Medical Device Regulatory Requirements for Chile

Updated: March 2006

Disclaimer: The information contained in this profile, derived from public sources, is intended for basic market planning. While this and other profiles on this site are updated periodically and are current to the best of our knowledge, regulatory systems are subject to change. For detailed and definitive information about a country's laws and policies, the government of the country concerned should be consulted. Please contact us if you discover any necessary changes.

For general information on Chile, please visit the CIA World Factbook entry on that country at www.cia.gov/cia/publications/factbook/geos/ci.html.

Web links were current as of March 2006

Regulatory Update:

In 1998 the Chilean Ministry of Health (MINSAL) approved regulations (Ruling DTO 825) controlling medical products, requiring medical devices that enter the commerce of the country to possess proper certification in accordance with Article 101 of the Sanitary Code. These regulations were introduced during a five-year phase-in period, ending in 2003.

Article 3 of these regulations states that parties intending to manufacture, import, distribute or otherwise enter medical devices into the market must obtain proper certification of conformity by the Institute for Public Health (ISP). Likewise, medical devices must also receive a Certificate of Quality from the ISP before entering the market.

Regulatory Framework

Medical device regulations in Chile apply to the sale and advertising for sale of medical devices and their importation. These regulations also apply to *in vitro* diagnostic products.

The ISP states that Chilean medical device regulations are based largely on those of the United States, Canada and the European Union and are adapted to local market and social situations. ISP representatives have stated this is the case given that more than ninety percent of medical devices on the market in Chile are imported. ISP expects that its regulatory system will help ensure the safety, performance and quality of medical devices, and ultimately better use resources spent by the government and the private sector on health services.

Basic elements in the Chilean medical device regulatory system that may be familiar to U.S. medical device manufacturers include:

- Use of quality systems in production processes
- Product classification (I – IV) based on risk assessment
- Conformity assessment based on ISO standards, conducted by an independent organization
- Post-market surveillance

General Procedure:

To obtain authorization for the ISP to verify conformity with its medical device regulations, the interested party must provide the following information:

a) Name of the interested party or institution, with contact information
b) Name of the owner or legal representative
c) Name of the responsible technical director
d) Listing of items for verification of conformity
e) Indication of compliance with existing rules
f) Listing of personnel that will be involved with such verification

The ISP will then conduct an audit to verify the compliance with existing rules and reserves the right to request further information to determine conformity. Thirty working days after either the original request for audit or from the ISP's request for further information, the ISP will issue a ruling of conformity or non-compliance. Such ruling may be contested within fifteen working days.

The Director of the ISP may authorize the sale or temporary use of medical devices without verification of conformity in the case of "national emergency" or other urgent need. Likewise, the Director of the ISP may authorize the importation of medical devices for use in trade shows or similar exhibitions, as long as it is clear that the device is not intended to enter the market until conformity has been verified.

Post-Market Vigilance

Manufacturers are required to ensure that medical devices meet safety and effectiveness requirements and to maintain data establishing the same. Manufacturers are likewise obligated to identify the risks inherent in the device, eliminate or reduce possible risk, and provide for appropriate protection from those risks.

Article 28 of Chile's medical device regulations states that institutions using regulated medical devices must inform the ISP of any and all defective product performance or any other product defect, including lack of information in labeling or in operating manuals that may result in death or in injury to patients. Also, importers or manufacturers must also inform the ISP of any product recalls arising for whatever reason.

The U.S. – Chile FTA and Import Duties

The U.S. -- Chile Free Trade Agreement (FTA), which was approved by Congress in 2003, is a state-of-the-art agreement that eliminates bilateral tariffs, lowers trade barriers, promotes economic integration and expands opportunities for the peoples of both countries. U.S. Trade Representative Robert B. Zoellick signed the agreement on behalf of the United States, and Chilean Foreign Minister Soledad Alvear signed for Chile, at the Vizcaya Museum and Gardens in Miami. The U.S.- Chile FTA is the first free trade agreement between the United States and a South American country.

Medical devices and instruments from HTS codes 9018 through 9022 have been exempted from import duty into Chile since January 1, 2004. This is also the case for bandages within the 3005 HTS classification and dental chairs within the 9402 range.

Terms of the agreement at article 3.3 state that neither party may increase or adopt any customs duty on a good originating within either country.

Distribution

For the past decade, reforms in Chile's economy have improved the living standards of its people. Business practices in Chile are similar to those in the United States. Channels most used are importers, commission agents, direct purchase, and subsidiary and branch offices.

Experience dictates that the most efficient way to enter the Chilean medical device market is through established local contacts with close ties with the national health service and private entities. No particular legislation governs distribution or agency agreements or termination other than contract law. U.S. companies are encouraged to seek local legal counsel when drafting an agency or distribution agreement.

Contacts

Government Agencies

Chile Customs Headquarters
Plaza Sotomayor 60
Valparaíso, Chile
Tel: 56-32-200500
Email: consultas@aduanas.cl

Institute for Public Health (ISP)
Instituto de Salud Pública de Chile
Marathon 1000
Santiago, Chile
Tel: 56-2-239-1105
Fax: 56-2-237-1504
URL: www.ispch.cl

Ministry of Health (MINSAL)
Ministerio De Salud de Chile
Mac-Iver 541
Santiago, Chile.
Tel: 56-2-639-4001
URL: http://www.minsal.cl

Ministry of Public Health--Government Purchasing Agency
Central de Abastecimento del Sistema Nacional de Servicios de Salud
Av. Matta 644
Santiago, Chile
Phone: 56-2-556-9061; 555-3061
Fax: 56-2-556-7899

National Health Fund (FONASA)
Fondo Nacional de Salud
Monjitas 665
Santiago, Chile
Phone: (56-2) 639-5923
Fax: (56-2) 639-9725

U.S. Embassy Santiago
Patricia Jaramillo, Commercial Advisor
Tel: 56/2/330-3402
Fax: 56/2/330-3172
E-Mail: patricia.jaramillo@mail.doc.gov

Associations

Clinics and Hospitals Association
Asociación de Clínicas y Hospitales
Don Carlos 3187, Oficina D
Santiago, Chile
Phone: 56-2-246-3288; 246-3328
Fax: 56-2-231-4986

Health Insurance Companies Association
Asociación de Isaprés de Chile
Magdalena 275, Las Condes
Santiago, Chile
Phone: 56-2-231-3160
Fax: 56-2-246-2133