CHINA SET TO RELAX REGULATIONS ACCELERATING TIME-TO-MARKET FOR THE MEDICAL DEVICE AND IVD PRODUCTS

On June 25, 2018, the Chinese Ministry of Justice announced amendments to the Supervision and Administration of Medical Devices Regulations (the Regulation) and called for public comment. The proposal is being celebrated by a variety of stakeholders across the medical device and IVD industry following years of lobbying to have the Regulation amended. However, some apprehension regarding the implementation of the proposed Regulation remains.

Since 2014, there have been a series of regulatory changes across the entire medical device industry, creating barriers to introducing new products to the market for both global and domestic companies. An area of significant concern to our global clients is the legislative requirement for 'clinical evaluation' for all Class II and Class III products unless exempted - a separate process considered by many in the industry as vague and somewhat comparable to the "substantial equivalence" concept.

If ratified, Medical device and IVD innovators should expect to experience some challenges during the transition period, with procedures for setting guidelines often interpreted differently among stakeholders. For example, the proposed Regulation permits the use of international clinical data to replace the need for a Chinese focused registration study, based on the condition that such data is "compliant with the relevant requirements of medical device registration in our country." What are such 'relevant' requirements? This loophole creates some flexibility for policymakers and administrators when enforcing the new law.

While the new Regulation will improve time-to-market, scrutiny will increase for post-approval activities. Sales and use of second-hand or refurbished devices will remain prohibited.

It is imperative that foreign innovators seeking to take up the opportunity to launch a new product in China consider the effects that a regulatory change will have on domestic companies. Accessing in-market expertise will be essential to gaining an advantage on Chinese based companies in a new regulatory environment. Innovators should also consider the breadth of new players seeking to access the market when developing their commercial strategies.

The Regulation holds significant potential for innovators seeking to achieve commercial success in the Chinese market. Boston Healthcare has extensive in-country expertise across all aspects of healthcare, including pharmaceuticals, medical devices, and diagnostics. If you would like to learn more about our capabilities in China, please contact Betty Su, Vice President. Comments on the amendments are due by 24 July 2018.

Key changes of interest to device and IVD companies:

- Foreign clinical trial data is accepted under the proposed Regulation - provided it meets China's 'relevant' requirements.
- The extra control point to obtain approval from the Chinese authorities to conduct a clinical trial for high-risk Class III devices remains, however, approval will be implied if innovators do not receive feedback after 60 working days from applying.
- The pre-requisite that a product gains approval by the relevant authority in the country of origin for approval in China has been lifted for devices recognized as 'innovative products.'
- According to the current draft, the applicant could provide a testing report for registration requirements. Currently, the registration testing report has to come from one of the Chinese FDA designated labs.
- Conditional approval under special circumstances for life-threatening and rare diseases lacking alternative treatment methods is included in the legislation.
- It provides further details to enable the transition from a manufacturing-based registry system to the Marketing Authorization Holder mechanism, which is also occurring in the pharmaceutical industry.

About Boston Healthcare

Boston Healthcare is a global consulting firm that develops successful market access and value optimization strategies for emerging and established medical device, diagnostics and pharmaceutical companies seeking to commercialize specialized products and services that have the potential to transform standards of care and significantly improve health outcomes. We combine our multi-disciplinary consulting expertise and analytic rigor, with a deep and current understanding of evolving market and sector dynamics and trends, enabling our global clients to implement value and access strategies across their product portfolio successfully. Please visit our website for more information. www.bostonhealthcare.com

Asia-Pacific
Room 51, 5th Floor, No. 1438 Hongqiao Road, GIFC
Shanghai, China 200336
E: infoasia@bostonhealthcare.com