Ã?mit Dereli â?? Secretary General, AIFD, Turkey

The pandemic reinforced the importance of manufacturing, but we need to think beyond the local market towards exports. There is a new understanding of the pharma industry in Turkey and the value it can bring

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Ã?mit Dereli is secretary general of the Turkish Association of Research-Based Pharmaceutical Companies (AIFD), which has 35 multinational member companies that together account for almost 50 percent of the Turkish market. In this interview, he discusses the impact of COVID-19 on the research-based, innovative, pharmaceutical industry in Turkey, AIFD initiatives to foster the biotech ecosystem, and how Turkey has set in government policy papers the objective for the pharmaceutical industry to be globally competitive in all links of the global value chain.

The big development since the last time we spoke is the ongoing COVID-19 pandemic. What has been the main impact for your members and how did AIFD respond?

It has been an unprecedented situation for everyone, but one that is still ongoing. A year has passed since the World Health Organisation declared a global pandemic and in late 2019 and early 2020 many underestimated the impact it would have. By the middle of March 2020, the first case was announced in Turkey and we all moved to a different world.

Just after the first case in Turkey, AIFD took a leadership role and advised all of our members to call their people in the field and ask them to begin working remotely wherever possible. Following that, the Turkish Medicines and Medical Devices Agency (TITCK) and other authorities began regulating and prohibiting in-person activities to avoid physical contact. We wanted to first and foremost protect the healthcare professionals and ensure the well-being of people working in the pharmaceutical industry.

The demand for healthcare services to treat COVID-19 patients was so high that systems around the world began almost exclusively focusing on those patients. Therefore, many chronic patients, in particular, refrained from going to hospitals even for their regular appointments and immediate needs.

Turkey was somewhat fortunate in that the country had already invested in areas like hospital infrastructure and intensive care unit (ICU) beds. We did not face that initial overload of hospitals and ICUs, even though the number of patients has recently increased.

The result for pharma companies was a steep decrease in prescriptions. The government put into effect a regulation to help chronic patients to continue their treatment via an automatic renewal prescription service but with very few new patients going into hospitals, there was an overall decrease in pharmaceutical consumption.

A common situation across different countries was an initial hoarding of some medicines followed by a scarcity. How robust was the supply chain in Turkey to continue supplying medicines to patients in need?

Turkey felt repercussions from the bottlenecks in global supply chains. There were long queues at the borders with Bulgaria and Greece and truck drivers were required to have PCR tests and quarantine if necessary. Airfreight costs were also impacted because the number of passengers declined, and the number of flights was reduced. However, the pharma industry in Turkey, together with the authorities, responded very well to this logistical challenge. We are proud of the fact that, while there was anticipation about shortages of many consumer goods in Turkey last year, there was never a danger of medicine shortages.

The Ministry of Health, together with the Science Committee, took the lead to secure medicines to treat COVID patients, defining a patient management algorithm which was extremely helpful. Turkey was also able to rapidly manufacture three or four off-patent medicines to treat patients. In general, I would say that the pharmaceutical industry, in terms of manufacturing and logistics, effectively and responsibly responded to the multiple challenges of the pandemic.

Was the quick manufacturing response a result of the often-criticised manufacturing localisation policies that have been in place for several years in Turkey?

Turkey already had a strong domestic capacity to locally manufacture drugs. In terms of volume, Turkey produces more than 80 percent of drugs available in the market. This capability has helped Turkey to better address difficulties arising from the pandemic. On the other hand, Turkeyâ??s Vision 2023, as defined in the 11th Development Plan, has changed the countryâ??s vision regarding pharmaceuticals; we are now aiming to make our countryâ??s industry globally competitive. This ambitious, global, goal differs greatly from the former objective of becoming a manufacturing hub to supply domestic demand.

One critical element of the Vision 2023 is becoming a regional leader in clinical trials, an area in which the country progressed in 2020. In 2019 we worked with the government on actualising global opportunities in clinical research and fostering more R&D activity. These areas have an economic value, but also expand a countryâ??s capabilities and make it a stronger part of global networks. Additionally, clinical trials can bring early access to innovation for unmet clinical needs.

We worked with government bodies, including TITCK and TUSEB (National Health Institutes Agency), and agreed on a roadmap. Following the launch of the aforementioned roadmap in the format of a comparative report in September 2020, all relevant stakeholders, including government bodies, started to collectively work on the implementation of the recommendations of the report. Moreover, Turkey really progressed and saw an increase in clinical trials, including for some of the vaccines that are making global headlines today.

In summary, the pandemic reinforced the importance of manufacturing, but we need to think beyond the local market towards exports. There is a new understanding of the pharma industry in Turkey and the value it can bring and the perception is not as limited as before.

How do your members assess the infrastructure required for clinical trials in other areas like oncology and rare diseases?

Almost all industry-supported clinical trials conducted in Turkey are led by AIFD member companies, most of them in oncology and rare diseases. Rare diseases are particularly important for Turkey and the MENA region because of the prevalence of genetic disorders here. Turkey today has the ability to host clinical trials right from Phase I to Phase III and there has been an increase in the number of centres able to conduct Phase I trials in recent years.

The country knows that if we are to achieve global competitiveness, TITCK must be a globally respected regulatory authority. We are now moving in that direction, looking at Swissmedic, FDA, EMA and others as an example. In this regard, TITCK becoming a member of PIC/S (Pharmaceutical Inspection Co-operation Scheme) and ICH is the most important development regarding the sector in recent years.

To achieve global competitiveness, the country also needs a strong domestic innovation ecosystem. How do you assess the ecosystem in the country and how is the association working to foster that environment through initiatives such as BIO Start-up?

Our BIO Start-up initiative began as a recognition that global innovation in pharmaceuticals now mostly originates in start-ups; 6 out of 10 new molecules approved by the FDA originated from start-ups.

The picture has changed dramatically from 20 years ago when most medicines that received global authorisations were developed by big pharma companies. Globally, big pharma companies are developing competencies and capabilities to identify these early start-ups, embrace them, and help them flourish.

Therefore, for Turkey to have a globally competitive pharmaceutical industry, we have to provide an environment where start-ups can be identified and supported. That is why we run the BIO Start-up program, the first and only life sciences and biotechnology accelerator program in Turkey

We receive around 50-60 applications every year, out of which 15-20 start-ups are admitted to the program based on their competence in terms of team quality, business idea and the maturity stage like proof of concept. Having completed several trainings and mentoring sessions, start-ups in the BIO Startup Program present their projects before a jury composed of subject matter experts and KOLs from the government, industry and academia. The jury selects 5 start-ups to participate in the BIO Convention, the worldâ??s largest biotechnology event, organized in the US. Hopefully, those start-ups will become the next success stories from Turkey

To illustrate the importance of start-up innovation, two of the currently approved COVID-19 vaccines came from Moderna and BioNTech; both start-ups. That shows that the future of innovation in pharmaceuticals cannot be limited to certain geographies, innovation is everywhere, and we cannot afford to miss out on any opportunity.

You have mentioned several times Turkeyâ??s goal of achieving global competitiveness through Vision 2023. With the trends you mentioned in mind, where will the countryâ??s industry be in 2023?

I must reiterate that COVID-19 has had a big impact on Turkey. People had to be taken off the field, resources went to COVID patients, and some markets suffered significantly. Another significant impact of the pandemic was on the regulatory review process, not only in Turkey but around the world. GMP inspections were delayed which has caused a bottleneck, forcing TITCK to carry out inspections on paper with conditional approvals to continue facilitating access to priority medicines.

However, the most challenging part of the approval process has been the commission meetings. Against the backdrop of the pandemic stakeholders now have to meet online and, since they have to look at confidential and sensitive information, there has been a lack of movement. One of the most important items for TITCK will be clearing that huge backlog.

This situation will have an effect on our journey to global competitiveness but, from my perspective, Turkey is committed to its 2023 vision and that is a very good sign.

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