

## **China Agrees to Streamline Device Regulatory Process**

Devices & Diagnostics Letter

November 9, 2009 Monday

China's State Food and Drug Administration (SFDA) soon will no longer require devicemakers to register products in the country of export as a condition of registration and will not automatically require clinical trials in China for certain classes of devices. The changes are part of an overhaul of the country's device regulations in which the SFDA also says it will consider establishing an exemption from its requirement to test product samples in Chinese labs prior to approval if a device maker demonstrates compliance with international standards and provides sound scientific evidence.

During a meeting last month of the U.S.-China Joint Commission on Commerce and Trade (JCCT), the SFDA agreed to accept a product registration document issued by any foreign country regardless of its export origin, country of manufacture or legal manufacture, according to a statement from AdvaMed, a trade association that has been working to eliminate redundancies in the Chinese regulatory process.

**Clinical Trials:** The country also announced it will use a risk-based approach and consider results from clinical trials conducted in other countries for certain classes of devices instead of automatically requiring clinical trials in China. "The clinical trial requirement previously outlined by China could have affected all but 2 percent of U.S. medical device exports to China, putting at risk more than \$1 billion of exports," Ralph Ives, executive vice president of global strategy and analysis for AdvaMed, says in the statement. The possible change to the sample testing requirements was particularly important to AdvaMed, which has sought an exemption to the requirements for several years.

Calling this latest move an "important step in the right direction," Nancy Travis, vice president of global strategy and analysis for AdvaMed, told D&DL that up until now, there's been no possibility of exempting products from local testing unless a Chinese lab didn't have the equipment to do the test. "Now that this door is being opened, AdvaMed will continue to work with the SFDA to "make some exemption criteria that are meaningful," Travis added.

**Harmonization:** China has pledged to adhere to international regulations, vowing to strive to implement regulations, rules and notices consistent with device guidelines issued by the Global Harmonization Task Force and the Asia Harmonization Working Party. "I think China, having a personal interest in harmonization, is now realizing that the things [AdvaMed] has been asking for really are what the rest of the world does, and I think perhaps they're viewing it as part of their own evolution toward a more internationally compatible system," Travis said. China has not indicated a date when the new requirements would take effect, Travis said. She noted the country is rewriting its device regulations -- a process it plans to complete by the end of the year. Travis expects the new requirements to be written into those regulations. "Obviously, it would be desirable for them to be implemented sooner since China's regulatory process often can take a long time, and they may not meet that goal of getting the new regulations out by the end of the year," she said.

The proposed changes come as China is reforming its healthcare structure. That \$100 billion-plus would include the rebuilding or refurbishing of thousands of hospitals, which would create a demand for new devices and diagnostic equipment (D&DL, Oct. 19).