3 Regulatory Guidelines for Navigating China's Drug Delivery and Medical Device Markets

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Global spending on healthcare medicines is expected to reach $1.3 trillion by end of year 2018.[1] While many of these medicines may be developed in the traditional dosage forms, companies are increasingly developing more and more drug delivery devices, in order to deliver patient convenience, more effective routes of administration through targeted therapies, and value to the global payors. As the world's second largest medical device market, China offers a significant opportunity for drug delivery companies to expand their global footprint in Asia. Pharmaceutical spending alone, in China, is expected to grow at almost 70% over the next five years. However, with this great opportunity come considerable challenges. One of the most obvious ones, especially for those familiar with doing business in the United States, is navigating the regulatory pathway of the Chinese Food and Drug Administration (CFDA).

Although there are a number of similarities between the CFDA and the FDA, such as the classification of medical products, a key difference is their size. Currently, the CFDA receives over 10,000 new drug applications each year, but only has the capacity each year to review 5,000 to 6,000 of those. This has created a backlog at more than 21,000.[2] Due to the limited number of CFDA resources, a company desiring to take a drug or device product to market could experience some degree of delay in inspections, dossier review periods, and application approvals.

A company desiring to enter the Chinese medical device market can increase their likelihood of first-pass success and speed-to-market by making a concerted effort to understand the CFDA and its expectations throughout the lifecycle of the review and approval process. By doing so, the CFDA will view your organization as one that is committed to doing the right thing, is pro-active, and is operating within the local jurisprudence of the region.

The following guidelines can be used to help facilitate a deeper understanding of the CFDA's regulations:

1. **Put boots on the ground.**

   An effective way to learn any new task is by applying action rather than just thought. The same applies when trying to gain a more complete discernment of how to navigate China's regulatory landscape. Essential in achieving this is to have a strong site leadership team working within China, not just to run your facility, but to also keep abreast of changing regulations and/or guidelines of the CFDA and local district office. Drilling down into regional and local jurisdictional requirements also helps provide a clearer understanding of all the potential nuances of the regulatory pathway. This is done by establishing "boots on the ground." In November 2013, Phillips-Medisize announced its Suzhou, China facility had registered with the CFDA and that the facility had received ISO 13485 certification. To achieve this milestone, Phillips-Medisize had established a team in China that dedicated itself to understanding potential customer requirements and product regulatory strategy, as well as CFDA

[1] IMS Institute, Global Outlook for Medicines Through 2018: http://static.correofarmaceutico.com/docs/2014/12/01/informe_ims.pdf
[2] Forbes.com, Reforms To China's Drug Approval Process Are More Important Than Ever: http://www.forbes.com/sites/benjaminshobert/2015/11/11/reforms-to-chinas-drug-approval-process-are-more-important-than-ever/#45d8fb48629e

requirements, and then melding those requirements together. The local site team, which consisted of dedicated resources from engineering, quality, and regulatory functions, established consistent interactions through open communications with the CFDA regulators and at the same time, attended CFDA local training events in order to better understand the applicability for any new regulatory standard and guidance document.

2. **Learn how your local office interprets the guidelines.**
When seeking approval for a combination product in the U.S., a company will work through one of three primary review jurisdictions: the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), or the Center for Biologics Evaluation and Research (CBER). Each of these offices varies somewhat in their respective processes, regulations, best practices, and benchmarks. This also applies to the CDFA, where each local office within China may have its own interpretation of the country's regulatory requirements. In addition to this, there are two other key national offices for which the company should become familiar. First, the Center for Medical Device Evaluation (CMDE). The local company will have interaction with the CMDE primarily during the dossier review period of the medical device registration process. Second, there is the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ). This organization conducts evaluation for food, cosmetics and certain devices (e.g. radiation emitting). For this reason, it would be good practice to engage in conversation with the officials from the jurisdiction where your facility resides to better understand how they interpret the regulations and acceptability for how your data should be presented for submissions. Stay in close contact with the regulators throughout the product application submission process by having frequent calls and meetings as appropriate, in order to check in on the progress for critical stages of the registration process. Close and timely follow-up is important to help clarify critical items and avoid mistakes that would require starting the registration process over. Companies should also periodically check/download CFDA regulations from the official website, as they have changed fairly frequently in the past couple of years. If there is ever a discrepancy in the information provided by different investigators, ask questions about the differences and determine where mistakes or misunderstandings occurred. This can be a very positive conversation that leads to new knowledge for future investigations. One additional note on product registration as it relates to testing requirements for dossier submissions. Depending on the Class of medical device being registered, the CFDA may or may not accept testing results from foreign testing centers. Especially for Class II and III devices or combination products, it is imperative that the sponsor company understands where their local testing centers are located and all comments from the testing center be submitted with the original testing reports.

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3. **Seek helpful information and regulator engagement through training and industry conferences.**

   The Suzhou facility marked the first time Phillips-Medisize had expanded into China. To prepare, company colleagues participated in annual meetings and conferences that CFDA representatives attended, such as the Parenteral Drug Association (PDA), Drug Information Association (DIA), Regulatory Affairs Professionals Society (RAPS), as well as Medical Tech (MEDTEC) events. By interacting with regulatory authorities in person, you can engage in dialogue and obtain an even deeper level of understanding than you could from the website. These conferences also present an opportunity to set up individual meetings.

   If you attend a presentation by a CFDA representative, prepare and submit questions prior to the session whenever possible. It is also good practice and custom to introduce yourself to the speaker after the presentation and take advantage of the one-on-one opportunity. In addition to engaging with the CFDA through conferences, companies seeking expansion into China should attend the local training offered by the CFDA. Most often, the inspectors are involved in those trainings, which are regionally based. Typically, training events are also held by the CFDA when significant regulations are about to be released/implemented. An invitation letter will be published to local pharma/medical companies by the respective CFDA office. Consultancy agencies also offer trainings in China, covering topics, such as GMP, risk management, testing, and microbiology. Engaging with, and even hiring, these agencies as another resource to help navigate China's regulatory pathways is also recommended.

Summary

The Chinese medical device market was recently valued at $27.7 billion in 2014 and is projected to grow to an estimated $50.8 billion in 2020[3]. With both medical device sales and the population in China growing at such a rapid pace, this is undoubtedly a market that drug companies are going to want to not only understand its challenges, but also capitalize on its opportunities. By gaining an in-depth knowledge of the country's regulatory body, an organization can leverage this experience to both advance its product as well as create a stable foundation for a global expansion strategy in China and beyond.

[3] GlobalData, *China's Medical Device Market Will Burgeon Beyond $50 Billion by 2020*: https://healthcare.globaldata.com/media-center/press-releases/medical-devices/chinas-medical-device-market-will-burgeon-beyond-50-billion-by-2020-says-globaldata

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