



Chinese Importation Rules & Used Medical Equipment

August 10, 2005

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China represents a market of over 1.3 billion people

The Chinese government is standardizing the rules covering the importation of refurbished medical equipment. In the past, China has had problems with imported used equipment. According to IAMERS President Diana Upton, "Severe restrictions on refurbished and remanufactured medical equipment [have been] a means of dealing with the unfortunate 'dumping' of obsolete or inoperable medical equipment in China [that occurred in the past.]"

Upton and others traveled to Washington, D.C. to meet with representatives of the Department of Commerce and their Office of Health Industries and Consumer Goods division, regarding this issue. Present at the meeting were Jeffrey L. Gren, Director of the Office of Health Industries and Consumer Goods; Richard H. Paddock, Director, Medical Devices; and Simon Francis, Senior International Trade Specialist.

The new rules that China appears to be ready to issue hold mixed promise for the secondary market. On the one hand, they will open up current restrictions on the importation of refurbished devices into the vast Chinese market. On the other hand, the rules provide that the OEMs play a significant role in ensuring the quality and upgrade of used equipment. (Officials at the Commerce Department told DOTmed they were unable to confirm or deny that China has actually enacted such new rules yet.)

A Chinese trade consultant, Hong Kosalos -- principal of Tradeology USA, and a native of Beijing -- explained China's position to DOTmed this way, "Although the Chinese government is reluctant to allow the importation of refurbished equipment [because of past safety problems], the U.S. government and other countries are pushing China to do so," she said. "Other countries allow refurbished equipment to be sold, so if China wants to be part of this market, they have to provide opportunities for foreign companies to sell in China."

The DOTmed web site, which gets over 10,000 visitors a day, has a number of registered users from China who are active. DOTmed see numerous sales going to these users. Philip Jacobus, President of DOTmed -- who has traveled to China over 70 times over the last three decades -- believes there are many companies out there using "special" permits to bypass the current regulations. He also notes that the Chinese are very resourceful business people, and if there is a way to make a profit, they will find a legal way to make that profit.

Past problems with used medical equipment were due in part to a disregard of standard medical procedures, including instances in which single-use devices were reused. Both Upton and Hong caution that the new Chinese regulations stipulate OEM authority in certifying used equipment quality. "[It's] necessary for the OEM to approve every piece of pre-owned medical equipment sold into that country," Upton

indicated. (DOTmed's call to the Commerce Department could not get anyone there to confirm this as fact.) If a company other than the OEM does the refurbishing, the refurbisher needs documents or a contract with the OEM to ensure quality controls, according to Hong.

With 1.3 billion people, China is such a huge market that it may require an interplay of OEMs and refurbishers to satisfy the demands of this market. DOTmed News will continue to report on events and news as they develop.

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