

# Challenges Loom Under Proposed Revisions To China's Regulatory and Reimbursement Systems

By Diane Whitworth



China's State Food and Drug Administration (SFDA) is close to finalizing a new regulatory system for medical devices that likely will toughen the registration and approval processes and require testing of some devices being imported into and exported out of the country.

The SFDA is seeking comments on its draft "Interim Requirements for Further Intensifying and Standardizing the Registration of Medical Devices" and has selected a team of evaluation experts to implement standardized scientific procedures for examining medical devices. The agency's formation of the team of experts and request for comments were followed by a notice stating that 73 device standards have been released. Among those standards, 33 are considered mandatory and will be implemented on Dec. 1, 2009, and 40 are considered recommended and will be implemented on June 1, 2009.

The SFDA is determined to increase supervision throughout all stages of device development to ensure safety and compliance. For example, the agency has instituted higher penalties for violations and noncompliance. Any violation — such as manufacturing without a proper license, without passing a quality management system (QMS) inspection or without product registration — will carry a penalty of 10 to 20 times the product's value, depending on the severity of the violation. Distributors that sell products without proper product registrations or proper distribution permits will face fines of five to 10 times the product's value and possibly have their distribution permits suspended.

The current regulatory system was established in 2000 under the Regulations for the Supervision and Administration of Medical Devices. The Regulations contain five chapters and 47 articles pertaining to general administration; the administration of medical devices; the manufacturing, distribution and

use of devices; supervision of the QMS and product testing; and penalties for violations. The proposed draft, issued by the SFDA in September 2007, contains six additional chapters and 126 articles and would incorporate amendments introduced over the past eight years.

## Details of the Proposed Draft

The new chapters would address such issues as device importation and export management, advertisement management, supervision and technical management, and supervision for QMS assessments and product testing.

Although these revisions would simplify the registration for Class I medical devices (those considered low risk and currently regulated by provincial governments), Class II device (those considered modest risk and currently regulated by provincial governments) and Class III device (those considered high risk and currently regulated by the SFDA) would have to undergo a more complicated registration process. More specifically, Class I domestic product registration would be reviewed by a provincial SFDA office instead of at the city governmental level, which would shorten the review time for imported Class I registrations to 40 days. However, Class II and III devices, particularly implantable and sterile products, would face an initial technical review by a provincial SFDA office before a registration application could be submitted to the state office.

In addition, the entire review time frame for Class II and III products, which was not specified in the draft, likely will be affected by the new import and export product testing and registration requirements that will be developed jointly by the SFDA and the General Administration of Quality Supervision Inspection and Quarantine (AQSIQ).

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Moreover, in June 2007, the AQSIQ released a policy, which became effective in December 2007, requiring imported products to be tested before importation. The AQSIQ and SFDA are in the process of compiling the list of products that must be tested at importation.

Companies that operate Chinese manufacturing facilities also are anticipating a longer and more difficult application process for obtaining manufacturing permits and product registrations, because they will have to contend with provincial FDA offices for design review before approaching the SFDA for final registration. On a more positive note, the term of product registration has been extended from four years to five years with the requirement to begin the renewal process six months before expiration.

Not only would these amendments put more pressure on importers, but they also are expected to increase manufacturing costs. Furthermore, due to the new emphasis on quality management and tracking requirements, manufacturers and distributors — as the designated primary parties under the revised regulations — would be required to maintain product records (including adverse event reports and product recall notices) for two years beyond the life of the product.


### **Reimbursement Changes**

China's current reimbursement system also has had a significant impact on medical device importers due to the country's complicated health insurance and hospital systems. The fundamental problems center on a lack of uniformity in policies and procedures from region to region and a lack of cooperation among participating agencies. Most hospitals are public and administered by China's Ministry of Health (MOH) or other government agencies at the provincial or local level. However, a gradual shift has occurred in which hospitals have been receiving less central government funding in exchange for greater operating autonomy in which user fees, drug markups and medical tests have become the main source of revenue.

The combination of reduced government income and oversight has resulted in hospitals overprescribing medicines and sanctioning unnecessary and expensive medical testing to cover costs. These hospital system challenges are compounded by the lack of adequate health insurance coverage provided to rural and urban constituents. Under both the rural and the urban insurance systems, patients pay the majority of medical expenses out-of-pocket.

Given the limited funding available from health insurance, China has been trying to limit medical device prices by introducing several reimbursement schemes that put the greatest cost burden on hospitals. According to the International Trade Association, the Chinese government has required a formal tendering process for all imported products in order to strengthen the transparency of the purchase process and to reduce the price paid by the end user since 1999.

The National Development and Reform Commission (NDRC), which is responsible for determining economic and social policies and generating the guiding five-year health care plan and associated budgets, has worked with the MOH for several years in an effort to hold down the cost of medical technologies. The commission is in the process of implementing sweeping changes to the country's health care system by providing a safety net through a system of nonprofit public hospitals and advanced care through private health providers. The MOH has simultaneously reinstated control over purchases of high-end medical equipment to curb hospital spending, increased the use of technology already installed, and demanded public bidding for each new purchase with the primary goal of containing corruption within the distribution chain.

The changes underway in China's health care and medical device regulatory systems require importers to stay informed. Importers should work closely with their in-country distributor or agent to ensure compliance with all the necessary registration, testing and documentation requirements for imported devices. 

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for Patients and Providers Act of 2008, Pub. L. No. 110-275, the statute retroactively delayed implementation of the program for 18 months and mandated, among other things, new accreditation requirements for DME suppliers (see related story, "Competitive Bidding Program Delayed for 18 Months," p. 6).

"As indicated, CMS is currently taking additional actions to strengthen both the 25 standards and its oversight of the DMEPOS supplier enrollment process; however, these actions will only be successful if those tasked with ensuring compliance exercise due diligence when conducting screenings and inspections," the GAO said in the report. "Our covert tests clearly demonstrate that a simple paperwork review is not sufficient. Unless CMS and its contractors scrutinize suppliers to ensure that they are responsible, legitimate businesses, DMEPOS

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