



## Brazilian Medical Device Market in Flux

### *Changing Regulatory Landscape Brings Confusion, Opportunity for U.S. Firms*

With a medical device market worth \$1.5 billion and a rapidly growing population in need of healthcare, Brazil has attracted an increasing number of U.S. device manufacturers. Enticing though the Brazilian market is, it also presents several obstacles for importers. Brazil's size and diversity mean that initial entry into the country's medical marketplace is often tortuous, and foreign manufacturers face unusually high import taxes. Furthermore, a new medical regulatory body assumes authority this year, posing as yet unknown bureaucratic and regulatory challenges. Like France, Brazil has stringent translation requirements. And the country currently is experiencing a major currency crisis. Still, significant long-term rewards await firms with the patience to weather these obstacles.

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and 50% market share**

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The first challenge a foreign manufacturer faces is choosing a point of entry. All exporters are required by law either to be established in Brazil or have a distributor there, according to Dr. Ermano Marchette Morais, Director of the Brazilian Association of Dental, Medical and Hospital Equipment (ABIMO) in São Paulo. Most exporters initially gravitate towards the nerve center of Brazilian business, São Paulo. With an economy larger than that of many South American countries, the city and state of São Paulo drives Brazil's bottom line. This financial vitality extends, to a lesser degree, throughout the southern states of Paraná, Santa Catarina, and Rio Grande do Sul, and north to the state of Rio de Janeiro. These regions welcome U.S. companies.

According to the Department of Commerce, U.S. firms enjoy a positive image and 50% market share, with the remainder going to European and Japanese firms. An area of great potential for U.S. vendors is the market for high-tech medical imaging equipment, such as angiography suites and MRI, CT, and ultrasound scanners. Implants and prosthetic devices also hold great potential. U.S. manufacturers currently do not fare as well in the disposable medical products segment, where Asian companies tend to dominate due to their competitive pricing.

Among the potential pitfalls of the Brazilian market are the high import duties the country's government slaps on imported equipment, according to Mark Cooper, a medical equipment export specialist at the U.S. Department of Commerce Export Assistance Center in Indiana. "We're typically asked about taxes and tariffs in Brazil, because they double the price of products,"

Cooper said. Indeed, exporters may want to investigate the feasibility of using free-trade zones within Brazil, although it is unclear whether medical devices can take advantage of this mechanism. The Brazilian government is aware of the dampening effect of its high import fees, not only on business but on the costs typically passed on to consumers, and may move to lower tariffs on medical products in the future.

### **New Regulatory Agency**

In addition to dealing with economic pressures, the government has been forced to introduce changes to the country's medical products regulatory agency. A series of drug counterfeiting scandals, including the sale of placebo birth control pills to women, made international headlines in 1998 and exposed the ineffectiveness of Brazil's product registration and control mechanisms. Indeed, Brazil's Health Ministry estimated that 5% to 7% of medications being sold in the country last year were fake, according to published reports.

Brazilian authorities responded by cracking down on the responsible regulatory agency, the Sanitary Inspection Secretariat (SVS), firing the agency head and over 30 employees. The legislature passed strict laws which dictated that the sale of false or adulterated pharmaceuticals or foods is punishable by 10 to 15 years in prison. The government recognized that an effective regulatory body was the key to ending circumnavigation of proper device registration. A new Health Inspection Agency, the *Agencia de Vigilância Sanitária*, or *Agevisa*, modeled after the U.S. FDA, will replace the SVS following a constitutional change that takes effect in 1999.

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During the transition to the new agency, many manufacturers and distributors may find themselves in legislative limbo. Since 1977, the SVS has possessed sole authority to grant or deny product registration within 90 days of filing. Currently about 60,000 requests are still pending at the SVS; some have been waiting for six years. Companies traditionally have obtained a preliminary court order to allow sale of their products when the period of SVS action has expired, and importers use this loophole almost exclusively. Once the *Agevisa* assumes authority, it may close this loophole. It remains to be seen how

the *Agevisa* will deal with both new and pending applications, and whether this will speed up the approval process and decrease import tariffs.

### Regulatory changes leave translation requirements in a state of confusion

The *Agevisa* also inherits regulatory oversight of translated product documentation, traditionally a murky area. To be fair, U.S. firms often slip up when initially addressing the translation issue for Brazil, assuming English or perhaps Spanish documentation will suffice. In fact, only translations into Brazilian Portuguese are acceptable.

Even with properly translated product documentation, however, firms face a confusing approval process. "Proof of market clearance in the U.S. by the FDA or another similar body is required, and [product documentation] must be translated into Portuguese by a translator notarized with the seal of the Brazilian consulate," according to ABIMO's Dr. Morais. A *tradutor juramentado* or "sworn translator" is the only officially recognized linguist who may approve a translation.

According to J. Clovis Lemes, a business development specialist with the U.S. Embassy in São Paulo, a *tradutor juramentado* receives such status after taking a lengthy government course which covers language, legal, and general technology issues. These sworn translators, however, are not necessarily medical device specialists. "Proficiency in language is the key requirement," according to Mr. Lemes.

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Since most translations produced for U.S. manufacturers are done by linguists who specialize in the medical field, they rarely are performed by translators with *tradutor juramentado* status. In fact, the role of the *tradutor juramentado* in the product approval process is unclear. Government sources in Brazil did not respond to *Medical Device Translation News* questions about the approval process, i.e., whether official government approval means having a *tradutor juramentado* actually perform the translation of all product documentation or simply sign an affidavit attesting to the translation's accuracy. It is unknown whether the *Agevisa* will introduce changes to this requirement or clarify the official translation approval process.

In summary, Brazil's changing regulatory landscape, the country's currency crisis, and unclear translation approval regulations present formidable obstacles to any U.S. manufacturer wishing to penetrate the Brazilian market. Nonetheless, one of the largest device markets in the world cannot be ignored. The market's long-term outlook is still positive, and thus deserving of the attention to detail that successful importers must devote to realize eventual profits.

## Spotlight: Argentina

### Products without FDA market authorization...

#### CE-marking alone insufficient to import medical devices into Argentina

Argentine law provides that merely having a CE-Mark for a medical device is not necessarily enough for the product to pass through customs. Rather, the manufacturer may also be required to submit clinical trial information to the *Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* ("ANMAT") before marketing authorization is granted. The trial requirements must be similar to those established under Argentine law (*Disposición 969/97*). Manufacturers should be cautioned, however, that the U.S. State Department advised in a 1998 report to Congress that Argentine "data confidentiality" law "fails to provide effective protection for test data submitted to Argentine health authorities by companies seeking marketing approval for pharmaceutical and agrochemical products," a concern which has also been shared by the medical device industry.

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