Turkish Social Security Institution (SGK) updated the mandatory discounts and agreed on a 2.5 percent increase of the overall net prices of pharmaceutical products. This clearly proves that the government is trying to make the current pricing equation more sustainable, although the recent adjustments still do no meet the needs of the industry.

As Turkey is considered a reference market by other countriesâ?? pricing agencies, including neighboring markets such as Russia, Egypt, and Saudi Arabia, as well as in far-fetched countries like Colombia, the negative impact of Turkeyâ??s pricing system truly goes beyond our countryâ??s borders. At present, list pharma prices in Turkey are at 50 percent of the lowest European price in real terms, and our countryâ??s pricing is becoming a problem for the global pharmaceutical industry in other parts of the world.

With regards to Turkeyâ??s pricing system, which adjustments or reforms would AIFD suggest implementing?

UD: The pricing system needs to be adjusted at a realistic level, although we do not aim to alter the basket of reference countries or any other structural changes. First of all, we would like to see the FX adjustment to be carried out as stated in the legislation in force.

In this regard, one should keep in mind that we are not talking of price increase, but only of the adjustment of the exchange rate to ensure prices are not impacted by the volatility of the exchange rate.

This aspect is actually crucial to all pharmaceutical companies, regardless of the country of production of their medicines: even locally produced medicines require imported APIs, solvents, and even packaging materials. In the current context, the industry is paying its invoices in hard currencies while selling products in Turkey via an unrealistic, fixed exchange rate. This creates a widening, unsustainable imbalance that must be fixed.

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What has been the impact of the first waves of localization recently implemented by the government on the Turkish activities of research-based companies?

UD: Rather than its impact, I would first question the legal ground of â??delisting toolâ?? employed in this localization policy. As AIFD we never objected the localization policy per se. We acknowledge the fact that every country in the world has a right to bolster its local industry and we support the ambitions of our government to develop a strong pharmaceutical industry in our country. Nevertheless, we consider that the approach that has been favored so far, which is more coercive than incentivizing, is not the proper one to reach this objective.

To put into motion its localization policy, the government has chosen to de-reimburse selected imported products, leaving the industry with only two options at hand: either production is localized, or products will no longer be reimbursed by the SGK. However, this approach is based on no legal ground: the relevant legislations and regulations do not entitle the social security institution to de-reimburse/de-list products based on the country of manufacturing. As per the law, the SGK can make such decisions according to a productâ??s budget impact, cost-effectiveness, its clinical outcomes and a few other factors, but â?? again â?? not based on the country of manufacturing.

In this regard, localization policies contradict Turkeyâ??s trade obligations stemming from international treaties, including those relating to the World Trade Organizations and the EU-Turkey Customs Union Decision.

Through these forced localization policies and the de-reimbursement of products that do not comply with the latter, Turkey is furthermore sending a mixed message to global investors. As you can imagine, it is particularly difficult to convince foreign companiesâ?? headquarters to further invest in a given country when â?? in the meantime â?? these companiesâ?? products are getting de-reimbursed on what we believe an inexistent legal basis.

Moreover, medicines concerned by these localization policies are off-patent generics, a product category where economies of scale truly matter to reach targeted affordability. In this vein, it is impossible for multinational companies to attain the critical production capacity needed if they must localize their production in every country they operate in. As a result, the governmentâ??s objective to locally produce all medicines consumed in Turkey is unrealistic, as it is impossible to render such model sustainable from business and economic standpoints.

Overall, the scope of these policies is inappropriate; by focusing on catering to the domestic demand, they lack a global perspective. By targeting off-patent products, i.e. commodities at the low end of the pharmaceutical value chain, one can also doubt they will contribute to uplift the Turkish ecosystem.

Which actions or parts of the value chain should be targeted in priority in order to truly uplift the Turkish pharmaceutical ecosystem?

UD: R&D activities account for the lionâ??s share of the investments globally conducted by research-based pharmaceutical companies; every year, they make up investments of around USD 160 billion, which is significantly higher than the resources annually allocated to manufacturing by pharmaceutical companies.

As a country, we are currently concentrating our efforts on attracting a very small part of our industryâ??s global investments, while our ecosystem has made little progress when it comes to enhancing its attractiveness for R&D activities. Nevertheless, a great news to highlight is that AIFD and the government have been working hand-in-hand over the past months to urgently raise the bar and ensure our country steadily becomes an investment magnet for R&D oriented investments.

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Cengiz AydÄ±n (CA): Therefore, we suggested adding in the draft of Turkeyâ??s 11th Development Plan (2018-2022) *[whose final version is set to be submitted to the Parliament by the government in the coming months â?? Ed.]* the ambition to build up Turkey as a globally competitive power in the pharmaceutical industry and â?? above all â?? across the entire value chain, with a special focus on R&D along with manufacturing and exports.

The largest share of global R&D investments concerns clinical research activities. In Turkey, AIFD companies altogether invest around US130 million in clinical trials annually, i.e. the vast majority of all clinical research investments conducted in the country. Moving forward, our objective is to develop an ecosystem that will enable to increase this number multifold within the next five years, leveraging our countryâ??s large population, its strong medical expertise and the quality of our health system infrastructure.

The common success factor amongst all countries that have established themselves as globally competitive R&D hubs is the quality of the policy environment. In this regard, it is of the utmost importance that TiTCK continues its efforts to integrate leading regulatory networks and organizations, and we shall not encounter any setbacks when fulfilling this ambition.

What would be your final message to our international readers?

UD: As part of Turkeyâ??s 10th Development Plan (2014-2018), the pharmaceutical industry was established as a strategic sector for our economy, which was a great decision that can really uplift our country in the long term. On the other hand, contestable developments such as Turkeyâ??s localization policy, its regrettable focus on off-patent medicines and on catering to domestic needs, was also an outcome of this Development Plan.

In this regard, the upcoming 11th Development Plan (2019- 2023), which was built by integrating the perspectives of various stakeholders including AIFD, stands as a great opportunity to get things right. Both its vision and main principles are particularly solid and precise. Given the consultation spirit through which it has been designed, I have no doubt that it will be supported and followed by all parts of the value chain in Turkey.

Moving forward, I am confident that the right policy choices will be enacted in the coming months and great industrial outcomes will stem out of this ambitious Development Plan.

The â??ecosystemâ?• may sound like a clichÃ© nowadays, but it truly stands as the best word to define the mindset shaping the Turkish context â?? and we should stick to this important concept. Together, we must define what are the pillars of the stronger ecosystem we want to enable and continue to jointly identify the areas for improvements to be targeted in priority.

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