Interview: Isidro RodrÃguez â?? CEO, Entimem â?? Mexico

23.06.2015

Tags:

cofepris, medical devices, regulation, government

The implementation of third authorized parties has been a very proactive effort implemented by Mexicoâ??s regulatory authority Cofepris to expedite the time to issue sanitary registrations. The CEO of Entimem provides an overview about the system currently in place, the challenges faced as well as benefits such a system offers to consumers and the industry alike.

What are third authorized parties and what was the vision behind their creation?

Third authorized parties were implemented by Mexicoâ??s regulatory authority Cofepris to support manufacturersâ?? registration process of drugs and medical devices. The objective is to facilitate and expedite administrative procedures and shorten the time necessary to issue sanitary registrations. Their main responsibility is to review in advance the dossier the company submits to Cofepris to ensure it fulfills all requirements. Somehow we are an extended branch of the authority, as we help guarantee the process is done correctly and Cofepris can speed up approval times.

So far Cofepris has authorized 17 parties, auditing two important aspects: the regulatory know-how of the staff and the quality systems in place. Today third authorized parties are responsible of preparing preliminary opinions on the registration of drugs and medical devices, as well as to oversee establishments such as drug stores, pharmacies and points of sale. For each of these processes they must be certified.

What are the main differences for the authorization process of drugs, medical devices and establishments?

The main difference lies in the information you need to review. For drugs and medical devices it mostly implies examining the dossier of the drug or device; for establishments we need to visit them in person to conduct the audit. As for drugs and medical devices the main difference is the degree of technical information required.

This adds a high degree of complexity for medical devices.

Yes, this is true. For the purpose of sanitary registration, medical devices are classified by risk of use into three classes: Class I, that is devices of proven safety and efficacy familiar to medical practice, which are not usually introduced into the body; Class II, inputs that may vary in terms of materials and are generally introduced into the body where they remain less than 30 days; and Class III, that is inputs which are introduced into the body and remain there for more than 30 days. Given the broad variety of devices the category encompasses, the regulation for medical devices has many points that need to be taken in consideration.

Do other countries in Latin America feature a similar system?

I understand that Mexico is pretty unique in the world. The system has been praised in other countries, as it has helped drastically improve approval times, so we may see it replicated in other parts of the world. At the beginning manufacturers were skeptical about the process and questioned its compliance, as it is an increasingly important issue in the industry. However, Cofepris ensured the responsibilities of parties were well-defined and transparent and over time the industry has come to understand that the extra step is not a fast-track process. The fact that companies are paying this additional revision process does not necessarily mean they will get the authorization. Thatâ??s something the authority stressed from the very beginning. Itâ??s only a way to make the authorization process faster and more efficient.

Also, using a third authorized party is optional for companies; they may or may not use this process. When a product is registered in countries such as the US, Canada and Japan, for example, the manufacturer can register it here in Mexico thanks to a mutual equivalence program in place, something we do not review. The manufacturer decides which option is the best, also because it implies additional expenses. Over time the price gap among parties diminished, however it still implies an extra cost. Also, information from third parties is public, so companies can freely choose. The authority has been very neutral with regard to this.

When was Entimem established and what kind of companies do you work with?

The company started in 2011. Back then we mainly focused on medical devices, but today we also work with drugs. The proportion changes every year. In 2014, for instance, Cofepris focused on catching up the backlog of pending dossiers for drugs and gave manufacturers the option to collaborate with third authorized parties to speed up the process. This drove an increase in our business with medical devices.

What are the main challenges you were faced with?

At the beginning the major challenge was to establish a transparent and replicable process, which could fit the revision process for each company and product. To make sure it could work we included a number of security locks. First of all, our personnel is very knowledgeable about the regulation and its changes. Second, we implemented the Mexican standard NMX 17020 for all our processes and a quality system, which is audited by Cofepris and must be renewed every two years. Last but not least, we have a legal responsibility related to the review process, thus also an insurance, which covers the company in case of any issues. This is the model Cofepris implemented to make third-authorized parties accountable for the information they review, sign and deliver.

What is the added value you offer to clients?

Our mission is to ensure the Mexican population relies on the best and most innovative drugs and medical devices. The documents Cofepris requires are specific to the Mexican market, so itâ??s not always easy for our clients to understand the local requirements. We are somehow the mediators, especially for foreign companies that are not familiar with the local regulatory environment.

Having third authorized parties reduces the time Cofepris needs to invest to review poor dossiers, hence enhancing their process. We provide Cofepris with a technical review, which is a feedback about the dossier. We explain why we consider the information provided is safe.

What are your future ambitions for the company?

Weâ??d like to get certified also to audit establishments. Also, with the implementation weâ??d like to enter the authorization process for biotech products and vaccines, both more complex than drugs and medical devices. Cofepris may also provide authorization for pesticides in the close future, and thatâ??s also a segment we are interested in.

Our mission is to make Mexico a better market: we want the drugs and medical devices a family uses are safe and secure. Cofepris shares the same view and itâ??s the first time we are seeing such a tight collaboration within the industry. Over this time we have gained the respect of Cofepris and have turned into real partners for the authority and the industry. The fact that Cofepris is raising the bar is positive for consumers and the industry alike.

As human beings we often only complain about what is not working. We know the system with third authorized parties is not perfect and that there areas which require improvement; however, since its implementation I think the system has improved dramatically and will continue to do so, to ensure the Mexican population can have the safety it deserves. Itâ??s part of a number of efforts Cofepris and the industry as a whole are doing. I do not think in the good guys vs. bad guys story: we have a shared responsibility and commitment, we somehow stand in-between and itâ??s a very interesting place to be.

Click here to read more articles and interviews from Mexico, and to download the latest free pharma report on the country.

See more interviews