Interview: Özkan Ünal – President, TITCK (Turkish Drug and Medical Devices Agency)



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The president of the Turkish Drug and Medical Device Agency (TITCK) discusses new initiatives and reforms being carried out by his agency, including its work towards becoming a PIC/s member, and the introduction of several changes designed to accelerate timelines for GMP certifications and marketing authorizations.

You began your TITCK presidency in December 2014; what have been some of your initiatives so far?

I have been president for the last six months, and we have taken three important steps during this period. The first was to evaluate the marketing authorization (MA) procedures and processes, and following this evaluation it was made apparent that the activities relating to MAs had been spread to three different departments. We are now in the process of carrying out structural reforms to bring all of these activities into a single, well-organized department, and these changes will be completed soon.

The second important change that we have made relates to the obligatory laboratory control and analysis that must be carried out as part of the MA procedure. Waiting times for these analysis reports can be quite long, so we have now introduced the requirement that they be completed before an MA request can be submitted.

Finally, we recently made the decision to allow manufacturing facilities to extend they three-year GMP certificates by one and a half years via a dossier submission process. This means that there is no requirement for inspectors to travel to the site, as they make their decision based on the information reviewed in the dossier, which will accelerate the extension process and reduce the workload for our inspectors.

What is the status of Turkey's application to become a PIC/s member?

Turkey applied to become a full member of the PIC/s in 2013, and the application process is still ongoing. The accreditation of our pharmaceutical control laboratories is still ongoing, inspectors have been making evaluations and submitting reports to the PIC/s committee, and we have projects underway on both the regulatory side and laboratory side. At present, we are aiming to become a full member of PIC/s in one year, and once this accreditation comes through it will bring many new opportunities to our pharmaceutical manufacturers in export markets.

Under Turkish law, the TITCK will recognize the GMP certificates issued by countries that have mutual recognition agreements with Turkey; becoming a PIC/s member will facilitate mutual recognition, and thus reduce the number of inspections that the TITCK is required to make. As manufacturers are required to hold a valid and recognized GMP certificate before they can apply for MA, being able to recognize foreign GMP approvals that we are not able to at present will reduce the overall time it takes for a product to receive its MA.

How will your agency ensure that there is good market access in the meantime, while Turkey waits to be accepted as a PIC/s member?

At present, applicants can apply to our agency for GMP priority based on the criteria that their product is innovative, a first generic, or brings strong public health benefits and the potential to reduce overall healthcare expenditures. The GMP inspection calendar is prepared based on the level of priority we assess the product to have, and if the product is evaluated as GMP category one, the MA review procedure and GMP inspection are carried out concurrently.

For MA application dossiers that are found to be adequate in the pre-assessment step, which is carried out within 30 days of submission, the main registration process takes 210 days. We offer another accelerated mechanism for innovative products that are of major interest from a public health perspective, which decreased this 210 day period to 180 days. At present, our agency is following these guidelines manually, but we are in the process of developing new software that will help to improve our agency's adherence to these timelines.

We also have an early access program, where in certain cases, products without MA can be imported into Turkey. First, the medication must have MA in another country, second an individual patient must apply for access to that medication and the patients clinical situation must be evaluated, and third, the patients clinical needs must be compatible with the medication's indication and there must be clinical evidence that the medication could work for that individual patient. If the patient is approved by the TITCK following the evaluation, then the medication is supplied by authorized importers.

What steps are you taking to improve the regulation of medical devices specifically?

We recently published our new regulations on the test controls and calibration requirements for medical devices, which will allow us to more effectively regulate this area of the market.

I would also like to highlight that while Turkey is following the EU's approach in terms of recognizing products with a CE certificate, we are also working with them in order to improve the quality and the medical devices that are able to enter our market. Recently, we have had some problems with lower quality medical devices being able to enter the market due to having a CE mark, and healthcare professionals are requesting that we introduce stricter regulations on the quality of medical devices to prevent similar incidents from happening again.

How does the TITCK prevent counterfeit medications from reaching the market?

We have a very sophisticated pharmaceutical track and trace system called ITS, which tracks medications from the factory where they are produced all the way to the retail pharmacy where they are given to the patient that will consume them. The procedures used at each step of distribution chain are regulated by our authorities, and all manufacturing sites, warehouses, hospitals and retail pharmacies are required to notify our system of any product movements or sales. As such, we have a vast amount of information regarding the medications manufactured, available and consumed in Turkey, and use this system to ensure that illegal pharmaceuticals cannot enter our controlled distribution system.

Moreover, we are very proud to say that the quality of the data we have is very high, and is probably already better than IMS's data. As such, we are using this information to inform our decisions in different departments, and at present there are several epidemiological studies underway that are making use of this data.

We also have a new project based on our ITS system, which is called UTS; the UTS system will track and trace medical devices and cosmetics sold in Turkey. The software for this system is currently

underdevelopment by TUBITAK, and once complete we will begin by integrating our current database of medical devices and cosmetic products into the new system, and then greatly expanding this database until all medical device and cosmetic products are registered within it. At this point, we will make the decision regarding which cosmetic products need to be tracked, as it would clearly be ineffective to track and trace every single cosmetic item in Turkey.

How is the TITCK supporting the development of biotech manufacturing activities in Turkey?

Turkey is not a leading country in the area of biotech and biosimilars, and we lag behind several important countries in this area; as such, its development is considered quite important at present by the Turkish government. The TITCK is supporting the development of this sector by developing an appropriate regulatory access approach that will allow biosimilar products to be evaluated more quickly and effectively once they are ready for registration. Furthermore, as we want Turkey to effectively catch up with other markets in this area, we have made it a goal to see at least one new molecule developed by a Turkish company and brought to market by 2023.

What steps is the TITCK taking to develop orphan drug policies and regulations for Turkey?

Legislation for a rare disease law will be prepared after we generate an action plan and create the necessary infrastructure. In this context, there are several items on our agenda that must be completed:

- Create “Orphan Diseases National Database ” within the Ministry of Health
- Establish diagnostic and treatment centers with in structure of Turkish Public Hospitals İnstitution
- Five different codes to identification of rare diseases in the data collection system
- Form a record system that allows current data collected from diagnostic and treatment centers to be queried
- Appoint a Commission for designation of rare disease of Turkey in the Ministry of Health, to determine rare disease prevalence criteria with the participation of:

1. Relevant clinicians
2. Representatives of rare diseases civil society organizations and
3. The pharmaceutical and healthcare sector

- Make an agreement to establish an interface with “Orphanet” as a reference portal for information on rare diseases and orphan drugs, and with other data bases available in this subject

Finally, after establishing infrastructure of Rare Diseases data, we will then be able to prepare national regulations for orphan drugs and develop national policies on pricing, reimbursement and incentives for pharmaceuticals in this group.

What steps is the TITCK taking to reform the current reference pricing model in Turkey?

Following an extraordinary meeting of the Price Evaluation Commission on May 18th, 2015, the decision was taken to make a periodic Euro valuation update TRY 2.00 from TRY 1.9595, an increase of 2.06 percent, which became effective June 1st 2015.

More generally, the government has made it a national goal for Turkey to become a global pharmaceutical R&D and production center in the long term. Under the Tenth Development Plan, the Program of Structural Transformation in Health Industries aims to encourage the production of high-added value products within Turkey, and to produce a larger proportion of medical devices and medicines demanded by Turkey domestically. Within this scope, it is aimed to enhance the local production capacity in the medium term, develop R&D and entrepreneurial ecosystem, and to attain a structure where new molecules may be developed, and medicines and medical devices with a higher added value may be produced, within the long term.

To meet these objectives and support the production in our country, the Pricing Decision will be updated. In this context, the pricing of high added value medicines such as high-tech medicines (blood products, biosimilars, for example) will be able to be priced under a different mechanism than currently used. Medicines that have critical importance for public health, as determined by the Price Evaluation Commission, will also be eligible for alternative pricing. In this way, we will ensure Turkish patients do not face the risk of losing access to critical medications.

What are some of the TITCK initiatives that the Turkish healthcare community can look forward to in the coming months?

Staring on the first of July, we will begin having monthly meetings with representatives of the pharmaceutical sector to facilitate better communication and cooperation. We will use these meetings to discuss and analyze the problems of the pharmaceutical industry, share opinions, discuss potential solutions, and most importantly to keep the industry informed as to the types of pharmaceutical products that we want them to produce in Turkey.

Another new step that we will be taking will be to expand our involvement in the area of herbal products and teas. This is an area that the public wants us to be more active in, as health problems have been caused by adulterated herbal products that have been taken inappropriately.

Our final point relates to the volume of clinical research being conducted in Turkey. At present, there are a limited number of clinical trial study centers capable of carrying out Phase I clinical trials and bioequivalence studies; last month, the number of such centers increased to six. Our goal is to encourage the development of more centers capable of carrying out these studies, and our target is to increase the number of clinical trials by 25 percent each year until 2023.

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