

Global Import Regulations for Pre-Owned (Used and Refurbished) Medical Devices



**U.S. Department of Commerce
INTERNATIONAL
TRADE ADMINISTRATION**

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**Global Import Regulations
for Pre-Owned (Used and Refurbished)
Medical Devices**

2006 Edition

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ABBREVIATIONS AND ACRONYMS

AAMI	American Association of Medical Instrumentation
ACV	Agreement on Customs Valuation
AdvaMed	Advanced Medical Technology Association
AMCHAM	American Chamber of Commerce of Guatemala
AMH	Association Medicale Haitienne
BFAD	Bureau of Food and Drug Administration
BOT	build-operate-transfer
CD&TE	Cancer Diagnostic and Treatment Equipment
CE mark	conformité européenne (EU certificate of conformity)
CFGDCT	Management and Development of Local Community
CFG	Certificate to Foreign Government
CIF	cost and insurance and freight
CIHI	Croatian Institute Of Health Insurance
CMDR	Center for Medical Device Regulation
CNSS	National Social Security
CPF	Customs processing fee
CRF	Clean Report Findings
CS	Commercial Service
CT	computer tomography
DGFT	Directorate General of Foreign Trade
DOC	U.S. Department of Commerce
ECRI	Emergency Care Research Institute
EEA	European Economic Area
EU	European Union
FCS	U.S. and Foreign Commercial Service
FDA	Food and Drug Administration
FOB	freight on board
GHTF	Global Harmonization Task Force
GOG	Government of Guinea
GON	Government of Niger
GOT	Government of Turkey
GOTX	Government of Turkmenistan
HDDMEQC	Head Department of the Drug and Medical Equipment Quality Control
HIMA	Health Industry Manufacturer Association
HS	Harmonized System
HSA	Health Sciences Authority
HTS	Harmonized Tariff Schedule
IAMERS	International Association of Medical Equipment Remarketers and Servicers
ICC	in-country caretaker
IDF	import declaration form
IDR	Import Duty Report
IGSS	Instituto Guatemalteco de Seguridad Social
IMI	International Market Insight
ISA	Industry Sector Analysis
ISO	International Organization Standards

ITBIS	Tax of Industry Products and Services
ITS	Intertek Testing Services
JFMDA	Japan Federation of Medical Devices Associations
KFDA	Korea Food and Drug Administration
KMDIA	Korea Medical Devices Industry Associations
KTL	Korea Test Laboratories
MAFS	Ministry of Agriculture and Food Security
MDMA	Medical Device Manufacturers Association
MHLW	Ministry of Health, Labor, and Welfare
MHRA	Medicines and Health Products Regulatory Agency
MHW	Ministry of Health and Welfare
MOH	Ministry of Health
MPG	German Medical Product
MRI	Magnetic Resonance Imaging
MSF	Ministry of Health and Family
NAFTA	North American Free Trade Agreement
nesoi	not elsewhere classified or included
NCM	Mercosur Common Nomenclature
NDA	National Drug Authority
NEMA	National Electrical Manufacturers Association
NGOs	non-governmental organizations
OEM	original equipment manufacturer
OHCG	Office of Health and Consumer Goods
OMMI	Office of Microelectronics, Medical Equipment, and Instrumentation
SGS	Société Générale de Surveillance
SSK	Social Security Agency
SUD	single-use device
TBS	Tanzania Bureau of Standards
TGA	Therapeutic Goods Administration
TSE	Turkish Standards Institute
UNDP	United Nations Development Programme
USDOC	U.S. Department of Commerce
VAT	value added tax
WTO	World Trade Organization

PREFACE

Purpose

This is the fifth edition of a report first issued in May 1999. This report seeks to collect and compile information on the regulations relating to the importation of pre-owned (used and refurbished) capital medical equipment in countries around the world. It also includes some information on market demand for such equipment.

Although this report is intended to serve as a general reference, it is not a definitive study and data are either not available or incomplete for some countries. This report is formally updated periodically, but since this report is posted on the International Trade Administration health Web site, revisions to the country entries are made throughout the year if new material becomes available.

This report does not attempt to address the issue of re-use of single-use devices (SUDs). Such re-use remains a controversial practice and poses different safety issues than pre-owned medical equipment, which is designed for use with multiple patients over many years. Moreover, single-use devices are typically reprocessed by or for the original purchaser and thus generally do not enter into international trade.

Sources

The main sources for this report are responses filed by the staff of the U.S. Commercial Service (CS) stationed in U.S. embassies and consulates around the world to an annual request for information. This request, made by the Office of Health and Consumer Goods (OHCG), formerly, the Office of Microelectronics, Medical Equipment, and Instrumentation (OMMI), asks the Commercial Service trade specialists to review the existing entry and provide answers to several questions. In 2005, the questions were as follows:

1. Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?
2. If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc.?
3. Can public health institutions buy used or refurbished medical devices?
4. Is there a market for used or refurbished medical devices?
5. If there is a market, what types of used or refurbished medical equipment are in the greatest demand?
6. Are single-use devices being reprocessed and sold on the local market? If so, is this activity regulated? Please provide any details.

The second of these questions was asked for the first time in 2003 and again in 2005 in order to clarify the ability of refurbishers—especially those not affiliated with the original equipment manufacturer (OEM)—to readily ship refurbished devices internationally.

The responses provided by the trade specialists vary from full-length reports—typically *International Market Insight* (IMI) or *Industry Sector Analysis* (ISA) reports—to short replies submitted by cable or e-mail. In many cases, the specialists simply confirm the existing entry. Entries submitted in report format are given the title and date of the report. Other entries are simply identified by whether they were submitted to OHCG by cable or e-mail and the date it was submitted. If the trade specialist confirms information submitted in previous years, both the original date of submission and the date of the confirmation are provided.

Thirty-two CS posts responded (including Niger for the first time) to the cable in 2005, somewhat fewer than in past years, perhaps reflecting the overall lack of change in import regulations for pre-owned

medical devices. The 32 responding posts either prepared new IMI reports on pre-owned-medical equipment or sent a cable or e-mail to OHCG addressing the above questions.

The report also includes a small number of reports on the medical-device sector prepared by the CS trade specialists independently of OHCG's request for information on the used-equipment sector, as well as some cables that many CS posts submitted in 1998 in response to a request from the Department of Commerce soliciting information on import regulation for used and refurbished equipment generally. Entries based on responses to this request carry a source indicating that the CS post submitted them via cable and bear a date in 1998.

Although an effort has been made to preserve the text of the original sources as much as possible, text has been reformatted and abridged in order to present a standardized and concise format. In some cases, the original sources have been summarized or edited.

Limitations of This Study

Because of the limitations of the sources, this report cannot be considered a definitive study of import regulations relating to pre-owned medical devices. Information, unfortunately, remains lacking for numerous countries.

In addition, many of the cables that were in response to the 1998 request for information about import regulations for used/refurbished equipment do not explicitly deal with medical equipment. The reporting officer, for example, may have looked only at general import regulations and thus not considered the possibility of more restrictive health regulations that affect the importation of used medical devices.

Finally, medical regulations are constantly changing. What may have been accurate when the market research was prepared may not be the case today. In addition, custom or health officials may interpret regulations that do not seem to present a problem in such a way as to result in market restrictions.

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EXECUTIVE SUMMARY

Findings

Information on import regulations for pre-owned medical devices was available for 105 markets.¹

Of these 105 markets, 84 markets (including India and Niger) appear to permit the unrestricted importation of used or refurbished medical equipment on the same terms as new.² India recently lifted its restrictions, and Niger submitted its report for the first time and indicated that it has no restrictions. Sixteen markets impose restrictions. Five generally prohibit the importation of pre-owned devices.

For the purposes of this report, unrestricted importation of used or refurbished medical equipment on the same terms as new means that if a device has been approved for sale in a market:

- That the device can be imported either as new or pre-owned;
- That the pre-owned device is not subject to additional safety or registration requirements; and
- That the pre-owned device is not subject to duties and tariffs not also levied on like new items.

Such unrestricted importation roughly corresponds to the unregulated resale of medical devices in the internal U.S. market, where the U.S. Food and Drug Administration does not regulate the resale of medical devices already in the U.S. as long as the original specifications in FDA's regulatory approval of the device is not modified.

Unrestricted importation of pre-owned devices does not mean that a country allows the importation of devices that were never approved by regulators. To import a medical device, new or used, into the European Union (EU), the device must bear the CE Mark, which indicates that the device has been approved for sale in the EU.³

The "Blue Guide" while it is a non-binding guide, it is the only "official" interpretation available and applies to all new approach directives, including medical devices. It says that used CE marked devices in EU can be sold without retesting, whereas imported used devices from third countries "must meet the provisions" of the directive because they are considered as "new" being placed on the market for the first time in the EU. "Meeting the provisions" means that the manufacturer has to ensure that the used (pre-owned) medical device from the U.S. which is already CE marked, is in compliance with the directive (either through self-certification or with the help of a notified body, depending on the type of product). It's the manufacturer's (exporter's) responsibility to declare compliance, but market surveillance authorities "have an obligation to ensure this". Retesting, adapting to the latest standards, etc, undoubtedly comes into the picture of compliance verification of a device which is already CE marked. Exporters of pre-owned medical devices should thus fully investigate whether a device has been approved for sale in the target market before attempting to export the device in a pre-owned condition.

¹ This includes some double counting—information was available for the European Union, which can be considered a single market from the viewpoint of import regulations, as well as for 13 of the 15 EU member countries. Thus the count of 104 includes the EU as a whole plus 13 of its member countries.

² For several of these markets, however, it is safer to say that there are no reported restrictions since available reports either do not mention restrictions on pre-owned medical equipment when discussing the import regime for medical devices or simply indicate that authorities permits the importation of used equipment generally without a specific reference to medical devices.

³ The use of the CE Mark has been required since 1995. Medical devices without the CE Mark legally sold to a customer in a EU member state before that year can be freely resold inside the EU, but identical equipment originally sold to users in other markets cannot now enter the EU. In the short term, this discriminates against vendors trying to sell pre-owned devices into the EU. Over the longer run, however, this problem will be resolved as equipment approved for sale in EU-member countries before the use of the CE mark becomes too old or out-of-date to be marketable.

That a market permits the unrestricted importation of pre-owned medical devices does not mean that it represents a good market for pre-owned devices. Traditional buying practices favoring the latest devices, negative impressions of pre-owned equipment, and government procurement policies all affect the market. Of these, the last is perhaps the most readily quantifiable. Of the 84 markets that permit the unrestricted importation of pre-owned medical devices, 24 have laws or policies that prevent or discourage public healthcare institutions from purchasing pre-owned equipment. Although private healthcare facilities in these countries can buy pre-owned equipment, the private healthcare sector often represents a relatively small share of the market.

**Markets that Permit the Importation of Pre-Owned Medical Devices
On the Same Terms as New**

Australia	Hungary	Oman	Yemen
Bahamas	Iceland	Panama	Zambia
Barbados	India	Paraguay	
Belize	Indonesia	Philippines	
Bolivia	Israel	Poland	
Botswana	Jamaica	Romania	
Cameroon	Jordan	Russia	
Chad	Kazakhstan	Saudi Arabia	
Chile	Kyrgyzstan	Serbia and Montenegro	
Costa Rica	Kenya	Senegal	
Czech Republic	Liberia	Singapore	
Dominican Republic	Luxembourg	Slovenia	
Ecuador	Malawi	Sri Lanka	
El Salvador	Malaysia	Switzerland	
Ethiopia	Mexico *	Taiwan	
Finland	Morocco	Tanzania	
Gabon	Mozambique	Trinidad & Tobago	
Ghana	Nepal	Tunisia	
Guatemala	Netherlands	Turkmenistan	
Guinea	New Zealand	Uganda	
Haiti	Nicaragua	Ukraine	
Honduras	Niger	United Arab Emirates	
Hong Kong	Nigeria	Venezuela	

* Mexico permits unrestricted sales to end-users, but restricts cross-border transactions between brokers, refurbishers, etc.

Source: U.S. Department of Commerce

Countries with Public Procurement Policies Barring or Discouraging Purchase of Pre-Owned Equipment

Bahamas	Ghana	Oman	Senegal
Cameroon	Guinea	Panama	Sri Lanka
Chile	Honduras	Paraguay	Tanzania
Costa Rica	Indonesia	Philippines	Uganda
Ecuador	Mexico	Romania	United Arab Emirates
El Salvador	Nicaragua	Saudi Arabia	Venezuela

Source: U.S. Department of Commerce

Sixteen countries—Argentina, Bangladesh, Brazil, Canada, Colombia, Croatia, Japan, South Korea, Moldova, Pakistan, Peru, South Africa, Turkey, Uruguay, Uzbekistan, and Vietnam—impose restrictions of various severities on the importation of pre-owned medical devices. These restrictions include such regulations as the following:

- Taxes on pre-owned device or device over a certain age
- Ban on devices older than a certain age or beyond a set percentage of estimated useful life
- Requirement that device be refurbished by original manufacturer
- Requirement for warranties
- Requirement that parts and service be available

Restrictive rights for importation (e.g., only by holder of registration or by end-user)

- Requirement for new licensing or approval
- Bureaucratic obstructionism not codified in law

In some cases, the restrictions are so severe as to be tantamount to a prohibition. This is often so if the regulations require that the pre-owned device be submitted to new safety licensing. Some countries do not consider the used/refurbished device to be covered by the safety approval granted to the like new device and require that it be submitted for a safety review as if it were a new type of device entering the market. It would rarely be economical for the importer to obtain a safety review for an individual piece of refurbished equipment.⁴

Countries that Restrict the Importation of Pre-Owned Medical Equipment

Argentina	Japan	Turkey
Bangladesh	Korea, South	Uruguay
Brazil	Moldova	Uzbekistan
Canada	Pakistan	Vietnam
Colombia	Peru	
Croatia	South Africa	

Source: U.S. Department of Commerce

⁴ The requirement for re-registration is sometimes confusingly described as treating used devices on the same terms as new devices, i.e., because new devices are subject to registration, so are used devices.

Only five countries—China, Egypt, Kuwait, Syria, and Thailand—appear to ban the importation of pre-owned medical equipment outright.

Countries that Prohibit the Importation of Pre-Owned Medical Equipment

China	Syria
Egypt	Thailand
Kuwait	

Source: U.S. Department of Commerce

Unfortunately, information about import regulations for pre-owned medical equipment is not available for all countries and markets.

Appendix A lists 86 countries/markets for which such information was not available.

Importance of the Restricted Markets for U.S. Exporters of Pre-Owned Medical Devices

Although only 22 countries are known to bar or restrict the importation of pre-owned medical devices, these countries represent key potential markets for U.S. exporters. Not only are most of them low or middle-income countries where buyers might be attracted to the lower cost of pre-owned devices, the combined population of these countries (approximately 3.4 billion people) represents 58.6 percent of the total population of potential U.S. export markets.⁵ The upliftment of tariff and non-tariff trade barriers in India and China would accelerate the demand for pre-owned medical devices. Recently, India removed its restrictions on the importation of pre-owned medical devices and it is anticipated that China may do so in the future. The combined population of these two countries is about 2.5 billion people (about 41 percent of the world's population), thus could create a huge potential market for pre-owned medical devices.

⁵ Because the United States does not export to itself, the population of the U.S. export market is equal to world population minus U.S. population, about 5.8 billion.

MARKET LISTINGS

ARGENTINA

General Market Condition: Restrictions

Source: Report from CS Post (via E-Mail), 28 April 2005

Import Regulations for Pre-Owned (Used and Refurbished) Medical Devices

The Government of Argentina places restrictions on imports of used capital goods, including medical equipment. This situation, however, implies a significant liberalization of imports of these products since 1994, after years of a virtually total ban on the importation of used medical equipment.

The principal concern of Argentine authorities regarding imports of used medical equipment is that of easing the way for well-established and qualified suppliers to enter the market, while protecting the industry from unreliable suppliers which have at different times sold badly refurbished machines or equipment without appropriate after-sale support.

Restrictions and bans on the imports of used medical equipment are established by Resolution MEOSP 909/94, issued by the Ministry of Economy in 1994 (and Resolution MEOSP 1472/94 and subsequent amendments) and by Annex II and III of the Resolution MEOSP 748/95, (and by Resolution MEOSP 235/99) determining a classification of imports as follows:

1. Used products that can be imported if the conditions stated below for the manufacturer, purchaser and sales representative are met (equipment certified by manufacturer, availability of after-sales servicing and availability of spare parts, purchaser must prove it is unable to purchase new equipment, etc.).
2. Used products that cannot be imported.
3. Used and refurbished products that may be freely imported.

Annex II of Resolution MEOSP 748/95: Used Medical Equipment that can be imported under Certain Conditions

[This Resolution replaced Annex I of Resolution 909/94.]

For items listed in the table below, refurbished goods must be accompanied by a certificate issued by the original manufacturer, or by a technical assessment certificate ensuring good condition of the equipment, and authenticated by the Commercial Section of the Argentine Embassy or the Argentine Consulate in the export country, as proof of refurbishment. Technical assessment certificates should specify the type of trials performed on the product, any refurbishment carried out; the technical standards used as reference, and should state that the product has been updated to comply with original manufacturing standards.

Refurbishment can be done in Argentina by the importer, provided he is the end-user, and these goods cannot be resold. In this case, the goods must remain in his or her possession for a period of two years, during which time donation or sale of the goods is prohibited. The end-user is subject to a proof of destination fee of 2 percent on the CIF value.

For importing refurbished goods, the foreign vendor must ensure the buyer of the availability of after-sales service and spare parts, provide user's manuals, and have an exclusive sales agent based in Argentina who will be able to implement the servicing required during the period of guarantee.

Used equipment may not be older than 10 years, except for extraordinary circumstances with the previous agreement of ANMAT, Argentina's health regulatory authority.

Nominal electric voltage for the equipment should be compatible with Argentina's electric system (220v. 50 Hz) or with an adapter already included.

Re-importing of used goods, which had been previously exported temporarily in order to be repaired or to undergo any other improvement, are exempted from the refurbishment certification requirements.

HS Codes of Items subject to Annex II of Res. MEOSP 748/95

9018.49.30	9018.49.40	9022.13.11	9022.13.90	9022.14.90
9024.10.10	9024.10.20	9024.10.90	9025.19.10	9025.19.90
9025.80.00	9026.10.11	9026.10.19	9026.10.20	9026.20.10
9026.20.90	9026.80.00	9027.10.00	9027.20.20	9027.30.11
9027.30.19	9027.30.21	9027.30.22	9027.30.23	9027.30.29
9027.30.31	9027.30.39	9027.50.10	9027.50.20	9027.50.30
9027.50.40	9027.50.90	9027.80.11	9027.80.12	9027.80.13
9027.80.14	9027.80.20	9027.80.30	9027.80.90	9028.10.10
9028.10.90	9028.20.10	9028.20.20	9028.30.11	9028.30.19
9028.30.21	9028.30.29	9028.30.31	9028.30.39	9028.30.90
9030.20.10	9030.20.21	9030.20.22	9030.20.29	9030.20.30
9030.39.90	9030.40.20	9030.82.10	9030.82.90	9030.83.10
9030.83.20	9030.83.30	9030.83.90	9031.10.00	9031.20.10
9031.20.90	9031.30.00	9031.80.11	9031.80.12	9031.80.20
9031.80.30	9031.80.40	9031.80.50	9031.80.60	9031.80.90
9032.89.30				

Annex III of Res 748/95: Goods that are temporarily banned from importation.

[Replaces Annex II of Res. 909/94]

Below is a list of HS codes, for which the importation of used equipment is temporarily banned. However, parts and components of goods classified under Chapter 84-90 of NCM (Mercosur Common Nomenclature) are exempted from this ban (i.e. they can be legally imported), if they have been refurbished by the original manufacturer and carry a guarantee certificate. Such items can be imported for use paying a 28 percent import tariff, plus 0.5 percent statistics fee and 2 percent of proof of destination fee.

Additional exemptions from this ban are:

- Goods imported for Turnkey Projects
- Goods destined to scientific and technological research, under the system established by Decree 732/72; and
- Used goods that had been temporarily exported in order to be repaired or to undergo any other improvement.

Annex III of Resolution MEOSP 748/95: Prohibited Items

9018.11.00	9018.12.90	9018.14.00	9018.19.20	9018.19.80
9018.19.90	9018.20.00	9018.31.11	9018.31.19	9018.31.90
9018.32.11	9018.32.12	9018.32.19	9018.32.20	9018.39.10
9018.39.21	9018.39.22	9018.39.23	9018.39.29	9018.39.30
9018.39.90	9018.41.00	9018.49.11	9018.49.12	9018.49.19
9018.49.20	9018.49.99	9018.50.00	9018.90.10	9018.90.21
9018.90.29	9018.90.39	9018.90.40	9018.90.50	9018.90.91
9018.90.92	9018.90.95	9018.90.99	9019.10.00	9019.20.10
9019.20.20	9019.20.30	9019.20.40	9019.20.90	9020.00.10
9020.00.90	9021.11.10	9021.11.20	9021.11.90	9021.19.10
9021.19.20	9021.19.91	9021.19.99	9021.21.10	9021.21.90
9021.29.00	9021.30.11	9021.30.19	9021.30.20	9021.30.30
9021.30.40	9021.30.80	9021.30.91	9021.30.99	9021.40.00
9021.50.00	9021.90.11	9021.90.19	9021.90.80	9021.90.91
9021.90.92	9021.90.99	9022.13.19	9022.14.11	9022.14.12
9022.14.13	9022.14.19	9022.19.90	9022.21.10	9022.21.20
9022.21.90	9022.29.00	9022.30.00	9022.90.11	9022.90.12
9022.90.19	9022.90.80	9022.90.90	9023.00.00	9024.90.00
9025.11.10	9025.11.90	9025.90.10	9025.90.90	9026.90.10
9026.90.20	9026.90.90	9027.90.10	9027.90.91	9027.90.92
9027.90.93	9027.90.99	9028.90.10	9028.90.90	9029.10.10
9029.10.90	9029.20.10	9029.20.20	9029.90.10	9029.90.90
9030.10.10	9030.10.90	9030.39.21	9030.90.10	9030.90.20
9030.90.30	9030.90.90	9031.90.10	9031.90.90	9032.10.10
9032.10.90	9032.20.00	9032.81.00	9032.89.11	9032.89.19
9032.89.21	9032.89.22	9032.89.23	9032.89.24	9032.89.25
9032.89.29	9032.89.81	9032.89.82	9032.89.83	9032.89.84
9032.89.89	9032.89.90	9032.90.10	9032.90.91	9032.90.99
9033.00.00				

Used goods not included in either list

Used goods not included in either list may be imported into Argentina. Equipment such as ultrasonic scanners and magnetic resonance imaging apparatus, among others, are not on either of the above lists and used equipment of these types may be imported.

General Import Regulations and Trends for Used Medical Equipment

While Argentina recently established a system of harmonized medical product regulations applicable to new medical products (Regulations 2318 and 2319/02, and Mercosur Disp.3801/04 and 3802/04 regarding a unified record for the registration of a medical product and the registration of the manufacturing or importing company), these regulations do not apply to used/refurbished medical equipment, which continue to be ruled by the previous system, as described above. However, the importer must be registered with ANMAT and must comply with ANMAT Disposicion 191/99 regarding Good Manufacturing Practices of Medical Products.

In order to be able to import used/refurbished medical equipment, the importer should open a file with ANMAT, prior to the shipment of the goods, in order for the sanitary authority to determine in which conditions the equipment may be.

Most used goods are subject to an average import fee of about 28 percent (varying according to product) plus the Statistics Fee of 0.5 percent. Some others will pay around 16.5 percent or 12.5 percent, plus Statistics Fee. (Resolution ME 8/01 – Annex I)

Public health institutions depending on the national, provincial or municipal government, and religious or welfare organizations accredited as such (Resolution MP 37/2003) can receive donations of used equipment (which must be no lesser than five years old).

National public health institutions buy new equipment. Public hospitals or other non-profit organizations are, however, exempted from any tax levies on imports of certain new medical products.

There is currently a federal sanitary emergency due mainly to a lack of imported medical and pharmaceutical supplies, and parts, caused by the peso devaluation and by the economic and financial crisis that occurred in Argentina in late 2001 and 2002. Therefore, imports of some new critical accessories and parts are exempted from tax duties.

Regarding reuse of certain medical disposable products, Resolution 255/94 (Annex I) establishes that some articles such as hemodynamic catheters may be reused (up to three times) even if the manufacturer recommends a single use. Under the Sanitary Emergency, Decree 486/02 (Art. 33) and Res. 244/03 establish the requirements for the reuse of pacemakers and other cardiological implants, within the same healthcare institution. Resale of used implants is not allowed.

While used equipment may represent an attractive alternative for the tighter budgets of the health system due to the reasons explained above, government authorities and the private sector are mainly concentrating their purchases on critical supplies, rather than investing on updating technology. U.S. medical firms have always had an excellent reputation in Argentina for producing top high technology. Therefore, opportunities should be considered on a case-by-case basis.

Mercosur HS Codes and U.S. Schedule B HS Codes

Below is a list of Mercosur HS Codes and a list of US Schedule B HS Codes, with product description (applicable to medical equipment) to assist you in classifying your product.

List of Mercosur HS Codes

HS Code	Description
9018	Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic and other electro-medical apparatuses and sight-testing instruments; parts and accessories thereof:
90181	Electro-diagnostic apparatus (including apparatus for functional exploratory examination or for checking physiological parameters) parts and accessories thereof:
90181100	Electrocardiographs
90181200	Ultrasonic scanning apparatus
90181210	Echographs with spectral Doppler analysis
90181290	Other:
90181300	Magnetic resonance imaging apparatus
90181400	Scintigraphic apparatus
90181910	Endoscopes
90181920	Audiometers
90181930	Gamma cameras
90181980	Other
90181990	Parts
901820	Ultraviolet or infrared ray apparatus, and parts and accessories thereof
90182010	For operation of the cornea by laser surgery
90182090	Other
90183	Syringes, needles, catheters, cannulae and the like
901831	Syringes, with or without needles; parts and accessories thereof
9018311	Made of plastic
90183111	Of lesser or equal capacity to 2cm ³
901832	Tubular metal needles and needles for sutures
90183910	Needles
9018392	Sondes, catheters and cannulae
90183921	Rubber catheters
90183922	Polyvinyl chloride (PVC) catheter, for arterial embolectomy
90183923	Polyvinyl chloride (PVC) catheter, for termodilución
90183929	Other
90183930	Lancets for vaccination and cauteries
90183990	Other
90184	Other instruments and appliances used in dental sciences:

HS Code	Description
90184100	Dental drill engines, whether or not combined on a single base with other dental equipment
901849	Other
9018491	Drills
90184911	Instruments made of tungsten carbide
90184912	Instruments made of steel to vanadium
90184919	Other
90184920	Files
90184930	Files, those which operate by laser, for buccal treatment
90184940	Those which operate by kinetic particle projection, for buccal treatment
9018499	Other
90184991	Instruments for the design and construction of ceramic pieces for dental restoration, computerized
90184999	Other
90185000	Other ophthalmic instruments and appliances
901890	Other instruments and appliances
90189010	Instruments for blood transfusion or intravenous infusion
9018902	Bistouries
90189021	Electrical instruments
90189029	Other
9018903	Lithotomes and lithotriptors
90189031	Lithotriptors, by shock wave
90189039	Other
90189040	Artificial kidneys
90189050	Diathermy apparatuses
9018909	Other
90189091	Baby incubators
90189092	Appliances for the measure of arterial pressure
90189093	Equipment for microwave intrauretal therapy apt for the treatment of prostate infections, computerized
90189094	Endoscopes
90189095	Clamps and clips, their applicators and extractors
90189099	Other
9019	Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus; parts and accessories thereof:

HS Code	Description
90191000	Mechano-therapy appliances, massage apparatus, psychological aptitude-testing apparatus
901920	Ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus
90192010	Oxygen therapy apparatus
90192020	Aerosol therapy apparatus
90192030	Artificial respiration apparatus
90192090	Other
9021	Orthopedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect of disability; parts and accessories thereof:
90211	Orthopedic or fracture appliances, and parts and accessories thereof:
902111	Prosthetic appliances
90211110	Femoral
90211120	Myoelectrical
902119	Other
90211910	Orthopedic appliances and accessories
90211920	Appliances and accessories for fractures
9021199	Parts and accessories
90211991	Orthopedic appliances and accessories, jointed
90211999	Other
90212	Artificial teeth and dental fittings, and parts and accessories thereof:
902121	Artificial teeth
90212110	Of acrylic
90212190	Other
90212900	Other
902130	Other artificial parts of the body and parts and accessories thereof
9021301	Cardiac valves
90213011	Mechanical
90213019	Other
90213020	Intraocular contact lenses
90213030	Artificial vascular arteries
90213040	Non-implantable artificial breasts
90213080	Other
9021309	Parts and accessories
90213091	Parts of modular prostheses that replace body parts

HS Code	Description
90213091	superior or inferior
90213099	Other
90214000	Hearing aids, excluding parts and accessories thereof
90215000	Pacemakers for stimulating heart muscles, excluding parts and accessories thereof
902190	Other
9021901	Parts implanted to compensate for a defect or incapacity
90219011	Heart defibrillator
90219019	Other
90219080	Other
9021909	Parts and accessories
90219091	Of cardiac stimulators (pacemakers)
90219092	Of hearing aids
90219099	Other
9022	Apparatus based on the use of X-rays or of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus, X-ray tubes and other X-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like; parts and accessories thereof:
90221	Apparatus based on the use of X-ray tubes and other X-rays, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus:
90221200	Computed tomography apparatus
902213	Other, for dental uses
9022131	Of diagnosis
90221311	Of panoramic maxillary tomography
90221319	Other
90221390	Other
902214	Other, for medical, surgical or veterinary uses
9022141	Of diagnosis
90221411	For mammography
90221412	For angiogram
90221413	For bone density, computerized
90221419	Other
90221490	Other
902219	For other uses
90221910	Spectrometers or spectrographs of X-rays

HS Code	Description
90221990	Other
90222	Apparatus based on the use of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus:
902221	For medical, surgical, dental or veterinary uses
90222110	Radiocobalt apparatus (cobalt pump)
90222120	Gamma therapy apparatus
90222190	Other
90222900	For other uses
90223000	X-ray tubes
902290	Other, including parts and accessories
9022901	Appliances
90229011	Tension generators
90229012	Radiological screens
90229019	Other
90229080	Other
90229090	Parts and accessories of X-ray apparatus
90230000	Instruments, apparatus and models, designed for demonstrational purposes (for example, in education or exhibitions), unsuitable for other uses, and parts and accessories thereof
9024	Machines and appliances for testing the hardness, strength, compressibility, elasticity or other mechanical properties of materials (for example, metals, wood, textiles, paper, plastics), and parts and accessories thereof
902410	Machines and appliances for testing metals
90241010	For traction testing or compression
90241020	For durability testing
90241090	Other
902480	Other machines and appliances
9024801	Machines and appliances for textile testing
90248011	Automatic, for spinning
90248019	Other
90248020	Machines and appliances for testing paper, cardboard, linoleum, plastic or flexible rubber
90248090	Other
90249000	Parts and accessories

HS Code	Description
9025	Hydrometers and similar floating instruments, thermometers, pyrometers, barometers, hygrometers and psychrometers, recording or not, and any combination of these instruments; parts and accessories thereof:
90251	Thermometers and pyrometers, not combined with other instruments:
902511	Liquid-filled, for direct reading
90251110	Clinical thermometers
90251190	Other
902519	Other
90251910	Optical pyrometers
90251990	Other
90258000	Other instruments
902590	Parts and accessories
90259010	Thermometers
90259090	Other
9026	Instruments and apparatus for measuring or checking the flow, level, pressure or other variables of liquids or gases (for example, flow meters, level gauges, manometers, heat meters), excluding instruments and apparatus of heading 9014, 9015, 9128 or 9032; parts and accessories thereof
902610	For measuring or checking the flow or level of liquids
9026101	For measuring or volume control
90261011	Measurers – electronic transmitters, which function primarily by electromagnetic induction
90261019	Other
90261020	For measuring or level control
902620	For measuring or checking pressure
90262010	Pressure gauges
90262090	Other
90268000	Other instruments and apparatus
902690	Parts and accessories
90269010	Instruments and apparatus for measuring and level control
90269020	Pressure gauges
90269090	Other

HS Code	Description
9027	Instruments and apparatuses for physical or chemical analysis (for example, polarimeters, refractometers, spectrometers, gas or smoke analysis apparatus); instruments and apparatus for measuring or checking viscosity, porosity, expansion, surface tension or the like; instruments and apparatus for measuring or checking quantities of heat, sound or light (including exposure meters); microtomes; parts and accessories thereof:
90271000	Gas or smoke analysis apparatuses
902720	Chromatographs and electrophoresis instruments
9027201	Chromatographs
90272011	Of gas
90272012	Of liquid
90272019	Other
90272020	Electrophoresis instruments
902730	Spectrometers, spectrophotometers and spectrographs using radiation (ultraviolet, visible, infrared)
9027301	Spectrometers
90273011	Of optical emission (atomic emission)
90273019	Other
9027302	Spectrophotometers
90273021	Of ultraviolet, visible or infrared rays
90273022	Of atomic absorption
90273023	Of optical emission (atomic emission)
90273029	Other
9027303	Spectrographs
90273031	Of optical emission (atomic emission)
90273039	Other
90274000	Exposure meters
902750	Other instruments and apparatus using optic radiations (ultraviolet, visible, infrared)
90275010	Color meters
90245020	Photometers
90275030	Refractometers
90275040	Saccharimeters
90275090	Other
902780	Other instruments and apparatuses
9027801	Calorimeters, viscosity meters, densitometers, pH meters
90248011	Calorimeters
90278012	Viscosity meters
90278013	Density meters

HS Code	Description
90278014	pH meters
90278020	Mass spectrometers
90278030	Polarographs
90278090	Other
902790	Microtomes; parts and accessories:
90279010	Microtomes
9027909	Parts and accessories
90279091	Optical emission spectrometers (atomic emission)
90279092	Optical emission spectrographs (atomic emission)
90279093	Polarographs
90279099	Other
9028	Gas, liquid or electricity supply or production meters, including calibrating meters thereof; parts and accessories thereof:
902810	Gas meters
90281010	Compressed natural gas, electronic
90281090	Other
902820	Liquid meters
90282010	Of weight less or equal to 50kg
90282020	Of weight greater than 50kg
902830	Electricity meters
9028301	Single-phase for alternate current
90283011	Digital
90283019	Other
91028302	Dual-phase
90283021	Digital
90283029	Other
9028303	Triple phase
90283031	Digital
90283039	Other
90283090	Other
902890	Parts and accessories
90289010	Electricity meters
90289090	Other

HS Code	Description
9029	Revolution counters, production counters, taximeters, odometers, pedometers and the like; speedometers and tachometers, other than those of heading 9014 or 9015; stroboscopes; parts and accessories thereof
902910	Revolution counters, production counters, taximeters, odometers, pedometers and the like
90291010	Revolution counters, production counters
90291010	Revolution counters, counters of production or hours of work
90291090	Other
902920	Velocity meters, tachometers; stroboscopes
90292010	Velocity meters and tachometers
90292020	Stroboscopes
902990	Parts and accessories
90299010	Of velocity meters and tachometers
90299090	Other
9030	Oscilloscopes, spectrum analyzers and other instruments and apparatus for measuring or checking electrical quantities, excluding meters of heading 9028; instruments and apparatus for measuring or detecting alpha, beta, gamma, X-ray, cosmic or other ionizing radiations; parts and accessories thereof:
903010	Instruments and apparatus for measuring or detecting ionizing radiations
90301010	Radioactivity measurers
90301090	Other
903020	Cathode-ray oscilloscopes and cathode-ray oscillographs
90302010	Numeric oscilloscopes (digital)
9030202	Analogical oscilloscopes
90302021	Of frequency greater or equal to 60 MHz
90302022	Vector scope
90302029	Other
90302030	Oscillograph
90303	Other instruments and apparatus, for measuring or checking voltage, current, resistance or power, without a recording device:
90303100	Multimeters
903039	Other
9030391	Volt meters
90303911	Digital
90303919	Other
9030392	Ammeters
90303921	Type used in automotive vehicles

HS Code	Description
90303929	Other
90303990	Other
903040	Other instruments and apparatus, specially designed for telecommunications (for example, cross-talk meters, gain measuring instruments, distortion factor meters, psophometers)
90304010	Protocol analyzers
90304020	Selective level analyzers
90304030	Numeric (digital) transmission analyzers
90304090	Other
90308	Other instruments and apparatus:
903082	For measuring or checking semiconductor wafers or devices
90308210	Of integrated circuit tests
90308290	Other
903083	Other, with a recording device
90308310	Continuity test of printed circuits
90309320	Automatic test of printed circuits with their mounted components
90308330	Measurement parameters characteristic with signals from television or radio
90308390	Other
903089	Other
90308910	Logical analyzers of digital circuits
90308920	Frequency spectrum analyzers
90308930	Frequency meters
90308940	Phase meter
90308990	Other
903090	Parts and accessories
90309010	For articles of subheading 9030.10
90309020	For articles of subheading 9030.31 or 9030.39
90309030	For articles of subheading 9030.82 or 9030.83
90309090	Other
9031	Measuring or checking instruments, appliances and machines, not specified or included elsewhere in this chapter; profile projectors; parts and accessories thereof:
90311000	Machines for balancing mechanical parts
903120	Test benches
90313010	For motors
90312090	Other

HS Codes	Description
90313000	Profile projectors
90314	Other optical instruments and appliances:
90314100	For inspecting semiconductor wafers or devices or for inspecting photomasks or reticles used in manufacturing semiconductor devices
90314900	Other
903180	Other instruments, appliances and machines:
9031801	Dynamometers and rugosimeters
90318011	Dynamometers
90318012	Rugosimeter
90318020	Machines for three-dimensional measurement
90318030	Master measuring devices
90318040	Digital appliances used in automotive vehicles for measurement and indication of multiple measurements, such as: average velocity, actual and average consumption, and capacity (on board computers)
90318050	Apparatus for textile analysis, computerized
90318060	Charging cells
90318090	Other
903190	Parts and accessories
90319010	Test benches
90319090	Other
9032	Automatic regulating or controlling instruments and apparatus; parts and accessories thereof
903210	Thermostats
90321010	Of fluid expansion
90321090	Other
90322000	Manostats (presostats)
90328	Other instruments and apparatuses:
90328100	Hydraulic and pneumatic
903289	Other
9032891	Voltage regulators
90328911	Electronic
90328919	Other
9032892	Type of electronic controllers used in
9032892	automotive vehicles
90328921	Of anti-lock break systems
90328922	Of suspension systems
90328923	Of transmission systems

HS Code	Description
90328924	Of ignition systems
90328925	Of injection systems
90328929	Other
90328930	Digital control equipment for railway vehicles
9032898	Other equipment for the regulation or control of non-electrical levels
90328981	Of pressure
90328982	Of temperature
90328983	Of humidity
90328984	Of electrical motor speed for frequency variation
90328989	Other
90328990	Other
903290	Parts and accessories
90329010	Circuits printed with mounted electrical or electronic components
9032909	Other
90329091	Of thermostats
90329099	Other
90330000	Parts and accessories (not specified or included elsewhere in this chapter) for machines, appliances, instruments or apparatus of chapter 90

List of U.S. Schedule B HS Codes

HS Code	Description
9018110040	Electrocardiographs
9018110080	Parts and accessories for electrocardiographs
9018194000	Apparatus, functional exploratory examination& pts
9018198020	Patient monitoring system, temperature, pulse,etc
9018198030	Basal metabolism and blood pressure apparatus
9018198035	Electroencephalographs and electromyographs
9018198045	Ultrasonic scanning apparatus
9018198050	Other electro-diagnostic apparatus, nesoi
9018198060	Parts and accessories for electro-diagnostic apparatus
9018200000	Ultraviolet or infrared ray apparatus, and parts and acc
9018310040	Hypodermic syringes, with or without their needles
9018310080	Syringes, with or without their needles, nesoi
9018310090	Parts for syringes, with or without their needles
9018320000	Tubular metal needles and needles for sutures and parts
9018390030	Bougies, catheters, drains and sondes and pts and access
9018390050	Cannulae and the like and part and accessories
9018410000	Dental drill engines and parts and accessories
9018490000	Inst and appln for dental science, and parts and acc, nesoi
9022190000	Apparatus base on x-ray for other use, ex medical, etc
9022294000	Appts, alpha, beta, etc radiation for smoke detector
9022298000	Appts, alpha, beta, etc radiation for other use, nesoi
9024100000	Machines and appliances for testing metals
9024800000	Machine and appliance, test hardness, strength, etc, nesoi
9024900000	Pts, machine and appln, test hardness/strength, etc
9025112000	Clinical thermometers liquid-filled
9025114000	Thermometers liquid-filled, direct reading, nesoi
9025194000	Pyrometers not combined with other instruments
9025198040	Clinical thermometers, not combind with other inst, nesoi
9025198080	Thermometers, not combined with other inst, nesoi
9025200000	Barometers, not combined with other instruments
9025800000	Hydrometers, hygrometers, psychrometers, etc, nesoi
9025900000	Parts, hydrometers, therometers, pyrometers, etc
9026105000	Flow meter for meas/checking flow/level of liquids
9026107000	Inst and apprts, meas/check flow/level of liq, nesoi
9026200000	Inst and apprts, measuring/checking pressure
9026800000	Inst measure/checking variable of liq/gases, nesoi
9026900000	Parts, inst and apprts measure/check variables liq/gas
9027100000	Gas or smoke analysis apparatus
9027202000	Gas chromatographs
9027204040	Electrical electrophoresis instruments
9027205000	Liquid chromatographs
9027209000	Chromatographs and electrophoresis inst, nesoi
9027304040	Spectrophotometers using optical rad nonelectrical
9027304080	Elec spectrometers and spectrographs etc., opt radtn
9027308020	Spectroscopes using optical radiations, nonelec

HS Code	Description
9027308080	Spectrometers and spectrograph, opt rad, nonelec, nesoi
9027400000	Exposure meters
9027502000	Thermal analysis instruments and apparatus
9027504050	Photometers
9027505000	Other chem analysis instruments and apparatus, nesoi
9027509000	Inst, physical/chem analysis opt radiation, nesoi
9027801000	Nuclear magnetic resonances inst exc heading 9018
9027802000	Mass spectrometers
9027803100	Electrochemical instruments and apparatus,
9027803200	Chemical instruments and apparatus, nesoi
9027803500	Phys analysis inst, exc optical radiations, nesoi
9027808000	Inst, measuring/checking viscosity etc, nesoi
9027902000	Microtomes
9027904030	Parts and access of schb 9027.30.4040 & 9027.30.4080
9027904040	Parts and accessories of articles of schb 9027.40.0000
9027904070	Parts and access of inst and appts for physical/chem etc
9030100000	Inst for measuring/detecting ionizing radiations
9030200000	Cathode-ray oscilloscopes and cathode-ray oscillograph
9030310000	Multimeters
9030390040	Apparatus to test voltage or current or resistance
9030390080	Inst and appts for measuring/checking power, nesoi
9030400000	Other inst, specially designed for telecommunication
9030810040	Inst to check semiconduct wafers and such that record
9030810080	Inst and app with recording device, nesoi
9030890080	Inst measuring/checking electrical quantitie, nesoi
9030904000	Parts for articles of subheading 9030.10
9030908010	Parts and access for article of subhdg 9030.20
9030908020	Parts and access of articles of schb subhdg 9030.31
9030908030	Parts and access of artcl of schb subhdg 9030.39
9030908040	Parts and access of articles of schb subhdg 9030.40
9030908050	Parts and access of arti of subhdg 9030.82 or .83
9030908060	Parts and access of articles of schb subhdg 9030, nesoi
9031100000	Machines for balancing mechanical parts
9031200000	Test benches
9031300000	Profile projectors
9031400020	Optical inst and app for inspecting photomasks
9031400040	Optical inst for inspecting semiconductor wafers
9031400060	Optical inst for inspecting semicond devices nesoi
9031400080	Optical instruments and appliances nesoi
9031800060	Equip, testing elec characteristics of engines
9031800070	Equip, testing exc elec characteristics of engines
9031800080	Measure/check inst, appln and machines, nesoi in chap 90
9031900000	Parts, of mach nesoi in this chap, and profile projectr

AUSTRALIA

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), May 2005

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

There are no specific tariffs that apply to used or refurbished medical equipment that do not apply to new medical equipment.

Any used or refurbished medical equipment must comply with the same regulations that apply to new medical equipment. This includes any relevant Australian standards and listing or registration with the Therapeutic Goods Administration (TGA). For information on medical regulations and the TGA, contact:

The Information Officer, Conformity Assessment Branch	Tel: 61 2 6232 8098
Therapeutic Goods Administration	Fax: 61 2 6232 8299
PO Box 100	E-mail:
Woden ACT 2606	CAB.Medical.Device.Information@health.gov.au
Australia	health.gov.au
	Web site: www.tga.gov.au

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc?

A third party cannot legally import the same device in used/refurbished condition without the device being subject to new listing or registration with the TGA because the TGA will have only approved the device for the original sponsor of the product. The third party will have to apply to the TGA for listing or registration of the used/refurbished device in Australia.

Can public health institutions buy used or refurbished medical devices?

Health institutions are able to purchase used/refurbished medical equipment with no restrictions. Preference is given to products that come with quality assurance and warranties. Suppliers of used/refurbished medical equipment are more likely to distribute products for which there are available spare parts.

However, since the Australian market for medical devices is mature and consumers are sophisticated, there is little demand for technologically obsolete devices. It appears that local health institutions are meeting much of the supply of used equipment with only a small amount being imported. Therefore, there has been little or no increase in suppliers or market for used equipment over the past few years. Major teaching hospitals are unlikely to expose themselves to the increased risk of purchasing used goods. Given the current strength of the U.S. dollar, the economic viability of importing used equipment of suitable quality into Australia is considered questionable at this time.

Is there a market for used or refurbished medical devices?

Demand for used medical equipment is limited. There is technically a market for used or recycled equipment. However, this is not considered a promising sector because hospitals and hospital groups often sell used equipment among themselves. The equipment moves down the 'food chain' from major hospitals to small private hospitals and outpatient clinics.

Technical advances and the desire to have the latest and best equipment, even in small hospitals, are making used equipment redundant. An export market of used equipment is developing with Australian distributors exporting to Asia, the Pacific Islands and Papua New Guinea. In addition, some equipment is being exported to overseas locations through church groups and organizations such as Rotary International.

If there is a market, what types of used or refurbished medical equipment are in greatest demand?

The market for used or refurbished medical equipment in Australia is small, with limited prospects for U.S. suppliers. Some prospects may lie in the low-technology sector of the market such as furniture (for example, beds), wheelchairs, and rehabilitation equipment.

Are single-use devices being reprocessed and sold on the local market? If so, is this activity regulated?

The issue re-use of single use medical devices (SUDs) in Australia has been under consideration since the early 1990s. It has historically been common practice throughout Australian health care facilities, however a survey undertaken in 2001 showed that the re-use of SUDs has dropped to 155 with more reuse occurring in larger hospitals than in smaller with larger hospitals.

The formal regulation of re-manufacture of SUDs for re-use was introduced in Australia on December 1, 2003. It applies to individuals or facilities that meet the definition of a manufacturer of medical devices under section 41BG of the Therapeutic Goods Act 1989 (the Act). This means that any facility (or individual) involved in re-manufacturing SUDs for re-use that meet the definition of a manufacturer of medical device must comply with the regulatory requirements for manufacturing medical devices as specified in the Act and the Therapeutic Goods (Medical Devices) Regulations 2002.

AUSTRIA

General Market Condition: No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from CS Post (via E-Mail), March 30, 2005

All regulations, restrictions, and tariffs that apply to new medical equipment are also applicable to imports of used equipment. It is especially important that the products meet the European certification requirements and are CE marked. The CE mark signifies that a product fulfills all applicable EU requirements. If a manufacturer or its agent has registered a medical device in Austria, a third party can legally import the same device in used or refurbished condition without a new safety inspection, but only the, when no changes have been made to the original equipment. If a value-added refurbishment was done, the importer has to apply for a new CE certification.

Austrian public health institutions are at liberty to purchase used or refurbished medical devices, but in practice they rarely do, as they face a number of practical and legal issues, including product liability, maintenance problems, spare parts warranties, and training of medical personnel on the equipment, to name a few.

It is against the law to use reprocessed single-use devices in Austria.

Austrian industry experts report that there have been no exports of used medical equipment from the United States to Austria in the past five to ten years. Austria has a small market for used equipment, especially for x-ray and ultrasonic apparatus. Only one Austrian company has been involved in this business in the past. The majority of used items of surplus medical equipment have been exported to Austria's neighboring countries to the East.

BAHAMAS

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

Source: Report from CS Post (via Cable), 4 April 2001

The Bahamas Ministry of Health provided the following information in response to questions regarding the importation of used medical equipment.

The Government of the Bahamas applies the same restrictions to both used and new medical equipment. (Importation of new or used medical equipment is subject to a 42 percent customs duty.)

It is not a policy of the Ministry of Health to purchase used and/or refurbished medical equipment, implements, or devices. Bahamian public and private sector health institutions prefer to purchase new equipment.

BANGLADESH

General Market Condition: Restricted

Source: Report from CS Post (via E-Mail), 15 April 2002

The Government of Bangladesh imposes restrictions on the import of some used medical equipment. Second-hand and reconditioned machines, which would include medical products such as used X-ray machines, must be imported with a certificate from an established international inspection firm attesting that the equipment will last at least 10 years.

There are no special tariffs that apply to used or refurbished medical equipment. Customs valuation of the equipment is normally taken from the invoice presented by the importer.

The prospects in Bangladesh for American origin used medical equipment are good. There is a particular demand for dental chairs with drill systems, X-ray equipment, ultrasound machines, magnetic resonance and CT-scan equipment, and electrocardiographs. Private clinics and independent doctors have purchased used equipment, but have had difficulty locating local suppliers. Hospitals in the public sector, however, generally purchase new equipment.

BARBADOS

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 6 June 2000 (Information confirmed 29 March 2002)

There are currently no restrictions on the importation of used and refurbished medical equipment into Barbados.

The import duty applied to used or refurbished medical equipment is the same as applied to new medical equipment. The tariff rate on medical equipment varies between 5 percent and 20 percent depending on the type of medical equipment. There is also a 1 percent environmental levy and a 15-percent value-added tax applied to imports of medical equipment.

Ministry of Health officials advise that there are no restrictions on the importation of used medical or refurbished equipment by public health institutions. However, based on past experience relating to reliability and the conditions of used medical equipment, it is the practice of the Ministry of Health to purchase new medical equipment. The purchase of used medical equipment also does not adhere to the procurement practices of the Government of Barbados.

Private sector health care professionals can purchase used or refurbished medical equipment. However, the Ministry of Health needs to be advised of all purchases of used medical equipment being imported into Barbados.

There are no statistics available on the market for used or refurbished medical equipment in Barbados. Based on the strong preference by government and private sector health care professionals to purchase new medical equipment, we do not foresee much market potential for used medical equipment in Barbados.

BELGIUM

General Market Condition: No Restrictions, but CE Mark is Required

See also the entry for the European Community.

Source: Report from CS Post (via E-Mail), 17 April 2003

Are there special restrictions or tariffs that apply to used medical equipment?

No. Used medical equipment is treated identically as new medical equipment regarding CE mark and import duties.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subject to new safety inspections, etc.?

Yes, a third party can import the same device in used/refurbished condition if it has the CE mark. There is of course the issue of liability.

Can public health institutions buy used or refurbished medical device?

Yes, but hospitals are more reluctant to purchase medical equipment or to reuse medical devices because of liability issues. In Belgium, used or refurbished equipment is sometimes used to train students. A lot of used and refurbished equipment is exported to developing countries in Africa and the former eastern countries.

Is there a market for used or refurbished medical devices?

Yes, if the refurbished medical devices are of a superior quality compared with the existing medical devices. Belgian hospitals have the reputation of using very high-tech medical equipment.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

High-tech equipment.

BELIZE

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 5 April 2002

Based on information supplied by Belize's Assistant Comptroller of Customs, Everard Lopez:

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

There are no special restrictions or tariffs applied to used and refurbished medical equipment that are imported into Belize. A 10-percent import duty is levied on most of the new and used/refurbished medical equipment imported into the country. A very small percentage is exempted from import duty, a list of which may be obtained from the Belize Customs Department. Local importers also pay an eight percent sales tax and a one-percent environmental tax on all new and used/refurbished medical equipment.

Can public health institutions buy used or refurbished medical devices?

Public Health institutions and individual companies can and do buy used or refurbished medical devices.

Is there a market for used or refurbished medical devices?

Recent trade figures indicate that there is a growing market in Belize for used and refurbished medical devices.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

Based on recent import entry data, used lamps, chairs and optical projectors for eye examinations are in the greatest demand in Belize. Data indicate also that used medical equipment, which include universal radios, graph units, monographic optical delivery beds, and konica with stands are also in great demand.

BOLIVIA

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 23 April 2003

Regulatory Agency

The Ministry of Health and Sports is the regulatory agency for the healthcare sector. Reporting to this ministry are the Viceministry of Health and the Vice ministry of Sports.

Projects and Decentralized Institutions:

- Unidad de la Reforma de la Salud
- Unidad Ejecutora del Fondo Nórdico
- Proyecto de Salud Integrado (PROSIN)
- Programa de Apoyo al Sector de la Higiene y Salud
- Unidad del Escudo Epidemiológico y Apoyo a la Reforma de Salud (BID)
- Comité Nacional de la Persona Discapacitada
- Instituto Boliviano de la Ceguera
- Instituto Nacional de Seguros de Salud (INASES)
- Instituto Nacional de Salud Pública (INSP)
- Central de Abastecimiento de Suministros (CEASS)
- Seguros Delegados
- Instituto Nacional de Laboratorios de Salud (INLASA)
- Instituto Nacional de Salud Ocupacional
- Escuela de Salud de La Paz
- Escuela Técnica de Salud Boliviana – Japonés (Cooperación Andina - Cochabamba)
- Centro Nacional de Epidemiología y Salud Ambiental del Sur (CENESASUR)
- Instituto Nacional de Medicina Nuclear
- Instituto Boliviano de Biología de la Altura
- Centro Nacional de Enfermedades Tropicales (CENETROP)
- Central de Abastecimiento de Suministros (CEASS)
- Lotería Nacional de Beneficencia y Salubridad

- Servicios Departamentales de Salud
- Instituto Nacional de Psiquiatría Gregorio Pacheco
- Instituto Nacional Psicopedagógico

Both the public and the private sector provide healthcare in Bolivia. The following are public sector health service providers:

- Servicios Departamentales de Salud
- Caja Nacional de Salud
- Caja Petrolera de Salud
- Caja Bancaria Estatal de Salud
- Caja de Salud de Caminos
- Caja de Salud de la Banca Privada
- Seguros Sociales Universitarios
- Caja de Salud CORDES

Private sector providers include profit hospitals and clinics, and non-profit hospitals and clinics. Public institutions care for approximately 75 percent of existing patients.

Import Regulations for Used/Refurbished Medical Equipment

The Government of Bolivia does not impose restrictions on the importation of any kind of used/refurbished equipment. All imports of used equipment are treated the same as new.

The market for used medical equipment has always been open for U.S. products. In fact, a number of small businesses are looking for suppliers of used/refurbished equipment because they find U.S. products more attractive for reasons of quality, easy access to spare parts and quick maintenance, if required.

Public health institutions can buy used or refurbished medical devices. To do so, they normally call for public bids with a deadline between 30 to 45 days to present proposals. Consequently, it is advantageous for U.S. companies to have a local representative to keep them abreast of new projects in the public sector.

There has been special preference for used/refurbished medical equipment, such as medical diagnostic systems, optical instruments, anesthesia apparatus, operating room furniture, patient room furniture, other hospital furniture, and surgical instruments and apparatus.

Import Duties and Taxes

A sworn declaration form is required by the National Customs Office, when a product does not require inspection by government inspection companies. This form has a cost of 1 percent of FOB product value.

Product verification by the government's inspection companies has a cost of 1.75 percent of the FOB product cost.

Importers must pay the respective customs tariff, as if new, which is 10 percent of the CIF price, plus a Value Added Tax of 14.94 percent. Products that are classified as a "capital good" pay a duty rate of only 5 percent. While most industrial equipment falls into this category, medical equipment does not.

Pre-shipment Inspection

Most medical equipment does not require inspection by the official government inspection companies, SGS or Inspectorate, to determine the real FOB value of the equipment before shipping. However, the National Customs Office requires a sworn declaration form.

The Government of Bolivia does not require pre-shipment inspection of used medical equipment. The Bolivian Customs Office will inspect the merchandise once it is in the country.

Distribution

Generally, foreign manufacturers have a local representative. The representative can be exclusive or non-exclusive. Some dealers sell several lines of equipment and some offer after-sale service, while others do

not. Manufacturers should be cautious in choosing their local representatives. The government only buys products from accredited local representatives.

Public sector purchases must be carried out in accordance with Government Procurement Regulations (Normas Básicas) and the budget of each agency. Purchases by the public sector exceeding US\$2,600 must be made through public tenders or selective invitations to bid. Foreign firms who wish to bid must appoint a local representative with a Representation Agreement.

Purchases made by private firms or individuals are bought directly for the importer from his stock of equipment, or imported from the manufacturer through the representative.

Contact Information

Government Agencies

Ministerio de Salud y Deportes
Plaza del Estudiante sin número final el Prado
Tel: +591-2 249-2734
Fax: +591-2 249-2734
Contact: Mario Ribera, Purchasing Manager

Trade Associations

ASOFAR
Pharmaceutical Association
Tel: +591-2 220-1788
Fax: +591-2 220-1811
E-mail: asofar@kolla.net
Contact: Oscar Medina R.

National Chamber of Commerce
Edificio Cámara Nacional de Comercio
Piso 1
Avenida Mariscal Santa Cruz No. 1392
La Paz - Bolivia
Tel: +591-2 237-8606
Fax: +591-2 239-1004
www.BoliviaComercio.org.bo
cnc@boliviacomercio.org.bo

National Chamber of Industry
Avenida Mariscal Santa Cruz No. 1392
Edificio Cámara Nacional de Comercio
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Tel: +591-2 237-4477
Fax: +591-2 236-2766
E-mail: cni@caoba.entelnet.bo
www.bolivia-industry.com

BRAZIL

General Market Condition: Restricted

Source: Brazil: Country Commercial Guide FY 2002

Best Prospects for Non-Agricultural Goods and Services—Sector: Medical Equipment and Devices

A New Market for Refurbished Equipment

Brazil approved a law that regulates the import of refurbished medical equipment. Companies that are interested in this niche have to comply to a rigid set of guidelines, including, date of refurbishment, accurate adjustment & calibration. The refurbished equipment must meet the exact same performance of new equipment. Also, the manufacturer must provide technical assistance in Brazil or designate a local representative to provide the service.

Trade Barriers, including tariffs, non-tariff barriers and import taxes—Import Licenses

Automatic License

As a general rule, Brazilian imports are subject to the ‘automatic import license’ process. This procedure requires that the Brazilian importer submits information concerning each import, including description of the product as well as the harmonized tariff classification number, quantity, value of the shipment, shipping costs, etc. This information will be used for purposes of preparing the ‘Import Declaration’ (locally known as the DI). Subsequently, all information is fed into Brazil’s customs computer system known as the SISCOMEX. The Brazilian Foreign Trade Secretariat (SECEX) is the government agency responsible for granting import licenses.

Non-Automatic License (LI)

Whenever imports are subject to the Non-Automatic License (LI) regime, the importer must provide information concerning each shipment to Brazilian customs authority either prior to shipment or prior to customs clearance. The required information includes a description of the product as well as the harmonized tariff classification number, quantity, value of the shipment, shipping costs, etc.

- Prior to Customs Clearance: Products imported under the drawback regime, as well as imports destined to the free trade zones and the National Council for Scientific and Technological Development.
- Prior to Shipment Clearance: Products subject to special controls from SECEX or which require approvals from other Brazilian government agencies. Such products may include: used products in general, products that enjoy import tariff reductions, imports that do not involve payment from importer to the exporter -- e.g., samples, donations, temporary admission, psychotherapeutic drugs, products for human or veterinary research; weapons and related products, radioactive products and rare earth metal compounds, crude oil, oil derivatives or other petroleum derivatives, anti-hemophilic serum, medications with plasma and human blood, products that may be harmful to the environment—e.g., CFC, mailing machines, stamp selling machines, airplanes, etc.

Shortly after feeding the SISCOMEX system information concerning a specific shipment, the SISCOMEX system will indicate whether or not a ‘non-automatic import license’ is required.

Source: Report from CS Post (via E-Mail), 17 May 2001

On February 15th 2001, ANVISA (National Health Administration Agency) published resolution RDC n° 25, which regulates imports of used medical equipment. The resolution imposes strict requirements that used equipment must meet before it can be imported into the country. Some of the requirements include:

- Registration with Brazil's *Vigilância Sanitária* agency. If the product does not require such registration, submit evidence to support your claim;
- Obtain an import license. The license must state the country of origin, detailed information of product, name of manufacturer, model and technical specifications;
- The equipment must be thoroughly cleaned and refurbished;
- All parts and pieces subject to wear and tear must be replaced;
- The equipment must be professionally calibrated to meet original specifications which must be certified by the original manufacturer;
- New labels must be affixed and an instruction manual must be provided;
- Submit the year the equipment was refurbished;
- The equipment must pass thorough quality control tests; and
- Make spare parts and components available in Brazil during the useful life of the equipment.

There are severe penalties for companies that do not follow the requirements listed above, including assessment of stiff fines and even confiscation of the equipment. Therefore, it is critical that U.S. exporters of used medical equipment coordinate closely the transaction with the Brazilian importer. We also strongly advise that U.S. companies obtain the services of a reputable Brazilian customs brokerage firm with significant experience related to imports of medical equipment.

For further information please contact

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BOTSWANA

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 12 March 2002

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No. Used medical equipment imports are subject to the same tariffs as new medical equipment. Used medical equipment that comes into Botswana as donations to the public hospitals/institutions is generally exempted from tariffs. There are no specific restrictions on the importation of used medical equipment, but at the point of customs clearance, the equipment is subject to rejection should it be found to be significantly out-of-date.

Can public health institutions buy used or refurbished medical devices?

Yes.

Is there a market for used and refurbished medical devices?

Importation of used medical equipment is minimal. Most of the imported used or refurbished medical devices imported to Botswana are donations to public hospitals/institutions. Generally speaking, the Ministry of Health through the government tender process usually purchases new medical equipment in Botswana.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

Not applicable.

CAMEROON

General Market Condition: No Restrictions, but Not Accepted in Public Tenders for Public Health Facilities

Source: Report from CS Post (via E-Mail), 28 March 2002

According to Mr. Charles Tawamba, Technical Adviser to the Minister of Economy and Finance. (prior to his current post, he was the Legal Affairs Director in the Ministry of Commerce and Industrial Development (MINDIC):

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

There are no special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment.

Can public health institutions buy used or refurbished medical devices?

Public health institutions cannot usually buy used or refurbished medical devices on a government budget. The health strategy being planned by the Government of Cameroon will pass management of district hospitals to a community-based board of directors. The community, after surveying its needs, will decide where and when to acquire medical devices.

Is there a market for used or refurbished medical devices?

There is an important market for used or refurbished medical devices. Cameroon is slowly emerging from a deep economic crisis that resulted in reduced spending on health. Since Cameroon is eligible (Decision Point reached) for the Highly Indebted Poor country initiative, funds previously used to repay its debt will be reoriented toward health and education spending and will result in increased spending on medical devices.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

In the countryside, a dearth of medical equipment of all sorts exists. Rural hospitals have a critical need for all types of medical equipment, particularly laboratory tests equipment, hospitalization equipment, surgical equipment, and feeding tubes and other intubation products.

Source: Report from CS Post (via Cable), 13 March 2001

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

There are no restrictions on the import of used/refurbished equipment in Cameroon. However, used equipment imported from the United States is often penalized due to overvaluation at the Cameroonian customs when customs duties are assessed. The duty on used equipment imported from the United States is calculated on the basis of the price of similar equipment imported from European markets, not on the selling price in the United States

Can public health institutions buy used or refurbished Medical devices?

Used medical equipment is not accepted in public-sector tenders for the supply of equipment and materials to government-owned public health facilities. However, private clinics and religious hospitals have no restriction on purchasing such equipment.

Is there a market for used of refurbished devices?

The Cameroonian market for used medical equipment is relatively small. Germany has the largest market share with its Siemens brand. Cameroonian medical establishments sometimes import used radiology and echography medical equipment from European suppliers.

CANADA

General Market Condition: Restricted

Source: Report from CS Post (via E-Mail), 2 May 2000

The content of ISA Medical 970901 (*see below*) concerning used/refurbished medical equipment remains fairly current with the following observations and additions:

Although we remain unable to quantify this market, it is fair to assume that demand for used/refurbished medical equipment has grown in Canada over the past three years. It remains minimal in comparison to the total market. It is in the area of refurbishing for existing customers that most market gains would have been achieved in recent years. Surgical endoscope, both rigid and flexible, is one popular product for refurbishing for existing customers.

Equipment maintenance people in Canadian public hospitals have had to face more budget cuts in the second half of the 1990s. They have learned to use the Internet to access used/refurbished medical equipment businesses on web sites that proliferate and are believed to conduct more sourcing for in-house reconditioning. There is also an occasional demand for used and refurbished equipment destined to backup support, particularly in blood and biochemistry laboratories.

Some market gains have been made by private health care businesses in Canada in the past few years, namely in the laboratory, diagnostic, as well as in aesthetic and minor surgery fields. Many of these businesses are strong potential buyers of used/refurbished equipment.

The large demand created by Canada's 950+ network of public hospitals is essentially for new, state-of-the-art medical equipment.

Sources at Health Canada's Medical Device Bureau indicated that used medical equipment refurbished for resale/exports to Canada would be subjected to licensing like new equipment, unless the refurbisher is the original manufacturer that originally obtained licensing for the equipment in Canada. In these cases, the review for licensing clearance would be conducted based only on the specification changes made to the equipment.

Source: ISA Medical, 1 September 1997

Although minimal in volume, sales of used/refurbished medical laboratory equipment may be expected to show growth over the next two years in Canada.

Used and refurbished medical laboratory equipment

Difficult to quantify, sales of used and refurbished medical laboratory equipment in Canada appear to be minimal in relation to total market sales. The purchase of used and refurbished equipment does not fit well with Canada's current public hospital procurement practices. Amortization, manufacturers' warranties, personnel training, and long-term servicing arrangements constitute the most important buying criteria. Some used and refurbished equipment may find a place in public hospital laboratories for backup support, provided it can be serviced by the same company that sells and services the newer, more

advanced equipment. This seems to be the case for blood and chemistry analyzers. Only U.S.-made used and refurbished instruments appear to be purchased by Canadian hospital laboratories.

Future privatization of healthcare delivery services in Canada could affect the market for used and refurbished medical laboratory equipment, presenting new opportunities. However, no major new legislation in favor of privatization of healthcare in Canada is anticipated in 1997 and 1998. Market conditions are therefore not anticipated to change for at least the next two to three years.

CHAD

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 1 July 1998

There are no restrictions on the import of used equipment. All imports of used equipment are treated the same as new equipment. There are no exceptions. Chad imports substantial quantities of use and refurbished equipment and goods, including clothing, shoes, ties, used vehicles, heavy equipment, computers, office machines and business equipment, etc. The importation of used equipment is expected to remain an important sector of the economy.

CHILE

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

Source: Report from CS Post (via E-Mail), 9 March 2001

Import Regulations For Used Medical Equipment

Trade Barriers

Chile generally has few barriers to imports or investment. Foreign firms operating in Chile enjoy the same protection and operate under the same conditions as local firms. The Chilean tariff rate for 2001 is currently eight percent on nearly all products from most countries, although many products from countries with which Chile has trade agreements enter with lower or no duties. Duties on capital goods purchased for use in export production may be deferred for a period of seven years and waived under some circumstances. Imports are subject to the same 18-percent Value Added Tax (VAT) as are domestic goods.

Customs Valuation

Chilean customs valuation uses the normal value of merchandise, without special discounts, plus freight and insurance (CIF). Used goods are valued by customs according to the current new value of similar merchandise, estimates the actual value of the equipment, based primarily on depreciation tables. The normal 8 percent duty will be applied plus an extra charge for used equipment of 4 percent. All imports are subject to the 18-percent Value Added Tax (VAT).

Pre-Owned (Used and Refurbished Medical Devices)

There are no restrictions/prohibitions to import used/reconditioned medical equipment/devices into Chile. However, internal regulations of public health institutions and lending banks may require that new equipment be purchased. Large private clinics in Chile prefer to buy new equipment and occasionally will purchase used equipment as long as it does not endanger the life of a patient, i.e. electrical beds, etc.

Health institutions are able to purchase used/refurbished medical equipment with no restrictions. Preference is given to products that come with quality assurance and warranties.

Sanitary Code

Chile's Ministry of Health amended the Sanitary Code in March of 1997 to authorize the Institute of Public Health (ISP) to regulate medical devices.

These regulations classify medical devices, the same way it is done in the United States by the FDA, with three classes based on risk to the patient. This new system requires that devices have to be tested for quality by a Chilean authorized testing facility and to receive from ISP a Certificate of Quality before they can be sold in Chile. Devices must have an ISP approval seal on their labels.

Additional Information

Servicio Nacional de Aduanas de Chile
(Customs)

Plaza Sotomayor 60

Valparaiso, Chile

Tel: +56-32-20-0500

Fax: +56-32-23-0591

Web site: www.aduana.co.cl; www.estado.cl

E-mail: informac@aduana.cl

Ministerio de Salud Publica (Ministry of Public Health) Instituto de Salud Publica de Chile

Registros-Control Nacional

Marathon 1000

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E-Mail: info@minsal.cl

CHINA

General Market Condition: Prohibited to Restricted

Source: Report prepared by the Office of Health and Consumer Goods, Manufacturing and Services (U.S. Department of Commerce), 20 April 2005:

Refurbished medical devices are not allowed into China.

Source: IMI, 5 November 1998

Summary

The January 8 International Business Daily published a notice jointly issued by four ministries and commissions tightening control over the import of used machinery and electric products.

Text

From January 1, 1998, except for special needs with the approval of the State Machinery and Electric Products Import and Export Office, all import of used machinery and electric products are forbidden, regardless of the source of foreign exchange, means of trade, and import channels.

Without approval, units with the right of foreign trade are not allowed to sign contracts or binding agreements for the import of used machinery and electric products.

Foreign exchange administration agencies and banks pay or sell foreign exchange upon presentation of the 'Quota Products Certificate' issued by the State Machinery and Electric Products Import and Export Office, the 'Certificate of Machinery and Electric Products Import,' or the 'Registration Form of Machinery and Electric Products Import.'

The customs office inspects and approves import of used machinery and electric products upon presentation of the 'Certificate of Quota Product,' 'Certificate of Machinery and Electric Product,' 'Import Registration Form of Machinery and Electric Products,' and 'Import Certificate' issued by the State Machinery and Electric Products Import and Export Office and the Ministry of Foreign Trade and Economic Cooperation with a used product note, and the 'Memorandum of the Import of Used Machinery and Electric Product' issued by the State Administration of Import and Export Commodity Inspection.' Violators will be subject to treatment of relevant regulations.

Commodity Inspection Agencies conduct inspections on all the used machinery and electric products approved by the government. The Commodity Inspection Agencies issue 'Notice of Conditions of Import Commodity Inspection' for the used machinery and electric products that conform to the state safety and environmental protection enforced criteria and the inspection criteria as stated in the contract. Unqualified products will be subject to treatment according to relevant regulations of commodity inspection.

Use of import documents for new machinery and electric products to clear used machinery and electric products through customs is strictly forbidden. If discovered, the products will be confiscated by Customs. The customs tariff or other taxes and fees are to be charged based on 60 percent of value of the new product.

Comment

The January 7 *People's Daily*, published the notice in part, and mentioned the following products: used liquid pressure bulldozers, diesel engines for ship use, CT for medical use, and X-ray diagnostic instruments for medical use.

COLOMBIA

General Market Condition: Restricted

Colombia: Country Commercial Guide FY 2000

Import Licenses: Colombia has two types of import licenses. The most common is a standard import registration form known locally as 'Registro de Importacion,' which all importers must complete. These forms are for record keeping/statistical purposes and are available at the Colombian Foreign Trade Institute (INCOMEX). The other license applies to closely monitored, sensitive products such as precursor chemicals and weaponry. The majority of 'used' goods, such as personal computers, cars, tires, and clothing, are effectively prohibited from import, and those that are allowed (e.g., used medical equipment) are subject to prior licensing.

COSTA RICA

General Market Condition: No Restrictions, but Public Institutions Cannot Buy

Source: Report from CS Post (via Cable), 18 March 2002

The Costa Rican Government does not impose any restrictions on the import of used medical equipment.

There is a strong preference for new medical equipment. Some private clinics and independent doctors occasionally purchase used equipment. Hospitals and clinics within the public sector, however, purchase only new equipment, consistent with well-established government policy.

There is a limited market for used medical equipment in Costa Rica. Used equipment purchased in Costa Rica is usually refurbished by the manufacturer or by an authorized dealer of the manufacturer. It is common for refurbished equipment to carry a minimum six-month guarantee. Used equipment buyers also require assurances that parts and maintenance can be obtained locally.

There are no special restrictions or tariffs that apply to used/refurbished medical equipment. Customs valuation of the equipment is normally taken from the invoice presented by the importer. Costa Rican customs has become concerned about the problem of intentional undervaluation of products being imported into Costa Rica. Exporters and importers can expect special scrutiny of documents for products entering the country that do not reflect reasonable market value.

Used medical equipment imported during past several years includes X-ray equipment, magnetic resonance equipment, electrocardiographs, microscopes, centrifuges, ovens, spectrophotometers, blister packaging for pharmaceutical products, sterilizers, dental chairs with drill systems, and lately, linear accelerators, among other items.

CROATIA

General Market Condition: Restricted.

Source: Report from CS Post (via E-Mail), 12 April 2005

Medical Equipment Market in Croatia

Introduction

Croatia recently embarked on a reform of the health system with the main goal to stabilize health care expenditures. The key player in the Croatian medical industry is the Ministry of Health. The Ministry of Health develops principal health policies, prepares the health care budget and medical sector investment program as well as oversees all state-owned health institutions. A part of their responsibilities is to apply rules and regulations on production, imports and sales. The Croatian Institute for Health Insurance (CIHI) works closely with the Ministry on development of primary policies for health care equipment and it is also responsible for quality control and regulation. The need for health care system restructuring remains crucial in Croatia due to escalation of overall medical expenditure. The government, through Croatian Institute for Health Insurance, mostly funds Croatia's medical sector. CIHI pays for most of health care and it is suffering financial difficulties caused by increasing health expenditure.

Medical Equipment Market

The size of Croatia's medical equipment market is estimated at approximately \$112 million USD and it is dominated by imports that account for 95% of the market. Since there is no significant medical equipment production in Croatia, most imports come from the neighboring countries of Germany, Italy and Austria, as well as imports from Switzerland, U.S. and Japan.

Due to recent reforms in the Croatian health care system, the medical equipment market has been rather stagnant in the past years. Croatia's improving economic situation shows that this market will show growth over the next few years. One of the main goals is to establish a well-equipped health care system that will ensure faster and more accurate diagnosis and provide better treatment. The hospital market is very promising because of inadequate hospital medical equipment. The Croatian market is very receptive to U.S. products, especially medical equipment that is well known for its excellence and refinement. There is a great sales potential for medical device manufactures dealing with diagnostic equipment such as electrocardiographs, endoscopes, scanners, digitalized x-ray and computer tomograph imaging equipment, pace makers, clinical laboratory equipment and dialysis equipment.

Trade Regulations

The Ministry of Health regulates policies on imports of medical products. Customs tariffs currently range between 0 and 17.6% for industrial products with the majority subject to rates of 0 to 10%. U.S. medical equipment receives duty free treatment in Croatia. All medical devices, instruments and equipment need to be registered through the Agency for Medical Products and Devices. Only registered importers, wholesalers and local traders can sell in the Croatian market. The Agency provides the sale permit within 90 days of request.

The end user of refurbished equipment needs to file a request for equipment usage approval. Any used equipment to be imported must be less than five years old. Since Croatia does not automatically recognize mandatory technical/quality tests conducted in other countries, the Ministry has the authority to fully or partially recognize foreign tests on a case-by-case basis. Both new and/or used medical equipment can be traded in the Croatian market if it has a valid approval in the EU (CE certificate) and if no other country rejected it. The Medical product commission collects documentation about the product and submits it to the Ministry of Health for trade authorization.

In preparing this market update it became apparent that the market for used equipment, if it exists, is a small one. No one seemed familiar with any recent examples of imported used equipment. Given that Croatia is focused on EU membership, it will be unlikely to see any divergence between existing Croatian practice and EU rules and legislation. We surmise that opportunities may exist for those products used in laboratory analysis as opposed to patient diagnostic equipment, or when the acquisition cost is significant and the product would be in use over several years.

Documentation must consist of the following:

- 1.) Product description
- 2.) Packaging information
- 3.) Warranties

- 4.) Manufacturing procedure
- 5.) Clinical testing results
- 6.) Insurance policy information
- 7.) Manual (both original language and in Croatian)
- 8.) Manufacturing license
- 9.) Proof of trade approval in the EU countries (list of countries)
- 10.) Sample
- 11.) Registered distributor contract
- 12.) Proof of paid trade application fees

See also Croatia's *Country Commercial Guide* for general information doing business in Croatia.

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Web site: www.almp.hr

General Market Condition: Restricted

Source: Report from CS Post (via E-Mail), 28 March 2002

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No special tariffs exist for importing used or refurbished medical equipment. The import regime is the same as it is for the import of new medical equipment. However, there is a restriction that no imported medical equipment can be older than five years.

Can public health institutions buy used or refurbished medical devices?

Public health institutions can buy used or refurbished but never or very rarely do so. They are very skeptical about the quality, guarantees and servicing of used products and they consider it to be a risky business. Therefore, in almost cases, they avoid it.

Is there a market for used or refurbished medical devices?

Most medical equipment distributors do not work with used medical equipment because they argue that the market is too small, and that risks connected with this type of business too great. The only customers interested in buying used medical equipment are small private hospitals/enterprises which, faced with limited budgets, are prepared to purchase such equipment. However, even then, the sale of used medical equipment is done, not through distributors or local companies, but through private connections. For

example, when they hear about the planned replacement of equipment in a certain hospital in Germany, they buy off the old equipment

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

This small market demand described above includes the most expensive equipment such as X-rays, ultrasound, and electrocardiograph devices.

CZECH REPUBLIC

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 4 April 2001 (Information confirmed 25 March 2002)

There are neither special restrictions nor tariffs that apply to used medical equipment and not to new medical equipment. The same procedure applies to the importation of new, used and refurbished medical equipment. To import to the Czech Republic, a foreign producer must have an importer in the Czech Republic. To release a medical device on the Czech market, the manufacturer or importer must arrange for assessment of conformity with essential requirements for medical devices. A manufacturer or importer issues a written declaration of conformity on compliance with technical requirements and abiding by the stipulated conformity assessment procedure. In contrast to the practice applied in the EU countries, where products that have been assessed as to their conformity with the European Council directives bear the CE marking, in the Czech Republic, the declaration of conformity, issued by the producer or importer, is the proof of fulfilling the technical requirements and the conformity assessment procedure. Besides this, the manufacturer or importer assures distributors of the products in writing that the declaration of conformity has been issued. A medical device must meet medical and technical requirements determined by the manufacturer for the whole period of its use in terms of health care provision.

The Government Orders 180/1998 and 130/1999 stipulate medical devices classification. According to this order, medical devices are divided into the I, IIa, IIb, and III Classes according to their risk. The highest risk devices, including active implantable sanitary medium medical devices, are included in the III Class. The vast majority of devices are included in the I Class. For placing on the market a medical device from the I Class, the manufacturer or importer makes an assessment of conformity himself. For placing on the market a medical device from the IIa, IIb, and III Classes, the manufacturer or importer must arrange for conformity assessment by an authorized entity. Czech Office for Standardization, Metrology and Testing publishes the list of the entities authorized to assess the conformity in the Bulletin (*Vestník*). The Authorized Body assesses the conformity with technical requirements and issues a certificate.

There are no restrictions for public health institutions with regards to purchasing of refurbished medical devices. All health institutions can only purchase medical devices and equipment that are certified by the Czech Ministry of Health for the sale in the Czech Republic.

Czech authorities have no certifying experience with used or refurbished medical devices, as no application for importation of used or refurbished medical devices has been filed yet. However, due to restricted financial sources of healthcare institutions, used or refurbished medical devices may be saleable if price competitive to new medical devices already in the market.

All medical devices imported to the Czech Republic must comply with Czech standards, a warranty must be provided by producer, and service and spare parts must be available during the whole life of the product. Best prospects exist for but are not limited to X-rays, ventilators, operation tables and other price competitive medical devices.

DENMARK

General Market Condition: No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from CS Post (via E-Mail), 5 March 2001 (Information confirmed 4 March 2002); Updated 14 February 2005

Any used medical equipment that does enter the Danish market must carry the CE mark, the obligatory mark allowing the manufacturer/supplier to circulate their products freely within the European market. In general, there are no specific laws prohibiting the import of used medical equipment other than general ones regarding health, safety and environmental issues. Denmark, as a member of the EU, follows general EU directives.

Public institutions can buy used and refurbished equipment but there is little to no market for used and refurbished medical equipment devices in Denmark. Please note that following the reflection of the governing party in February 2005 there is expected to be a widespread overhaul of the Danish healthcare system. It is uncertain to what extent, if any, this will affect the market for used medical equipment.

DOMINICAN REPUBLIC

Import Regulations for Pre-Owned (Used and Refurbished) Medical Devices General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 2 May 2003; Updated 17 May 2005

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

The general import climate in the Dominican Republic is very favorable and medical products imported into the Dominican Republic do not need to go through a registration process or a safety inspection. The Dominican government does not impose restrictions on the importation of used/refurbished medical equipment and all imports of used equipment are treated the same as new.

Imports tariffs applicable to used/refurbished medical equipment are the same as the tariffs applicable to new medical equipment. Import duties levied on medical equipment is 3 percent of the CIF price (Cost+Insurance+Freight). Other taxes collected at Customs are: Exchange Surcharge (13 percent), and a 16 percent VAT called Tax to the Transfer of Industrial Products and Services (ITBIS). The only exception is the importation of wheelchairs, which does not pay any taxes (Law 42-00).

If the products final use will be in a public/government owned hospital, importers may receive import tax exemption. This is usually specified in the purchase contract.

B) If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc?

Medical equipment, either new or used/refurbished does not need to be registered with the local authorities. American standards are currently accepted and respected by the purchasing entities.

C) Can public health institutions buy used or refurbished medical devices?

Yes, government owned hospitals are allowed to buy used/refurbished medical devices. Public/government hospitals usually buy medical equipment through local distributors/importers;

therefore, American exporters interested in offering used/refurbish medical equipment to Dominican institutions, should offer these products to the distributors/importers instead of to the hospitals directly.

D) Is there a market for used or refurbished devices?

Yes, there is a market for used and refurbished medical equipment. The Dominican market prefers used equipment that has been refurbished by the manufacturer, who can use original replacement parts and provide a limited guarantee. In addition, buyers of used equipment usually require assurances that parts and maintenance can be obtained locally. Therefore, American firms interested in this market should appoint a local distributor.

It is important to note that the market for used devices (not refurbished) is limited to hospital furniture such as operating tables and hospital beds. There are good opportunities for these products, which do not always need to be refurbished and will generally be accepted with minor defects such as scratches and tearing.

US Companies are cautioned to become familiar with Dominican Law 173 before appointing an agent or a distributor in the Dominican market. Law 173 regulates the relationship between foreign and local companies. This law is designed to protect Dominican citizens who work as agents or distributors for foreign companies. Law 173 establishes and provides substantial penalties for foreign firms who unilaterally terminate contracts with local distributors or agents without “just cause”. Interested companies may request a copy of Law 173 from the U.S. Commercial Service at the U.S. Embassy in Santo Domingo.

The U.S. Commercial Service offers excellent programs to help American companies identify potential distributors. For more information on services available to U.S. business please visit our web site:

www.export.gov/caribbean

E) If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

According to importers of used and refurbished medical equipment, the following are categories with best sales potential in the Dominican market:

- Used equipment: Hospital furniture (hospital beds, surgical tables)
- Refurbished equipment: Electro-medical and diagnosis equipment (Tomography, Magnetone Resonance Imaging).

F) Are single-use devices being reprocessed and sold on the local market?

Yes, devices such as those used for dialysis (filters, catheters, etc.) are been sterilized and re-used. The sterilization is been done locally using gas-based autoclaves.

Prepared by: Isolda Frias

Approved by: Dennis Simmons

Date: May 17, 2005

ECUADOR

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

Source: Report from CS Post (via E-Mail), 3 May 2000

There are no restrictions/prohibitions to import used/reconditioned medical equipment/devices into Ecuador. However, internal regulations of public health institutions require that they purchase new equipment. Large private hospitals and clinics in Quito, Guayaquil and Cuenca prefer to buy new equipment and occasionally will purchase used equipment as long as it does not endanger the life of the patient, i.e., electrical beds, etc. On the other hand, small private hospitals and clinics in smaller cities favor used/reconditioned medical equipment of all types, but U.S. companies are required to provide one to five year warranties depending on the product. Although private clinics and hospitals will abide to lack of spare parts, provision of it will provide a competitive advantage. Best prospects for used equipment are surgical beds and lamps, electrical beds, X-rays, monitors and sterilizers.

The following companies have been identified as importers/distributors of refurbished equipment:

Advance Biomedical Services / Contact: Jorge Ruiz, Manager

Foch 147 y 12 de Octubre

Quito, Ecuador

Tel: & Fax: +593-2-238-472

(Importer/distributor of refurbished X-rays, anesthesia equipment, ventilators, respirators)

BIO-IN S.A. Sistemas Medicos / Contact: Boris Toledo A., General Manager

Datiles y 3ra., Local 12

Guayaquil, Ecuador

Tel: +593-4-881-569; 881-592; 991-330

Fax: +593-4-881-882; 881-331

(Importer/distributor of general medical refurbished equipment, including: X-rays, dialysis, electrical beds, sterilizers, anesthesia equipment)

EGYPT

General Market Condition: Prohibited

Source: Report from CS Post (via E-Mail), 14 April 2003; Updated 7 February 2005

Import Regulations for Used and Refurbished Medical Equipment

According to a January 2002 Government of Egypt (GOE) decree, the importation of used and refurbished medical equipment and supplies to Egypt is banned. The ban does not differentiate between the most complex computer-based imaging equipment and the most basic of supplies. This ban is clearly stated in Import Certificates issued by the Egyptian Ministry of Health (MOH) for any product. Specifically, the Customs and the Pharmaceutical Politics Department of MOH, from which any importer (company or individual) must obtain approval to release medical goods from customs, will not approve clearance of used or refurbished medical equipment.

In background, the GOE issued this ministerial decree after an increasing number of attempts by Egyptian companies to import used and refurbished medical equipment in the 1990's, when foreign companies actively contacted many university-affiliated and other hospitals offering a wide range of (primarily U.S. and U.K.-origin) used medical items including endoscopes, X-ray machines, ultrasound scanners and renal dialysis equipment. The proposals resulted in many concerns regarding the safety of such imports and the prospect of unscrupulous businesses taking advantage of inadequately informed customers in Egypt.

At present, even new medical equipment must be tested in the country of origin and proven safe before it will be approved for importation into Egypt. The importer must submit a form requesting the Ministry of Health's approval to import medical equipment. The importer will attach to the request a certificate issued by official health authorities in the country of origin, indicating that the medical equipment, subject to importation, is safely used there.

The importer will also present an original certificate from the manufacturer indicating the production year of the equipment and that it is new. In addition, the importer will present a certificate of approval from the Food and Drug Administration (FDA) or a certificate of approval from the European Bureau of Standards. The importer must prove that it has a service center that can provide after sales support for the imported medical equipment, to include spare parts and technical maintenance. The MOH's technical committee will examine and review the technical specifications of the equipment before granting an approval to admit it into Egypt.

The above regulations also apply to medical equipment that is being donated, not sold for profit.

Contact:

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EL SALVADOR

No Restrictions (except for Fetal Abortive Products), but Public Institutions Do Not Buy

Source: Report from CS Post (via Cable), 21 April 2003, Updated 15 April 2005

Are there special restrictions or tariffs that apply to used medical equipment but do not apply to new medical equipment?

New, used and refurbished receive equal treatment in importation. Import tariffs are not applied, except 13 percent of the value-added tax.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subject to new safety inspections, etc.

Medical devices have to register at:

Consejo Superior de Salud Publica

Lic. Loly Claros de Ayala, President

Inicio Paseo General Escalon, Frente a El Salvador del Mundo. San Salvador

El Salvador. C.A.

Tel: +503-245-3885

Fax: +503-298-2576

Other useful contact:

Ministry of Health
Calle Arce No. 827
Tel: +503-221-0966
Fax: +503-221-0991

A manufacturer or agent/distributor has to register a medical device at the Health Council once. A third party can import the same device in used or refurbished condition without the need to go over the same registration process.

After registration, the importer must still comply with the normal registration and certification processes by the Ministry of Health.

More information about importation requirements can be found at the following

Web site: www.mspsa.gob.sv/importaciones.htm.

Can public health institutions buy used or refurbished medical devices?

As a common practice, Ministry of Health purchases only new medical equipment through bidding process. Used/refurbished equipment is acquired on rare occasions or on a donation basis.

The Salvador Social Security Institute (Instituto Salvadoreño del Seguro Social) is another agency that buys medical equipment, but as the Ministry of Health, they prefer new equipment. These practices do not apply to private hospitals and clinics.

Is there a market for used or refurbished medical devices?

Market share for new medical equipment is 85%, and for used/refurbished equipment is 15%. Local production is limited to hospital furniture.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

Used equipment with high demand is x-ray equipment, surgery equipment, and operating tables. They are mostly purchased by private clinics.

Are single-use devices being reprocessed and sold on the local market?

Single-use medical devices are not being reprocessed and sold in the local market. There is no written law that regulates this activity.

Source: Report from CS Post (via Cable), 4 April 2000 (Information confirmed, 21 April 2003)

Post Review of IMI, 5 November 1998 (see below)

Post reviewed information extracted from the IMI report and found the information on El Salvador is up to date, but would like to complement the report with the following information:

Purchases by Public Hospitals and Clinics

Post would like to clarify that public hospitals and clinics do not buy used or refurbished equipment as a prevailing practice. It is not a written law or regulation. No change in this practice is expected. The Ministry of Health purchases medical equipment through bids, and although technical terms generally specify new equipment, the Ministry of Health has authorized the purchase of used equipment on occasion. The Ministry of Health also regulates the donation of used, refurbished, or new medical equipment. These practices do not apply to El Salvador's private hospitals or clinics.

Market share

Medical equipment distributors estimate that the market share for used/refurbished equipment is 20 percent versus 80 percent market share for new equipment. They project that the best prospects for used equipment are in image diagnosis, mainly X-rays and tomographic equipment used to provide mammograms.

Prohibited medical products and equipment

Imports of fetal abortive products continue to be explicitly prohibited by law.

Import regulations and tariffs

Used products are treated the same as new products for the purpose of importation. Used and new medical equipment are free of import tariffs; only a 13 percent value added tax is applied.

License requirements

Currently, no specific license is required to import medical equipment. However, post understands that the GOES' health sector modernization plan will require that every sector (public and private) involved in the supply of medical equipment and health services (clinics, hospitals, distributors, importers, producers, etc.) They must register with the Ministry of Health, and that only equipment that meets the standards set by the Ministry of Health will be allowed for importation. The GOES expects to implement the plan before 2002.

Source: IMI Medical, 8 November 2000

Summary

U.S. companies dominate El Salvador's medical equipment sector. In 1995, U.S. market share reached 72.9 percent, dropped to 66.8 percent in 1997 and rose once again to 79.4 percent in 1999. El Salvador's public and private hospitals and clinics prefer U.S. products due to their price, quality and geographic proximity. The importation of U.S. medical equipment is not restricted and no tariffs are applied for the introduction of medical equipment into the country. The only applicable tax is the 13 percent value added tax.

Best sales prospects

According to our survey, El Salvador is a good market for all types of medical equipment. Government hospitals, hospitals belonging to the Instituto Salvadoreño del Seguro Social (ISSS), hospitals under the military hospital, large private hospitals (40 beds or more), and some clinics are excellent markets for new equipment. While small private hospitals, particularly those outside of San Salvador, provide a good market for new equipment, they prefer refurbished equipment in order to reduce costs. In general, good sales prospects are as follows:

Harmonized System	Product
9018.13.00	Magnetic Resonance Imaging Apparatus
9018.19.40	Equipment for Diagnostic by Images
9018.19.55	Cardiac Monitors
9018.19.55	Vital Signal Monitors
9018.90.60	Equipment for Laparoscopic Surgery
9018.90.60	Boxes for Abdominal Hysterectomy
9018.90.40	Pediatric and Adult Biarticular Stethoscopes
9019.10.00	Respirators
9019.20.00	Respiratory Ventilators
9022.30.00	X-Ray Equipment
9026.10.20	Infusion Pumps
8421.12.00	Hospital Dryers
8450.11.00	Hospital Washers
9402.00.00	Surgery Tables
9402.90.20	Surgery Beds
9405.10.00	Ceiling Lamps

Competitive Situation

There are two basic market types: new equipment and refurbished equipment. The first is the largest, accounting for approximately 80 percent of total sales, and is concentrated in the metropolitan areas of San Salvador, Santa Ana and San Miguel. This market looks more for quality, durability, maintenance and availability of spare parts and accessories rather than price. The refurbished equipment market is concentrated outside of San Salvador and in small hospitals within San Salvador. These institutions generally consider price as the main factor when purchasing equipment. Customers for both of these markets tend to purchase locally and directly although there are a number of small hospitals and clinics that prefer to purchase overseas due to the high cost that local suppliers add to the price of the product.

The key to entering the market is to offer competitive quality, prices and post-sale services. It is also prudent to appoint a local supplier. There is a market for new equipment, as well as for refurbished equipment, which is generally sold to small hospitals. In general, products with favorable sales potential include: ceiling lamps, respiratory ventilators, respirators, equipment for intensive care units, x-ray equipment, equipment for image diagnosis, cardiac monitors, magnetic resonance, equipment for laparoscopic surgery, macro- and micro- infusion pumps, vital sign monitors, boxes for abdominal hysterectomy, pediatric and adult biarticular stethoscopes, surgery tables, surgery beds, and hospital washers and dryers. The products covered by this report correspond to the harmonized system sub-chapters: 901111 to 901210; 901320 to 901820; 901839 to 901920; 902150 to 902290.

The Ministry of Health only purchases new medical equipment; refurbished or used equipment is accepted on a donation basis only. The Ministry of Health purchases medical equipment based on hospital needs. To calculate the hospital's medical equipment needs, doctors and hospital personnel present reports to the Ministry of Health. While it is not necessary to have a local supplier in order to participate in the medical equipment bids offered by the Ministry of Health, it is highly recommended.

Large, private hospitals prefer to purchase new medical equipment from companies that offer good quality and post-sale services, while small- and medium-sized hospitals purchase new and refurbished medical equipment. Medium and smaller hospitals have observed that local suppliers offer medical equipment products at prices 300 percent over the U.S. price. Approximately 65 percent of small hospitals prefer to purchase their equipment directly from the U.S., and particularly Miami, due to its geographic proximity, competitive prices viz. Local suppliers, importing facilities, and common language.

ETHIOPIA

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 19 June 1998 (Information confirmed 28 March 2001)

There are no restrictions on the import of used equipment in Ethiopia. Importation procedure is the same as for new. The Ethiopian custom authority accepts only factory price.

No categories of equipment are restricted.

The used equipment market in Ethiopia is very good. Due to the shortage of foreign currency in Ethiopia, the private sector especially is more geared towards used equipment. U.S. equipment has a good reputation in Ethiopia for durability and performance, so U.S. firms engaged in used equipment export can take advantage of this growing market.

EUROPEAN UNION

General Market Condition: No Restrictions, but CE Mark is Required
See also entries for individual members states of the European Union.

Source: Belgium ISA Medical, 6 March 2000 (Information confirmed 4 March 2002); Information confirmed by CS Post (Via E-mail) 11 February 2005.

European Union (EU) Directives regarding used medical equipment

The EU Directives have become instrumental in promoting free trade and mutual recognition amongst EU member states.

One piece of legislation promoting uniform requirements for medical devices took effect in January 1995. This legislation (93/42/EC) requires all medical devices, regardless of the proposed use, to carry the CE mark before entering the European market. In order to gain such a mark, a device must pass a regulatory assessment determining whether it is in conformity with EU standards. In addition, the manufacturer is required to make specific information available as to proper and safe use. The Directive requires the manufacturer to specify how a device is to be used, taking into consideration the 'training and knowledge of the potential users.' The appropriate corresponding information for use must be contained in the packaging or labeling of the device. The Directive specifies that the device must be marked 'single use' if that is the manufacturer's intended use of the product. The Directive warns the manufacturer that if the product's 'intended purpose' is not immediately clear to the user, the manufacturer must clearly state it on the packaging, thus re-emphasizing the need for specific labeling so as to avoid misuse. Thus the Directive clearly identifies the liability for product deformity or malfunction as residing with the manufacturer and it outlines the limits of the manufacturer's warranty.

Once a device gains the CE mark, EU law prohibits member states from placing any further restriction on its movement within the EU. Accordingly, once a device has passed the regulatory assessment, the manufacturer's intent for the use of the device has been accepted and deemed appropriate for sale within the EU. This assertion means that the manufacturer's warranty for sale can only extend as far as the first use of the device.

This warranty argument may only apply, however, if the manufacturer has clearly delineated the intended single use in accordance with the Directive. Accordingly, the manufacturer may not specify that the device may be re-used if the manufacturer does not have data illustrating that the device will continue to comply with the Directive upon re-use. Without such data, the device will not receive a CE mark and if the device did enter the market in this fashion, the manufacturer would be in violation of the Directive.

For single use devices, there is an ongoing debate about reuse. The European industry association Eucomed (equivalent to Advamed) published a position paper on its web site, here is the link:

<http://www.eucomed.be/?x=4&y=46&z=125&id=442>

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Source: Report from CS Post (via Cable), December 24, 1996 (Information confirmed 4 March 2002)

[This cable reported on discussions with EU official regarding the need for imported used equipment to obtain a CE mark (i.e. are subject to inspection and surveillance). Devices that entered the European Union prior to the CE-mark requirement are grandfathered in and can be resold on the EU market without first obtaining a CE mark. Identical used items cannot be imported, however, unless they first receive a CE mark—even if such devices were legally imported into the European Union prior to the adoption of the regulation requiring the CE mark. This rule places importers at a disadvantage compared to European resellers since sale of used equipment within the EU requires no inspection, surveillance or CE mark if such equipment met regulatory requirements at the time of its original sale. The importance of this issue is gradually fading as medical devices produced before the 1995 introduction of the CE mark reach the end of their useful life.]

FINLAND

General Market Condition: No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from CS Post (via Cable), 6 March 2000 (Information confirmed as still valid, 25 March 2002)

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

No, Finland applies the EU directive on medical devices to both new and used equipment.

Can public health institutions buy used or refurbished Medical devices?

Yes, they can.

Is there a market for used of refurbished devices?

The market for used of refurbished devices is very small in Finland. The tendency is to buy new equipment directly from equipment manufacturers or distributors. Old or refurbished equipment is sold/exchanged directly between hospitals and other healthcare institutions. In most cases old equipment is donated/sold to Russia and the Baltic states.

Best prospects?

Equipment with a long lifetime—for example, imaging equipment.

FRANCE

General Market Condition: No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from CS Post (via E-Mail), 21 March 2002; Updated 14 April 2005

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

There are no restrictions, but CE mark is required.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc.?

A used device is subject to new CE marking and safety inspections.

Can public health institutions buy used or refurbished medical devices?

No. There is no market for France itself, but for French-speaking Africa, surgical equipment can be used. Public health institutions cannot buy, only private clinics and private practitioners can buy used or refurbished medical devices.

Is there a market for used and refurbished medical devices?

The market for used and refurbished medical devices is very marginal. Nevertheless, France should still be considered by American companies wishing to export used medical equipment to French-speaking Africa, as some trading companies headquartered in France have extensive distribution networks throughout French speaking Africa.

If there is a market, what types of used medical devices are in greatest demand?

There are no markets for France itself, for French-speaking Africa, surgical equipment to be used in private clinics are in great demand.

Are single-use devices being reprocessed and sold on the local market? If so, is this activity regulated?

No, it is illegal to reprocess single-use devices.

GABON

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 6 July 1998

Since the devaluation of the CFA Franc in 1994, there has been a significant increase of imports of used equipment, especially cars on the Gabonese market. There are no restrictions on the import of used equipment into Gabon.

GERMANY

General Market Condition: No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from Post (via E-Mail), 25 March 2005

Are there special restrictions or tariffs that apply to used medical equipment but do not apply to new medical equipment?

There are no special restrictions for used and refurbished devices.

In generally new and used medical devices are subject to the laws and regulations which were enacted in the European Directives 90/385/EEC, 93/42 EEC and 98/79 EC became national law (in Germany: "Medizinproduktegesetz").

Following the "Medizinproduktegesetz" the CE Mark is required for all medical devices. The term "medical device" is defined as any instrument, apparatus, or other article intended for human use in the diagnosis, prevention, monitoring, treatment and alleviation of diseases or as compensation for an injury or handicap.

The CE marking establishes that the medical device conforms to all applicable legal requirements. The CE Mark of refurbished devices must be renewed.

The fulfillment of all legal specifications must be proven in a conformity assessment procedure, which for medical devices means:

Safety

- risks and side effects are analyzed, assessed and minimized
- biocompatibility is ensured while reducing or eliminating risk of infection
- mechanical, electrical and electromagnetic safety is ensured
- only validated product combinations are allowed
- safety instructions for use are reviewed for completeness and comprehensibility

Performance and benefit

- compliance with product characteristics and specifications
- therapeutic or diagnostic benefit is ensured
- clinical or diagnostic evaluation of medical devices
- measurement accuracy is ensured

Monitoring

- of the manufacturer
- of the medical device during the entire life of the product.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subject to new safety inspections, etc.

In general the CE Mark is required for all medical devices. An importer has to confirm that his product conforms to the requirements of the CE Mark. There is a different way of confirmation for used and refurbished medical devices.

The importer of a used medical device has to confirm that his product does not differ from a new, already CE-marked product of similar type concerning safety and performance. In that case the used device does not have to be subjected to new safety or performance inspections.

In case of refurbished medical devices, the CE Mark has to be renewed for each imported product.

In exceptional cases, the importer can refer to the refurbishment process. The importer then has to confirm that the medical device has been refurbished in a reviewed process. In this review the importer has to prove that the process of refurbishment complies with CE Mark requirements. In this particular case there is an assumption that the refurbished device conforms to CE Mark requirements.

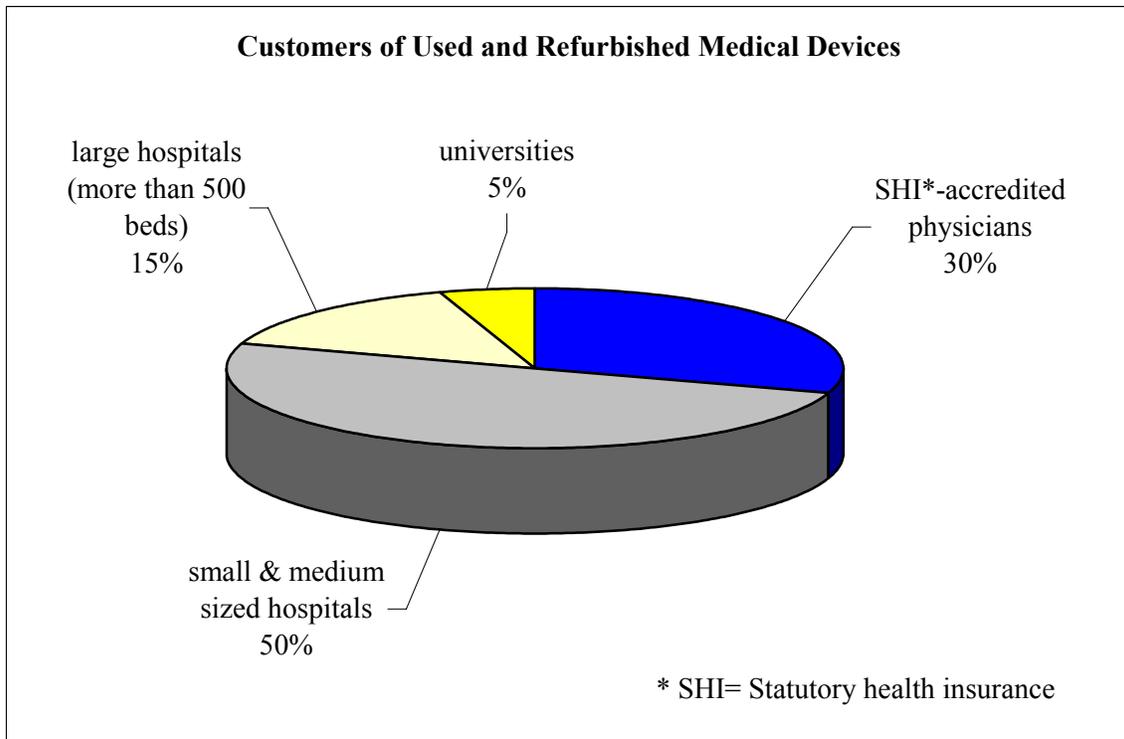
Can public health institutions buy used or refurbished medical devices?

As seen from the chart below, hospitals and universities are the most important customers in the used and refurbished medical devices market. In most cases, hospitals in Germany are using new medical devices just as well-refurbished medical devices. On the one hand they are using state-of-the-art medical devices for special, highly sophisticated medical examinations.

On the other hand German hospitals are using less expensive refurbished medical devices for the daily routine business.

Likewise, refurbished medical devices are in great demand with the SHI-accredited physicians (SHI=statutory health insurance). They receive a specific, fixed price for each medical procedure from the health insurance funds regardless if they are using new or refurbished medical devices.

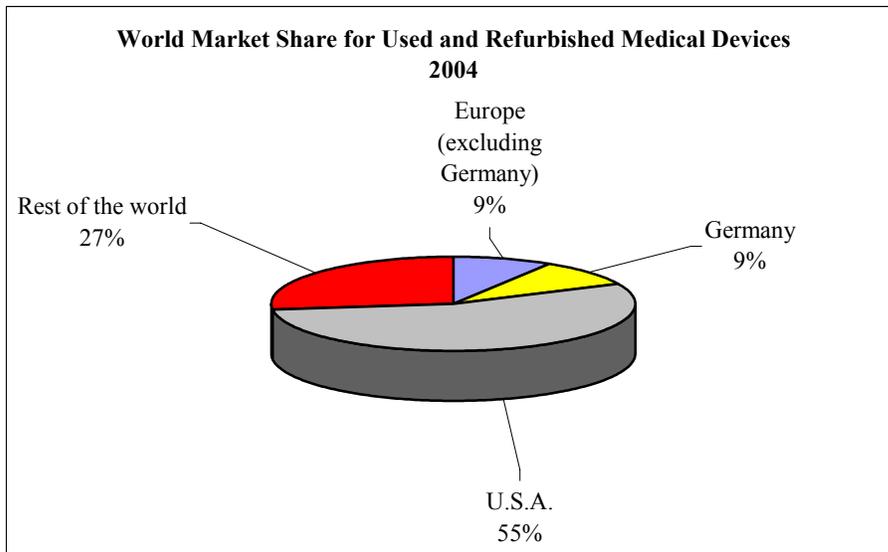
Because of high cost containment pressures in the German health care system it is estimated that the use of refurbished medical devices will become more and more popular among physicians and hospitals.



Is there a market for used or refurbished medical devices?

Experts estimated the world market for used and refurbished medical devices at about \$1.1 billion in 2004. Germany accounted for nearly a tenth of the worldwide market.

Region	Market Value 2004
Europe (excluding Germany)	\$ 99 million
Germany	\$ 99 million
Rest of the world	\$ 297 million
United States	\$ 605 million
<u>total</u>	<u>\$ 1.1 billion</u>

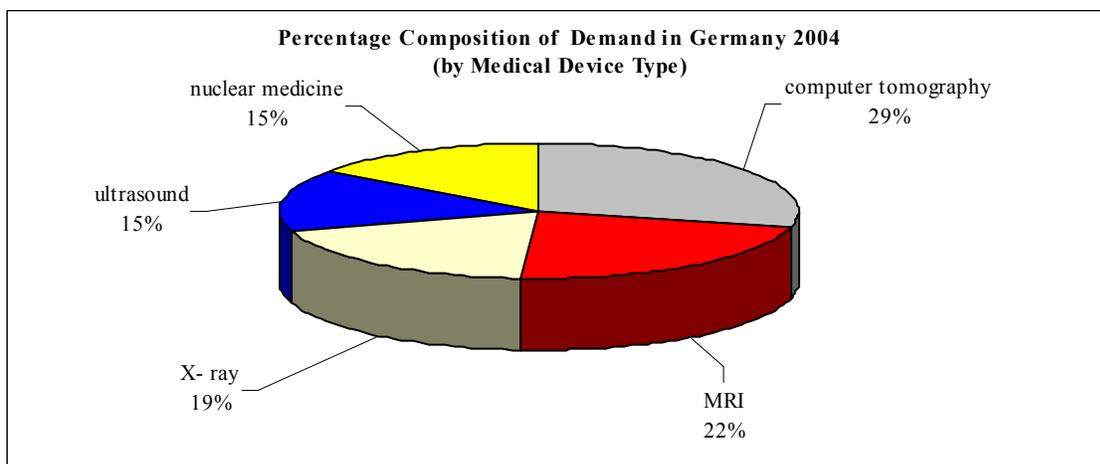


Worldwide, there is an annual increase of the market volume of about 15 percent. In Europe the market growth is higher than average, with an annual growth of the used and refurbished medical devices market of more than 20 percent.

Over the next few years, the annual market growth is expected to remain unchanged. The main reason for the above average expected market growth is that about 45 percent of all medical devices in the U.S.A. and about 15 percent of all medical devices in Europe have been leased. After the expiration of the contracts the medical devices will be returned to the manufacturer. After the manufacturer has refurbished the medical equipment, he will try to resell as quickly as possible.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

As you can see from the chart below, computer tomography devices followed by magnetic resonance (MRI) imaging devices are in greatest demand.



Source: International Marketing Insight, 26 March 2002 (Updated 17 April 2003)

[Note: this report is primarily discussing the re-use of single use devices, but see concluding paragraphs regarding the trade fair for used equipment.]

There are no restrictions on the import of used equipment into Germany. New and used equipment fall under the same custom tariff categories (category number: 9018), and the same safety standards apply for

both used and new products. In particular, CE marking is required for marketing both new and used medical equipment in Germany.

Traditionally, there has hardly been any market potential for refurbished equipment in Germany because of the existing strict medical product laws and because German buyers have a strong preference for new products. Recently however, and as a result of strong cost-containment pressures following the Health Reform Laws, industrial and commercial customers have positively responded to the refurbishing of medical products. At a conference organized by the German subsidiary of a U.S. provider of refurbished medical equipment, the German medical industry concurred in principle on the advantages of refurbished equipment, provided the highest quality control standards are applied.

There was a consensus that the field of invasive cardiology was particularly suitable for refurbishment. While Class I medical products such as heart catheters and pacemakers, are subject to extremely stringent quality requirements and can only be refurbished by specialist firms in the context of a Quality Management system according to DIN EN ISO 9001 and DIN EN 46001, Class II and III products such as suction tubes and oxygen masks, can be refurbished in hospitals in a fully automated process. The German medical industry, under great cost-containment pressures, has realized that refurbished medical equipment can result in great procurement cost savings. Thus a five-time refurbishment of 2,920 gastro gavage syringes saves a German hospital approx. \$ 13,666 on average and reduces the hospital's waste disposal volume by 567 kilograms. Thus, the German market for refurbished equipment is actually growing. U.S. suppliers have to ensure, however, that a specific medical device has been refurbished according to standards outlined in the revised German Medical Products Law ('*Medizinproduktegesetz-MPG*;' 2nd revision in effect as of January 1, 2002) and its respective Medical Products Operations Ordinance ('*Medizinproduktebetriebsverordnung*'). These tighten controls compared to the Medical Products Operations Ordinance of June 1998, in view of consumer protection and the current lobbying of industry associations against the refurbishing of so-called medical 'disposables.' The German government is promoting refurbishing for cost-containment purposes and has tightened controls, as per the revised ordinance, on some of the loopholes contained in the previous regulations. Revisions include, amongst others:

- A change in definition of 'bringing to market' (cf. Para 3, no. 11 MPG);
- A revised definition of 'refurbishing' in Para 3, no. 14 MPG;
- A regular conformity assessment applying to those who do not return refurbished equipment to the previous user but sell it to third parties (Para 10, section 3 MPG);
- Mandatory registration with the respective authorities (Health Ministry and BfArM) when refurbishing for third parties;
- Inclusion of external service providers in the quality control process (Para 26, section 1 MPG); and
- Amendments to the authorization for refurbishing/maintenance (Para 37; section 5 MPG).

Requirements for the refurbishing of medical products under the Medical Products Operations Ordinance are listed in Para 4, section 2 MPG, mentioning appropriate procedures and the security and health of patients, users, or third parties as top priority. Requirements include:

- Validated Refurbishing.
- Validated Packaging.
- Validated Sterilization Procedures.
- Refurbishing according to the RKI guideline. Recommendations of the Workgroup for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI), Berlin, formed the basis of the revised law. The so-called RKI guideline is available on the institute's website at www.rki.de and has been published in the German Federal Health Register.

- Liability for the health and functional safety of the refurbished products (i.e., the refurbisher takes on the product liability from the manufacturer).
- Quality management system according to DIN EN ISO 9001 and DIN EN 46001.

Refurbished medical products do not need a new CE certification in cases where the user outsources refurbishing and a special documentation safeguards that the refurbished products are returned to the user, i.e., that there is no change in ownership.

Refurbishing of medical products focuses on the following sectors: Electro-physiology; heart surgery; endoscopy; ophthalmic surgery; neurology; urology; heart catheters; digital imaging/angiography; anesthesia; intensive care; general surgery. Excluded from refurbishing are, for example, pressure gauge syringes; spiral lead wires; teflon-coated lead wires; locks and conductors; Olbert-PTA catheters; Wilson-Cook, Endo-Flex and Dispomedica-brand endoscopy balloon catheters; lithotomy baskets; ultrasound catheters, Endo units such as clip applicators; spreaders; Endo shears; plastic implants.

The largest companies in the German refurbished medical equipment market are Remed and Vanguard. Market leader Remed of Friedeburg has approx. 250 customers, mainly hospitals, universities and individual practices, under contract and according to their press spokesperson, expects strong growth over the next few years. Even though currently, roughly 30 percent of the German hospitals refurbish their medical equipment in-house, Remed expects an increase in outsourcing as a less expensive alternative. Remed has refurbished over 250,000 medical products and over 1,000 different medical product categories over the past years. Remed maintains a website at www.remed.de.

U.S. subsidiary and Berlin-based Vanguard GmbH Medical Services has successfully refurbished medical equipment in Germany since 1998 and now counts over 100 hospitals as clients. According to their chairman Robert Schroedel, the validated refurbishing can result in substantive economies of scale and savings, estimated at more than 500,000 million Euro annually for all of Europe, several million Euro for large hospitals or university clinics in Germany and 45,000 Euro annually for smaller offices and medical institutions. Vanguard Germany is currently refurbishing over 400 different medical products in validated procedures. See also their website at www.vanguard.de.

Participation in German trade fairs is one of the most cost-effective ways of testing the market's receptivity to a product, investigating competitors and of finding customers or potential agents and distributors. German trade fairs, due to their international significance and large attendance numbers, provide an excellent vehicle for introducing new technologies and products and present a gateway to both the markets of the EU and Eastern Europe. Unlike most North American trade shows, the typical German fair is much larger, represents virtually the entire industry, and is a highly successful sales point. German trade shows attract heavy attention from worldwide buyers. The following German trade show is establishing its reputation as the major European trades show for refurbished equipment. It is international in scope, giving visitors, buyers and exhibitors alike the foundation needed to start business relations.

This year's show featured more than 500 exhibitors presenting over 150,000 products.

Name: *RESALE: International Trade Fair for Used Machinery and Equipment*

Location: Karlsruhe, Germany

Dates: Monday 18 - Wednesday 20 April 2005

Opening time: *Daily from 9:00 am to 5:00 pm*

Entry prices: *1-Day ticket: EUR 20.00*

3-Day ticket: EUR 35.00

Trade fair catalogue: EUR 20.00

Product Groups: Machinery and equipment for the following industries: Building, Disposal, Energy Engineering, Food Processing, General Industrial, Medical Devices and Equipment, Metalworking, Packaging, Plastics Processing, Printing, Recycling, Textiles, Timber Processing, Utility Vehicles.

The show is an annual, trade-only event. Over 500 exhibitors presented more than 150,000 products at the show in 2003. According to organizer, large section with medical equipment. For further information on exhibiting or visiting the show, please contact:

Hess GmbH
Königsberger Straße 2
76356 Weingarten, Germany
Tel: +49 (0) 7244-7075-0
Fax: +49 (0) 7244-7075-50
E-mail: info@resale2005.de
Internet: www.resale2005.de (contains list of exhibitors; industry-specific)

For specific questions regarding the export of refurbished equipment to Germany or the marketing of refurbished equipment, please contact:

Mrs. Annette Salama
Sr. Commercial Specialist
U.S. Commercial Service Duesseldorf
U.S. Consulate General
Willi-Becker-Allee 10
40227 Dusseldorf, Germany
Tel: +49-211-737-767-60
Fax: +49-211-737-767-67
E-mail: anette.salama@mail.doc.gov

GHANA

General Market Condition: No Restrictions, but Government Health Institutions Are Discouraged from Purchasing

Source: Report from CS Post (via Cable), 2 March 2002

There have been no changes over the past year in import regulations for used medical equipment in Ghana.

Ghana does not have explicit import restrictions or tariffs that apply specifically to used or refurbished medical equipment or used equipment in general. As a matter of policy, government health institutions are discouraged from purchasing this equipment. Apart from assessment of value, customs officials treat all imported equipment in the same way as new equipment.

Used basic medical equipment such as hospital beds, wheelchairs, trollies and furniture, and items that are not high technology are more often purchased by the private sector. Government institutions tend to purchase items that have a higher technology component. Institutions can also accept used or refurbished medical equipment as gifts from donors. One disadvantage of acquiring used or refurbished medical equipment cited by officials is the frequent absence of operation manuals, appropriate training, and spare parts.

The market for used or refurbished medical equipment in both public and private medical institutions is generally limited. Private health institutions, which are increasing in number, present the greatest potential for growth in that market. Because of the lack of local financing resources, interested U.S. firms that can offer some financing in addition to warranty, spare parts, and training to support the equipment can best take advantage of this opportunity.

The major types of used or refurbished medical equipment in greatest demand include scanners, hospital beds, wheel chairs and furniture, ultra sound, sterilizers, X-ray equipment, and laboratory equipment, such as autoclaves.

GREECE

General Market Condition: No Restrictions, but CE Mark is Required
See also entry for the European Union.

Source: Report from CS Post (via Cable), 2 March 2002

In general, Greece does not apply any restrictions on imports of used equipment and machinery, provided it has the CE mark and complies with European Union safety and operations regulations. More specifically, regulations for used medical equipment are governed by EU regulations: 90/385 EEC, 93/42 EEC, 98/79 EC. No special restrictions or tariffs apply to used medical equipment that does not apply to new medical devices.

Despite the absence of restrictions on the purchase of used medical equipment, there does not appear to be much demand for such equipment in the Greek market.

However, some private health institutions, medical laboratories, and small to medium-sized clinics are purchasing used or refurbished dental equipment, scanning devices, ultra-sound and analytical equipment. Such purchases appear infrequent and isolated.

GUATEMALA

Medical Device Regulatory Requirements for Guatemala

Disclaimer: The information contained on this website is derived from public sources and is current to the best of our knowledge. For detailed and definitive information about a country's laws and policies, the government of the country concerned should be consulted.

Regulatory Agency

The Ministry of Public Health and Social Welfare (Ministerio de Salud Publica y Asistencia Social) supervises the health care system in Guatemala. Although regulations are in place they are not fully enforced. The Social Security Institute (Instituto Guatemalteco de Seguridad Social - IGSS), and the Ministry of Defense are the two other governmental agencies that provide health care and purchase medical equipment. Private hospitals, clinics and drugstores also buy medical devices but their needs are much smaller than those of the public sector.

Regulations

Under the Health Registration Law of July 1996 by the Ministry of Health, medical devices should be registered. The following is a list of required documents for medical device registration:

- a) Certificate to Foreign Government (or Certificate of Free Sale)
- b) Labels/Directions for Use

- c) Packaging Materials
- d) Quality Control Test Methods/Records
- e) Quality Control Certificate
- f) Biocompatibility Reports
- g) Product Brochure

Standards

Guatemala uses both the metric and English systems of weights and measures. Literature should be written in Spanish.

Used Equipment

Approximately 20 percent of medical equipment imported into Guatemala is used or reconditioned. This equipment consists of, but is not limited to, portable X-ray machines, ultrasound equipment, anesthesia equipment, operating tables, surgical equipment, etc. Clinics and small health care facilities known as “**sanatorios**” usually purchase their equipment from large Guatemalan hospitals or from a small group of firms that refurbish the equipment and offer some sort of short-term guarantee. Sanatorios are usually very small hospitals established by one doctor or a small group of doctors who often do not have the financial resources to purchase new equipment. Used equipment is also purchased by the dozen or so firms that rent home care equipment. The potential for used medical equipment with local representation is very good.

Import Duties and Taxes

All imports are subject to customs duties. In January 1997, the Central American Tariff Reduction Agreement came into effect. This agreement reduced tariffs to 0 percent beginning on January 1, 1998. There is a value added tax (VAT) of twelve percent, which must be paid, on the sum of ad valorem duty and the C.I.F. value of the import. This twelve percent tax can be credited against the local firm's income tax liabilities.

Distribution

Most firms selling into the Guatemalan market do so by means of a Guatemalan agent or distributor. However, used equipment dealers tend to sell directly to Guatemalan buyers. Generally speaking, the more pre-sales marketing and after-sales support and service that a product requires, the more important it is to have a local agent or distributor.

Formal agency or distribution agreements should be reviewed by a Guatemalan attorney hired by the U.S. exporter (independent of the Guatemalan party with which the agreement will be established). The Guatemalan legal system can be slow and the law, under certain conditions, offers local agents and distributors a great deal of protection. Under no circumstances should a U.S. exporter give a local agent or distributor the responsibility of registering any intellectual property (i.e., trademarks, trade names, copyrights, etc.); it should be done directly by the U.S. exporter with the assistance of a Guatemalan attorney.

Contact Information

Government Agencies

Ministerio de Salud Publica y Asistencia Social
(Ministry of Public Health and Social Welfare)
6 Avenida 3-45, Zona 11
01011 Guatemala, C.A.
Tel: +502- 2-475-2121 through 9
Fax: +502- 2-475-2168
Contact: Ing. Marco Tulio Sosa, Minister

Instituto Guatemalteco de Seguridad Social
(Guatemalan Social Security Institute)
7 Avenida 22-72 Zona 1, Centro Civico
01001 Guatemala, C.A.
Tel: +502- 2-232-8520
Fax: +502- 2-253-2180
Contact: Lic. Carlos Raul Sosa Aldana

Ministerio de la Defensa Nacional
(Ministry of National Defense)
Avenida Reforma 1-45, Zona 10
01011 Guatemala, C.A.
Tel: +502- 2-360-9907, + 502-2-360-9919
Fax: +502- 2-360-9909
Contact: Gen. Carlos Humberto Aldana V.

Trade Associations

Camara de Comercio de Guatemala
(Chamber of Commerce of Guatemala)
10 Calle 3-80, Zona 1
01001 Guatemala, C.A.
Tel: +502- 2-238-2681/5
Fax: +502-2-251-4197
E-mail: info@camaradecomercio.org.gt
Contact: Lic. Edgardo Wagner, President

Camara de Industria de Guatemala
(Chamber of Industry)
Edificio Camara de Industria
Ruta 6, 9-21, Zona 4, Nivel 12
01004 Guatemala
Tel: +502- 2-331 9191
Fax: +502- 2-334-1090
E-mail: informacion@industriaguatemala.com
Contact: Mr. Jaime Arimany, President

American Chamber of Commerce of Guatemala (AMCHAM)
5 ave 5-55 zona 14, Edificio Europlaza, torre 1, nivel 5
01014 Guatemala, C.A.
Tel: +502- 2-333 3899

Fax: +502- 2-368 3536
E-mail: trade@amchamguate.com
Contact: Ms. Carolina Castellanos, Executive Director

Camara de Industria de Guatemala
Gremial de Distribuidores de Productos Hospitalarios
Camara de Industria
(Chamber of Industry's Hospital Products Distributors/Guild)
C/o Equipo Médico Hospitalario S.A.
12 calle 2-65, Zona 1
01001 Guatemala, C.A.
Tel: +502- 2-369-0580
Contact: Héctor Centeno, President

Import Regulation for Used Medical Equipment

Source: Report from CS Post (Via E-mail) 3 May 2005

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

New and used equipment receive same treatment in the Country.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc.?

New safety inspections will not be applied to a type of device that has already been registered.

Can public health institutions buy used or refurbished medical devices?

Public entities are not allowed to purchase refurbished or used equipment. Private hospitals and clinics are the main used/refurbished equipment importers.

Is there a market for used or refurbished medical devices?

Yes, there is a market although it only represents 10-15 percent of the total market share for medical devices. As previously mentioned, this portion belongs to the private sector exclusively.

If there is a market, what types of used or refurbished medical devices are in the greatest demand?

Radiology equipment, scanning machines, laboratory and surgical equipment are the best prospects for refurbished equipment.

Are single-use devices being reprocessed and sold on the local market? If so, is this activity regulated? Please provide any details.

It is possible that a large hospital can sell a used piece of equipment to a smaller clinic; regulations are not strict in this case. It is considered a common sale.

GUINEA

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

Source: Report from CS Post (via Cable), 5 May 2000

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

In Guinea, there are no special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment. The importation of used medical equipment is authorized by the Government of Guinea (GOG).

Can public health institutions buy used or refurbished medical devices?

Public health institutions do not buy used or refurbished medical devices. The GOG provides these health institutions with new medical equipment. It is GOG policy not to buy used equipment.

Is there a market for used or refurbished devices?

The market for used or refurbished devices is very small. Private clinics or hospitals are free to purchase used or refurbished equipment but most of them have very limited resources.

Best Prospects?

Private clinics or hospitals are the best prospects since public health institutions depend on the Government for medical devices.

HAITI

Import Regulation for Used Medical Equipment

Source: Report from CS Post (via Cable), 10 April 2000; Updated 16 May 2005

REF: USDOC 00292

1. In response to reftel, Post submits the following information on regulatory requirements for used medical equipment:

Despite the small size of the market, there is a market for new, used and refurbished medical equipment in Haiti, especially if the equipment is not expensive. Haiti does not produce its own medical equipment. The Haitian Government is in the process of developing a national health program and will likely procure equipment for public hospitals and medical centers. A niche market may exist for low-tech refurbished medical equipment to be used by the private or the public sector.

2. In response to specific questions in reftel:

There are no special restrictions or tariffs applied to refurbished and used medical equipment imported into the country. The Embassy is not aware of any U.S. manufacturer or Haitian agent having registered a medical device in Haiti nor of any restriction to introduce new, used or refurbished medical equipment. There are no special safety inspections used to test refurbished medical equipment. Public health institutions can buy used, refurbished or new medical devices. Single-use devices are not now reprocessed in Haiti and are not sold in the local market. However, according to medical sector professionals, there is a market for all types of medical supplies and

equipment, especially laboratory equipment, surgery equipment and supplies, wheel chairs, X Ray equipment, orthopedic equipment, Otto-rhino-laryngologist equipment, and ophthalmologist equipment.

3. In addition, Post notes that:

All medical equipment entering Haiti, whether new, refurbished or used, is not subject to custom duty. However the following taxes are due:

Inspection fee: 4 percent on CIF; Storage duties: 2 percent of the customs value per month of storage; Value-added tax (TCA): 10 percent on CIF; Acompte: a 2 percent contribution tax to the fund for the management and development of local communities (CFGDCT) is applied to all imports, although pharmaceutical products are exempted.

In addition, the value of imported goods, either FOB or CIF, is converted into Haitian gourdes at the prevailing daily rate, prior to the application of duties and taxes.

The government of Haiti has a pre-shipment inspection agreement with Société Générale de Surveillance (SGS). Under this agreement, all imports with a value of at least US\$5,000 or which is an entire container, regardless of the value, must be inspected by SGS before being entering Haiti. SGS issues a verification certificate that the importer of the goods must submit for the purpose of customs formality. The inspection certificate with the declared value and the document is attached to normal shipping documents that accompany the shipment.

General Market Condition: No Restrictions

Source: International Market Insight, Regulatory Requirements and Market Prospects For Used Medical Equipment, 12 March 2002

Regulatory Agency

The Haitian Ministry of Public Health and Population supervises the healthcare sector for the country.

Regulations

There are no regulations for the enforcement of quality, technical or safety standards. The Haitian Government does not restrict the importation of used/refurbished medical equipment.

Standards

Both U.S. and European standards are currently accepted and respected by the purchasing entities.

Import Duties and Taxes

Used medical items entering the Haitian customs territory are subject to the same import tax treatment as new items. Import duties on medical devices are 16 percent. The tariff system is on a CIF basis. The value of imported goods, either FOB or CIF, is converted into Haitian gourdes at the prevailing daily rate, prior to the application of duties and taxes.

Distribution

The market prospects for imports of all types of used/refurbished medical equipment is relatively strong, since new medical equipment is considered to be expensive, U.S. companies have a number of options for entering the Haitian market place, including direct exporting, franchising, licensing, and wholesaling. The most common method involves the use of an official representative or distributor, as the Haitian commercial code does not allow foreigners to engage in wholesale or retail business without first obtaining a professional license. Agents in Port-au-Prince, who then distribute products to the provinces, represent most foreign firms. The commercial code is designed to protect Haitian citizens who work as agents and distributors for foreign companies. The Haitian tax code includes a withholding tax provision, which, in practical terms, discriminates against foreign investors. Foreign companies are subject to an additional levy of 30 percent on profits as a final tax on deemed distributions to foreign shareholders, whereas local firms are subject to only a 15 percent withholding tax on distributions. The government has committed itself to removing this disincentive to investment; however, further administrative action is required to implement this commitment.

Contact List for Medical Equipment and Health Services Exporters

Ministry of Public Health and Population
Palais des Ministeres
Rue Monseigneur Guilloux
Port-au-Prince, Haiti
Dr. Henry-Claude Voltaire, Minister
Tel: +509- 222-2728/222-7020
Fax: +509- 223-6248

Division d'Hygiène Publique
Direction Centrale de Pharmacie et de Controle
Des Substances Chimiques
59 Rue des Miracles
Port-au-Prince, Haiti
Mr. Eric Dubosse, Director
Tel: +509- 223-6826

Association Medicale Haitienne (AMH)
24 Rue Capois
Tel: +509- 223-8334
Fax: +509- 223- 9885
E-mail: amh@haitiworld.com

Hôpital de l'Université d'Etat
Rue Monseigneur Guilloux
Centre Ville
Port-au-Prince, Haiti
Tel: +509- 222- 1066/222- 4344/223 -4261

Hôpital Français
Rue du Centre
Port-au-Prince, Haiti
Tel: +509- 222- 5966/223- 9979/223- 9988

Hôpital St. François de Salles
Angle Rue Chareron et Rue de l'Enterrement
Port-au-Prince, Haiti
Tel: +509- 222- 5033/222 -71 32/222- 0232

Hôpital du Canapé Vert
Route du Canapé Vert
Port-au-Prince, Haiti
Tel: +509- 245- 0984/245- 0985/245- 6105
Fax: +509-245 0985

HONDURAS

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

Source: Report from CS Post (via E-Mail), 27 March 2002; updated 16 April 2003, and 22 April 2005

According to the Honduran Customs and Tax Division, there are no quotas for the importation of remanufactured, rebuilt, and/or used medical equipment to Honduras. There are no tariffs on most imported medical devices considered to be capital goods, including used equipment. For consumable medical products, tariffs range from 0 to 15 percent. A customs agent carries out the appraisals for remanufactured, rebuilt, and/or used medical devices including reprocessed, single-use devices at the port of entry. Used medical equipment and supplies are not subject to government certification, inspection or regulation.

According to a major U.S. medical equipment in the Central American region, making it an important market for U.S. medical equipment exporters. GE has sold magnetic resonance equipment to private hospitals in San Pedro Sula, making Honduras one of the first countries in the Latin American region to import this kind of sophisticated technology in the health sector. Honduras is the number one importer of medical equipment.

At present, public health institutions are only allowed to purchase medical equipment and supplies through public and international bids. However, these requests for bids typically solicit new equipment, rather than used. Bids are managed through UNDP (see www.undp.un.hn/licitaciones), with the funds for purchasing products often provided by the World Bank, Inter-American Bank for Development or international donors. Each international funding organization specifies the bidding procedures and equipment specifications.

Due to a marked decrease in the availability of international development funds for medical equipment purchases, hospitals are beginning to secure medical equipment through a mechanism called "Por Dato." Under this system, a contract is signed and the medical facility pays a fee based upon equipment usage. It is not considered a finance lease, as at the end of the contract period, the equipment is returned to a local provider, the medical facility is in no intent to keep the equipment. Any company providing equipment under this system must be registered as distributors/representatives in the Ministry of Industry and Commerce.

Approximately 30 percent of medical equipment imported into Honduras is used or reconditioned. The main buyers of refurbished/used equipment are private hospitals. An increasing number of opportunities are opening to companies who supply parts and service for medical equipment. Even though the government doesn't purchase used equipment, it sometimes obtains this equipment from foreign countries and will therefore be in need of local technical service and parts.

The medical equipment brands of greatest demand in Honduras are: General Electric, Storz, Medtronic, Ortosintese, Getinge Casde, Wlchallyn, and Aesculap.

Among the best prospects are: X-ray and monitoring equipment, hospital beds, wheelchairs, uniforms, lab coats, stethoscopes, liftman stethoscopes, thermometers, breast pumps, scissors, dental care equipment, digital blood pressure equipment, ophthalmoscopes, eye exam kits, examination gloves, heart rate monitoring equipment, X-ray view boxes, blood chemistry and collection equipment, sterilizing equipment, instrument cleaners, instrument lubricants, ultrasonic cleaners, rapid diagnostic test kits, and surgery, intensive-care equipment and disposable medical supplies.

For additional information on the market for used and refurbished medical equipment in Honduras, please contact Roy Alonzo at the Commercial Service Office in Tegucigalpa, Honduras, tel: +504- 238-5114, fax: +504- 238-2888, Roy.Alonzo@mail.doc.gov

HONG KONG

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 13 March 2002

In Hong Kong, there are no special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment. Hong Kong agents and distributors in this industry prefer to source the 'newest and latest' equipment. There is limited market for used and refurbished medical equipment. Public hospitals, private hospitals and health institutes in Hong Kong do not buy used medical devices. There is very little business opportunity for used/refurbished medical equipment in China due to government restrictions.

HUNGARY

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 26 March 2002

Are there special restrictions or tariffs that apply to used medical equipment?

No, there are no special restrictions/tariffs that apply to used medical equipment, that apply to new medical equipment.

Can public health institutions buy used or refurbished medical devise?

Yes, public health institutions can buy used medical devices.

Is there a market for used or refurbished medical devices?

The market is very limited for used/refurbished medical devices. Most of the healthcare institutions are state-owned and 'are not interested in saving on equipment purchases.' Right now clinics prefer to wait until they have enough money for a new device instead of 'saving on time and money' by purchasing used or refurbished equipment. There has not been a tradition of buying used equipment in Hungary and people seem reluctant to buy pre-owned devices. Hungarians do not consider purchasing refurbished medical equipment as a real option.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

There are only ad-hoc purchases of pre-owned equipment.

Source: Industry Sector Analysis, Medical Equipment, 15 February 2002

Leasing of medical equipment has no tradition in Hungary and is in its very early stages. The market for used/refurbished medical equipment has also been very limited in Hungary. However, with increasing privatization opportunities, their sales prospects might improve.

Source: Report from CS Post (via E-Mail), 26 March 2001

In Hungary the use of used/refurbished medical equipment is rather limited. The reason might be the regulation below, or simply little tradition so far.

In response to an inquire with the Authority for Medical Devices in the Hungarian Ministry of Health, The Deputy Director advised that there are no special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment. Public Health institutions can buy used/refurbished medical devices. The general rule, that applies to all medical equipment and devices (whether imported or locally manufactured) is a Ministry Decree of 1998 (21/1998/VI.3), Annex 17. This annex lists all medical equipment/devices with the 'approved / authorized length of life,' it actually tells/prescribes to all medical institutions how long they can use their equipment. In practice, as the Hungarian health care system lacks funding, the Ministry does not 'check' how old the equipment are, as the government-owned hospitals/clinics could hardly afford to buy new equipment. However if a clinic would want to buy a piece of used equipment, the Authority for Medical Devices would register/check how old the equipment to-be-imported is, and would tell the clinic for how many more years it could use the equipment.

ICELAND

General Market Condition: No Restrictions, but CE Mark is Required

Source: Report from CS Post (via E-Mail), 4 March 2002

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No, there are no special restrictions or tariffs that apply to used medical equipment. The same rule applies to both new and used medical equipment. However, as in most European countries, Iceland requires the CE mark on all medical equipment, used or new.

Can public health institutions buy used or refurbished medical devices?

Yes, they are allowed to buy used or refurbished medical equipment but so far no interest has been shown to do so, simply because health institutions prefer to purchase new equipment.

Is there a market for used or refurbished medical devices?

According to the Icelandic Ministry of Health there has not been a market for used or refurbished medical equipment, since institutions prefer to purchase new equipment.

If there is a market, what types of used or refurbished medical equipment are in greatest demand?

Not applicable.

INDIA

General Market Condition: No Restriction

Source: Report from CS Post (via E-Mail), 12 April 2005
Import Regulations For Used/Refurbished Medical Equipment

There are no restrictions on import of used/refurbished medical equipment. Used/refurbished medical equipment is imported under the same category as the new products. Hence, tariff rates applicable on used/refurbished medical equipment are same as that for the new equipment. Tariff on medical equipment/devices range from 5 to 30 percent. Equipment and devices designated as "life- saving" are levied 5 percent duty, also direct import by government hospitals are eligible for import duty concessions.

In the absence of regulations on medical equipment/device a third party can import refurbished medical equipment/device. Government hospitals do not import refurbished equipment. There exists a demand for refurbished high valued medical equipment. There are no regulations on medical devices.

According to industry contacts re-use of single use-devices is a concern for the companies.

The Web link <http://dgft.delhi.nic.in> provides details on India's trade policy. Below is the contact information for office of the Directorate General of Foreign Trade.

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Directorate of Foreign Trade
Ministry of Commerce and Industry
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Source: Industry Sector Analysis, Cancer Diagnostic and Treatment Equipment, 28 April 2001

End-users are becoming increasingly aware of the state-of-the-art Cancer Diagnostic and Treatment Equipment (CD&TE) equipment available in the world market. Most of India's leading cancer specialists attend medical conferences in the United States and Europe to keep abreast of the latest technologies. Price, product features and payment terms are key factors, which influence purchase decisions of hospital administrators. Charitable organizations and rural hospitals unable to afford the latest, new equipment often purchase used or reconditioned equipment imported from abroad.

Used medical equipment also has market potential in the country. The present government of India's current Export-Import policy allows imports of used equipment including used CD&TE equipment. Used equipment including CD&TE equipment that is less than 10 years old can be imported into the country. The importer should not sell, transfer or otherwise dispose of this equipment within a period of two years from the date of import. The Director General of Foreign Trade, New Delhi, will grant a waiver to this

requirement. Price-sensitive Indian end-users prefer to buy refurbished medical equipment including cancer treatment equipment for some low-end applications. However, these buyers look forward to continued support for spare parts and service commitments.

Source: Report from U.S. Commercial Service, November 2000

In July 2000, India's Directorate General of Foreign Trade (DGFT), Ministry of Commerce, issued a policy circular detailing guidelines for importing second-hand capital goods, including medical equipment. The policy incorporates changes to paragraph 5.3 of the Export Import Policy of 1997-2002 and paragraphs 5.29 and 5.30 of the handbook of procedures. As per the provisions contained therein, import of second-hand capital goods is restricted and subject to import licensing procedures.

The inter-ministerial Restricted Items Licensing Committee under the DGFT, New Delhi, considers applications for such licenses. The Committee will consider such applications according to the following guidelines:

- Capital goods not older than 5 years: The committee will normally allow imports of such capital goods automatically.
- Capital goods older than five years but less than ten years old: The committee will take into consideration the comparative advantages/benefits of such imports vis-à-vis new capital goods.
- Capital goods older than 10 years: Imports of such capital goods normally will not be allowed except for heavy equipment in the infrastructure and core sectors.

The imported capital goods will have to conform to acceptable environmental and industrial safety norms. Apart from the criteria mentioned above, the committee might establish any other criteria, as it may deem necessary.

Source: IMI, 9 December 1999

Under immense pressure from the domestic industry the Indian Government has eased the imports of second-hand machinery. The Government of India will now allow second hand capital goods imported into the country under the special import license route. An importer has to purchase the special import license from the open market at a premium and can import the second hand machinery, which is less than five-years-old. For machinery more than five-years-old the current procedure for imports will apply. It will not be possible for importing capital goods more than ten years old. The Indian government is preparing a notification to this effect.

Ministry officials said applications for import of second-hand machinery more than five years old would be placed before special licensing committees in the same manner as application for import of other restricted items.

When the new export import policy was announced in March 1999, several industry associations had complained that import of used equipment must be made easier so that the Indian industry can acquire the latest equipment and compete globally. This new announcement is in keeping with the demand from the user industry and the chamber of commerce representations.

Capital goods account for 25 percent of total imports and 75-80 percent of the capital goods imported into India was used machinery and equipment. Such a large percentage of imports will now be able to bring in latest equipment. This will also facilitate the import of used equipment by small-scale sector, which cannot afford new capital equipment.

Source: ISA Medical, 31 March 1999

Best Prospects

Refurbished medical laboratory instruments also find a ready market in India. These instruments are used as back-up machines in top-of-the-line hospitals. Less sophisticated hospitals and district hospitals view refurbished medical laboratory instruments as optimal for their laboratories because the investment cost is substantially lower than for new instruments. Some international companies operating in India also sell used medical laboratory instrument to their Indian customers. Also, Indian hospitals and agents demand continuous service support for these instruments and require spares when needed. U.S. Companies in the used/refurbished medical instruments business may consider setting up liaison offices in India to promote their products.

Source: IMI, 16 July 1998

There are several restrictions on the import of used equipment in India, prescribed by India's import-export policy, in force from 1997 to 2002. Actual users of such equipment without a license can import second-hand capital goods with a minimum residual life of 5 years. The importer is required to furnish a self-declaration to the customs department specifying the residual life of the second-hand capital goods in a prescribed format.

The importer is also required to furnish a certificate from an internationally reputed inspection and certification agency that the purchase price of the equipment is reasonable. This certificate is required at the time of clearing the goods through customs, where the CIF value of the goods exceeds Indian rupees 10 million (US\$238,000). Where the second-hand equipment has a CIF value of up to RS. 1 million (US\$23,800), customs authorities will not insist upon such a certificate.

The second hand equipment shall not be transferred, sold or otherwise disposed of within a period of 5 years from the date of import, except with prior permission of the director general of Foreign Trade. While selling, U.S. firms should remember that valuation of used or second-hand equipment is a very technical area with frequent disputes between customs and the importer. For problems, U.S. exporters can contact:

Mr. L.N. Lakhan Pal,
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Ministry of Commerce Government of India
Udyog Bhavan, Maulana Azad Road
New Delhi 110001,
India
Tel: +91-11-301-1777
Fax: +91-11-301-1779

Spares, including accessories and tools for the maintenance and operation of such equipment, can be imported to the extent of 15 percent of the value of the equipment.

India is a high-cost economy for capital equipment, and Indian manufacturers and investors constantly seek to reduce their capital costs. For this reason, demand for used and reconditioned equipment is high across a range of industry sectors. The best opportunities for U.S. firms to pursue are in the industry sectors of construction, mining, medical, machine tools, plastics, steel, oil refining, computers, printing, packaging and dairy equipment.

While rates of customs duty vary from product to product, they are, generally speaking, lower for used equipment as compared with new equipment.

INDONESIA

General Market Condition: No Restrictions, but Public Institutions Cannot Purchase

Source: IMI Medical, 18 February 2000

The Ministry of Health prohibits public hospitals from using used or refurbished medical equipment, however, this prohibition does not apply to private hospitals. Given the poor economic condition in Indonesia, the purchase of new medical equipment is no longer affordable for most hospitals. The situation has compelled private hospitals to seek alternative medical products at an affordable price.

Indonesian medical suppliers discovered that since 1999, the request for used/refurbished medical equipment has increased. This is because hospitals need to replace the old equipment, which was mostly purchased before the economic crisis. According to the medical suppliers, the purchases for used/refurbished equipment are still very low, however, they anticipate the demand will gradually increase in the future.

To protect their image, medical equipment suppliers refused to sell both new and used equipment, although they would do it on a case-by-case basis upon order. Hospitals were unwilling to buy used/refurbished medical equipment because they claimed that they did not get good service from the manufacturer, spare parts were hard to replace, and after sales service was poor. To take the greatest advantage of export opportunities, used/refurbished equipment suppliers should be able to provide training, technical assistance, spare parts, and after sales service.

The import tariff for medical equipment for both used and new ranges from 5 to 10 percent with a value-added tax of 10 percent.

Source: Report from CS Post (via Cable), 22 February 2000

The Ministry of Health (MOH) prohibits public hospitals from using used or refurbished medical equipment but there is no written regulation on this.

Private hospitals are not bound to the above policy. Imports of used or refurbished equipment had not been very significant in the past. Because of low purchasing power, private hospitals are beginning to show interest in used or refurbished medical equipment.

Local medical suppliers anticipate that the demand for used or refurbished medical equipment will gradually increase in the future.

The import tariff for both used and new medical equipment ranges from 5 to 10 percent. It is subject to a value-added tax (VAT) of 10 Percent.

ISRAEL

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 14 April 2003

Summary

The Israeli market for used medical equipment is very small and considered insignificant for US exports. There is no special tariff that applies, and the official import requirements are the same as for new equipment. However, in practice, the Ministry of Health (MOH) permits the import of used/refurbished equipment only by specific end-users, and does not issue registration certificates for imported used equipment.

The Registration Process

By law, all medical equipment used in public health institutions requires MOH Registration. MOH registration provides the health institution legal protection in the event of mal-function of the device. Hospitals and other health institutions may import or receive donated equipment if it is for their own use only. However, they will not receive the MOH “blessing” and they will operate the equipment at their own risk. MOH does not approve imports of used/refurbished equipment by commercial agencies/distributors for resell in the market.

Import Requirements

In order to release used medical equipment from customs, MOH requires the end-user to report in details the complete history of the device: by whom, for how long, and where the equipment was used and / or refurbished and where it was tested to comply with technical standards. The end-user must declare that the used equipment is for its own use and provide a proof of available chain of supply (of spare parts) from the original manufacturer.

Parallel Imports

If a manufacturer or its agent registered a medical device in Israel, a third party cannot rely on this registration to import the same device in used/refurbished condition without being subject to the above import requirements. The same applies to parallel imports of new equipment.

Type of Used/Refurbished Equipment already in the Market

Existing used or refurbished equipment in local hospitals include ultra-sound and laser.

Contact Information

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Government of Israel Contacts

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ITALY

General Market Condition: No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from CS Post (via E-Mail), 22 march 2002

There are no restrictions or special tariffs on imports of used and refurbished medical equipment into Italy. However, the CE mark is required for all used or refurbished medical equipment and devices, and the same safety standards apply for new and used alike.

Though there are no impediments to the purchase of used and refurbished medical equipment, but the prevailing practice in public hospitals and medical facilities is to purchase new equipment because of liability issues. Public hospitals are forced to comply with current regulatory issues, which mandate that all equipment and devices utilized in public healthcare facilities has to be in accordance with CE mark regulations, in effect from June 1998, by Directive 93/42/EC. The public healthcare service accounts for over 75 percent of expenditures for medical equipment.

The Italian market for used medical equipment is very small and is mostly confined to the private sector. The majority of used medical equipment now available has been on the market prior to the directive, and in most cases does not have the CE Mark, nor does it meet the stringent safety parameters. The process of refurbishing medical equipment to the point of meeting the requirements of the directives and to acquire the CE Mark is very costly and, once completed, makes the selling price of pre-owned equipment prohibitively expensive. Consequently, savings are not enough to justify the purchase of used equipment. To be appealing, the price of used and refurbished medical equipment should be approximately 40 percent less than the selling price of new equipment. Pre- and post-sale marketing and technical assistance must support sales of refurbished medical equipment.

A niche market exists for used and refurbished medical equipment that can be sold to small, privately owned healthcare facilities—which due to their size and specialization are exempted from fully complying with the existing regulations—and to private practitioners. Thus, the best selling used medical products are diagnostic imaging equipment, EKG, monitoring equipment, ultrasonic equipment, ophthalmology equipment, dental chairs and dental equipment, and apparatus and equipment for physical therapy and rehabilitation.

JAMAICA

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 3 May 2000

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

None of which the Post is aware, but all imported equipment should ideally be approved by the Jamaica Bureau of Standards.

Can public health institutions buy used or refurbished medical devices?

Yes, but again subject to the conditions above. All of last year, Y2K was a big thing. Health services were announcing that they would only be buying items that were Y2K compliant.

Is there a market for used or refurbished devices?

In theory there should be, but new items are greatly preferred.

Best prospects?

Unknown.

JAPAN

General Market Condition: Restricted

Source: Report from CS Post (via E-Mail), 26 March 2002. Information re-confirmed by CS Post, 17 April 2003.

Are there special restrictions or tariffs that apply to used medical equipment?

All imports of used equipment are treated the same as new, and thus each product must obtain MHW (Ministry of Health and Welfare) approval for import.

Although there are no tariffs levied on medical devices, this area is highly regulated by the Pharmaceutical Affairs Law of the Ministry of Health, Labor and Welfare (MHLW). In order to market a foreign medical product in Japan, an importer must obtain “manufacturing approval” (*shonin*) for safety and efficacy of a medical product. In order to handle a shonin-approved product, an importer or a seller needs to obtain “*kyoka*” license based on its facility, personnel and qualification of a technical director. A foreign manufacture may obtain the *shonin* approval by using an in-country care taker (ICC). If a foreign manufacturer receives a *shonin* approval, an importer is not required to obtain a shonin approval for such items.

In many cases, a Japanese importer receives “manufacturing approval” (*shonin*). It means that an importer who has a *shonin* approval will have a full control. If a different importer wishes to sell the same product (either used or new), this importer must receive a product approval from the Ministry. If a U.S. manufacturer holds an approval, they can sell their product through multiple distributors that have “*kyoka*” license to sell medical devices in Japan. A Japanese doctor can import a medical device to treat his/her patients at his/her risk. However, in this case, no reimbursement is given for those treatments, and thus direct import from Japanese general clinics and hospitals is very limited. Japanese beauty clinicians and veterinarians often import new and used medical device, as their treatments have no reimbursement coverage in Japan’s system.

Can public health institutions buy used or refurbished medical device?

Although there is no statistical information available, used/refurbished medical equipment is becoming more attractive to medical institutions, including public hospitals, because of cost factors. This trend may continue coming years as the financial status of many Japanese hospitals is also becoming more precarious. Over 70 percent of Japanese hospitals are believed to be operating in deficit and the number of hospitals declaring bankruptcy is increasing. More efficient use of used/refurbished medical equipment may be needed to meet these growing financial challenges.

Is there a market for used or refurbished medical devices?

The sale of such equipment in Japan is a more viable option for local manufacturers and re-sellers than for third-party exporters. Industry sources indicated that market demand for such equipment is particularly strong for ultrasonic diagnostic equipment, X-ray equipment, clinical examination/laboratory equipment, etc.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

The Japan Federation of Medical Devices Associations (JFMDA) has prepared a guide on the handling of second-hand medical devices with the objective of establishing a closer network system between manufacturers and medical facilities and to ensure the safer and more effective use of these devices.

JORDAN

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 28 June 1998

Equipment is assessed the tariff that applies to its Harmonized Tariff Schedule (HTS) category, regardless of whether it is new or used. The base value of used equipment, however, is depreciated according to the judgment of the customs inspector. Therefore, the net customs levy on used equipment may be lower or even higher than on new equipment, depending on the customs inspector.

No customs duties apply to new or used industrial equipment if it used for production.

KAZAKHSTAN

General Market Condition: No Restrictions

Source: IMI 26, August 1998

Kazakhstan does not have any special regulations for the importation of used/refurbished equipment. This type of equipment can be imported in accordance with regular customs import requirements. Licenses and certificates of conformity may be required for the import of certain types of equipment.

Kazakhstani customs does not distinguish between new and used equipment when being declared for customs clearance. Used equipment is released subject to completion of the customs clearance process, which is same as for new equipment. There are no special duties for the importation of used equipment in Kazakhstan.

Licenses are required to import equipment that may affect the health of citizens, the environment, or national security. These types of equipment are subject to mandatory safety certification.

The best industry sectors for the export of certain types of used/refurbished equipment to Kazakhstan are: automotive, oil and gas, power generation, medical, agriculture, and food processing. Subject to the availability of warranties and spare parts, cheap used medical, agricultural, and food processing equipment is believed to have better marketability versus expensive new equipment.

KENYA

General Market Conditions: No Restrictions

Source: ISA Electro-Medical Equipment Market, 29 April 2003

Competitive Analysis

Key competitive factors that serve to limit the potential for the sale of U.S. electro-medical equipment include price, promotion and after-sales service. Many of the industry stakeholders identified promotion as a major limitation that resulted in their lack of knowledge and awareness of medical technologies from the United States. Unlike the U.K., German and Dutch medical equipment suppliers who have over the years actively promoted their products to the Kenyan market, only a few U.S. suppliers such as G.E. Medical systems were identified but still accused of not being as active as their European counterparts.

Secondary to promotion is the issue of after-sales service backup. Many of the health institutions that had purchased U.S. medical equipment cited poor after-sales service as a major problem. The lack of locally available spares and parts was attributed to the absence of local representative offices for the U.S.

companies. It is recommended that U.S. companies consider appointing local agents or representatives to facilitate this after-sales service component that could also be used to promote U.S. medical equipment technology. This is the path, which successful European suppliers have chosen. Aggressive promotion campaigns can only be successful if they are not limited by the lack of a perpetual presence in any market of interest.

Considering the dynamism of medical science, a number of Kenyan health institutions would like U.S. medical equipment suppliers to consider the sale of used and refurbished equipment as well as leasing options for new upgradeable equipment as enviable marketing strategy.

Import Climate

Medical equipment imports into Kenya require an import license, as is the case with all other health sector inputs. The import climate for U.S. medical equipment market in Kenya is good. There are no import barriers, and the customs duty range from 0 percent to 15 percent.

The following documentation is required to facilitate importation of medical equipment:

Import declaration form (IDF) Commercial invoice Airway bill (airfreight) or bill of lading (sea freight)
Pre-shipment inspection Clean Report of Findings (CRF).

Imports with a Free on Board (FOB) value over U.S. \$5,000 are subject to a pre-shipment inspection, at the port of shipment. Pre-shipment inspection can be done by one of the two appointed supervision services companies, namely Cotecna Inspection SA and Intertek Testing Services (ITS) International. The cost of pre-shipment inspection is 2.75 percent of the cumulative cost, insurance and freight (C.I.F) value, payable as an import declaration form (IDF) processing fee. If not indicated, freight is calculated at 18.5 percent of the consignment cost, and insurance 1.5 percent of the sum of the consignment cost and freight.

Medical equipment is generally exempt from both import duties and value added tax (VAT). Exceptions include microscopes and dental chairs, which attract 5 percent duty and liquid-filled clinical thermometers that attract 15 percent import duty and 18 percent VAT.

No approval is required to import any kind of irradiating device. However, prior to installation of any irradiating device the Radiation Protection Board must conduct an inspection and thereafter grant a license. There is no ban on the import of any type of pre-owned (used and refurbished) medical equipment to Kenya so long as the performance characteristics conform to the existing national standards and where none exist, reference is made to the International Organization Standards (ISO).

The trademark name and country of origin must be displayed in English and/or Kiswahili for all categories of medical equipment. In addition, an expiry date must be shown for all medical consumables.

KOREA, SOUTH

General Market Condition: Restricted

Source: Report from CS Post (via E-Mail), 18 April 2003

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No. However, each unit of imported used medical equipment is subject to testing in medical device testing facilities approved by the ROKG.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc?

When a third party legally imports used/refurbished medical devices (which have been previously imported as newly-manufactured products by a registered import agent), these used/refurbished medical devices are subject to the same kind of inspection and certification process as are the new products. The Korean regulatory agency, Korea Food & Drug Administration (KFDA), requires an equal amount and degree of product information for approvals for both new and used products. In practice, each used/refurbished piece of equipment is treated as a separate, re-manufactured product. As part of the process, the importer of used/refurbished equipment must submit a certificate to foreign government (CFG), which is issued by the U.S. FDA, as well as extensive technical information on the products.

Can public health institutions buy used or refurbished medical devices?

See below for discussion in report submitted in 2002.

Is there a market for used or refurbished medical devices?

See below for discussion in report submitted in 2002.

If there is a market, what types of used or refurbished medical equipment are in the great demand?

Best prospects for the used medical equipment include clinical chemistry analyzers, Immunofluorometer equipment, and CTs.

Statistics

Official 2002 Korean statistics for used medical equipment will not be available until May 2003. Below are unofficial estimates for major categories of used medical equipment from the Korea Medical Devices Industry Association (KMDIA).

Korea: Import Statistics for Major Used Medical Equipment, 2002

	Unit	Price (US\$)
Flow-type clinical chemistry analyzer	42	537,816
Immunofluorometer equipment	8	385,024
Computed Tomography (CT)	7	203,351
Tracheal tube & catheter	1 150	33,762
Angiographic X-Ray	1	21,171
Ultrasonic imaging diagnostic equipment	1	19,000
Total	1,209	1,200,124

Source: Korea Medical Devices Industry Association (KMDIA)

Source: Report from CS Post (via E-Mail), 29 March 2002

Summary

There is a small, but growing demand in Korea for used/refurbished medical products, particularly for the latest models of internationally recognized premium brands of radiography equipment. Market demand is strongest for used computer tomography (CT), magnetic resonance imaging (MRI) equipment, X-ray mammography equipment, and premium quality ultrasound scanners. Although the Korean government implemented major regulatory changes to open the market for imports of used/refurbished medical equipment in 1997, such imports are still encumbered by requirements for extensive technical information

and U.S. FDA certificates for local pre-market approvals. Thus, the sale of such equipment in Korea is more of a viable option for manufacturers than for third-party exporters. Under current regulations, the realization of this growing market potential is heavily dependent on the ability of U.S. exporters to provide such information for their Korean distributors to obtain necessary approvals.

Market overview

Prior to July 1997, the Korean government prohibited the importation of used/refurbished medical equipment. Since the ban was lifted through regulatory changes, the market demand has grown significantly and primarily for expensive radiography equipment. A growing demand has emerged for a few types of used capital goods for medical institutions, including Computer Tomography (CT) equipment, magnetic resonance imaging (MRI) equipment, mammography X-ray equipment, premium quality ultrasound scanners, and diagnostic biochemical analyzers. There is also a strong demand for laser printers used for diagnostic X-ray imaging equipment. In particular, local end-users are mostly interested in recent models of internationally renowned premium brands that would otherwise very expensive, if purchased new. In terms of numbers of units, the strongest market demand has been for blood analyzers, diagnostic X-ray equipment and ct equipment. The market demand for diagnostic blood analyzers increased from 19 units in 1998 to 84 units in 1999 but dipped to 63 units in 2000. The demand for computer tomography equipment steadily increased from 45 units in 1998 to 103 units in 1999 to 114 in 2000. In 1998, 15 units of diagnostic X-ray equipment were sold in Korea; that number increased to 44 units in 2000.

Commercial Service (CS) Korea will update the table below on import statistics after the Korean Government publishes its 2001 statistics in April 2002. Import statistics from 1998 to 2000 for some of the used/refurbished medical equipment that have been in greatest demand are listed below.

**Import Statistics for Selected Categories of Used/Refurbished Medical Equipment
1998–2000**

	1998	1999	2000
Diagnostic X-Ray	15 units	14 units	44 units
CT	45 units	103 units	114 units
MRI	4 units	12 units	13 units
Diagnostic Blood Analyzer	19 units	84 units	63 units
Surgical Laser	—	11 units	14 units

According to local industry sources, imports of used medical equipment in 2001, including Computer Tomography (CT) and Magnetic resonance Imaging (MRI), decreased for the first time since 1997. Below are unofficial import statistics from Korea Test Laboratories (KTL) for major categories of used medical equipment. KTL is an independent medical device testing facility approved by the ROKG.

Import Statistics of Major Used Medical Equipment, 1997–2001

	1997	1998	1999	2000	2001	Total
CT	21 units	38 units	101 units	114 units	41 units	315 units
MRI	—	2 units	12 units	9 units	5 units	28 units
Mammography X-Ray	—	—	—	—	22 units	22 units
Surgical Laser	—	—	7 units	11 units	17 units	35 units
Others	6 units	5 units	14 units	35 units	59 units	119 units
Total	27 units	45 units	134 units	169 units	144 units	519 units

Source: Korea Test Laboratories

Despite Koreans' strong disposition against used products in general, the market demand initially emerged in the midst of the country's economic crisis, which erupted in late 1997. Although Korea is recovering from the overall economic crisis, a new crisis, the near bankruptcy of the national healthcare system, has begun to put severe cost-containment pressure on the market demand for all types of medical equipment. Additionally, the dramatic depreciation of the Korean won has precluded many health institutions' ability to purchase expensive, imported equipment in the price range of a few hundred thousand dollars to a million dollars. All of these factors are causing Korean hospitals to seek alternatives to the latest models of highly expensive equipment and to opt for used/refurbished equipment that incorporates the best technologies at considerably reduced prices.

Major players

The major players active in the re-marketing sector of used/refurbished medical equipment are the same as those active in marketing new products of the same brands. For example, large multinational radiography equipment suppliers, such as General Electric, Toshiba and Hitachi and Philips have all begun to implement re-marketing programs for their proprietary brands. Foreign manufacturers re-market used/refurbished products either through their Korean subsidiaries or through their Korean distributors. Imports of used/refurbished equipment sourced from third-party re-marketers are very few in number, primarily as a result of regulatory requirements for product approvals and the advantage that manufacturers' distributors enjoy in terms of product knowledge and after-sales service.

Future prospects and competitive elements

There is a strong consensus among industry experts that the market demand for used equipment will continue to increase over the next several years. With Korea's healthcare system experiencing a financial crisis, the pressure for cost-containment is expected to remain high, and local healthcare institutions will continue to seek inexpensive alternatives for capital medical equipment.

Although competitive pricing is a critical competitive factor, Korean health care institutions are also very concerned about the quality of used/refurbished equipment. They expect to be offered comprehensive warranties and to work with a trustworthy, technically qualified distributor who can provide competent after-sales service.

The full realization of this high market potential, however, will have to rely heavily on the ability of foreign exporters to provide together extensive technical information and U.S. FDA certificates for pre-market approvals, as described below.

Regulatory Environment

There are no special restrictions or tariffs that apply to used medical equipment that do not also apply to new medical equipment. Just as new products are subject to pre-market approvals, so are imports of used/refurbished equipment. Since an approval for a product is granted to a locally-based firm, the full

process of review for approval must be repeated for the same product each time a different local firm imports the product.

The Korean regulatory agency, Korea Food & Drug administration (K DFA), requires an equal amount and degree of product information for approvals for both new and used products. In practice, each used/refurbished piece of equipment is treated as a separate, re-manufactured product. As part of the process, the importer of used/refurbished equipment must submit a certificate to foreign government (CFG), which is issued by the U.S. FDA, as well as extensive technical information on the product. Most Korean distributors are aware from their experiences in working with U.S. third-party exporters that the CFG is usually available only from the U.S. manufacturer. Therefore, it is very difficult for the Korean importer who does not have a direct business relationship with the U.S. manufacturer to provide the necessary documents for approval. As a result, Korean importers of used/refurbished equipment are either local subsidiaries of the manufacturers or authorized distributors for new products of the same brands.

Korean regulations mandate additional testing requirements for used medical devices. Each piece of used/refurbished equipment must be tested by a K DFA-authorized lab not only as part of the pre-market approval process but also throughout the post-approval marketing period. (In contrast, newly manufactured equipment is required for testing by an authorized-authorized lab only for pre-market approvals.) Nonetheless, Korean importers do not view this approval process as a major import barrier since testing is normally straightforward and fees are reasonable.

In order to encourage small hospitals to share expensive equipment, regulations require hospitals to receive prior approval from the Ministry of Health and Welfare (MHW) for purchases of equipment costing over US\$500,000. Under the present system, only hospitals that specialize in radiology, have 200 beds or more, and have on-staff at least one physician specializing in diagnostic radiology can own MRI equipment. General hospitals must have 70 beds or more in their own facilities with an additional 130 beds or more in other facilities in order to share an MRI.

Used/refurbished equipment purchases by public institutions

There are no special regulations prohibiting public hospitals from purchasing pre-owned equipment. However, public hospitals do not appear to consider purchasing used/refurbished equipment, as a viable option since as non-profit organizations, there is no internal incentive to control operational costs. Another factor is the long cycle involved in obtaining budget appropriation approvals from funding authorities. Since the availability of supply of used/refurbished equipment is not known far in advance, public hospitals prefer to work with predictable cost factors and, therefore, to purchase new equipment, regardless of cost.

KUWAIT

General Market Condition: Prohibited

Source: Report from CS Post (via Cable), 29 April 2002

Kuwait's public health institutions do not buy used/refurbished medial devices. All tenders call for new devices and equipment. The public health sector represents about 90 percent of the total market, with the remaining 10 percent for the private sector. The latter does not buy used devices. Tariffs are imposed on new equipment only (currently at 4 percent of value); it will be increased to 5 percent in 2003. Used equipment will not be permitted to be imported. Used/refurbished equipment does not have a market in Kuwait.

Source: Report from CS Post (via Cable), 19 October 1998 (Information confirmed 18 March 2001)

The export market for used equipment in Kuwait is extremely limited. As a policy, the Government of Kuwait will not purchase used equipment for use in any of its ministries or para-statal companies. Since

these two categories account for approximately 90 percent of the economy, the limited potential is readily apparent.

In addition, outright prohibitions exist in Kuwait against the importation of the following:

- Used medical equipment and instruments.
- Used vehicles manufactured prior to five years from the date of importation.
- Used clothes and other items of personal wear.

KYRGYZSTAN

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 7 August 1998

The Kyrgyz Republic has the following regulations for importation of used/refurbished equipment:

Currently, there are no restrictions on the imports of used equipment to Kyrgyzstan. All equipment, whether used or new, imported into the country is treated in the same way. However, if a company intends to import used/refurbished equipment, it is strongly recommended to specify this in agreements and other documents. According to Kyrgyzstani experts, the used/refurbished equipment can be used almost in all industries, first of all in such branches as electric power, electro-technical, light and food industries as well as agriculture. Unfortunately, the National Statistical Committee does not track the market for the equipment in question.

LIBERIA

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 2 March 2002

Overview

Liberia does not have restrictions on the importation of used or refurbished medical equipment. There are no specific laws that govern the importation of used or refurbished medical equipment. Neither government nor private health institutions are discouraged from importing or purchasing used medical equipment. However, the Ministry of Health must certify drugs and other medical expendables that are imported into the country.

Used medical equipment is not treated or handled differently from new equipment with regards to custom and tariffs.

Most of the medical equipment used in Liberia at the moment is not of high technology. According to sources at the Ministry of Health in Monrovia, most medical equipment used in government hospitals is used or refurbished, donated by NGOs from the United States and Taiwan.

Private health institutions are the biggest importers and users of used and refurbished medical equipment and statistics indicate that they will remain so for the next couple of years, as most government health institutions remain closed or in derelict state.

The major types of used or refurbished medical equipment in greatest demand in both public and private health institutions include laboratory equipment, hospital beds and furniture, X-ray equipment, scanners,

surgical equipment, cardiac monitors and printers, baby incubators, pediatric weight scales, iv poles, transfusion pumps, and phaco-emulsifier machines.

Responses to Specific Questions

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

There are no special restrictions or tariffs that apply to used or new medical equipment. Neither used nor new medical equipment have special restrictions or tariffs that favor one over the other.

Can public health institutions buy used or refurbished medical devices?

Yes, public health institutions can buy used or refurbished medical devices.

Is there a market for used or refurbished devices?

Yes. As a matter of fact, used or refurbished medical equipment are imported or bought more often than new ones, primarily because of economic reasons.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

Used or refurbished medical equipment in greatest demand include laboratory equipment, hospital beds and furniture, x-ray, scanners, surgical equipment, cardiac monitors and printers, baby incubators, pediatric weight scale, i.e. poles and transfusion pumps and phaco-emulsifier machines.

Sources

Mrs. Sodey Lake, Administrator, Tubman National Institute of Medical Arts (Tnima)
Amelia Ayomanor Nursing Administrator, John F. Kennedy Medical Center
Ministry of Health, Information Section
Ndu L.Adighibe, Assistant Minister of Commerce for Foreign Trade

LUXEMBOURG

General Market Condition: No Restrictions, but CE Mark is Required

See also the entry for the European Community.

Source: Report from CS Post (via E-Mail), 15 April 2003

Are there special restrictions or tariffs that apply to used medical equipment?

There are no restrictions in Luxembourg that apply to used medical equipment other than EU restrictions that apply to new medical equipment.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subject to new safety inspections, etc.?

A third party may legally import a registered second hand medical device without being subjected to new safety inspections

Can public health institutions buy used or refurbished medical devices?

Public Health institutions may use refurbished medical devices

Is there a market for used or refurbished medical devices?

There is no important market for used medical equipment. Some private (non governmental) institutions purchased used medical devices in the past but the trend is to purchase new devices now.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

There is no important demand for used equipment.

MALAWI

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 15 October 1998

Malawi has no policy, regulations, or restrictions on the importation of used equipment, according to a representative of Malawi's Ministry of Commerce and Industry.

[This cable does not specifically address used medical equipment.]

MALAYSIA

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 29 March 2002, Updated 29 March 2005

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

Medical devices and appliances have no import duty. No duty is imposed on used medical devices or equipment.

Can public health institutions buy used or refurbished medical devices?

Government hospitals do not ban used or refurbished medical devices. However, due to safety reasons and after-sale service issues, they prefer to buy new medical devices. Moreover, it is not common for medical products distributors to sell used medical devices to public hospitals.

Is there a market for used or refurbished medical devices?

The market is very small, almost negligible.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

Not applicable.

Source: Industry Sector Analysis, Healthcare Sector Overview, 26 September 2001, Updated 29 March 2005

About 90% of medical equipment, worth about \$368 million was imported. The main exporters to Malaysia are the U.S. followed by Japan, Germany and China. All medical products are not dutiable. Public hospitals and big private hospitals are still reluctant to use refurbished medical equipment due to its safety concerns and back-up service. Moreover, the level of health care services still needs to be upgraded to satisfy the demands of an increasingly affluent and health-conscious population. A survey carried out by the Ministry of Health in 2003, indicates that the number of active medical devices used in Malaysian hospitals totaled 130,296 with an estimated cost of \$500 million. The local medical devices industry mainly concentrates on the rubber-based products such as medical gloves and catheters, and is currently the world's leading producer. Other medical devices manufactured include syringes, needles, procedural kits, and surgical and dental instruments. A growing network of suppliers operating to world-class standards supports the Malaysia's medical device industry. Their services include: sterile medical packaging, medical compounds, contract modeling and assembly, tool and die making, clean room engineering and machining engineering. The Ministry of Health, together with other regulatory agencies

is working closely with healthcare companies towards the global harmonization of regulation and certification of products. A regulatory framework for medical devices has been developed jointly by the industry and the government with implementation projected for 2006 (voluntary) and 2007 (mandatory).

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MEXICO

No Restrictions when Imported by End-User; Restricted when Imported for Resale; Public Institutions Cannot Purchase

Source: Industry Sector Analysis, Medical Equipment, 29 September 2001

Private clinics and sanatoriums usually purchase used equipment sold by large public or private hospitals. They also buy domestically refurbished equipment or refurbished equipment imported from the U.S. Few clinics and sanatoriums have budgets for purchasing new equipment.

Medium size private hospitals may purchase new or refurbished equipment depending on budget. Private medical centers mainly look for state-of-the-art equipment. They like to get financial support from manufacturers or distributors, when possible.

All private health care units select suppliers by requesting price quotations. Their decisions are based on the best equipment at the best price.

Source: Report from CS Post (via E-Mail), 17 April 2000

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

Same as specified in ISA, 1 February 1998 (*see below*). Requirements have not changed.

Can public health institutions buy used or refurbished medical devices?

No. Public institutions are not allowed to purchase used or refurbished medical equipment in Mexico.

Is there a market for used or refurbished devices?

Yes. Most small and medium hospitals in Mexico lack resources to purchase new equipment. To optimize the use of funds, they look for refurbished equipment that is in good operating conditions and have technical support available.

Best prospects?

All kinds of medical equipment, instruments and accessories have good potential in the Mexican market. Please see IMI 27 September 1999 (*see below*).

Source: IMI Medical, 10 December 1999

Summary

On October 19-21, 1999, the U.S. Commercial Service, Mexico City, held the first show in Mexico for refurbished medical equipment. The show was a complete success. All companies participating had

immediate sales or obtained serious sale leads. The show will be repeated annually. Next show will be held on October 17-19, 2000.

Body

On October 19-21, 1999, the U.S. Commercial Service, Mexico City, held the first show and seminar series in Mexico for refurbished medical equipment. In this show, 15 American companies exhibited a wide variety of medical equipment and accessories. Also as exhibitors were a custom broker, a publisher, an American trade association, and a Mexican professional association. In the seminars, several exhibitors explained the advantages of good refurbished medical equipment. The Mexican association of biomedical engineering presented the Mexican end users point of view and requirements, and a FDA officer presented the FDA policies on this matter.

During the three days of exhibition, there were 972 qualified visitors, including hospital and clinic managers, private doctors, and distributors of medical products.

Floor sales reached us \$95,000.00 and potential sales for the next 12 months are estimated in \$2.2 million. Each exhibiting company obtained an average of 50 sales leads as well as several potential agents or representatives in Mexico.

After the successful 1999 event, the U.S. Commercial Service, Mexico City has decided to annually organize an event for refurbished medical equipment. The next will be held in October 17-19, 2000.

The October 2000 event will again include parallel seminars. Plans include increasing the number of exhibitors and adding the participation of medical associations in Mexico.

This show will offer American companies the opportunity to:

- Exhibit equipment or catalogs directly to the decision makers;
- Participate in seminars to explain characteristics and benefits of their equipment and services;
- Meet personally with the purchasing managers of medium and small hospitals in Mexico willing to discuss their products and services; and
- Contact Mexican companies that are currently providing technical support to Mexican hospitals and that are available to be their technical counterpart in Mexico.

Best prospects include:

- | | |
|---|-------------------------------------|
| • All kind of equipment for gynecology | • All kind of equipment for urology |
| • Anesthesia equipment | • Bronchoscopes |
| • C-arms | • Defibrillators |
| • Developing apparatus for x-ray plates | • Duodenoscopes |
| • Electrosurgery equipment | • Endoscopy flexible apparatus |
| • Fluoroscopic equipment | • Gastrosopes |
| • Hemodialysis machines | • Hospitals beds and furniture |
| • Hydraulic and ambulance stretchers | • Imaging equipment |
| • Incubators | • Intensive therapy equipment |
| • Laparoscopy equipment | • Lithotriptors |
| • Magnetic resonance | • Patient monitors |
| • Radiant incubators | • Sterilizers |
| • Surgery instruments | • Surgery lamps |

- Surgery tables
- Ultrasounds
- Vital signs monitors
- X-rays
- Transport incubators
- Urethrosopes
- Volume and pressure ventilators

Commercial Implications For U.S. Firms

The Mexican market for refurbished medical equipment has proven to be an excellent niche for American companies that offer good quality products with technical support and warranty.

Source: IMI Medical 27, September 1999

Summary

The Mexican market for refurbished medical equipment represents an unexploited niche for American companies. Due to the economic conditions, only large and medium private hospitals can afford purchasing new equipment. Almost 85 percent private hospitals in Mexico are currently purchasing or looking to purchase refurbished medical equipment and devices.

Body

Mexico has 2,945 private medical facilities. Only 3.2 percent or 95 units are large hospitals having more than 50 beds. The remaining 96.8 percent or 2,850 medical units are small clinics and hospitals having from 5 to 49 beds.

The small and medium medical units do not have the financial resources to buy new equipment. The preferred way they have to increase their equipment inventory or to substitute obsolete equipment is through the acquisition of refurbished medical equipment that is in good conditions and has availability of service and spare parts in Mexico.

Most of the 2,850 small and medium hospitals are already importing refurbished equipment from the United States or are willing to do so.

If each of these hospitals invest at least US\$ 10,000 a year in refurbished equipment, there is a potential minimum market of US\$ 28.5 million.

There are also 105,000 Mexican doctors with private offices. They like to have their own small or portable equipment for better attention to their patients, such as ultrasound, X-ray, imaging equipment, microscopes, sterilizers, etc. If each of these doctors invest at least US\$ 500 a year in refurbished equipment and devices, the potential market would be of US\$ 75 million.

The key to this market is to offer equipment that is in good operational conditions, at a good price and offering technical support in Mexico.

Best prospects include:

- All kind of equipment for gynecology
- Anesthesia equipment
- C-arms
- Developing apparatus for x-ray plates
- Electrosurgery equipment
- Fluoroscopic equipment
- Hemodialysis machines
- Hydraulic and ambulance stretchers
- Incubators
- All kind of equipment for urology
- Bronchoscopes
- Defibrillators
- Duodenoscopes
- Endoscopy flexible apparatus
- Gastrosopes
- Hospitals beds and furniture
- Imaging equipment
- Intensive therapy equipment

- Laparoscopy equipment
- Magnetic resonance
- Radiant incubators
- Surgery instruments
- Surgery tables
- Ultrasounds
- Vital signs monitors
- X-rays
- Lithotriptors
- Patient monitors
- Sterilizers
- Surgery lamps
- Transport incubators
- Urethroscopes
- Volume and pressure ventilators

Source: ISA Medical, 1 February 1998

Refurbished Medical Equipment

This report focuses on used and refurbished medical equipment purchased by small and medium private sector users. Distribution channels are developing, as many end-users purchase directly from foreign sources. This is an emerging and a so far unexploited market that offers very good opportunities for U.S. exporters of such equipment.

Because of the market dependence upon imported equipment and a lack of economic resources, small and medium private clinics have for decades bought used medical equipment from large public and private hospitals. Public health care institutions do not buy used or refurbished medical equipment.

The high cost of medicine is also driving private doctors to install portable or small equipment in order to provide simple laboratory tests, analysis and outpatient surgery, and so help patients to avoid hospital expenses.

The main distribution channel is through those medical equipment repair firms serving specific clients. Most pieces of refurbished medical equipment are purchased and imported directly by end- users. Statistical information on the value of the imports is not available. This equipment is included either as imports of new equipment, or as scrap or products of limited value.

Some Mexican repair companies provide advice to their customers on the purchasing and importing of used or refurbished medical equipment. However, very few repair company's import directly for resale or to maintain an inventory. Mexican Government Sanitary and Customs import requirements are difficult to comply with and costly to implement. This situation does not leave the Mexican repair firms with a reasonable profit margin.

The Mexican market for refurbished medical equipment is estimated at US\$ 14 million for 1997. Ninety percent of this market is supplied by imports from the U.S. This market could grow at an annual average of 10-15 percent in the coming years if foreign suppliers offer warranties and service in Mexico. Providing financial support to end-users would also prove a very successful marketing strategy.

Best prospects include equipment for: anesthesia, hospital waste management and treatment, intensive care, laparoscopy, patient monitoring, radiotherapy, respiratory therapy, sterilization, tomography, ultrasound diagnosis, and X-ray.

While public health care institutions and large private hospitals are augmenting and modernizing facilities and equipment, they do not purchase used or refurbished equipment. However, small and medium size private hospitals do buy refurbished equipment and are improving their facilities to provide more and better services.

Best Prospects

Best sales opportunities for refurbished medical equipment include:

- Anesthesia
- Incubators
- Respiratory therapy
- Ultrasound diagnosis
- X-rays
- Defibrillators
- Intensive care
- Sterilization
- Diagnostic imaging
- Home care
- Laboratory
- Tomographers
- Ventilators
- Patient monitoring

The market for this equipment can increase if products are offered with a warranty and a service provision. Offering financial assistance will provide an excellent tool to develop the market. Those U.S. companies who do not have a representative in Mexico could try signing contracts with those Mexican companies offering medical equipment repair service in order to offer technical support to buyers of used and refurbished medical equipment. The best competitive factor to successfully penetrate the Mexican market for used and refurbished medical equipment would be offering credit to end-users. Many small private hospitals and private doctors are willing to buy equipment but lack the immediate financial capacity to do so.

Another important competitive factor is after sale service, including training and spare parts availability. Of course, quality or properly operating equipment is just as important.

Domestic production consists of imported used medical equipment used sold by large Mexican public and private hospitals and refurbished by Mexican companies for specific clients or for sale to others. This refurbishing activity is very limited. Most used equipment sold by large health care institutions is scrap, as it is usually in poor operating condition. Some refurbishing firms cannibalize equipment—taking parts for several units to complete one unit.

Some private hospitals buy used equipment from U.S. companies but hire a Mexican company to refurbish the units. Very few Mexican firms import used equipment for refurbishing and resale. The investment is too high to be profitable.

The United States is the only foreign supplier of used and refurbished medical equipment in the Mexican market. Some private hospitals and doctors that imported refurbished equipment from Europe and Asia in past years found the process of obtaining technical support or even parts for the equipment very frustrating. End users of used and refurbished medical equipment prefer suppliers with geographical proximity.

There is no official information on imports of used and refurbished medical equipment. However, it is estimated that in 1997 these imports reached US\$ 12.9 million. Most of these imports were made directly by the end users.

End users of refurbished medical equipment are small and medium private hospitals and private doctors who prefer to have small or portable equipment in their offices. Public health care institutions currently do not purchase used or refurbished medical equipment.

The recent Mexican economic crisis resulted in many small private hospitals not being able to replace obsolete equipment and acquire new units. Clinics and *sanatorios* have traditionally purchased the equipment discarded by large public and private hospitals. They also buy equipment that has been refurbished in Mexico or have directly imported refurbished equipment from the United States. Some private hospitals purchase used equipment, from domestic or U.S. sources, and hires a company to refurbish it. These clients always seek to save money while obtaining the best equipment. Very few clinics and *sanatorios* have budgets for purchasing new medical equipment.

Medium size private hospitals may purchase new or refurbished units depending on available budget, the condition of the equipment and its capabilities. However, they often will not buy refurbished units because they do not trust the condition of the equipment or a warranty or technical support is not provided.

Private medical centers [a 50+ bed hospital] do not buy refurbished equipment. They prefer state of the art units.

To be imported to Mexico, used and refurbished medical equipment and accessories have to meet legal, technical and tax requirements. These include applying for import permits with the Secretariat of Health and complying with regulations on labeling, quality standards, and certificate of origin, duties and providing after sales services to clients.

Importation of Used or Refurbished Medical Equipment for Resale

The Secretariat of Health specifies that only Mexican companies registered as medical products distributors may import used or refurbished medical equipment for resale. To be authorized, Mexican companies must comply with the following requirements:

1. Be legally established, registered and authorized as medical product distributor. Authorization from the Secretariat of health is required.
2. Designate a responsible person. This person must be a biochemical engineer or the like, with the professional background and ability to verify the equipment condition, according to specific tests.
3. Maintain a registration log that is approved by the Secretariat of Health. This log must contain all information concerning the importation of the equipment, including:
 - Name of the apparatus
 - Importation sanitary permit number
 - Operation tests applied
 - Invoice number
 - Warranty and services provided to end user
 - Brand name
 - Date of import
 - Name of importer
 - Sale or lease date
4. Present a document proving the sterilization system used, if applicable.
5. Present the equipment invoice specifying that the equipment is used or refurbished and that it is in operating condition. If the equipment or the apparatus is to be dismantled to obtain parts, it must be so specified in the invoice.
6. Offer warranty and technical services to customers.
7. Present the FDA export certification.
8. Comply with the Mexican standards for specific equipment such as X-rays, infrared rays, etc.

Importation of Used or Refurbished Medical Equipment by the End User.

When the used or refurbished medical equipment is imported into Mexico by the end user (hospital, private doctor), there are no barriers. The only requirement is to obtain an import permit from the Secretariat of Health and present the invoice specifying that the product is imported, specifying if the equipment is used or refurbished and that it is for private use and not for resale.

As there are no third persons involved, the importer is responsible for the operation and use of the equipment. The importer will also need to request directly from the supplier, a warranty or the technical support, if offered by the seller.

Equipment Registration with the Secretariat of Health

Used and refurbished medical equipment does not need to be registered with the Mexican Secretariat of Health.

Labeling for Imports

On January 16, 1997, the Mexican Official Gazette published for comments, NOM-137-SSA1-1995, which will regulate the labeling of health care products, diagnostic agents and medical equipment whether domestically manufactured or imported, including used and refurbished equipment. This NOM is still in the process of being approved.

- According to this standard, the label should contain:
- Product name (trademark or commercial name brand of the product).
- Name or business name and address of the manufacturer.
- Name or business name and address of the importer.
- Country of origin.
- Sanitary registration number or letter specifying that registration is not required.
- Expiration date or date of recommended consumption or use.
- Lot or serial number.
- Net contents (as specified in NOM-030-SCFI-1993).
- Warnings or precautions on hazardous products.
- Use, handling, and care instructions, when they are not obvious. If required, instructions must be attached. In these cases the label must specify-See attached instructions.
- According to the consumers' law, the medical equipment label or instructions must specify the location of the repairs, and include instructions or manual and warranty.
- For sterile products specify-sterility will not be granted if the original package is broken.
- Legend specifying that the product is free of toxins or pyroxenes, when applicable.
- Specification for disposable products, when applicable. Information required in points 3, 5, 9, 10, 11, 12, 13 and 14 may be attached to the products after the importation custom process, but before selling the product to the public. For bulk products, information is only required in the bulk container.

These requirements do not apply to:

- Highly specialized medical equipment.
- Medical equipment to be used in commercial, industrial or service areas.
- Medical equipment imported by persons or institutions for their own use.
- Medical equipment imported by educational or scientific institutions.
- Samples of health care products or diagnostic agents imported to be used exclusively for the certification process to comply with Mexican standards.
- Other medical equipment that because of size or nature cannot bear a label, or when the label size is not adequate to contain the information required. In such cases the Secretariat of Health will determine the course of action.

- Other medical equipment, health care products or diagnostic agents determined by the Secretariat of Health.

This information must be on products prepared for retail sale. Listing this information on the container in which a product is packed for shipment will not satisfy the labeling requirement. The above-mentioned requirements also comply with the labeling standard NOM-050-SCFI.

There are few Mexican standards for medical equipment and accessories, but various agencies are preparing more standards to be issued in the near future. As of January 1998, Official Standards for medical equipment are:

- NOM-001-SCFI-1993 for ultraviolet & infrared ray apparatus published in the Official Gazette, October 13, 1993.
- NOM-003-SCFI-1993 for electric massage apparatus, published in the Official Gazette, October 13, 1993.
- NOM-157-SSA1-1996, for protection and security measures for the use of diagnostic X-ray equipment, published in the Official Gazette, September 29, 1997.
- NOM-158-SSA1-1996, for technical specifications for X-ray medical equipment, published in the Official Gazette, October 20, 1997.

The December 28, 1995 decree provides a list of products by Mexican tariff number, which are subject to NOMs. A clarification and update of this list was published on June 28, 1996, but that list is not all-inclusive. All NOMs apply the same for new and used or refurbished pieces.

For information on the NOM certification process, please consult the Industry Sub-sector Analysis (ISA) on the Process of Standardization and Certification in Mexico, by Jesus Gonzalez, September 1996, and available on the National Trade Data Bank.

Certificate of Origin

The basic Mexican import document is the *pedimiento de importación*. A commercial invoice must accompany this document (in Spanish), a bill of lading, and documents demonstrating guarantee of payment of additional duties for undervalued goods (see 'Customs Valuation') if applicable, and documents demonstrating compliance with Mexican product safety and performance regulations (see 'Standards'), if applicable. The import documentation should either be prepared or submitted by a licensed Mexican customs broker, or by a person with customs experience.

Products qualifying as North American must use the NAFTA Certificate of Origin in order to receive preferential treatment. This may be issued by the exporter or broker and does not have to be validated or formalized. Certificate of Origin information is available on the NAFTA Facts in documents 5000-5003 at telephone number (202) 482-4464. Government agencies, producers, exporters, or industrial and commercial chambers of commerce or associations that are legally authorized in the U.S. or other countries may issue the Certificate of Origin.

Mexican customs law is very strict regarding proper submission and preparation of customs documentation. Errors in paperwork can result in fines and even confiscation of merchandise as contraband.

Import Fees

Used or refurbished medical equipment pays the same import duties as new units. The following 52 products, classified under the harmonized system, are listed. Under NAFTA, starting in January 1998, 50 of these codes are duty free for American products, against 10 to 20 percent ad-valorem duty for third country products. (*See table on next page.*)

Mexico Tariff Schedule

Harmonized Numbers Schedule	Current Import Duties Other/USA	Product	NAFTA Tariff Reductions
9011.1001	10/0	Microscopes for surgery	B
9011.1099	20/0	Other microscopes	B
9011.2099	20/0	Microscopes for Micro projection	B
9011.8099	20/0	Other microscopes	B
9011.9001	10/0	Microscope accessories	B
9012.1001	10/0	Diffraction apparatus	A
9012.9001	10/0	Accessories for diffraction apparatus	A
9013.2001	10/0	Lasers, other than laser diode	A
9018.1101	10/0	Electrocardiographs	A
9018.1201	15/0	Ultrasound diagnostic apparatus	A
9018.1301	10/0	Magnetic resonance imaging apparatus	A
9018.1401	10/0	Nuclear medicine diagnostic apparatus	A
9018.1901	10/0	Tonometers and retinoscopes	A
9018.1902	10/0	Electro-encephalographers	A
9018.1904	10/0	Diathermy apparatus, short-wave	A
9018.1905	15/0	Patient monitoring equipment	A
9018.1906	0/0	Audiometers	FREE
9018.1907	10/0	Cardioscope	A
9018.1908	10/0	Gamma ray apparatus	A
9018.1909	15/0	Incubators	A
9018.1910	10/0	Electro-surgical apparatus	A
9018.1911	10/0	Dermatomere	A
9018.1912	10/0	Defibrillator and surgical appliances	A
9018.1913	10/0	Electro-ejaculators	A
9018.1999	10/0	Other medical apparatus	A
9018.2001	10/0	Ultraviolet and infrared ray apparatus	A
9018.9004	15/0	Anesthetic apparatus	A
9018.9005	15/0	Equipment for cephalorachidian liquid control	B
9018.9014	10/0	Pleural suction pumps	B
9018.9015	20/0	Suction apparatus	A
9018.9020	10/0	Actinotherapy apparatus	A
9018.9022	10/0	Accessories for anesthetic apparatus	A
9018.9025	10/0	Electronic detectors of pregnancy	B
9018.9026	10/0	Modular circuits for electronic detectors of pregnancy	B
9019.1001	10/0	Hydrotherapy and mechano-therapy appliances	A
9019.1002	15/0	Massage apparatus	A
9019.1003	10/0	Accessories for therapy appliances	A

Harmonized Numbers Schedule	Current Import Duties Other/USA	Product	NAFTA Tariff Reductions
9019.1099	10/0	Other therapy apparatus and accessories	A
9019.2001	10/0	Respiration therapy apparatus	A
9021.1904	10/0	Appliances for fracture treatment	A
9021.2199	10/0	Other accessories	A
9021.5001	10/0	Pacemakers for stimulating heart muscles	A
9021.9099	10/0	Other orthopedic appliances	A
9022.1201	10/6	Tomography equipment	C
9022.1401	10/0	X-ray equipment	A
9022.1499	10/0	Other radiation equipment	A
9022.2101	10/0	Cobalt pumps	A
9022.2199	10/6	Other radiation apparatus	C
9022.2901	10/0	Calibrators beta	A
9022.3001	10/0	X-ray tubes	A
9022.9003	10/0	Accessories for X-ray apparatus	A
9022.9099	10/0	Other parts or accessories for X-ray apparatus	A

B: Full duty elimination occurred on January 1, 1998.

C: Duties shall be removed in 10 equal stages of 10 percent of the NAFTA base rate. This reduction began on January 1, 1994, with full duty elimination on January 1, 2003.

The Import Duty is calculated on the U.S. plant value (invoice) of the product(s) plus the inland U.S. freight charges to the border and any other costs listed separately on the invoice and paid by the importer such as export packing. In addition, a customs processing fee (CPF) of 0.8 percent is assessed on the total of the selling price of the product, inland freight cost, other fees (export packaging), plus duty paid and the custom broker fee, if this service is employed.

According to recent modifications in the Mexican customs law, the participation of a customs broker is not obligatory for imports if all legal and technical requirements are met. The participation of a customs broker is suggested when the exporter is not familiar with the Mexican standards and customs processing procedures.

A 15 percent value-added tax (VAT) is then assessed on the cumulative value consisting of the U.S. plant value (invoice) of the product(s), plus the inland U.S. freight charges, any other costs listed separately on the invoice such as export packing plus the duty. The importer will pay other VAT fees for such services as the inland Mexico freight and warehousing. The VAT is recovered at the point of sale.

Distribution/Business Practices

The distribution of refurbished medical equipment in Mexico is not developed. Most end users import equipment directly into Mexico, for their personal or institutional use.

Very few companies are legally registered with the Secretariat of Health to sell or distribute imported refurbished medical equipment. Companies involved in this business are mainly those offering repair service and equipment for lease. These firms advise end users on the equipment to buy. The end user negotiates the price and warranty with the foreign supplier. The equipment is imported by the end user and the Mexican company offers maintenance and repair service.

Sometimes, Mexican repair companies arrange with foreign suppliers to provide repair service to the end user as part of the equipment purchase contract.

Few repair companies have a product display area or stock equipment for immediate delivery. Only companies offering equipment for lease carry an inventory. It is common for leasing companies to offer a purchase option.

There are many American companies already selling refurbished medical equipment to Mexican hospitals. However, none of them have branch offices or exclusive representatives in Mexico. Many repair companies and distributors of new equipment sell only one or two medical equipment lines. Others include the selling of instruments or supplies.

Service

Service is one of the most important competitive factors for used and refurbished medical equipment. Most hospitals prefer to have permanent maintenance services and repairs accomplished within 24 hours. This means that spare parts and trained technicians must be available to respond adequately to client requirements.

It is important that new-to-market firms make a careful selection of a repair firm to represent the US firm and be sure that the Mexican company has the capability to provide timely and quality service.

Large distributors of new equipment usually have nationwide coverage; technical departments, a strong sales force and a solid financial background, but do not like to sell refurbished equipment.

MOLDOVA

General Market Condition: Restricted

Source: Report from CS Post (via E-Mail), 5 April 2001

According to the Ministry of Health and Customs Department, there are no restrictions for import [*but see conditions listed below*] and sale of used/refurbished medical equipment. Imports of used equipment are treated the same as new. Duties are charged based on the cost of the product. Documentary evidence of cost is preferred.

Generally speaking, three types of taxes are paid on all imports of medical equipment:

- Tax on customs procedures which typically constitutes 0.25 percent of the value of shipment;
- 20-percent value added tax;
- customs tariff tax, which is 0 percent for most medical equipment.

Donated medical equipment is exempted from any customs duties.

The decision to allow certain medical equipment into the country is made on a case-by-case basis. The adequacy of any medical equipment brought into Moldova is assessed against an internal regulation of the Ministry of Health dealing with donated medical equipment. As a rule, the Ministry will allow into the country equipment less than ten years old (from the date of manufacture). The regulation sets the following requirements for medical equipment:

- It should be accompanied by documents certifying the origin, quality, name and type of item, name of producer, date of manufacture, date of installation, name of the institution that has been using the equipment, date of de-installation, whether or not the equipment is operational, technical specifications and warranty period;
- Any container should be accompanied by a document containing information on the number of packages, size, and weight;

- Information has to be provided for each package concerning the name and type of the item, manufacturer, number of items in the package, date of packaging;
- The cost of equipment has to be similar to the country of export or world level;
- Proper operational guides must be provided.

The market for used/refurbished equipment in Moldova is extremely limited. However, Moldovan public health institutions use some small amounts of used equipment, which has been donated by institutions and individuals from overseas, including the United States. Although prices for used/refurbished equipment tend to be significantly smaller than those for brand new equipment, the paying ability of Moldovan public health providers is still very small. Private health institutions are few and account for only a small portion of the health services market. Most purchases made by public health institutions are made through public tenders.

Few medical equipment distributors exist in Moldova. The state-owned company Moldtehoptimed is the most important provider of medical equipment. Separate licenses, which are issued by the Ministry of Health, are required for each of the following activities:

- Dealing in medical equipment and
- Importation of medical equipment.

MOROCCO

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 21 April 2003

Summary

Approximately 20 percent of the total imported medical equipment is used or reconditioned. It consists of heavy equipment such as X-ray machines, magnetic resonance imaging apparatus, ultrasonic scanning apparatus, patient monitoring systems (except medical equipment that require direct contact with internal organs), surgery equipment and operating tables, sterilization equipment, and bedding (except mattresses). This equipment is used by private hospitals, known as “clinics,” private specialty hospitals known as “centers,” such as radiology centers, cardiology centers, dialysis centers, and private testing laboratories. Reconditioned equipment with guarantees offers excellent opportunities.

Public Sector

Under the Moroccan regulations, the public sector is required to purchase medical equipment through tenders. Although no law forbids purchase of used equipment, tender documents often require procurement of new equipment. Three government entities provide healthcare and purchase medical equipment. These are the Ministry of Health (*Ministère de la Santé*), the National Social Security (*Caisse Nationale de Sécurité Sociale—CNSS*), and the Ministry of Defense (*Ministère de la Défense*). They respectively provide healthcare through “hospitals,” “polyclinics” and “military hospitals,” and they have independent budget and complete autonomy in purchasing medical equipment.

Regulatory Agency

The Ministry of Health is the government agency in charge of the Moroccan healthcare system.

Regulations

Under the Moroccan law 005/71 of October 12, 1971, on Protection against Ionization, import into Morocco of new or used radiology equipment requires a special authorization from the Center of Protection against Radiation of the Ministry of Public Health.

For used equipment, U.S. exporters must provide Moroccan buyers with the following:

- Compliance certificate
- FDA authorization
- Technical documentation/directions for use of the product
- Certification that the equipment is in good Electro-technical and radiological working order
- Documentation/history on previous maintenance.

When a manufacturer or its agent has registered a medical device in Morocco, a third party cannot legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections. For any piece of used/refurbished medical equipment that enters the country, the third party, as did the manufacturer or its agent, must provide the same as above, namely:

- Compliance certificate
- FDA authorization
- Technical documentation/directions for use of the product
- Certification that the equipment is in good electro-technical and radiological working order
- Documentation/history on previous maintenance

Import Documentation

Medical equipment and device other than radiation equipment requires approval from the Ministry of Health that the equipment meets Moroccan health standards. Morocco recognizes certifications provided by the FDA.

A commercial invoice is required. The commercial invoice should fully describe the goods in French. Certification as to country of origin is required. Payments are made through bank-to-bank irrevocable letters of credit. Pro-forma invoices must be provided in most cases. Invoices, which should be on company letterhead, are required for both import licenses and foreign exchange transfers. "To order" bills are acceptable as bills of lading.

Labeling Requirements

No special regulations apply to the exterior marking of containers for shipments to Morocco. Indication on outer containers of the net weight in kilograms, and other identification markings, will however assist in locating goods on arrival and speed their clearance through customs.

Import duties and taxes

There are no restrictions or tariffs that apply to used or reconditioned medical equipment. New or used medical equipment is subject to 2.5 percent import duties paid on ad valorem. There is a value-added tax of 20 percent paid on the compounded ad valorem and import duties.

Standards

Morocco uses the metric system exclusively and the 220 Voltage. Dates should have the date format dd/mm/yy. Literature in the French language is recommended.

Distribution

Foreign firms sell into the Moroccan market through distributors/agents. Agents/distributors are often necessary to assist the U.S. firm with documentation in the French language. Key to success in the used medical equipment sector lay in the technical support and warranty given to end-users of reconditioned medical equipment.

MOZAMBIQUE

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 5 April 2001 (Information confirmed 20 February 2002)

Regarding special restrictions or tariffs applied to used equipment, the Mozambican Customs Authority does not levy any restrictions. Used imported medical equipment is treated as new, and is liable for duties stated in the harmonized tariff in force.

Public health institutions can purchase used or refurbished medical equipment provided that it is in good condition. Maputo has sixteen private clinics and several hospitals that may be interested in used or refurbished medical equipment at affordable prices.

Source: Report from CS Post (via Cable), 31 March 2000 (Information confirmed 20 February 2002)

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

No, the Mozambican customs office does not apply any restrictions or tariffs to the importation of used medical equipment, although such products are liable to normal duties stated in the harmonized tariff schedule.

Can public health institutions buy used or refurbished medical devices?

Yes, they can purchase used or refurbished medical devices, provided they are in good condition.

Is there a market for used or refurbished devices?

Perhaps, although only at a low volume in a very limited number of institutions. Maputo has sixteen private the clinics that may be interested in used or refurbished medical equipment if offered at affordable prices.

NEPAL

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 16 April 2003

Are there special restrictions or tariffs that apply to used-medical equipment that do not apply to new medical equipment?

The government of Nepal requires no licensing of medical equipment and imposes no specific restrictions on used medical equipment. Tariff rates for medical equipment, as per the Harmonized Tariff Schedule of Nepal, range from 5 to 10 percent. On top of the tariff, an importer is required to pay 10 percent Value Added Tax (VAT) and 1.5 percent Local Development Tax on the gross value of the equipment (invoice value + tariff).

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc.?

No specific license or registration is required for importing used or new medical equipment. Private nursing home/hospitals importing equipment must attach a copy of their corporate registration certificate for getting foreign currency approval from the Nepal Rastra Bank (Nepal's central bank) and customs

clearance of the consignment. Private traders, who deal in such equipment, need to show their general export/import license.

Can public health institutions buy used or refurbished medical devices?

Public health institutions are free to import used and refurbished medical devices to meet their needs. However, none of the public health institutions contacted by the Embassy have done so—the used equipment they receive has been donated.

Is there a market for used or refurbished medical devices?

No market survey is readily available regarding new or used medical equipment. However, the Embassy assesses that there is a potential market for high-value used medical equipment--devices like X-ray machines and ultrasound machines, which are relatively inexpensive, are normally imported brand new.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

Products like CT Scan and MRI may have some demand in the Nepalese market.

Government of Nepal Contact

Secretary, Mahendra Nath Aryal
Ministry of Health
His Majesty's Government of Nepal Ram Shah Path
Kathmandu, Nepal
Tel: +977-1-426-2590
Fax: +977-1-426-2706

NETHERLANDS

General Market Condition: No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from CS Post (via e-mail), 25 April 2003

Are there special import duties or restrictions on used medical equipment that don't apply to new medical equipment?

No. The Netherlands has no import restrictions specifically applicable to the importation of used equipment. Imports of used equipment are treated in the same way as new products.

If a manufacturer or its agent has registered a medical device in the Netherlands, can a third party legally import the same device in used or refurbished condition without the used device being subject to new safety inspections?

Because sales of used equipment in the Netherlands need to be approved by the original manufacturer, the device should not be subject to new safety inspections. Most used equipment imported into the Netherlands is not sold here but is refurbished and exported to developing countries.

Can Dutch public health institutions buy used or refurbished medical devices?

Yes.

Is there a market for used or refurbished medical devices?

The market for used and refurbished equipment plays a minor role in the Dutch economy. A relatively high standard of living combined with government incentives and tax deductions stimulate the purchase of new as opposed to used equipment. Equipment in the Netherlands is usually replaced long before its technical value has expired. In the respect, the Netherlands exports significant quantities of use equipment

itself. Refurbished medical equipment is one area where there is potential for U.S. suppliers. Budget cuts and the necessity to save money on large capital outlays are forcing Dutch hospitals to consider purchasing refurbished equipment. However, there is still resistance to buying used medical equipment within the sector. The Dutch manufacturer Philips Medical System now offers a line of refurbished Philips diagnostic equipment under the name *Philips Select*.

NEW ZEALAND

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 2 May 2000

New Zealand's current legislation controlling the manufacture, import and distribution of medical devices (including used medical devices) is expected to change when the New Zealand and Australian Governments finalize their discussions on a joint therapeutic goods regulatory body. The discussions are still at a preliminary stage, but once the consulting process is completed and both the Australian and New Zealand Governments pass new legislation, no medical device will be accepted into New Zealand unless it is recorded on the joint register. There will be various criteria for a device to be accepted on the register. It is expected the proposed joint regulatory body will be operative in 1-2 year's time.

Under the existing regulation, it is possible to import medical devices into New Zealand (provided they meet internationally-recognized standards) with very little Government intervention. The existing legislation does not require medical devices to be registered. The market relies on compliance by importers and manufacturers to established standards that is enforced by post-market surveillance. Medsafe is the Government agency that oversees the post-market surveillance.

Though existing legislation makes it possible to import used medical equipment into New Zealand Medsafe could intervene if it had concerns over the safety of used equipment. As a result and in view of this country's medical device legislation soon changing, medical device companies looking to do business in New Zealand should contact Medsafe first before entering this marketplace. The business contact details are:

Trevor Nisbet
Senior Adviser (Science)
Medsafe
Public Health Directorate
Ministry of Health
PO Box 5013
Wellington
New Zealand

Tel: +64 -4- 496-2364
Fax: +64-4- 496-2599
Web site: www.moh.govt.nz
E-mail: trevor_nisbet@moh.govt.nz

NICARAGUA

General Market Condition: No Restrictions, but Ministry of Health Does Not Buy

Source: Report from CS Post (via Cable), 27 March 2000

According to the Nicaraguan Customs Department and Ministry of Health, there are no restrictions for the importation of new, used and/or refurbished medical equipment into Nicaragua. New, used and/or refurbished medical equipment have a zero percent tariff.

The Nicaraguan Ministry of Health only purchases new equipment. Local clinics and private hospital do purchase used or refurbished medical equipment.

Our assessment is that there is a market for used or refurbished equipment.

Best prospects include intensive care, surgical, laboratory and X-ray equipment.

Import of medical equipment from the U.S. into Nicaragua over the past three years is estimated at \$8.3 million for 1997, \$8.8 million for 1998 and \$10.0 million in 1999.

NIGER

Source: Report from CS Post (via Cable), 18 March 2005

Subject: Niger: Import Regulations For Used Medical Equipment

REF: USDOC 00292

Summary

To date the Nigerien government has not passed legislation distinguishing between the imports of new, used or refurbished medical equipment. Existing legislation is in the process of being revised and will probably be issued by the end of the year 2005. The market for used or refurbished medical equipment is very limited. In Niger the biggest purchaser of medical devices is certainly the Government of Niger (GON) because most hospitals in Niger are government owned. Important impediments to the sale of used/refurbished medical equipment remain due to public procurement procedures and also to technical constraints concerning the norms and standards. For medical equipment suppliers, the GON usually imposes French medical equipment standards. For example, electrical plugs must be 220V and the equipment must be able to accept this type of voltage. Post answers to questions in reftel are listed below. END SUMMARY.

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

Niger has no special restrictions or tariffs that apply to used or refurbished equipment that do not apply to new equipment. There is no import tax on medical equipment and most-medical devices are exempted from Value Added Tax (VAT).

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc?

Medical equipment does not need to be registered with local authorities. Present Nigerien legislation lacks any mention of medical equipment registration.

Can public health institutions buy used or refurbished medical devices?

Public health institutions do not buy used or refurbished medical devices. Under current legislation, they are bound to purchase only new medical equipment.

The Market for Used or Refurbished Medical Devices in Niger.

There is a market for used or refurbished medical devices. Private clinics, with limited resources, are free to purchase used or refurbished equipment.

Are single – use devices being reprocessed and sold on the local market? If so, is this activity regulated? Please provide any details.

Under current legislation, reprocessed single-use devices cannot be used or sold on the local market.

Further Information Can Be Obtained From:

Monsieur Maman Elhadj Maty

Directeur de la Pharmacie, des Laboratoires et de la Pharmacopée Traditionnelle

Ministère de la Santé Publique et de la Lutte contre les Endémies

Tel: +227 72 2665 or 20 3236

Fax: +227 73 3570

NIGERIA

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 2 May 2000

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

No.

Can public health institutions buy used or refurbished medical devices?

Yes.

Is there a market for used or refurbished devices?

Yes.

Best prospects?

Scanners, diagnostic equipment, medical disposables and ECG equipment.

Source: IMI Medical, 9 March 2000

Summary

Nigeria still depends on imports for most of its medical equipment needs. Local production is limited to peripheral items such as hospital beds and gurneys.

The Nigerian year 2000 budget is yet to be released, therefore this report is hinged on projections for 1999, which to the best of our knowledge is still very relevant. The Government of Nigeria will spend an estimated US\$ 125 million on hospital equipment this fiscal year. It also restated its commitment to the resuscitation of the nation's health care delivery system through systematic funding and mobilization in line with the Bamako Initiative Program, a series of reforms in response to the deterioration of public health systems in developing countries. As in the previous years, private sector participation continues to account for much of Nigeria's imports in 1998, valued at approximately US\$ 400 million.

The 1998 - 2000 national rolling plan objectives also include the completion of teaching hospital projects at Ahmadu Bello University, Zaria, University of Nigeria, Nsukka, and Ado Bayero University, Kano, rehabilitation of Ibadan University teaching hospital and equipment of several medical health centers and primary health care centers.

There is no doubt that the political situation and the resultant economic crunch had some negative effects on imports. However, with the change in government and possible political and economic reforms, this

sector promises strong growth rates with an increasing demand for equipment such as analytical and examination instruments, ultra sound scans, anesthesia equipment, mortuary and laboratory equipment.

Nigeria's health policy is centered on primary health care delivered through an estimated 15,500 health institutions. The caption 'Health For All By The Year 2000', still remains the cornerstone of the Nigerian health care sector and therefore health care delivery is still high on the Nigerian government priority list. The World Bank funds a number of projects under different loan agreements, especially for the rural areas.

The purchasing power of most Nigerian end-users is waning owing to devaluation of the national currency, and the widening gap between new technologies and developing economies. Refurbished and used equipment are therefore in high demand. A significant segment of this market in Nigeria is dominated by imports from Europe. However, U.S. Suppliers stand a good chance of competing successfully because Nigerians like U.S. equipment.

For further details, interested U.S. firms should contact the Commercial Service at the U.S. Embassy, Lagos, at the mailing address below:

The Commercial Service
U.S. Embassy, Lagos
Department Of State
Washington, DC 20521-8300

Tel: +234-1-2610241

Fax: +234-1-2619856

Source: Report from CS Post (via Cable), 2 October 1998

There are no regulations for importation of used equipment in Nigeria. Official guidelines relating to import duties use of letter of credit for payment of imports and containerization of imports valued more than US\$ 1,000 apply to both used and new equipment.

Import duties on used equipment are the same as for new. Duties are determined by the Nigerian customs service based on the invoiced value of equipment and an import duty report (IDR) issued by a government-appointed inspection agent.

Like several other imports, used equipment is often imported into Nigeria overland through third countries and ports, and as accompanied luggage of air travelers. Currently Nigeria's market for used equipment is dominated by imports from Germany, the Netherlands, Belgium, and the United Kingdom.

Price is the single most important driver of imports in this sector of the Nigerian market. Several local firms interested in used U.S.-origin equipment and parts including vehicles complain of high cost of importation from the United States, which according to them often results in an uncompetitive pricing strategy. Nigeria is a growth market for U.S.-origin products and services, but requires patience, resilience, a long-term relationship with a local partner (not a customer) and an export-cost strategy that recognizes Nigeria's large population but low per-capita income.

NORWAY

General Market Condition: No Restrictions, but CE Mark is Required

See also the entry for the European Community.

Source: Report from CS Post (via E-Mail), 14 April 2003

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No, there are no special restrictions or tariffs that apply to used medical equipment. The same rule applies to both new and used medical equipment. In general, Norway follows EU and European Economic Area (EEA) directives. Norway requires the CE mark on all medical equipment, used or new.

Concerning registration of companies and their devices, Norway has chosen to go a little further nationally than what is strictly required by the EU directives. Obligation to register with the Norwegian Register for Medical Devices, Manufacturers and Distributors is incumbent upon all companies manufacturing or trading with medical devices, and with a business address in Norway. A company may be a manufacturer, a manufacturer's authorized representative in the EEA, a sole distributor, a distributor, or a combination thereof. The national authority overseeing this register is the Norwegian Directorate for Health and Social Affairs.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc.?

No, the third party must still register the product and the company with the Norwegian Register for Medical Devices, Manufacturers and Distributors and the product must still carry the CE mark.

Can public health institutions buy used or refurbished medical devices?

Yes, they are allowed to buy used or refurbished medical equipment as long as the products comply with current regulations, but so far there has been no indication that they are interested in doing so.

Is there a market for used or refurbished medical devices?

According to Norwegian government, procurement and trade association sources there has not been a market for used or refurbished medical equipment. When replacing outdated medical equipment the public health institutions prefer to purchase new equipment.

If there is a market, what types of used or refurbished medical equipment are in greatest demand?

Not applicable.

OMAN

General Market Condition: No Restrictions, but Ministry of Health Does Not Buy

Source: Report from CS Post (via Cable), 29 March 2000 (Updated and Corrected by CS Post (via Cable), 2 April 2001)

The Ministry of Health is the main buyer of medical equipment in Oman. As a matter of practice, the Ministry of Health does not purchase used or refurbished medical equipment. Normally, when the ministry decides to purchase equipment, it contacts regular suppliers and requests the latest equipment; in some cases such purchases are conducted through tenders. Generally, equipment is purchased along with a minimum five-year maintenance contract.

Post does not know of any special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment.

Given the Ministry of Health's practice of purchasing new equipment only, prospects for sales of used and refurbished medical equipment in Oman remains extremely limited. It is possible that private hospitals and clinics could be potential purchasers of used medical equipment since their procurement does not go through the Ministry of Health. However, at this time, there are only two private hospitals in Oman.

PAKISTAN

General Market Condition: Restricted

Source: Report from CS Post (via E-Mail), 6 April 2001

Pakistan offers a promising market for used or reconditioned medical equipment and devices such as diagnostic equipment, electro-medical apparatus and laboratory equipment. Demand is expected to grow at an accelerated rate for items such as dialysis machines, diagnostic equipment, electro-cardiographs, scanners and X-ray apparatus.

In recent years, thousands of new medical centers have been set up all over the country. The majority of these private centers/clinics are run by reputable medical professionals. The increasing involvement of the private sector in health facilities is a positive development for U.S. suppliers of used medical equipment to consider marketing their products in Pakistan.

Under the import policy for 1999-2000, customs duty and sales tax on used medical equipment are as follows:

Summary of Import Policy Order, 1999-2000 For Used Medical Equipment

HS Code	Description of Goods	Relevant Rules Under Import Policy Order 1999-2000
9018.1 to 9018.19	Second hand or used surgical equipment like dialysis machines and electro-medical equipment	Import shall be allowed subject to the condition that these are not more than five years old.
9018.13	Second-hand/used diagnostic equipment	Import of this equipment shall be allowed if importer arranges for the foreign exchange resources.
9018.19	Testing equipment/analytical	
9024	Equipment including CT scanner	
9026	MRI equipment, etc.	
9027	Instruments for physical and chemical analysis	
9030	Instruments for measuring and testing electricity and electrical signals	
9031	Other measuring and checking instruments	

Customs and Sales Tax

Customs duty and sales tax on imported used medical equipment is as follows:

Customs Duty and Sales Tax on Imported Used Medical Equipment

HS Code	Description Of Goods	Customs Duty (ad valorem)	Sales Tax on Imports
9018.1100	Electro-cardiographs	10%	15%
9018.1200	Ultrasonic scanning apparatus	10%	15%
9018.3100	Syringes with or without needles	25%	15%
9018.9070	Cine angiography film equipment	10%	15%
9022	Apparatus based on the use of X-rays	15%	15%

Customs Duty and Tax Exemptions on the Items Imported by Non-Profit Institutions

Below is a list of used medical equipment that, if imported by a charitable non-profit institution or by a hospital run by the Federal or provincial government, is exempt from customs duty and sales tax:

Used Medical Equipment Exempt from Customs Duty and Sales Tax if Imported by Charitable, Non-Profit Institutions or Hospitals Run by the Federal or Provincial Government

HS Code	Description of Goods
9018.11	Electrocardiographs
9018.12	Ultrasonic scanning apparatus
9018.13	Magnetic resonance imaging apparatus
9018.14	Scintigraphic apparatus
9018.19	ETT machine, Echocardiography, Electro-cenephlograph, Radio-isotope scanners,
9018.90	Angioplasty balloon, Cardiac catheters, Endoscopy equipment
9018.80	Dialysis equipment
9018	Medical instruments

Source: ISA Medical, 1 March 1998

Public sector hospitals procure medical equipment through tenders whereas private hospitals obtain these through distributors and suppliers who can ensure quality, technical services, and backup supplies. U.S. manufacturers benefit by appointing agents in Pakistan's major cities to market their superior quality products. Used/reconditioned equipment is often preferred as the private sector is price-driven. Import duties and sales tax were reduced in 1997.

Private sector health care is a significant factor in the market as more private hospitals are being established, generating a demand for imported equipment. Local or expatriate Pakistani doctors set up most private hospitals and clinics as commercial ventures. Most of these end-users seek either used or reconditioned equipment or, if new, they source it from the cheapest supplier.

The equipment listed above is imported either new or used. Generally, the following considerations are taken into account by end users when deciding between new or used machinery/equipment:

- Size—When the end user is a large hospital/organization, the preference is for new machinery/equipment.
- Value—When high value machinery is imported, and there is an appreciable difference in the price of new and used items, the preference is for used items, e.g. magnetic resonance imaging system, computerized tomography scanners.
- Basic Use Items—When the machinery/equipment to be imported is basic, involving simple technology, the preference is to import new items, e.g. ultra sound scanners, ophthalmic appliances.

Source: ISA Laboratory, 1 October 1998

Most laboratory and analytical equipment is being imported—either new, used or in reconditioned form. The general criteria for importing new machinery are low prices and appropriate technology. For example, basic items are imported new; the relatively expensive items are imported both in new and used forms. Larger hospitals generally prefer new items even if they are expensive, but the smaller laboratories or individual doctors prefer used items.

PANAMA

Market Condition: No Restrictions, but Public Institutions Cannot Buy

Source: Report from CS Post (via Cable), 6 March 2000; Updated 3 May 2005

Import Regulations for Used Medical Equipment

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc.?

Panama does not have a medical equipment registration system. In the public sector, major purchases of equipment are subject to technical approval by ad hoc committees that are appointed on a case-by-case basis. There are no restrictions for importing used/refurbished equipment for private sector use.

Can public health institutions buy used or refurbished medical devices?

No. By law, public institutions can only buy new equipment.

Is there a market for used or refurbished medical devices?

There are some market opportunities for used/refurbished medical equipment, especially in small hospitals and private hospitals in Panama City and the interior of the country.

If there is a market, what types of used or refurbished medical devices are in the greatest demand?

Best prospects are: diagnosis equipment, imaging equipment, and home care equipment.

Are single-use devices being reprocessed and sold on the local market? If so, is this activity regulated? Please provide any details.

No.

Source: Report from Post (via E-Mail), 25 April 2003

Regulatory Agency

The Ministry of Health manages the health care system in Panama. Along with the Social Security System, it is responsible for procuring all of the medical equipment in the public sector. Private hospitals and clinics are the other major buyers of medical equipment in Panama.

Regulations

There are no local additional regulations, technical or safety standards. Both U.S. and European standards are accepted in Panama. There is a requirement however, to provide Spanish language labeling. Labels may be multi-lingual (e.g., in English and Spanish), but Spanish is required.

Import Duties and Taxes

In 1998 import duties for medical equipment were lowered to 10 percent, from the previous levels of 35 percent and 27.5 percent. Import duties in Panama are assessed on the CIF value. Additionally, a 5-percent value added tax is charged on the aggregate of the CIF value plus the import duty.

Used Equipment

There are some market opportunities for used/refurbished medical equipment, especially in small hospitals and private hospitals in the interior of the country. The government does not purchase used or refurbished equipment. There are no special regulations for used equipment in comparison to new equipment.

Medical equipment in high demand includes: cardiovascular, electro-diagnostic, ultrasound, anesthesia, intensive care, dental, optical, and ozone-therapy equipment.

Third-party companies legally can import any equipment in used/refurbished condition without the need for new safety inspections, etc.

Contact Information

Government Agencies

Colon Free Zone Administration
P.O. Box 1118 ZLC, Panama
Tel: +507- 445-1033
Fax: +507- 445-2165
E-mail: zonalibre@zolicol.org
Contact: Jorge Fernandez, Director

Caja de Seguro Social
P.O. Box 1393
Panama 1, Panama
Tel: +507- 261-8002
Fax: +507- 261-2208
Contact: Juan Jovane, Director

Ministerio de Comercio e Industrias
Viceministerio de Comercio Exterior
P.O. Box 61897
El Dorado, Panama
Tel: +507- 236-0511
Fax: +507- 236-0521
E-mail: vicomex@mici.gov.pa
Contact: Meliton Arrocha, Vice-Minister

Ministerio de Economia y Finanzas
Direccion General de Aduanas
P.O. Box 1671 Balboa, Ancon
Tel: +507- 232-5355
Fax: +507- 232-6494
Contact: Mercedes Villalaz, Director

Ministerio de Salud
P.O. Box 2048
Panama 1, Panama
Tel: +507- 225-6080
Fax: +507- 227-5276
Contact: Fernando Gracia, Minister

Trade Associations

American Chamber of Commerce and Industry of Panama (AMCHAM)
P.O. Box 74, Balboa, Panama
Tel: +507- 269-3881
Fax: +507- 223-3508
E-mail: amcham@sinfo.net
Contact: David Hunt, Executive Director

Asociacion de Usuarios de la Zona Libre de Colon
P.O. Box 3118 ZLC, Panama
Tel: +507- 441-4878
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E-mail: au@sinfo.net
Contact: Digna Donado, President

Panamanian Chamber of Commerce, Industry and Agriculture
P.O. Box 74, Panama 1, Panama
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E-mail: cciap@panama.phoenix.net
Contact: Jose Ramon Varela, Executive Director

Sindicato de Industriales de Panama
P.O. Box 64798, El Dorado, Panama
Tel: +507- 230-0284
Fax: +507- 236-0166
E-mail: sip@sinfo.net
Contact: Daniel Vega, Executive Director

Source: International Market Insight, *Commercial Opportunities for Used/Refurbished Medical Equipment in Panama*, 2 March 2002

Summary

Panama offers good opportunities for exporters of used/refurbished medical equipment. Although government organizations by law cannot acquire used equipment, there is a potential market in the private sector, especially small to medium clinics and hospitals both in Panama City and in the interior of the country. U.S. medical equipment has an excellent reputation and is preferred by most doctors and hospitals. There are no restrictions/regulations for importing used medical equipment and import duties are relatively low. End Summary.

Body

The Ministry of Health manages the health care system in Panama. Along with the Social Security System, it is responsible for procuring all of the medical equipment in the public sector. Private hospitals and clinics are the other main buyers of medical equipment in Panama.

There are no regulations, technical or safety standards applicable to new and used medical equipment in Panama. Both U.S. standards and European standards are accepted. Both used and new equipment is subject to the same treatment. By law, public institutions cannot buy used or refurbished equipment. The Panamanian international banking center offers excellent facilities for international trade transactions. The U.S. dollar is legal tender in Panama. No payment or exchange restrictions exist.

In 1998 import duties for medical equipment were lowered to an average of 10 percent, compared to the previous levels of up to 35 percent. Import duties in Panama are assessed over the CIF value.

Additionally, a five percent value added tax is charged on the aggregate of the CIF value plus the import duty. Product reputation, as well as quality and service are the most important factors for end users when making a purchase decision, followed by price.

There are good market opportunities for used/refurbished medical equipment, especially in small hospitals and private hospitals both in Panama City and in the interior of the country. Products in greatest demand are imaging, x-ray, laboratory and diagnosis equipment.

For more information on Panama's health sector, please contact:

Ministerio de Salud
PO Box 2048
Panama 1, Panama
Tel: 507-225-6080
Fax: 507-227-5276
Contact: Fernando Gracia, Minister

PARAGUAY

General Market Condition: No Restrictions, but Public Institutions Cannot Buy

Source: Report from CS Post (via E-Mail), 25 April 2003

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

Paraguay has no special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used /refurbished condition without the used device being subjected to new safety inspections, etc.?

Yes. Paraguay has no safety inspection requirements.

Can public health institutions buy used or refurbished medical devices?

Public health government institutions cannot buy used or refurbished medical devices.

Is there a market for used or refurbished medical devices?

There is a market for used and refurbished medical devices.

What types of used or refurbished medical equipment are in the greatest demand? Diagnostic imaging equipment is in the greatest demand.

PERU

General Market Condition: Restricted in Practice not Law

Source: Report from CS Post (via Cable), 2 May 2005

The Ministry of Health, DIGEMID (Direccion General de Medicamentos, Insumos y Drogas) is the regulatory agency for the health care sector. The country's health services are encompassed in two sub-sectors, public and private. The public sub-sector is made up of the Ministry of Health (MINSA), Social Security (ESSALUD) and the health services of the Armed Forces and the National Police.

Import of used and refurbished medical equipment is only permitted when Peruvian physicians return to the country and is required for its own professional practice.

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No. There are no special restrictions. However, Peruvian FDA, DIGEMID (Direccion General de Medicamentos, Insumos y Drogas) of the Ministry of Health does not issue the sanitary registry for used/refurbished medical equipment.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc.?

No, unless this is for the physician's professional use.

Can public health institutions buy used or refurbished medical devices?

No. By law, public, social security and armed forces hospitals can only acquire new *medical equipment and devices*.

Is there a market for used or refurbished medical devices?

No.

If there is a market, what types of used or refurbished medical devices are in the greatest demand?

N/A

Are single-use devices being reprocessed and sold on the local market? If so, is this activity regulated? Please provide any details.

No.

General Market Condition: Restricted in Practice not Law

Source: Report from CS Post (via Cable), 5 April 2002

Summary:

There is no explicit restriction on the importation of used/refurbished medical equipment into Peru. However, as a matter of practice over recent years, the Directorate General of Pharmaceuticals, Inputs and Drugs (*Dirección General de Medicamentos, Insumos y Drogas-DIGEMID*) of the Ministry of Health is not authorizing the import of used medical equipment and devices.

By law, public health hospitals, social security hospitals and armed forces hospitals can buy only new medical equipment and devices. Private sector clinics and hospitals can purchase used medical equipment.

Imports of general used equipment are treated the same as imports of new equipment. Under General Health Law No. 26842, imports of medical equipment and devices require a 'Sanitary Registration' issued by DIGEMID of the Ministry of Health. It is necessary to obtain the Certificate to Foreign Government from the U.S. Food and Drug Administration (FDA) to be able to get the Sanitary Registration. The inspection certificate issued by one of the three authorized companies, i.e., SGS, COTECNA, and Bureau Veritas, is also required. These companies charge US \$250 for imports valued from \$2,000 to \$25,000 and 1 percent for imports valued over US \$25,000.

Both new and used products pay 7 percent or 12 percent custom duties applicable on the CIF value, in addition to the 18 percent sales tax.

In addition, the Customs Circular 1071 dated September 16, 1999, states that the Sanitary Registration is mandatory to release the products from customs. However, as a matter of practice DIGEMID only issues the Sanitary Registration for new medical equipment. The latter circular only authorizes the import of used medical equipment when it is for the immediate use by a professional returning to Peru.

PHILIPPINES

General Market Condition: No Restrictions, but Public Institutions Cannot Buy

Source: ISA Radiological Equipment, 21 August 2002 [Extracts]

Market Highlights and Best Prospects:

The average total market size of the radiology equipment market from 1999 to 2001 is approximately US\$13 million. Industry players project that market demand will grow by fifteen percent in the next three years due to hospital expansion, development of Department of Health projects and population growth. Private hospitals in Metro Manila and its suburbs, which have the financial resources for upgrading, will drive demand in this sector. Imports account for 98 percent of total radiology equipment; prototypes and locally assembled equipment from surplus materials account for the remaining 2 percent. Prototypes, however, are not sold commercially and are used only in Department of Health equipment laboratory tests and training centers.

There are locally produced equipment parts but their value is insignificant. More often, it is cheaper to import parts from China than to manufacture locally. France, Germany, the Netherlands and Hong Kong also supply radiology equipment parts and accessories (high-tension generators, control panels and desks, screens and examination tables).

The period of 1999 to 2001 also saw the completion of the much-touted Asian Hospital in Alabang, Muntinlupa. The hospital is managed by the Singapore-based Vista Healthcare Asia Pte. Ltd. GE Medical Systems, the largest U.S. company in the medical business in the Philippines, outfitted the Asian Hospital's various specialty departments. This 250-bed hospital showcases the best technology that U.S. companies can offer – from hospital design and administration, to healthcare service delivery and medical/laboratory equipment. GE dealers also report that they installed 12 out of the 17 X-ray machines in 2001—7 new equipment and 5 refurbished—an accomplishment despite what many businessmen considered "hard times." There is a growing market for refurbished medical equipment. Private hospitals and clinics outside metropolitan Manila tend to purchase used/refurbished equipment, whether x-ray, cardiology or surgery. To date, about 55 percent of all medical equipment supplied to hospitals and clinics are refurbished, according to equipment dealers.

Market Access:

The Philippines imposes a 3 percent tariff duty and a 10 percent value-added tax (VAT) on imported medical equipment. The Bureau of Radiation Health Services, Department of Health, requires that radiation-emitting devices be registered before introduction to the local market. Local testing is required only for certain radiation equipment. There are no import quotas for products in this sector, including used and refurbished medical equipment.

Source: Report from CS Post (via E-Mail), 1 July 2002

Medical Device Regulatory Requirements for the Philippines, July 1, 2002

There are no special restrictions on the importation of medical equipment provided these are imported by duly authorized and licensed medical equipment importers and distributors. Importers/Distributors must secure this License to Operate (LTO) from the Department of Health.

The Bureau of Health Devices does not impose any restriction on used medical equipment except that these should be comparable in safety with new equipment. Refurbishers of used equipment must obtain a clearance from the original equipment manufacturer and must conform to good manufacturing practices. Refurbishers are also not allowed to distribute commercially, any device that has not been produced in conformity with such requirement.

Only X-ray machines and other radiation-emitting devices require registration before introduction to the local market. Local testing is required only for certain radiation equipment like the Linear Accelerator.

The validity period for initial registration of a medical device is one year. Under Bureau of Food & Drug Administration (BFAD) Circular #05, series of 1998, length of renewal registrations has been extended to five years.

The Bureau of Health Devices and Technology under the Department of Health is the primary agency that monitors medical equipment (ionizing and non-ionizing, radiation dosimetry, radiation, non-radiation, laboratory, medical physics, etc.)

The Philippines imposes a 3 percent tariff duty and a 10 percent value-added tax (VAT) on imported medical equipment, including used and refurbished. As a policy, however, the government can only procure new equipment.

The Department of Health or the health units under the local government supervision may, however, accept used equipment if these are donated, provided the equipment includes an operation manual to ensure its safe operation. The government discourages Philippine importers from buying used equipment without proper documentation and operation handbook.

There are good opportunities for used/refurbished medical equipment: it accounts for 40 percent of the Philippine market. Like new equipment, the most promising sub-sectors are X-ray equipment and medical/surgical instruments. Major end-users are the primary and secondary hospitals in Metro Manila and the provinces.

There are 3 classifications of Philippine hospitals:

- Primary Hospitals—capable of handling general medicine, pediatrics, obstetrics and minor surgeries;
- Secondary Hospitals—can handle all services available in a primary hospital including gynecology, general surgery, and other ancillary services;
- Tertiary Hospitals—fully departmentalized hospitals that can handle more specialized services than secondary hospitals.

Contact Information

Department of Health of the Philippines:
 San Lazaro Compound, Tayuman, Sta. Cruz
 Manila, Philippines 1003

Web site: www.doh.gov.ph/bfad

Organization E-mail: bfad@mc.pworld.net.ph

Tel: +63-2- 743-8301; 711-6016

Fax: +63-2- 711-6824

Dr. Manuel Dayrit

Secretary, Department of Health

Ms. Agnette P. Peralta

Director, Bureau of Health Devices and Technology

Engineer Cecila Matienzo

Engineer V,

Bureau of Health Devices and
 Technology

POLAND

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 3 March 2005

Import Regulations for Used Medical Equipment in Poland

Prepared by Zofia Sobiepanek

Market Overview

With a population of 38.2 million people, Poland would seem to represent one of the largest health care markets in Central/Eastern Europe. However, the health care sector in Poland is going through difficult times and the short-term outlook is very poor. Since 1999 the health care sector has gone through several un-successful reform attempts. The current Minister of Health (seventh in this government) is trying to implement major changes to the existing Health Care Law regulating health care management, contributions and costs. The main concerns are in the areas of restructurization, privatization, transparency in treatment standards, and control of the reimbursement system.

One way to cure the Polish system is to open the market for private investors. The limited resources of the state budget make it even more logical to attract private investors. The traditional public health care sector needs investment and management skills to meet the growing demand from patients and at the same time remain within cost controls. Also, plans are in the works to introduce private health care insurance companies. Once the legal basis is established through legislative reform, we will see significant opportunities for U.S. companies in the above areas.

There are no restrictions in Poland on imports and/or the purchase of used medical equipment by either state-owned or private health care facilities, but market opportunities for medical equipment in general are currently very limited. Used equipment purchases are made but no specific buying pattern has been identified. Leasing of medical equipment is not widespread in Poland. However, with an increasing number of private clinics and financial limitations within the public health care sector, their sales prospects might improve in the next few years.

Please note that price is the main factor considered by all buyers of medical products in Poland. Important too is the local availability of services and spare parts. Quality is usually the next element considered.

Investment type purchases, such as advanced medical equipment like mammography equipment, EEG equipment, Magnetic Resonance Imaging units, radiography/tomography units, X-ray equipment, etc., are currently extremely limited.

Registration/Certification

The Ministry of Health regulates the requirements on Registration of Medical Apparatuses and Equipment acquired by Health Care Institutions of April 20, 2004, which can be found in government publication Dziennik Ustaw (Journal of Law), Dz. U. 93 item 896.

As Poland is now a member of the European Union, import regulations for medical equipment are harmonized with the European Union's Medical Device Directives, which cover essential safety, health and environmental requirements.

The three regional European standards organizations, CEN, CENELEC and ETSI, are mandated by the Commission to develop technical standards that are consistent with the essential requirements of EU Directives. Products manufactured to standards adopted by CEN, CENELEC and ETSI, and published in the Official Journal as harmonized standards, are presumed to conform to the requirements of EU Directives. The manufacturer then applies the CE Mark and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the European Union.

However, the CE mark is accepted in Poland for Class I and Class IIa (low risk) medical products that do not need testing by a certified body in any country. Class IIb and Class III products are required to obtain registration with the following office:

Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Środków Biobojczych
(Office for Registration of Medical Products)

Rejestracja Sprzętu Medycznego
(Medical Equipment Register)

ul. Zabkowska 41

03-736 Warszawa, Poland

Tel: +48/22 492-1171

Fax: +48/22 492-1199

www.urpl.gov.pl

Contact: Joanna Kilkowska, Chief — Medical Equipment Register (Kierownik Rejestracji Sprzętu Medycznego)

American exporters should be aware that electrical voltage in Poland is 220, and the current frequency is 50 Hz. Power cables and plugs must be consistent with Polish standards. Labeling and instructions for use (operation manual) must be in Polish language.

Tariffs

With its accession to the European Union on 1 May 2004, Poland became part of the EU customs union.

Most Polish customs provisions were replaced with respective EU regulations including the Community Customs Code and the Community Tariff and implementing provisions. Membership in the customs union required abolition of any physical and fiscal barriers (customs control, customs duties) between Poland and other EU members. Transactions involving transfer of goods between Poland and other EU states changed their nature from imports/exports into intra-Community acquisition and supply. Transfers of goods between Poland and non-EU member states retained their classification as imports/exports and are subject to the uniform EU customs rules.

Tariff Rates

Information on the customs duty rates can be currently obtained from TARIC (the electronic integrated Community Tariff) http://europa.eu.int/comm/taxation_customs/dds/cgi-bin/tarchap?Lang=EN

There are no differences in tariffs for new or used medical equipment. In addition to tariffs, a value-added tax (VAT) of 22 percent is added to medical equipment regardless of origin.

Sales Prospects

In Poland the end-users of medical equipment are the health care service providers themselves. Service providers include public hospitals, private clinics, and private doctors' offices. Please take into account the differences between the average patient in a private clinic and the average patient of public hospitals and medical facilities. The public sector (the largest sector of health care in Poland) receives very limited annual funding for equipment purchases. The number of private clinics is still relatively small and provide services including out-patient one-day-surgery, cosmetic surgery, medical check-ups, lab tests, etc. where patients pay either out of their own pocket or through private health care packages offered by some major companies as a fringe benefit to their employees. Private clinics try to maintain a stock of products based on current demand.

The current public health care system operates on the basis of dual financing. The owners of public hospitals and clinics—the local governments—finance major investments such as equipment purchases, construction and maintenance of the facilities. The National Sick Fund is responsible for financing the operating costs of the health care system in Poland, i.e. the daily costs of the primary care, outpatient and in-patient care, as well as reimbursement for medical supplies. The National Sick Fund operates on the actual, current contributions of employers and employees. The Ministry of Health directly finances clinical academies and research hospitals and specialist institutes.

Finding an interested distributor, under the current conditions is very difficult. U.S. Commercial Service Warsaw is willing to assist American companies, but we must make it clear from the start that current negative circumstances make it very difficult to provide our clients with quality contacts within the health care sector and we are concerned that even if we succeed in getting some initial interest, there is little likelihood of developing real sales leads. If we see reasons to change our assessment we will advise immediately.

Additional Information

For further information regarding medical sector in Poland, please contact:

U.S. Commercial Service
American Embassy Warsaw
IPC Business Center
ul. Poznanska 2/4
00-680 Warsaw, Poland
Tel: +48/22 625-4374
Fax: +48/22 621-6327

www.buyusa.gov/poland (it will come up in Polish, but you can click on the English version)

Contact person: Zofia Sobiepanek-Kukuryka, Commercial Specialist

PORTUGAL

No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from CS Post (via E-Mail), 22 April 2003

Portugal is governed by the EU harmonized legislation/directive, which covers the importation of new and used medical devices to Europe. The appropriate Portuguese authorities must certify the importation of new and used medical equipment for use in Portuguese public hospitals and/or private clinics and medical centers. These devices, when imported from third countries to be sold in Portugal, have to undergo a complicated certification process by a credited entity in the EU. If devices pass this certification, they are marked 'CE' and may move freely and be sold in all countries in the EU.

This EU directive primarily focuses on certain minimum requirements for the medical devices entering Portugal. All credited organizations are attributed a 4 digit identifying code by the European Commission. In Portugal, the official entity that is credited to attribute the CE mark is:

LEMES — Laboratório de Ensaios e Metrologia da Saude
Av. Padre Cruz
1600-560 Lisboa
Tel: +351-21- 757-5853 / 757-3557
Fax: +351-21- 757-3671
Contact: Eng. Faria Gomes, President

Import duties are equally applied to new and used medical equipment; these vary between 0 and 7.5 percent when entering from third countries and 0 percent when of EU origin. Once cleared by customs in any one EU country, goods may move free of duty within the EU. A Value-Added Tax (19 percent) is applied ad valorem to all goods entering Portugal.

ROMANIA

General Market Condition: No Restrictions, but Public Institutions Cannot Buy with State-Guaranteed Loans

Source: Report from CS Post (via E-Mail), 28 February 2002

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

Customs tariffs for used equipment are similar to the ones for new equipment

The Ministry of Health and Family (Ministerului Sanatatii si Familiei—MSF) does not acquire refurbished medical devices through sovereign guarantees

The refurbishment program applies to the existing pieces of equipment already operational on the Romanian market

Can public health institutions buy used or refurbished Medical devices?

MSF is not allowed to make purchases in a centralized manner based on state guaranteed loans.

Is there a market for used of refurbished devices?

In Romania there is a market for used or refurbished medical devices, but this is currently not well defined.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

As the size of this market has not been determined yet, it is difficult to establish its structure. Checking up on the private market of medical services may be beneficial although it is unlikely that a relevant database might exist.

RUSSIA

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 24 March 2005

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

There are no special restrictions or tariffs that apply to used equipment. The tariffs apply to the product category and are the same for new and used medical equipment and devices, which belong to the same category. The most common tariff for medical equipment is 5 percent. There are only a few exceptions to this tariff rate. All disposable syringes except for those used to inject insulin, IV solution transfusion systems, and hydro massage bath tubs are all subject to a 15% tariff.

If a manufacturer or its special agent registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc.?

If the manufacturer or its agent had registered a medical device when it was new in Russia, a third party can legally import the same device in used/refurbished condition if it has a valid registration certificate from the Ministry of Health. If the term of certificate has expired, it should be renewed. In addition to the Ministry of Health registration a third party should obtain a special certificate of conformity with the Russian safety and quality standards issued by the State Standards Committee. The duration of such certificate is from one to three years.

Can public health institutions buy used or refurbished medical devices?

As a rule, Public Healthcare Institutions do not buy refurbished medical equipment directly. Generally procurement of Public Health Institutions is arranged by Regional Health Authorities responsible for procurement of medical equipment in their respective regions. The authorities that control the healthcare expenditures in the region are not interested in buying used medical equipment, as they prefer to buy brand new medical equipment because they receive a percentage of the purchase price as a reverse commission on the transaction. Small refurbished equipment and devices can be purchased by public healthcare establishments via distributors out of internal obligatory insurance funds available at those establishments.

Is there a market for used or refurbished devices?

The market for refurbished medical equipment is very limited. For years Russian healthcare priorities have focused more on high technology “cutting edge” medical products than on preventive medicine and basic medical needs. As mentioned above, regional Health Authorities are not interested in purchases of used/refurbished equipment for their territorial hospitals.

Generally, refurbished medical equipment is in higher demand in the Russian regions versus Moscow where the majority of financial resources for the healthcare sector as well as the economy on the whole, are concentrated. Used medical equipment distributors in the regions can be considered as potential

partners for U.S. companies specializing in such medical equipment.

Another obstacle, which diminishes incentives for purchasing used medical equipment, is a lack of servicing and maintenance support that is provided by foreign suppliers of such equipment. As servicing and maintenance of used medical equipment is crucial for successful sales and application in clinics and hospitals, distributors are not interested in working with such equipment unless the foreign dealers of used medical equipment in cooperation with manufacturers of such equipment establish servicing centers in Russia. The manufacturers supplying them with spare parts and arranging maintenance should support such centers.

According to our estimate, used medical equipment accounts for only 3 percent of the total medical equipment market.

What types of used or refurbished medical equipment are in the greatest demand?

The best prospects for used equipment include X-ray equipment, magnetic resonance imaging, ultrasonic and laboratory diagnostic equipment.

Are single-use devices being reprocessed and sold on the local market? If so, is this activity regulated?

Reuse of reprocessed single-use medical devices for the Russian law strictly forbids medical treatment purposes.

Source: IMI Medical, 23 May 2001

Summary

Russia would appear to have the potential to sustain a healthy market for used medical equipment, particularly for equipment used in the manufacture of pharmaceuticals. Domestic Russian pharmaceutical manufacturers are currently enjoying very favorable market conditions. To date, however, sales of imported used medical equipment have proved disappointingly small. The difficulty of meeting the mandatory registration and certification requirements, in a system not geared to deal with foreign-source used equipment, acts as a constraint. So too does the fragmented structure of the used market and the lack of servicing support from foreign suppliers. These difficulties need not be insurmountable, and Russia has an abundance of inexpensive, skilled and easily trained technicians able to support medical equipment refurbishing and assembling operations.

Body

The Russian market possesses many of the characteristics, which should make it attractive to suppliers of used medical equipment. It has a large population (145 million), many of whom are aged. The state healthcare system suffers significant budgetary constraints, and is limited in its ability to purchase expensive new equipment. Local equipment manufacturers have made few technological advances over the last decade and consequently cannot offer the most advanced equipment.

The total size of the Russian medical equipment and supplies market is currently estimated at about US \$2 billion, and has been growing rapidly. Since the August 1998 economic crisis, this growth has exceeded even the robust rates of growth of the Russian pharmaceuticals market. However, the market for used medical equipment has proved disappointing to date. According to the author's estimate, based on consultations with industry experts and distributors, used equipment accounts for only 5 percent of the total market for medical equipment.

The market for refurbished medical equipment is very limited. While public health institutions and the many regional health authorities are permitted to buy imported used medical equipment, they usually prefer to focus on new and often expensive 'cutting edge' technology. It has even been reported that, in some cases, the desire by procurement staff to receive informal incentive payments from suppliers may

have driven the decision to purchase such equipment. Equipment for use in the provision of basic and preventative medicine is typically procured from local manufacturers.

The mandatory registration and certification requirements for imported equipment are not geared to used equipment and can be difficult, if not impossible, to satisfy. Russian distributors and healthcare institutes are permitted to purchase only used medical equipment that has been registered by the Ministry of Health and certified by Gosstandart, the Russian state standards agency. The Ministry of Health will register only new medical equipment, not refurbished equipment. This means that, if a certain make and model of new medical equipment has been registered previously, then refurbished models may be sold. Otherwise the used equipment cannot be sold in the Russian market. As for certificates of conformity, such certificates can be obtained from certification centers accredited by Gosstandart. With regard to customs regulations, there are no special restrictions or tariffs that apply to used equipment, once it is certified. The tariffs apply to the product category and do not differentiate between new and used medical equipment and devices, with the most common tariff for medical equipment being 5 percent.

The steep devaluation in the ruble in the aftermath of the August 1998 economic crisis made imports more expensive and resulted in the increased competitiveness of Russian manufacturing industry. Russian pharmaceutical equipment manufacturers have managed to compete against imports in a period when their customers, the Russian pharmaceutical companies, were similarly enjoying enhanced competitiveness. In 2000 alone, local pharmaceutical production increased by 20 percent and today local manufacturers supply over 45 percent of the total market, taking advantage of the sharp rise in prices of imported Western drugs. Many Russian pharmaceutical factories are in need of new and replacement equipment, including packaging and labeling equipment, and it is in this area that some reasonable sales prospects exist for foreign suppliers of used pharmaceutical manufacturing equipment. The Commercial Service works with the Russian Association of Pharmaceutical and Medical Equipment located in St. Petersburg to collect leads from Russian pharmaceutical manufacturers for foreign reconditioned production equipment.

In the case of used medical equipment for disease treatment, maintaining and servicing such equipment in Russia is problematic. Even though local labor costs are low, and the supply of proficient and trainable technicians abundant, the cost of new replacement parts and components can be prohibitively high. As a rule, local companies specializing in refurbishing used medical equipment has to buy new spare parts from the original manufacturer, as such parts are not produced locally. In some cases, the price of a replacement part can be higher than the purchase price of the used equipment itself. The problem is often compounded by the absence of long-term, direct relations between foreign suppliers and local medical equipment refurbishers. Shipments in the past have tended to be infrequent and were typically handled through intermediaries lacking the capability to provide adequate servicing and maintenance support. In some cases, Russian buyers of used medical equipment sustained losses as many spare parts were not available, and consequently the equipment was impossible to refurbish. The above problems notwithstanding, the best prospects for used equipment in this area include X-ray equipment, magnetic resonance imaging, ultrasonic and laboratory diagnostic equipment.

Because labor costs in Russia are much lower than in the West, several companies have found it cost effective to assemble equipment locally from imported components, rather than import finished product. A significant portion of production equipment for the pharmaceutical industry is assembled locally. The leading Russian company, which specializes in refurbishing and maintaining used Western medical equipment, is Izomed. This firm is seeking to establishing long-term cooperation with Western manufacturers based on at least a 6-month warranty period and servicing contracts. Another organization that is interested in cooperation with Western suppliers of refurbished medical equipment is the newly created Soyuzmedprom Association, which unites major Russian manufacturers and distributors of medical equipment.

It is not inconceivable that a well organized and well financed used medical equipment supplier could overcome the obstacles currently a feature of the Russian market to emerge successful, or that niche players might find profitable roles for themselves. At present, however, the current market structure and regulatory environment are not favorable for the others.

This information is provided to you by the Commercial Service (CS) in Moscow, part of the U.S. Embassy, which offers to U.S. exporters a number of services aimed at generating export sales, including identifying distributors and arranging meetings with prospective buyers during business visits to Russia. The CS in Moscow encourages U.S. companies wishing to do business in Russia to utilize its Gold Key Service. Experienced Commercial Specialists identify opportunities, arrange business appointments with pre-qualified Russian agents and distributors, and accompany you to the meetings. Gold Keys cost \$600 (basic prices) or \$1,200 (full logistical support price) for a full day of appointments (typically 4), and \$300 (basic price) and \$630 per additional day. Logistical support includes assistance with reservations at suitable hotels, several of which provide discounted rates to CS clients; airport pick-up/drop-off; ground transportation to meetings; and interpreter services for 8 hours a day. The Commercial Service requires sufficient company literature and price lists at least three weeks prior to the desired appointment dates, and accepts payment by VISA, MasterCard, American Express and Discovery cards. Additionally, as part of CS regional cooperation program, CS Moscow will share your Gold Key inquiry with other offices, which may contact you directly. For more information on FCS Moscow services, U.S. companies may visit our web site at: www.usatrade.gov or the BISNIS site at: www.bisnis.doc.gov or contact us directly.

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Source: International Market Insight, Healthcare Services, Medical Equipment and Supplies, and Pharmaceuticals Market in the Russian Far East, 22 March 2001

Dental equipment and supplies are in growing demand on the local market. The poor fluoride level in local water and tough climate conditions presuppose a larger than average need for dental services in Russia. All dental equipment supplies are imported. At the same time, dental clinics are usually private, market-oriented and profitable. The combination of these factors makes this subsector rather attractive for U.S. exporters.

Despite an obvious under-financing of this subsector [dental], used and second-hand medical equipment have very limited sales potential on the Russian Far East (RFE) market due to certification and other administrative impediments.

There is some potential though for pharmaceuticals' manufacturing equipment.

Source: ISA Medical, 1 January 2000

Home Healthcare Products and Equipment: Best Sales Prospects

In general, the Russian population and health care and social protection authorities prefer to buy new home healthcare products and equipment, therefore, used products and equipment are not in high demand.

Source: ISA Medical and Dental, 1 March 1999

Best Sales Prospects

Because many types of dental equipment and supplies, which are needed for treatment, are not produced locally, there will be unsatisfied demand for many types of products for the next three years. According to data provided by the Russian Dental Association, the best sales prospects in the Russian dental equipment and supplies market include:

- dental units
- dental X-ray equipment
- pastes for filling root canals
- equipment for dental orthopedics
- dental porcelains
- dental films and chemicals
- adhesive systems
- photopolimerizers
- dental disposable supplies
- dental anesthetic gels & solutions
- anchorage pin systems
- composite filling materials

In general, Russian dental clinics prefer to buy only new dental equipment therefore used dental equipment is not in high demand.

SAUDI ARABIA

General Market Condition: No Restrictions, but Ministry of Health and Government Hospitals Do Not Purchase

Source: Report from CS Post (via Cable), 9 September 1998

There are no Saudi standards nor any specifications that apply to used or refurbished medical equipment. The Ministry of Health and other Saudi government hospitals will, however, abstain from purchasing such equipment. Other clinics and hospitals might purchase the same only from an established local agent who should be able to provide maintenance and spare parts for 10 years. The only standard that applies relates to electrical specifications, i.e. 110 V, 60 Hz.

SERBIA AND MONTENEGRO

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 23 July 1998

The Former Republic of Yugoslavia (FRY) permits the importation of used equipment other than vehicles and construction equipment. Tariffs are generally the same or slightly higher than for new equipment of the same type. Vehicles equipped with medical equipment may be imported if they are not more than 4 years old.

The used equipment market in the FRY is relatively new and undeveloped. Most large firms are socially owned and appear to be adverse to purchases of used equipment. Reports indicate that price is often not the primary criterion for decision makers of such firms. Smaller firms appear to have some interest in used equipment, but face bureaucratic hurdles and possess low purchasing power. The Serbian government recently decided to prohibit imports of used clothing, which was beginning to gain a foothold

in the FRY. This ban sends a cautionary signal about prospects for significant development of the used equipment market, although the ban may be an isolated case since it was part of a set of actions taken to reduce imports of consumer goods.

SENEGAL

General Market Condition: No restrictions, but public institutions do not buy

Source: Report from CS Post (via Cable), 6 April 2001

The market for used/refurbished medical equipment in Senegal is very limited, if not nonexistent. In a country where the public sector is the biggest purchaser and user of medical equipment, major impediments to the sale of used medical equipment remain, due to public procurement procedures and to technical constraints.

In the public sector, all purchases of medical equipment are made either through international tenders financed by the World Bank and other multilateral donors or they are financed by the Senegalese government's special investment budget. A stringent requirement is that the equipment be new.

The technical constraints essentially concern the norms and standards. The Senegalese market is based on European standards: 50 cycles, 220 volts. Professionals in the sector report that sophisticated medical equipment, such as imaging equipment, radiography and echography that use the standard u.s. 110 volts, is degraded when stepped-up to 220 volts. Further, all documentation and training need to be available in French. The availability of spare parts and a technically qualified agent to deliver after-sales service are critical to achieving success in the market.

The private sector market consists of private clinics and practices almost exclusively based in the Dakar area. This market segment does not have the same restrictions as the public sector, therefore used/refurbished equipment could find acceptance here. However, the acceptance to date is somewhat limited. The importers contacted during this research mentioned that used equipment might have an image problem to overcome. The equipment is already perceived as old and there might be concern regarding its reliability and the availability of spare parts. Therefore, those importers rarely import used medical equipment. Some private purchases are done directly by the private clinics.

There are no government regulations barring the import of used medical equipment. As with other imports, used medical equipment is subject to import duties and taxes.

Key contacts

Government

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Minister: Mr. Abdou Fall

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M. Maguette Wade, Director
AGETIP is a World Bank-funded agency. AGETIP monitors public tenders for medical equipment.

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SINGAPORE

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 13 March 2001 (Confirmed as still valid, 4 March 2002); Updated 1 March 2005

Medical Device Regulatory Requirements for Singapore

Singapore's regulatory system for medical devices is evolving, and is expected to see further codification of regulations during the coming years. At present, medical devices approved for use in the U.S., Europe, Australia and Japan generally are acceptable when the appropriate certifications are available, e.g.; a "Certificate to Foreign Government" (CFG) from the U.S. Food & Drug Administration. Used medical equipment that are refurbished for re-use and refurbished devices are treated no differently than new medical device products.

Currently, there is no mandatory product registration for medical devices, except for radiation emitting devices and radioisotopes, HIV test kits, contact lens & related solutions, and condoms. However, manufacturer or their local authorized representatives must ensure that their devices or products meet widely recognized safety, quality and performance requirements before they can be sold in the local market. For example, devices that have USFDA 510(k) or PMA clearance/approval (as attested by a CFG from the United States), or bear the European Union's "CE mark," are deemed acceptable for sale in Singapore. Under Singapore's Radiation Protection Act, radiation emitting medical devices including X-ray machines, UV sunlamps, ultrasound machines, lithotripters, MRI units, pacemakers having radioactive battery components, and laser devices must be licensed by the Centre for Radiation Protection of the Health Sciences Authority (HSA), Ministry of Health (MOH). Among non-radiation emitting devices, the MOH's Medical Audit & Accreditation Unit must approve all new HIV test kits before they may be used in Singapore's accredited HIV testing laboratories.

The Health Sciences Authority (HSA), a statutory board under the Singapore Ministry of Health, provides a "one stop," multi disciplinary body to regulate health products. The HSA comprises seven centers providing scientific and regulatory expertise in health sciences and these are: The Centre for Drug Administration, Centre for Medical Device Regulation, Centre for Radiation Protection, Centre for Transfusion Medicine, Centre for Forensic Medicine, Centre for Forensic Science and the Centre for Analytical Science. As a multi-disciplinary agency, the HSA aims to deliver a coordinated, seamless, regulatory process for all therapeutic products.

The HSA's Centre for Medical Device Regulation (CMDR) is in the process of developing a system of statutory control to safeguard the quality safety and efficacy of medical devices available in Singapore. In the interim, CMDR began a "Voluntary Product Registration Scheme" under which local authorized representatives of medical device manufacturers are encouraged to register their medical products with CMDR. This program, which began in April 2002, was billed as a confidence-building period to evaluate the feasibility of the proposed medical device regulation framework and also an opportunity for stakeholders, both industry and government, to gain a learning experience from this exercise. The final version of these measures is expected to take effect by the end of 2005. See the Centre's website for further information: (http://www.hsa.gov.sg/html/business/cmdr_vpr_scheme.html).

As a first step, it is envisaged that only high risk, Class III medical devices placed on the market in Singapore will be subject to such notification/registration. Under this system, manufacturers or their authorized representatives in Singapore will be requested to submit detailed information on their products. For pre-market assessment, the center will adopt "consensus standards and

requirements on safety, quality and performance which satisfy the regulatory requirements of developed countries" (such as the U.S., European Union, Canada or Australia). The Singapore Medical Device Register will be promoted within public sector hospitals as a source of reliable information on devices, which meet these "benchmark requirements of safety and effectiveness." With regard to clinical trials, the requirements are informed patient consent and approval of the Institutional Ethics Committee. There is currently no statutory control, i.e., no national requirement for notification of intent to carry out clinical trials; however, the Centre for Medical Device Regulation nonetheless asks to be informed of the conduct and results of such trials. The Singapore Guidelines on Good Clinical Practices are applicable in all cases. It is understood that in developing its strategy for this initial voluntary system, the Centre for Medical Device Regulation has taken account of the work being done within the Global Harmonization Task Force and the regional Asian Harmonization Working Party on medical device regulation.

Contacts in the Health Sciences Authority of the Ministry of Health:

Centre for Medical Device Regulation (CMDR)

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Fax: +65-6478-9028

Contact:

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Ms. NG Yin Mei, Regulatory Scientist (Tel: +65-6866-3561)

Mr. Roger Seah, Corporate Support Officer (Tel: +65-6866-3569 - Contact Lens)

Web site: www.hsa.gov.sg/cmdrindex.html

General E-mail: hsa_cmdr_info@hsa.gov.sg

Centre for Radiation Protection

11 Outram Road

Singapore 169078

Tel: +65-6213-0838

E-mail: TAN_Annie@hsa.gov.sg (Ionizing Radiation devices)

E-mail: PHUA_Tan_Tee@has.gov.sg (Non-Ionizing Radiation devices)

Information on Singapore's licensing requirements for radiation-emitting equipment, along with a schedule of application fees and license application forms, please access:

http://www.hsa.gov.sg/html/business/crp_ir_nir_lic_fees.html. For more information on the Centre for Radiation Protection, please visit their web site:

http://www.hsa.gov.sg/html/business/crp_ir_nir_intro.html

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 13 March 2001 (Confirmed as still valid, 4 March 2002); Updated 1 March 2005

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new equipment?

No, there are no special restrictions or tariffs that apply to used medical equipment that do not apply to new equipment. Used medical devices have to be refurbished for re-use and are treated no differently than new medical device products. That is, refurbished medical devices are

subjected to the same regulatory scrutiny similar to the placement of other new medical device products for sale in Singapore. Any person who refurbishes a medical device and re-introduces it into the Singapore market is considered a manufacturer and he has to ensure that essential requirements pertaining to quality, safety and performance for the intended use of the product are met. As such, a refurbished device product must therefore carry the label of that manufacturer as the brand owner and there must be clear labeling to indicate that the product is a refurbished device product.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc?

Any person who refurbishes a medical device and re-introduces it into the Singapore market is considered a manufacturer and will be considered the brand owner of that refurbished device. Clear labeling must indicate that. As such, this manufacturer or its local representative will have to register to place the new device product under its own brand name. The third party will be treated as a new separate distinct entity when he chooses to import the same device in used/refurbished condition. This used/refurbished device will also be subjected to new safety inspections, etc.

Can public health institutions buy used or refurbished medical devices?

Yes, public health institutions can buy used or refurbished medical devices that are available legally in the Singapore market. The devices must also have met the safety and effectiveness requirements and registered with the Singapore Health Sciences Authority.

Is there a market for used or refurbished medical devices?

No, there is no market.

If there is a market, what types of used or refurbished medical devices are in the greatest demand?

Not Applicable

*Are single-use devices being reprocessed and sold on the local market?
If so, is this activity regulated? Please provide details.*

According to the health authorities, no information is available regarding single-use devices being reprocessed and sold in Singapore. The Health Sciences Authority's stand on this is that single-use devices should not be reprocessed for reuse or sold at all.

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SLOVENIA

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 25 March 2002

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

The regulations for the import of medical equipment are prescribed in the Official Gazette, issues 101/1999 and 82/2000. There are no special restrictions or tariffs that would apply to the imports of used medical equipment. The import regime is the same as it is for the import of new medical equipment.

Can public health institutions buy used or refurbished medical devices?

Public health institutions can buy used or refurbished, but do not choose to do so.

Is there a market for used or refurbished medical devices?

According to previous experiences of several U.S. companies trying to sell refurbished X-ray systems in the region about two years ago, there is (almost) no market in the country for the refurbished products. According to an industry source, the mentality of Slovenian doctors mentality is against refurbished products. Also, all hospitals are state-owned with the exception of a couple of recently built small medical sanatoriums for wealthy people.

SOUTH AFRICA

General Market Condition: Restricted

Source: Report from CS Post (via E-Mail), 8 April, 2005

Meeting with Mr. Leon du Toit, Head: Non Ionizing Radiation & Electro medical Devices (NIRMED), Department of Health, Directorate: Radiation Control

SAMED – South African Medical Device Distributors Association

According to the Department of Health, South Africa does not make a distinction between refurbished/used and new medical equipment. Medical equipment – other than electro medical devices – including disposable or single use devices, is not regulated. The South African Department of Health is currently in the process of drafting the necessary policy documents and has indicated that these may become available some time in the future.

As mentioned, there are, however, exceptions with regard to specific electro medical products (as listed at the end of this document). Although there is no distinction between new and refurbished/used equipment, all importers – whether the product is destined for commercial or personal use – must apply for a license in terms of Section 4 (1)(b) of the Hazardous Substances Act, 1973 (Act 15 of 1973) from the Department of Health, Directorate: Radiation Control. Potential importers must apply for a license FOR EACH MODEL and must supply the following documentation:

- Completed application form 41BM-1, obtainable from the Radiation Directorate
- A color brochure (including technical specifications) from the manufacturer
- A letter of appointment as authorized representative of the original manufacturer

- EC Certificate(s) issued by a Notified Body in terms of EC Directive 93/42/EEC, or 90/385/EEC (whichever one is applicable)
- EC Declaration of Conformity by the manufacturer in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable).

Please note that FDA-approved only electro medical products are no longer accepted for import in South Africa. The Directorate will recognize EC certification only.

If the intention is to conduct clinical trials with a listed electro medical product, before it has been licensed to be imported or manufactured in South Africa, the importer must supply the following documentation:

- Completed application form 41BM-1, obtainable from the Radiation Directorate
- Color brochure (including technical specifications) from the manufacturer
- A letter of appointment as authorized representative of the original manufacturer
- List of medical institutions where the clinical trials will be conducted
- List of the medical practitioners who will supervise the clinical trials
- Copy of the letter in which the Medical Ethics Committee of a medical institution gives approval for the clinical trials to be performed at that particular medical institution
- Copy of the approved Research Protocol for the clinical trials
- Copy of the “Informed Consent” form.

This product must be re-exported to the original manufacturer after completion of the clinical trials and may not be re-sold in South Africa. However, if the model is to be offered for local sale then EC documentation (as outlined in Point 3 and 4) must be submitted. Further, the date of importation or manufacture of units of that model may not precede the dates of the documentation required under Points 3 and 4.

There are no special tariffs or restrictions reserved for used/refurbished equipment, as there is no distinction made between new and refurbished/used medical devices.

No third party may legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, since each importer must obtain a license for each model that they import. There are no restrictions on the number of licensed importers allowed per model at present.

The sale of used equipment locally is not regulated. Public health institutions generally do not purchase refurbished/used medical equipment due to tendering conditions and/or internal hospital policy. However, there is no law prohibiting them from doing so.

Single use or disposable devices are being reprocessed and reused by health practitioners, and is frequently done so in both private and public hospitals. Although not regulated yet, this practice is of considerable concern.

The market for refurbished medical equipment is considered small - both for high- and low-end products. There is general public resistance due to perceived inferior quality and issues concerning product maintenance and repair.

Schedule of Listed Electronic Products

*Hazardous Substances Act, No. 15 of 1973
Regulation No. R. 1302, 14 June 1991*

1. **Any electronic product generating X-rays or other ionizing beams, electrons, neutrons or other particle radiation, namely-**
 - any diagnostic X-ray unit, including medical, dental and veterinary units;
 - Any therapeutic X-ray unit;
 - any X-ray unit used for industrial, research, educational, security or any other purposes;
 - any electron accelerator;
 - any heavy particle accelerator;
 - any neutron generator;
 - any electron microscope;
 - any visual display unit, including any television receiving apparatus and video display monitoring system, that employs a cathode ray tube with an accelerating voltage exceeding 15kV; and
 - any cold cathode gas discharge tube producing X-rays, including those for teaching of X-ray principles and high voltage switchgear.
2. **Any electronic product generating electromagnetic radiation in the ultraviolet region, namely**
 - any sunlamp designed for the tanning of the skin of a human being;

any therapeutic lamp;

 - any high-intensity mercury-vapour discharge lamp;
 - any intra-oral curing device; and
 - any ultraviolet A lamp, including ‘black lights’.
3. **Any electronic product emitting coherent electromagnetic radiation produced by stimulated emission, namely all laser products that emit radiation in excess of $0,8 \times 10^{-9}$ watt in the wavelength region up to and including 400 nm or that emit radiation in excess of $0,39 \times 10^{-6}$ watt in the wavelength region greater than 400 nm.**
4. **Any electronic product emitting electromagnetic radiation in the infra-red region, namely -**
 - any industrial heating and drying lamp installation exceeding 200 watt; and
 - any medical heating lamp exceeding 200 watt.
5. **Any electronic product emitting microwaves, radio or low frequency electromagnetic radiation, namely-**
 - any microwave oven;
 - any microwave diathermy unit;
 - any shortwave diathermy unit;
 - any electrosurgical unit;
 - any neuro-muscular stimulator;
 - any medical magnetic stimulator;
 - any radio-frequency generating device, system or installation, including radars, generating a radiofrequency output exceeding 200 watt RMS;
 - any low power radio-frequency generating device, system or installation, including citizen band radios, land mobile transmitters, marine transmitters and two-way (walkie talkie) radios, where

normal operation entails close proximity to the operator or third parties and generating a radio-frequency output exceeding 25 watt RMS;

- any microwave generating device, system or installation, including radars, generating a microwave output exceeding 400 watt RMS ;
- any radio-frequency sealer;
- any magnetic resonance imaging device; and

any blood warmer.

6. Any electronic product emitting ultrasonic vibrations, namely-

any diagnostic ultrasound appliance;

any therapeutic ultrasound appliance;

any surgical ultrasound appliance;

any lithotripsy appliance; and

any pest and rodent control appliance.

7. Any electronic product used for medical, dental or veterinary applications employing radioactive nuclides, namely -

- any gamma camera;
- any whole body counter;
- any positron emission tomography scanner;
- any linear scanner; and
- any single photon emission computed tomograph (SPECT).

8. Any high risk electronic product used for medical or dental applications, namely -

- any intra-aortic balloon pump;
- any electronically controlled ventilator;
- any electronically controlled anaesthetic machine;
- any cardiac pacemaker;
- any intra-cardiac electro- and phono-cardiographic monitor;
- any electroconvulsive therapy unit;
- any photocoagulator;
- any infusion pump;
- any syringe pump;
- any infant incubator;
- any infant transport incubator;
- any hyperbaric therapy chamber;
- any hemodialysis device;
- any peritoneal dialysis machine;
- any heart-lung bypass (perfusion) device;

- any shockwave lithotripsy device;
- any autotransfusion device;
- any high pressure injection device;
- any cryosurgical device; and
- any transcutaneous O₂/CO₂ monitor.

9. Any medium risk electronic product used for medical or dental applications, namely -

- any audiometer;
- any ambulatory electrocardiographic recorder;
- any electrocardiograph;
- any electroencephalograph;
- any electromyograph;
- any cardiac catheterisation laboratory system;
- any physiological monitor (ECG, pressure, respiration, temperature);
- any phonocardiograph;
- any non-invasive bloodpressure monitor;
- any cardiac output computer;
- any plethysmograph;
- any evoked response device;
- any pulmonary function analyser;
- any bloodgas analyser;
- any infusion controller;
- any interferential device;
- any capnograph; and
- any diagnostic exercise device, including treadmill and cycle ergometers.

SPAIN

General Market Condition: No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from CS Post (via E-Mail), 15 April 2005

Import Regulations For Used Medical equipment

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections?

To export to Spain, which is a member of the EU, an export of a medical device must include among the export documents the CE Mark Certification. The CE Mark Certification is the property of the manufacturer. Consequently an exporter of refurbished equipment has to have the authorization of the manufacturer to use the CE Mark Certification for export to Spain.

Can Public Health Institutions buy used or refurbished medical devices?

Yes

Is there a market for used or refurbished medical devices?

No. Both private and public health care hospital and clinics want new medical devices.

If there is a market, what types of used or refurbished medical devices are in the greatest demand?

Not Applicable

Are single-use devices being reprocessed and sold on the local market?

Practically all single-use devices in Spain are disposed of after use. They are not reprocessed.

SRI LANKA

General Market Condition: No Restrictions, but Government Healthcare Sector Cannot Buy

Source: Report from CS Post (via E-mail), 31 March 2002; Updated (via Cable) 11 April 2005

Subject: Import Regulations for Used Medical Equipment

REF: USDOC 0029

Reftel posed several questions on used/refurbished equipment. Answers were compiled from information received from the public and private health sector participants in Sri Lanka and are keyed to each particular question. Begin response to questions:

Are there special restrictions or tariffs that apply to new/used medical Equipment?

Government tariffs are applicable to both, new and used medical equipment. No special restrictions.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc?

A third party cannot import any device that is used/refurbished for his/her own use or to given as a donation nor for resale. Only the registered local agents are allowed to import used/refurbished devices for resale, by the Cosmetic Devices and Drug Authority (CDDA), they are also required to advertise such equipment as being used/refurbished.

Can public health institutions buy used or refurbished medical devices?

No, public health institutions cannot buy refurbished medical devices. The government health institutions have to procure new equipment through a tender procedure and such equipment should be the latest technology.

Is there a market for used or refurbished medical devices?

Yes, in the private sector. Approximately 2 percent to 5 percent of imported medical equipment is refurbished.

If there is a market, what type of used or refurbished medical devices are in the greatest demand?

Used/refurbished laboratory equipment, radiology systems, operating theater equipment, dental equipment and electro surgery systems.

Are single-use devices being reprocessed and sold on the local market? If so, is this activity regulated?

No, single user devices are not reprocessed and there is no regulatory body to monitor such issues.

SWEDEN

General Market Condition: No Restrictions, but CE Mark is required
See also entry for the European Union.

Source: Report from CS Post (via E-Mail), 23 March 2005.

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No, there are no special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment. The CE mark is required on all medical equipment marketed in Sweden, both new and used.

Can public health institutions buy used or refurbished medical devices?

Yes, they can buy used or refurbished medical equipment, but when replacing outdated medical equipment they prefer to purchase new equipment.

Is there a market for used or refurbished medical devices?

According to the Swedish trade association there is no market for used or refurbished medical equipment.

Are single-use devices being reprocessed and sold on the local market?

According to the Swedish trade association reprocessed single-use devices are not sold on the local market.

SWITZERLAND

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 13 March 2001 (Confirmed as still accurate, 25 February 2005)

Switzerland is a small, highly developed and affluent market. It maintains one of the best health care systems in the world. Therefore, importation of used medical equipment is practically non-existent. As a matter of fact, hospitals and doctors donate their used medical equipment/furniture to third world countries.

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

The same tariff rates apply to used medical equipment as to new ones.

Can public health institutions buy used or refurbished Medical devices?

Public health institutions can buy used equipment, however, it is practically never done.

Is there a market for used of refurbished devices?

No. The market is practically non-existent.

Source: Report from CS Post (via E-Mail), 25 February 2005

A distinction is to be made between a "fully refurbished device" and a used medical device that is in the state of operability and has been subjected to the necessary maintenance, but which has not been upgraded or otherwise altered. An altered or upgraded device ("fully refurbished device") has the identical status as a new device and must therefore be subjected by the refurbisher to a conformity assessment procedure for CE-marking as a new device before it can be placed on the market in its refurbished state. Any used device may be placed on the market provided it is appropriately CE-marked by the original manufacturer. A reprocessed single use device has the status of "fully refurbished device" and needs therefore a conformity assessment procedure for CE-marking.

Switzerland has fully transposed the European Medical Devices Directives 90/385/EEC, 93/42/EEC and 98/79/EC into national law. Due to the Mutual Recognition Agreement with the EU, Switzerland participates in the European Market of Medical Devices. The language requirements for the labeling of devices in Switzerland are German, French and Italian. For certain devices also English may be acceptable. Further details are available from the Medical Devices Ordinance (MDO) at the following website: www.swissmedic.ch/md.asp

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

There are no special restrictions or tariffs that apply to used medical equipment. Items 9018 to 9022 of the Swiss Customs Tariff cover medical devices. Import duty ranges from SF 14.00 to SF 88.00 per 100 kilograms gross weight. In addition a VAT of 7.6 percent is levied. Further information on tariffs can be obtained at:

Federal Customs Administration
Oberzolldirektion
Monbijoustrasse 40
CH-3003 Bern, Switzerland
Tel: +41-31-322-65-11
Fax: +41-31-322-78-72
E-mail: zentrale.ozd-tarif@ezv.admin.ch

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, etc.?

Parallel import of devices is possible. Anyone importing such a device must have the corresponding declaration of conformity (according to the requirements of the EU Directive 93/42/EEC) for the device and the necessary EC-Certificates. If a device of class I is imported from a non-EEA country, there is the obligation to notify Swissmedic (MDO, art. 6). This holds also for custom-made devices and system and procedures packs.

Can Public Health Institutions buy used or refurbished medical devices?

There are no legal provisions in the MDO prohibiting a Public Health Institution from buying or importing a used or refurbished medical device, as long as the conformity of this device can be demonstrated according to the requirements of 93/42/EEC and the importing party fulfills notification requirements (MDO art. 6) as well as the product surveillance responsibilities (MDO, sect. 5).

Is there a market for used or refurbished medical device?

There are no statistical data on the Swiss market of used and refurbished devices. However, this market it appears to be characterized by export activities.

SYRIA

General Market Condition: Prohibited (except for Expatriate Doctors Returning with Equipment for Their Own Use)

Source: Report from CS Post (via Cable), 3 April 2003

According to Syrian laws and regulations, the import of used or refurbished medical equipment is not permitted. The government has recently allowed expatriate doctors returning permanently to Syria to bring back their used hospital and medical equipment for use in their own clinics exclusively.

Source: Report from CS Post (via Cable), 17 February 2000

Syrian regulations prohibit the importation of used or refurbished medical equipment. The import licenses for medical equipment issued by the Ministry of Economy and Foreign Trade require the importer to acknowledge that the medical equipment being purchased is 'new equipment and not refurbished.'

TAIWAN

General Market Condition: No Restrictions

Source: ISA Medical Electro-Diagnostic Apparatus, 1 December 1999 (Confirmed as still accurate 28 March 2002)

U.S. Market Position

The market for used or refurbished medical devices is virtually nonexistent in Taiwan. Local hospitals prefer to buy new equipment and their budgets currently permit them to do so. Apart from the normal medical device registration, used equipment will likely face difficult market challenges in Taiwan.

Source: Report from CS Post (via Cable), 27 July 1998 (Confirmed as still accurate 28 March 2002)

The importation of the following categories of used equipment is restricted in Taiwan: cars; equipment and parts used in the aerospace industry; equipment and parts used in ships and vessels; and generators and compressors with diesel engines. All other imports are treated the same as new.

TANZANIA

General Market Condition: No Restrictions, but Public Institutions Cannot Buy

Source: Report from CS Post (via E-Mail), 15 March 2002

Tanzania is pursuing a very flexible import administration regime on used and refurbished equipment in general. According to the East African Customs and Transfer Tax Management Act of 1952 Revised 1970 as applied by Act Number 19 of 1977 Section 14 and 15, there is no import restriction on used equipment in Tanzania.

However, on consignment basis, importation of used equipment into Tanzania is subject to inspection, verification and certification on its usability, suitability and appropriateness as governed by the Standards administered by the Tanzania Bureau of Standards (TBS) and any other Law. This is mostly applicable to items in the sensitive sectors that affect health and security.

Several industrial sectors have licensing and inspection boards. For instance, the National Medical and Pharmaceutical Board, under the Ministry of Health, handles medical equipment whereas Tanzania

Bureau of Standards (TBS), under the Ministry of Industry and Trade, is charged with the administration of standards issues including 572 published standards. TBS is a member of the International Organization for Standards (ISO) and has been notified to the WTO as the contact point for issues related to the Agreement on Technical Barriers. Most Tanzanian standards are voluntary in nature and TBS adopts international standards whenever they exist. Sanitary and phytosanitary standards are the responsibility of the Ministry of Agriculture and Food Security (MAFS), which conducts an inspection and certification program for all imports of plant and animal products.

Motor vehicles of Japanese origin continue to be the largest single group of used/reconditioned-imported items into the country. The reforms that Tanzania has undertaken since 1985-and at a more accelerated pace in the past few years-have resulted in a trade policy framework that has been significantly liberalized and that is essentially based on tariffs. Liberalization of trade increased the volume of used equipment imported in other industrial sectors as well, especially office equipment (computers) and domestic appliances. Used items from various industrial sectors have been imported mostly through the free ports of the Middle East, South East Asia, Europe and South Africa. The United States of America continues to have negligible direct share of this trade in Tanzania despite the fact that some of the imported equipment is of U.S. origin.

Imports of used or refurbished equipment are receiving similar treatment as new ones. The whole scope of commercial goods being imported into Tanzania is subject to the same system of valuing goods for customs purposes, which is fair, uniform, neutral and conforms to commercial realities.

Tanzania is implementing WTO Agreements including the Agreement on Customs Valuation (ACV). The procedure for valuation of goods for taxation purpose that is now in use is known as 'Agreement on Customs Valuation (ACV)'. ACV prohibits the use of arbitrary or fictitious Customs values. Pre-Shipment Inspection (PSI) is applied to goods of a value of above US Dollars Five Thousand (\$ 5,000). Since duties are mainly levied on an ad valorem basis (based on value), a common problem is evaluating the equipment's current worth. Often, the customs department has blamed importers, for under invoicing. In such cases, depreciation of the equipment had to be re-evaluated by the customs in collaboration with local dealers of the subjected item before an appropriate duty could be levied.

The recent reform of Tanzania's customs duties (customs tariff structure) has resulted in a simplified four-tier structure with tariff rates of 0 percent, 10 percent, 15 percent and 25 percent in that order. Pharmaceuticals and medicaments, motor vehicles in CKD form and inputs for manufacturing pharmaceutical products, raw materials, capital goods and replacement parts fall under zero tariffs.

There is no absolute ban on the import of any type of used equipment to Tanzania. There is a market for used or refurbished medical equipment in Tanzania. Used hospital/medical equipment has to attain the approval of the National Medical and Pharmaceutical Board. Used X-ray machines are not recommended. Used dental and medical laboratory equipment are in the greatest demand. Neither public health institutions nor the Government of Tanzania can buy used or refurbished medical devices. Nuclear substance processing equipment requires an approval from the Commission on Atomic Power within the Tanzania Commission of Science and Technology.

Importation of used / refurbished equipment is growing fast in Tanzania. Motor vehicles of all ranges, tractors, television sets, computers, VCRs, refrigerators, cookers, photocopiers, sewing machines, hair dressing equipment, retread and used tires, used construction equipment, generators and engine parts, are some of the most notable used imported items. Japan has been leading in the export of reconditioned cars, which account for more than 75 percent of the value of the imported equipment. Germany, Sweden, United Kingdom, Italy, the Middle East, Denmark, Australia and South Africa are the main source of used domestic, industrial, construction and office equipment. These four industrial sectors are prospects for U.S. suppliers in Tanzania.

THAILAND

General Market Condition: Prohibited

Source: Report from CS Post (via Cable), 21 March 2002, Updated (via E-mail), 25 April 2005

The information on import regulation for used/refurbished medical equipment as contained in the website: www.ita.doc.gov/td/mdequip/regulations.html is still current and in effect. There is not any possible modification of the regulations in the future.

The Government of Thailand prohibits the importation of used or refurbished medical equipment into the country, but does not prohibit sales of those devices.

The potential market for refurbished devices is strong, especially for non-invasive, non-life-threatening devices. They include pulse oximeters, bedside monitoring devices, and blood pressure-monitoring devices.

Single-use devices are being processed and used at some of the public health institutions in Thailand. Sales of processed single-use device do not exist.

Source: Industry Sector Analysis, Healthcare Products, 8 March 2002

The Medical Devices Control Division, Food and Drug Administration, Ministry of Public Health, controls importation of medical devices into Thailand. Prior approval of importation and device registration through this office is required. Any devices that are not allowed to be marketed or sold in the manufacturing country will not receive permission to be registered in, or imported into Thailand. The Thai Government does not allow importation of used or refurbished medical equipment.

Source: Report from CS Post (via E-Mail), 1 April 2001 (Confirmed as still accurate, 21 March 2002)

The Government of Thailand prohibits the importation of used or refurbished medical equipment into the country, but does not prohibit sales of those devices. Public health institutions have a policy that prohibits the purchase of used or refurbished devices because of concerns about quality and reliability.

On the other hand, there is a market for refurbished devices among private health institutions, specifically non-invasive, non-life-threatening devices. The devices in this group include pulse oximeters, blood pressure monitoring devices, and other bedside monitoring devices. These devices are traded locally among the private health institutions. There is also a good potential for sales of device calibration services to both public and private hospitals in Thailand.

TRINIDAD AND TOBAGO

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 28 March 2002

There are no special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment. Duties are charged based on the cost of the product. Documentary evidence of cost is required. Public health institutions seldom buy used or refurbished medical devices. The market for used or refurbished medical devices is very small.

TUNISIA

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 30 October 1998 (Confirmed as still valid, 4 March 2002)

According to the Tunisian Ministry of Commerce, there are no statutory prohibitions on the import of used/refurbished equipment. Imports of used equipment are subject to strict control by the Ministry of Industry, whose inspectors verify the proper functioning of all used equipment imports.

There are no specific restrictions on individual categories of used/refurbished equipment, but each import is reviewed thoroughly and is admitted entry on a case-by-case basis.

While regulations are minimal, importation of used equipment into Tunisia is difficult as there is a strong preference for guarantees and after-sale service, which comes with new equipment. Local banks that finance industrial products normally require that purchased equipment be new. Used equipment is sometimes imported, as part of a foreign investor's contribution-in-kind to the capital of a project. The purchase of used equipment for government-funded projects is permitted only in exceptional circumstances.

The United States is Tunisia's fourth largest foreign supplier and U.S. technology is held in high regard in Tunisia for its state-of-the-art technology. Given the difficulty of assessing the true ease of entry for used equipment and the general Tunisian preference for new items, however, the Tunisian market is not particularly well suited for used/refurbished U.S. equipment exports.

TURKEY

General Market Condition: Restricted

Source: Turkey Country Commercial Guide FY 2002

Leading Sectors For U.S. Exports And Investments

Name of Sector: Medical Equipment

ITA Industry Code: MED

Turkey's demand for medical products and related equipment is expected to continue to grow in the coming years. The current total market size for the overall medical equipment sector is approximately US\$750 million, with the U.S. share being a healthy fifteen percent. The estimated annual growth rate of imports from the United States is 20 percent.

In recent years, the Government of Turkey has allocated more funding to healthcare, substantially improving most of Turkey's healthcare standards. However, healthcare services are still inadequate to cope with a rapidly expanding population (currently about 65 million and growing by nearly two percent annually). Health expenditures represent approximately 5 percent of GNP.

The Turkish Ministry of Health (MOH) is the largest provider of healthcare in Turkey. Health care facilities operated by MOH account for approximately 84,000 beds. Other government agencies including the Ministry of National Defense, Social Security Agency (SSK), various public sector medical faculties and municipalities account for an additional 70,000 beds. The private sector, including foreign organizations and various associations, operate a total of 15,000 beds.

The private sector is actively expanding its role in the health sector. New capital-intensive medical technologies, such as magnetic resonance imaging (MRI), computed tomography (CT), and megavolt radiation therapy will continue to be purchased by Turkish hospitals. Major suppliers are the United States, Europe, and Japan. The Turkish business community has a high opinion of U.S. medical equipment and suppliers.

Demand for used, refurbished equipment (traditionally low), has increased over the last few years and is becoming an alternative source for emerging distributors and end-users because of lower prices and shorter delivery time. Current Turkish import regulations permit the importation of used equipment, no more than five years old. Equipment between five and ten years old is technically subject to a 50 percent import duty. The importation of devices over ten years old is prohibited.

The World Bank contributes to the financing of the government's healthcare improvement projects and has lent \$76 million and \$140 million respectively for the First and Second Health Projects between 1991 and 2001. Total investment required for these two projects was \$346 million, and the Turkish Government supplied the remaining portion.

Most major government tenders outside the scope of the World Bank Health Project still require supplier credit. The GOT also encourages use of the "build-operate-transfer" (BOT) model as a means of procuring equipment for which funds are scarce. The BOT model calls for the vendor to install and operate the equipment, receive the revenues from the use of equipment, and finally transfer the equipment at the end of a specified period that covers expenses and profit.

Effective June 1, 1996, all medical equipment imports are subject to the Turkish Standards Institute (TSE) approval. USFDA approval is regarded as a seal of quality. Medical devices for sale (without restrictions) in the United States may normally be imported for sale in Turkey.

TURKMENISTAN

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 29 March 2000

So far, the government of Turkmenistan (GOTX) has introduced no rules regulating import of used and/or refurbished medical equipment in Turkmenistan. Import of such medical equipment is treated the same way as import of new equipment.

U.S. companies that plan importing used and/or refurbished medical equipment to Turkmenistan should be alert when a contract is negotiated. It should be clarified in the contract that import of used and/or refurbished medical equipment is agreed to by all parties participating in a transaction. Otherwise, a dispute with regard to the quality of imported equipment may arise. There have been such claims in the past.

So far, there have been no excise taxes or customs tariffs charged for imported used and/or refurbished medical equipment. Moreover, the customs and the state commodity and raw materials exchange do not charge service fees from those trade contracts where medical equipment is a part of a transaction. The main obstacle for U.S. companies planning to sell medical equipment in Turkmenistan is the non-convertibility of the Turkmen currency; hard currency is rationed, and importers must justify to the government their need for hard currency to pay for the goods they import.

The Turkmen market with a population of five million is relatively small and underdeveloped in terms of medical equipment supplies as well as medical personnel training and management. Needs are substantial, but means are limited. There is no medical equipment production in Turkmenistan and a potential market for used medical equipment does and will continue to exist here. So far, the GOTX has built a new pharmaceutical plant with the involvement of Indian Government credit line and maintains operation of an out-of-date pharmaceutical production facility in Ashgabat. Nonetheless, the Turkmen market relies heavily on imported medical items and pharmaceuticals. There are no Turkmen private clinics and hospitals in the country except for a Turkish private hospital, which has been operating in Ashgabat since 1998. The GOTX will continue to be the main partner in any investment project in the health care sector for the next decade. The only privatization that has taken place has involved the creation of local private drugstores. The Ministry of Health Care and Medical Industry, which handles the state investment fund

for health care sector development, is responsible for financing health care projects. According to the Ministry of Health Care and Medical Industry, the market demand for medical equipment is evaluated at US\$50 million. However, this figure could be much higher providing the GOTX has sufficient hard currency reserves in the investment fund.

In order to import foreign medical equipment into Turkmenistan including used and refurbished, one must be licensed for importation by the state center for registration of imported medical equipment and approved by Turkmenmedtehnika, a state company handling medical equipment use and importation. The state inspectorate 'Turkmenstandartlary' provides certification of the imported medical equipment. Other government approvals also apply.

UGANDA

General Market Condition: No Restrictions but Public Healthcare Institutions Do Not Buy Used Equipment on Open Tenders

Source: Report from CS Post Kampala (via E-Mail), 1 April 2003, Updated (via – E-mail), 3 March 2005

Are there special restrictions or tariffs that apply to used medical equipment but do not apply to new medical equipment?

There are no official restrictions or tariffs. However, the Uganda Revenue Authority may question the valuation of the used equipment and assign the equipment a value above that provided by the exporter.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subject to new safety inspections, etc.

Medical devices need not be registered in Uganda. However, used/refurbished medical equipment must be imported through a pharmaceutical company registered with the National Drug Authority (NDA). A fee based on the F.O.B. value must be paid to the NDA. The National Advisory Committee on Medical Equipment may advise the importer on the suitability/compatibility of the device in question but has no authority to bar an importer from importing whatever device it wishes to import. As a good business practice, importers should ensure that they could provide servicing for the refurbished goods through an authorized dealer or distributor prior to bringing the goods into the country.

Can public health institutions buy used or refurbished medical devices?

Yes, but not on open tender, which follows the normal public procurement guidelines, which stipulate that all equipment purchased has to be new.

Is there a market for used or refurbished medical devices?

Yes, particularly among private hospitals and clinics. Public health institutions rarely purchase used or refurbished medical devices. Government purchases normally are made using loans/grants from donor countries, which typically attach conditions to the loans/grants requiring that the equipment be purchased from the donor country.

If there is a market, what types of used or refurbished equipment medical equipment are in greatest demand?

Uganda has long been underserved by the health care sector. Recently, several private clinics have opened, increasing overall demand for medical equipment. While many of the clinics have focused on purchasing new products, they may also be interested in looking at used goods. The market for used equipment largely reflects that for new equipment. Areas of particular interest include:

Record management equipment and systems; ultrasound: electrocardiographs; x-ray equipment; dopplers for obstetrics; pulse oximeters; ventilators; cardiac echo machines; treadmill stress machines; lab equipment (including equipment needed for microbiology, haematology, chemistry, and histopathology), and medical furniture.

Are single-use devices being reprocessed and sold on the local market?

No.

UKRAINE

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 10 April 2003

Regulatory Agency

The State Department of Quality Control, Safety and Manufacture of Medicinal and Medical Use Products perform the act of registering or re-registering medical use products in Ukraine.

Registration Procedures

Procedures for registering medical equipment and medical use products were approved by the Ministry of Health of Ukraine on September 26, 2000. The procedure was filed by the Ministry of Justice of Ukraine on January 17, 2001, and is now law.

Registration is a requirement for the importation of medical products into Ukraine.

There is no special procedure for registration of used/refurbished medical equipment. There are no special restrictions or tariffs that apply to used medical equipment.

Applications for registration must be submitted (on a standard form) to the State Department on Control of Quality, Safety and Manufacture of Medicinal and Medical Use Products (see below).

In addition, the following must also be provided with the application:

- Catalogues of the product,
- Manuals,
- Technical specifications,
- Certificates (manufacturer's certificate, certificate of origin),
- Foreign certificates (if available),
- A certificate of conformance issued by a Ukrainian certifying agency (if available),
- Information on manufacturing standards (if available),
- Trade mark samples, and
- Manufacturer's registration documents.

Registration is performed by the State Department on Control of Quality, Safety and Manufacture of Medicinal and Medical Use Products, and is based on evaluation of the product by expert testing agencies. Once registered, a product is included in the State register of medical equipment and medical use products.

Registration is valid for five years. The procedure for renewal of registration is the same as described above.

If a manufacturer or its agent has registered a medical device in the country, a third party can legally import the same device in used/refurbished condition without the used device being subject to new safety inspections and registration.

Public health institutions can buy used/refurbished medical devices if these devices are registered in Ukraine.

Receptivity for used dental equipment is average; as the price difference between local and imported used equipment has narrowed, the motivation to purchase used equipment has also decreased. However, a potential market for used dental equipment exists, the preferred approach being the creation of a refurbishing joint venture with local partner.

Registration Form Requirements

A. General information

- Name of the medical use product -synonyms, trade mark (in original language, in English, and in Ukrainian).
- Applicant (country where the applicant is registered, address, phone, fax, e-mail, national registration number and code).
- Manufacturer (country where the manufacturer is registered, address, phone, fax, e-mail, national registration number).
- Document confirming the authority of an applicant to represent a manufacturer (if an applicant is not a manufacturer - a contract, or power of attorney).
- Ukrainian customs code for the medical use product.

B. A certificate of conformance issued by a Ukrainian certifying agency.

I certify that the applying product complies with quality and safety requirements, as stated in the supporting documentation, and with requirements of Ukrainian legislation as to quality and safety for human health and the environment.

Date Signature of applicant

The documents that confirm the compliance of goods with Ukrainian certification requirements are:

- A certificate of conformance issued by a Ukrainian certifying agency, upon certification of goods; or
- A certificate of acceptance of a foreign certificate issued by a Ukrainian-certifying agency, upon acceptance of a foreign certificate.

Note: Certificates issued by foreign authorities are recognized in Ukraine only to the extent provided in international treaties to which Ukraine is a party. No intergovernmental agreements on goods certification exist between Ukraine and the U.S. and a certificate of acceptance of a foreign certificate may not be issued without the actual testing of the product.)

Contacts

Contact at the State Department on Control of Quality, Safety and Manufacture of Medicinal and Medical Use Products, Division for Registration and Certification of Medical Equipment and Medical Use Products:

Yaroslav Penishkevich, Head of the Medical Equipment Division
120 Pobedy Ave., of. 9
Kiev 03142
Ukraine

Tel/fax: +380-44-444-7253, 444-2571, 444-1048

E-mail: yary@cmt.kiev.ua

For additional information on the medical industry sector in Ukraine, please contact your nearest USDOC Export Assistance Center, with a copy to:

Frank Carrico, CS Kiev Senior Commercial Officer
Olena Stephanska, CS Kiev Commercial Specialist,
The Commercial Service, U.S. Embassy Kiev,
4 Hlybochytska St., Kiev 04050, Ukraine
Tel: +380-44-490-4018;
Fax: +380-44-490-4046
E-mail: kiev.office.box@mail.doc.gov
E-mail: Olena.Stephanska@mail.doc.gov

Source: Report from CS Post (via E-Mail), 30 March 2001

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

There are no special restrictions or tariffs that apply to used medical equipment in Ukraine.

Can public health institutions buy used or refurbished Medical devices?

Public health institutions can buy used and refurbished medical equipment.

Is there a market for used or refurbished devices?

The market for used medical equipment is small in Ukraine—importers prefer to buy new equipment, although new equipment is more expensive.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

The demand for used equipment is to be identified on case-by-case basis.

UNITED ARAB EMIRATES

No Restrictions, but Public Health Institutions Cannot Buy

Source: Report from CS Post (via E-Mail), 16 April 2003

Are there special restrictions or tariffs that apply to used medical equipment?

There are no special restrictions or tariffs that apply to used equipment that do not apply to new equipment. The same customs charges of 5 percent are levied on both new and used equipment.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used/refurbished condition without the used device being subject to new safety inspections, etc.?

A third party can import used medical equipment even if its agent has registered the device in the United Arab Emirates (UAE). Yet this imposes after sale maintenance issues especially for high-tech equipment, where only registered agents have after sale maintenance capabilities and registered agents might not accept to provide maintenance. At the same time if import documents specify a brand that has an agent in the UAE, only the agent can clear on these items with Customs Department. With that said, the usual practice has been not to specify the brand/manufacturer, rather the name of supplier. Neither new nor used/refurbished medical equipment are subject to safety inspection by the local authorities.

Can public health institutions buy used or refurbished medical device?

Government regulations do not permit Public health institutions to buy used or refurbished medical equipment.

Is there a market for used or refurbished medical devices?

The government in the UAE is the main healthcare provider. Government healthcare services account for 80 percent of the market. Only 20 percent of the market for healthcare services is supplied by the private clinics and hospitals. The majority of the bigger private clinics and hospitals prefer and can afford new equipment. Therefore, the market for refurbished medical equipment/devices in the UAE is rather limited.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

As stated above, the market is limited to smaller private clinics and hospitals. These usually buy refurbished imaging, diagnostic, radiology and ultrasound equipment. Yet, although the market for refurbished medical equipment is limited in the UAE, there seem to be a market of the same for re-exports to neighboring countries.

UNITED KINGDOM

General Market Condition: No Restrictions, but CE Mark is Required

See also entry for the European Union.

Source: Report from CS Post (via E-Mail), 22 March 2002, Updated, 3 March 2005

The United Kingdom has a reasonably growing requirement for and interest in used medical equipment, across all sectors. The majority of such purchases are made by hospitals that are part of the United Kingdom's government-funded National Health Service (NHS). Such pre-owned equipment is subject to the same import duties and regulations as new devices.

The U.K. medical equipment market is driven by the NHS - the United Kingdom's universal, publicly funded healthcare system; which accounts for about 85 percent of total U.K. healthcare provision. As such, the NHS accounts for the majority of medical equipment purchases in the \$5.4 billion U.K. market.

The majority of used medical equipment procured by the NHS is purchased by individual hospital trusts, which are regional groupings of the 1,600 NHS hospitals. Contact information for these trusts can be found at www.dh.gov.uk.

The NHS also has a central purchasing organization-the NHS purchasing and supplies agency- (www.pasa.doh.gov.uk) that influences more than half of the NHS' total spend on supplies. Although NHS hospitals are not required to purchase from this agency, over 98 percent of NHS trusts place all, most, or some of their business with the organization. Contacts at this agency report that in the past they have done little procurement of used medical equipment but have recently been approached by a U.S. company who sells pre-owned medical equipment and was very interested in exploring similar opportunities. Senior buyers at PASA told us that there certainly was an important niche for pre-owned medical equipment in the UK market. The NHS purchasing and supplies agency can be reached on +44-118 980 8600.

In addition, in May 2004, the UK Secretary of State for Health announced that \$320 million had been pledged to modernize cancer equipment in the NHS, \$180 million of this funding will be used to replace all MRI and CT scanners that were installed before 1997. For further details please visit the Department of Health web site at www.dh.gov.uk.

The individual organization or hospital group finances private sector procurement of medical equipment. There are currently 230 private hospitals in the United Kingdom, and these organizations purchase very limited amounts of used equipment, if any at all.

There is no market for refurbished single-use devices in the UK. In terms of the reprocessing of single-use devices, the Medicines and Healthcare Products Regulatory Agency states very clearly that:

Devices designated for single-use must not be reused under any circumstances.

The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.

The reuse of single-use devices has legal implications. (a) Anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness. (b) Anyone who reprocesses a single-use device and passes it to a separate legal entity for use has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.

Any used or refurbished medical equipment sold in the U.K. market faces the same restrictions and regulations as new equipment. As with a new medical device, a used or refurbished medical device must obtain a CE mark that enables the product to be marketed anywhere within the EU. To obtain a CE mark, full compliance with the appropriate EU directive must be achieved. The three main EU medical devices directives are the Medical Devices Directive, the Active Implantable Medical Devices Directive, and the In-Vitro Diagnostic Medical Devices Directive (to be fully implemented in December 2005).

If a product has obtained a CE mark and is then refurbished, no re-registering is required if the product is refurbished with original equivalent parts (i.e. parts must meet manufacturer specifications). If significant alterations occur, previous regulatory approval could be invalidated.

Within the United Kingdom, the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) enforces regulations and deals with inquiries concerning compliance to the EU directives. Information about the MHRA and full descriptions of the EU directives can be obtained on the Web site:

www.mhra.gov.uk

Used or refurbished medical equipment is subject to the same import duties as new devices. The majority of medical equipment is classified into one of two categories in the Harmonized Tariff Schedule (HTS): HTS 9018 (medical, surgical, and dental instruments and apparatus) and HTS 9402 (medical, surgical, and dental furniture). New or used medical equipment classified under HTS 9018 and 9402 can be imported into the United Kingdom duty-free. A 17.5 percent value-added tax (VAT) is levied on the CIF value of the products (the value of the product, plus carriage, insurance, and freight).

For further information on the health care industry, and how the U.S. Commercial Service can assist U.S. firms develop their businesses in the UK, please contact:

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Web site: www.buyusa.gov/uk/eu/

URUGUAY

General Market Condition: Restricted

Source: Report from CS Post (via E-Mail), 28 March 2001 (confirmed as still accurate 21 March 2002)

Unfortunately there would appear to be no niche for used medical equipment in the Uruguayan market. Moreover, as a member of Mercosur, Uruguay applies a common external tariff to products coming from outside Mercosur. The common external tariff in some cases is as high as 16.5 percent, whereas the tariff on medical equipment coming from the other Mercosur countries is zero percent.

Although the same regulations apply to used equipment as to new equipment, the Ministry of Public Health tends to make the procedures extremely troublesome (even in the case of donations), so local importers do not look for used equipment. The Ministry of Public Health will accept used equipment as donations only, and they make it difficult for themselves also!

Local costs for repairing/refurbishing are low, with high skills. So when upgrading, high-end institutions/users tend to sell their equipment to those with lower technologies and they can then have it as new at low costs.

UZBEKISTAN

General Market Condition: Restricted

Source: International Market Insight, Import Regulations for Medical Equipment in Uzbekistan, 2 April 2002 (Updated: 16 May 2003)

Summary

The act of registering or re-registering of products for medical use in Uzbekistan is performed by the Head Department of the Drug and Medical Equipment Quality Control (HDDMEQC), Public Health Ministry of the Republic of Uzbekistan.

The procedures for registering medical equipment and related products were issued by the Cabinet of Ministers of Uzbekistan on May 25, 1995, and then were approved by the Ministry of Health.

Registration is a requirement for the importation of new medical products into Uzbekistan. Once registered, a product is included in the State register of medical equipment and medical related products.

Registration is valid for five years.

Regulations for Used Medical Equipment

Medical equipment that has been in use does not need to be officially registered in the Republic of Uzbekistan. However, all medical equipment imported to the territory of Uzbekistan should pass the governmental certification. The companies are advised to get the copy of the government quality technical standards, which are applicable to the imported type of equipment. The utilization of used and refurbished medical equipment in hospitals and testing institutions is possible only after passing the strict quality, suitability and security conditions in a technical evaluation with the technological experts from a special commission, created under HDDMEQC. Medical equipment, which is supplied through humanitarian aid, can be distributed to the final place of destination, only after certification testing.

Most Promising Markets for Used Medical Equipment

The best market potential for used and refurbished U.S. manufactured medical equipment is expected to be in the following areas: Dental equipment, diagnostic equipment, laboratory scientific instruments and supplies, and rehabilitation equipment for the private hospitals.

Methods of Procurement

The Ministry of Health officials (MOH) and local companies underlined that they prefer working directly with manufacturers, and not with intermediaries. Medical equipment and supplies are primarily financed from the State budget and loans from the World Bank or other banks and agencies.

To sell medical equipment to MOH entities, an American company must be sure: (1) the MOH has some funding either from the state budget or a loan, and (2) the main MOH suppliers of medical equipment (such as Uzmedexport or Tibmahsulot) have the necessary information about the American company’s products. U.S. companies interested in doing business in Uzbekistan should provide the two main Uzbekistan suppliers with catalogues of their products and information on the companies, their goods and services.

To sell medical equipment to other, non-MOH financed state medical entities, an American company should have a distributor or a dealer that will go to these clinics and hospitals to evaluate the needs, display the equipment, and persuade medical personnel to buy the equipment. If the company and medical personnel come to an agreement, the chief medical officer of the hospital or clinic will go to the relevant regional or municipal authorities to request funding. Such payments are generally done through the National Bank of Uzbekistan.

The NGOs are another tool for exporters to find end-users of medical equipment by means of the organizations of different types of seminars, training, launch meetings for local doctors within the country.

Non-state Purchasers

The medical technologies are a State-controlled sector. However, the private hospitals and doctors themselves could be potential customers for used and refurbished medical equipment. It is also necessary to point out that the older generation doctors who were trained during the Soviet period have the inclination to buy German or Russian medical devices. The younger generations of doctors have the opposite inclination to purchase modern digital equipment, manufactured in U.S. or Japan.

Resources of Uzbek Health Services

Uzbek Health Statistics

Item	Number
Physicians	73,389
Medium level medical personnel	249,337
Regional hospitals	22
Municipal hospitals	120
Central district and district hospitals in rural area	198
Community hospitals	198
Maternity homes	53
Other specialized hospitals and institutions	255
Institutions with units of resuscitation and intensive therapy	417
Number of their beds	3,016

Emergency medical centers	155
Number of their beds	131,478
Medical ambulatory-polyclinic institutions	3,679
Blood transfusion stations	17
First-aid stations (departments)	213
Sanitary-epidemiological stations	225

Main Contact Information

The package of standard forms can be obtained at the Receptionist Desk of Committee on new medical technology of the Head Department of Drug and Medical Equipment Quality Control at the address below.

More information can be obtained from:

Mr. Abdunamon Sidikov, Head of External Economic Activities Department
 Ministry of Health of Uzbekistan
 30 Abdullaeva Street,
 Tashkent 700011, Uzbekistan
 Tel: +998- 712 68 26 32, 68 08 11, 1690021
 Fax: +998-712 1690021

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 Ministry of Health of Uzbekistan
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International Mailing Address:

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Tashkent 700000 Uzbekistan

U.S. Mailing Address:

Commercial Service
Department of State
7110 Tashkent Place
Washington, DC 20521-7110

VENEZUELA

General Market Condition: No Restrictions, but Government Agencies do not Buy

Source: Report from CS Post (via E-Mail), 22 May, 2001; Updated 4 April 2005

Import Regulations for Used Medical Equipment

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

There are no special regulations or customs tariffs that apply to used or refurbished medical equipment that do not apply to new products. No customs duties discounts are granted for the import of used equipment. However, internal regulations within the Government prohibit all Government entities or operations from importing or using used equipment. While not subject to laws or regulations, private banks upon financing the acquisition of medical equipment, as a rule will not grant financing to imports of used or refurbished equipment. We have heard of some isolated cases, where a bank will entertain a request for financing if the refurbished equipment is covered by warranties.

If a manufacturer or its agent has registered a medical device in the country, can a third party legally import the same device in used /refurbished condition without the used device being subjected to new safety inspections, etc.?

If a medical device has been registered and authorized for sale by the Ministry of Health and has been given its registration number, refurbished equipment of the same type can be legally imported by another company. However, if the refurbishment included improvements or changes affecting key components or if the application of the equipment is different from the originally registered one, the importer should request a reading from the Ministry to determine whether a new application for registration would be required.

Can public health institutions buy used or refurbished medical devices?

Public Health Institutions owned by the government agency including the military are not allowed to buy

used refurbished or used medical devices.

Is there a market for used and refurbished medical devices?

There is a somewhat limited market for used or refurbished medical equipment among the smaller private hospitals and clinics or among individual physicians. Most of these potential buyers however will require the availability in the country of spare parts, service and in some cases a limited warranty. The used equipment market is driven mainly by the cost difference between used and new equipment.

If there is a market, what types of used medical devices are in greatest demand?

The potential market for used medical equipment consists mainly of electro-medical or other more expensive pieces of equipment, such as X-ray machines including dental units, electrocardiographs, ultrasound equipment, sterilizers, laparoscopy and colon or stomach viewers but normally does not include medical/surgical instruments.

Are single-use devices being reprocessed and sold on the local market? If so, is this activity regulated?

There appears to be no reprocessing on an industrial scope of single-use devices nor does there appear to be a commercial scale of sales of such reprocessed single-use devices. Individual doctors and some of the very small clinics might at times wash and re-sterilize such devices if they are considered to be in good enough condition.

Source: ISA Medical, 1 September 2000

Overall hospitals in Venezuela are not managed efficiently according to industry analysts. Therefore it has been difficult to build up a reserve fund for future technology upgrades and acquisitions. The same doctors work in both the public and the private sectors. However, in the public sector the government does not provide adequate tools and equipment, or the proper infrastructure. This has been the situation over the past twenty years. In Caracas over the past ten years private hospitals were unable to make direct investments as they were greatly affected by the recession. Nevertheless, they managed to form strategic alliances with the medical distributors, which resulted in many private hospitals having the latest technology. Unfortunately this kind of initiative has not taken place in the rest of Venezuela.

Demand of medical equipment and supplies will be determined mainly by importers' purchasing power, product price and the rate of growth in the market of used equipment. Local statistics indicate that imports of refurbished equipment have grown approximately 60 percent over the past two years. This is the result of the continuous currency devaluation, the limited access to import new equipment, increased health costs and patient's diminishing purchasing power. The demand for U.S. refurbished equipment is becoming an alternative source for distributors and end users, as long as technical support and service are available.

There is a need in the public health sector for high technology equipment, such as tomographers, ophthalmologic and optical instruments, cobalt pumps (nuclear medicine), magnetic resonance chambers, X-ray apparatus, laboratory and hematology testing equipment, infusion and transfusion equipment, cancer diagnostic and therapy equipment, hemodialysis equipment, electrocardiographs, electroencephalographs, linear accelerators, equipment for heart disease, apparatus for intensive care units and dental equipment.

VIETNAM

General Market Condition: Restricted

Source: Industry Sector Analysis, Medical Diagnostic Equipment, 31 January 2002

The Government has recognized that neither the State budget nor even the largesse of official development assistance (ODA) donors can cope with Vietnam's needs for investment in health care facilities, and over the past few years has promulgated measures to encourage private investment in this sector, which was previously reserved for the State. Although private hospitals only serve a limited market of wealthier Vietnamese and some foreign nationals, the number of private hospitals grew from 6 in 1999 to 10 in 2000, each with around US\$2 million in invested capital. Private hospitals are more open to purchasing new equipment and employing advanced techniques that will allow them to differentiate themselves in the market.

Supplementing hospitals, the system also has 19,836 private health care clinics (many run as "sidelines" by staff doctors from state-owned hospitals), 7,015 traditional medicine centers, 3,432 specialized clinics, and 550 family-run clinics. These establishments are predominately small-scale and are not likely to procure much high-end equipment. However, they may represent a market for used equipment with service and warranty.

Regarding used equipment, Decision 2019/1997/QD-BKHCMNT dated December 1, 1997, stipulates that the Ministry of Science, Technology, and Environment (MOSTE) must inspect imported used medical equipment. Imported used medical equipment must retain at least 80 percent of its life expectancy and must not consume more than 10 percent of fuels or electricity used by newer versions of the equipment.

Source: ISA Medical, 1 January 2001

Import Climate

Importation of medical equipment into Vietnam must go through a trading company that has an import license. In the past, only state-owned enterprises had licenses to import medical equipment to Vietnam, and these trading companies charged the real equipment buyers or distributors a few percent commission rate on the total value of the imported goods. Now, any business entity, including foreign invested enterprises that have a legally registered business license, can be engaged in direct import and export activities.

Decree 11/1999/ND-CP issued on 3 March 1999 stipulates the ban of medical equipment. Only medical equipment intended for sex enhancement and aphrodisiac purposes have been clearly identified as banned medical equipment. Decision 088/2000/QD/BTM issued 18/2/2000 provides further detailed instructions and a list of banned medical equipment.

According to the Government's Decree 89/CP promulgated on 12 December 1995, each year the Ministry of Health, in consultation with the Ministry of Trade, issues a list of equipment in which importation must be registered and approved by the Ministry of Health. Decree 89/CP has been altered many times and importation of medical equipment is now regulated by Decision 242/1999/QD/TTg issued on 30 December 1999. Decree 89/CP is now replaced by Circular 05/2000/TT-BTM issued 21 February 2000.

The current list for equipment needing to be registered and approved is detailed below:

- CT Scanner and gamma scanner;
- Cobalt and accelerator equipment;
- Simulator equipment;
- Magnetic resonance equipment;
- Blood filter/sterilizing equipment;
- Ultra-sound color Doppler equipment;
- X-ray equipment;

- Emergency/Recovery equipment;
- Laboratory equipment;
- Specialty equipment, i.e. obstetrician, pediatric, and optical equipment;
- Sterilizing equipment

Based on Decision 2019/1997/QD-BKHCMNT issued 1 December 1997, the Ministry of Science, Technology, and Environment must inspect imported used medical equipment. The Decision stipulates that imported used medical equipment must retain equal to or more than 80 percent of its life expectancy and must not consume more than 10 percent of fuels or electricity than newer versions of the equipment.

Import tax for medical equipment generally ranges from 0 percent to 5 percent, and the equipment is subjected to a value added tax. Effective as of 1 January 1999, a new value added tax was imposed on goods and services consumed in Vietnam. The standard VAT rate for medical equipment is 5 percent and a spare part is 10 percent. Unless otherwise approved by the Ministry of Finance, taxes are based upon the calendar year, regardless of a company's fiscal year. Medical equipment imported from countries that have bilateral trade agreements with Vietnam receive a preferential tax rate. Import taxes imposed on medical equipment are classified in Decision 172/TT-BTC issued on 22 December 1998.

In general, all importation procedures for medical equipment take about two to three weeks and there are no major difficulties during this process.

Labeling Requirement

On August 30 1999, the Prime Minister promulgated Decision No. regarding the regulation for labeling of domestically circulated goods and imported/exported goods. According to this law, label affixation is required for medical equipment. The importer must provide information on the label that mentions the

- Name of the equipment;
- Name and address of traders responsible for the equipment, i.e., the importer in this case;
- Instructions on using, operating and preserving the equipment; and
- Origin of the equipment.

ISA Medical, 1 May 2000

Used equipment that has been refurbished, has significant market potential in Vietnam, especially in the private Vietnamese clinic sector.

YEMEN

General Market Condition: No Restrictions

Source: Report from CS Post (via Cable), 27 March 2001

Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?

There are no restrictions on the importation of used equipment, except that it is in good condition. Tariff rates are lower for used equipment than for new equipment, and this applies to used medical equipment. The tariff on new medical equipment is five percent. The custom duties are exempted if the hospital is an investment project, but the used equipment must not be more than eight years old.

Can public health institutions buy used or refurbished Medical devices?

Yes, public health institutions buy used or refurbished medical devices when priced competitively with new equipment. Yemen's Ministry of Health buys medical equipment through the tendering system.

Is there a market for used or refurbished devices?

Yes, the market for used medical equipment is good, especially in private hospitals.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

The greatest demand for refurbished medical equipment is from small hospitals, clinics and health centers.

Yemen's ministry of Public Health is unable to cope with increasing demand for modern health services, so it has encouraged the private sector to establish hospitals and clinics. Statistics indicate that Yemen has over 105 government hospitals, 200 private hospitals, over 750 health care centers and clinics, and 2,900 pharmacies, representing a significant market for medical instruments, supplies, and pharmaceuticals. Yemeni expatriates and businessmen are planning to invest in larger hospitals. More than 60 private companies are importing and trading in medical instruments, supplies, and pharmaceuticals.

Report from CS Post (via Cable), 4 April 2000

There are no restrictions on the importation of used equipment, except that it be in good condition. Tariff rates are lower for used equipment than for new equipment, and this applies to used medical equipment. The tariff on new medical equipment is five percent.

Public health institutions buy used or refurbished medical devices when priced competitively with new equipment. Yemen's Ministry of Health buys medical equipment through the tendering system.

The market for used medical equipment is good, especially in private hospitals.

Yemen has over 100 government hospitals, 550 small private hospitals and clinics and over 2,700 pharmacies, representing a significant market for medical instruments, supplies, and pharmaceuticals. More than 50 private companies are importing and trading in medical devices. With a population of 17.7 million that is growing at a 3.5 percent rate, the need for all types of equipment is great and will continue to grow.

ZAMBIA

General Market Condition: No Restrictions

Source: Report from CS Post (via E-Mail), 1 March 2002

Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?

No. There are no special restrictions or tariffs that apply to importation of used medical equipment that do not apply to new medical equipment.

Can public health institutions buy used or refurbished medical devices?

Yes. Public health institutions buy used or refurbished medical devices however, they depend on donations and purchases through donor funded projects. Public health institutions are under funded by the central government.

Is there a market for used or refurbished medical devices?

Yes. There is a huge market for used or refurbished medical devices.

If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

There is a market for all types of used or refurbished medical equipment. There are no facilities for local manufacturing so all medical equipment is procured from abroad.

CONCLUSIONS AND NEXT STEPS

Based on the summary of information contained in this report, it is clear that U.S. exporters of pre-owned (used and refurbished medical devices) face significant market restrictions in some markets above and beyond those faced by exporters of new medical devices. These additional restrictions take a variety of forms, but include the following:

- Outright ban;
- High tariffs or fees;
- Ban on the purchase of pre-owned equipment by public institutions;
- Requirements that after-sale service or technical support be provided;
- Prohibition on the importation of pre-owned equipment that has not been refurbished;
- Restrictions on the importation of equipment unless it has been refurbished by the original manufacturer or its authorized agent;
- Special certification requirements;
- Requirements for warranties;
- Restrictions on the age of equipment; and
- Ban on pre-owned equipment that competes with locally produced devices.

To a large degree, these restrictions that target pre-owned equipment exist for the following reasons:

- The problems that the importing countries have experienced with pre-owned equipment in the past;
- The perception that the lower cost of used equipment does not justify the risk that the devices may not perform as well as new ones;
- The concern that replacement parts or service may be difficult or impossible to obtain for pre-owned medical devices;
- The perception that refurbished medical devices will perform better than pre-owned equipment that has not been refurbished;
- The perception that medical devices refurbished by the original manufacturer will perform better than equipment refurbished by a firm that is not the original manufacturer;
- The perception that pre-owned medical devices are of lower technology and result in lower quality healthcare; and
- The concern that pre-owned equipment may pose safety risks since the U.S. market for pre-owned devices is largely unregulated and no FDA approval is generally required for pre-owned medical devices exported from the United States.

The U.S. pre-owned equipment industry has several on-going activities that may improve the market for U.S. exports by addressing the concerns and perceptions listed above:

- One U.S. industry association, the International Association of Medical Equipment Remarketers and Servicers (IAMERS) has developed a code of ethics with which all members agree to comply. IAMERS responds to complaints against its members and on several occasions has removed member firms for failure to comply with its ethics code. IAMERS-associated firms, however, remain a small segment of the industry, and its membership is heavily dominated by firms focusing on the resale and servicing of imaging equipment.

- Several U.S. medical device original equipment manufacturers (OEMs) have established or are establishing units to buy back and remanufacture their own devices, which are then resold with a full warranty and service availability.
- Many U.S. pre-owned medical device firms are now offering some type of warranty with the products they sell.

An important development relating to the international trade in used and refurbished medical equipment occurred in May 2002. For the first time, refurbished medical equipment was the subject of a workshop at the Global Harmonization Task Force (GHTF) conference. At the Ninth GHTF conference, which took place in Singapore, May 12–16, 2002, a workshop focused on the “Regulation and Supply of Refurbished Medical Devices.” Although no report was issued by the workshop, the session was important for bringing increased attention to refurbished medical devices. Copies of the presentations made at Ninth Conference, including those from the workshop on refurbished medical devices, are available at the GHTF web site: <http://ghtf.org>

The GHTF is a voluntary group of representatives from national medical-device regulatory authorities and the regulated industry. The GHTF is comprised of representatives from five founding members (Australia, Canada, the European Union, Japan, and the United States). The purpose of the GHTF is to encourage convergence in regulatory practices. The primary way in which this is accomplished is via the publication and dissemination of harmonized guidance documents on basic regulatory practices. The GHTF also serves as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members.

To promote trade in pre-owned medical devices and encourage discussion of issues relating to the international trade in pre-owned medical devices, the Department of Commerce (DOC) will continue to update this report periodically. The Department of Commerce will continue to request each DOC Foreign Commercial Service Office to review the report as it relates to their country, checking it for accuracy and updating it as necessary. We are also requesting U.S. industry associations and firms involved with the sale of pre-owned medical devices to review this report and to inform us if their experience confirms or contradicts the information it contains.

APPENDIX A
MARKETS FOR WHICH NO INFORMATION WAS AVAILABLE

For the listed markets, there were no relevant ISA or IMI reports discussing pre-owned equipment or import regulations for medical devices and the U.S. Foreign Commercial Service post in that country did not provide a response to OHCG's cable requesting information.

Markets with No Available Information

Abu Dhabi	Comoros	Latvia	Rwanda
Afghanistan	Congo (Brazzaville)	Lebanon	St. Kitts and Nevis
Albania	Congo (Kinshasa)	Lesotho	St. Lucia
Algeria	Cote D'Ivoire	Libya	St. Vincent & the Grenadines
Andorra	Cuba	Liechtenstein	Samoa
Angola	Cyprus	Lithuania	San Marino
Antigua and Barbuda	Djibouti	Macedonia	São Tome and Principe
Armenia	Dominica	Madagascar	Seychelles
Azerbaijan	Equatorial Guinea	Maldives	Sierra Leone
Bahrain	Eritrea	Mali	Slovakia
Belarus	Estonia	Malta	Solomon Islands
Benin	Fiji	Marshall Islands	Somalia
Bhutan	Gambia, The	Mauritania	Sudan
Bosnia and Herzegovina	Georgia	Mauritius	Suriname
Brunei	Grenada	Micronesia	Swaziland
Bulgaria	Guinea-Bissau	Monaco	Tajikistan
Burkina Faso	Guyana	Mongolia	Togo
Burma	Iran	Namibia	Tonga
Burundi	Iraq	Nauru	Tuvalu
Cambodia	Ireland *	Palau	Vanuatu
Cape Verde	Korea, North	Qatar	Zimbabwe
Central African Republic	Laos		

* Although specific information is lacking, general rules of the European Community apply.

Source: U.S. Department of Commerce

APPENDIX B

PROPOSED VOLUNTARY SELF-REGULATION OF THE PRE-OWNED MEDICAL DEVICE INDUSTRY

Background

In 1999, a joint effort of the American Association of Medical Instrumentation (AAMI), the Emergency Care Research Institute (ECRI), the International Association of Medical Equipment Remarketers and Services (IAMERS), the U.S. Food and Drug Administration (FDA), and several new-product industry associations - the Advanced Medical Technology Association (AdvaMed) formerly the Health Industry Manufacturers Associations (HIMA), the National Electrical Manufacturers Associations (NEMA), and the Medical Device Manufacturers Association (MDMA) - led to a draft agreement for self-regulation of the pre-owned medical device industry. The proposed self-regulation included voluntary labeling that would have tracked the pre-owned equipment, registration of medical device resellers, and mandatory FDA review of medical devices when original specifications had been modified in any way. The draft agreement also called for a system for distributing recall and hazard notices.

Status of the Proposal

The draft proposal was submitted to the FDA in Fall 1999. The FDA took no action at that time.

In June 2001, a spokesperson for the FDA indicated that review of the proposal had been set aside temporarily in order for the agency to focus on issuing guidance for the re-use of single use devices (SUDs), which was believed to raise greater safety concerns. The FDA spokesperson anticipated at that time that the agency would soon return to the matter of the self-regulatory scheme. He indicated that the FDA did not intend to publish a regulation implementing the voluntary regulatory system, but rather to issue a Guidance Document explaining the application of the Food, Drug, and Cosmetic Act to remarketing and endorsing the voluntary proposal. As a first step, the FDA was apparently planning to encourage the organizations that originally drafted the proposal to move forward with establishing the third-party registry that would make hazard, recall, and safety-related service notices available to customers of participating re-sellers.

To date, the FDA has not issued such guidance.

Details of the Proposed Voluntary System of Self-Regulation

Under this proposed voluntary system of self-regulation, the participating organizations would have labeled the used equipment they service or remarket with the following information:

- The name of the servicing or remarketing organization;
- A toll-free telephone number or other contact information for the organization;
- Service documentation describing the work performed using standard terminology (see below);
The date the work was performed and/or the date the transaction was completed; and
- The appropriate Device Condition code (see below).

The proposed voluntary regulations defined 12 key terms relating to activities that could be undertaken as part of the equipment refurbishing process. The service documentation included on the label would have had to use this terminology. These terms included the following:

1. Calibration -is the checking and adjusting of a device's functions in a quantitative manner, to make those functions conform, within a specified tolerance to an identified standard.
2. Cleaning -is the removal of ordinary dirt or debris.
3. Cosmetic Restoration-is the restoration, or partial restoration, repair or replacement of any components of the device that do not have a direct effect on the device's functional performance or safety.

4. Decontamination-is the use of physical or chemical means to remove, inactivate, or destroy pathogenic organisms on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
5. Installation-is the setting of a device, or a hardware or software component of a device, into its proper position and making it ready for use according to the manufacturer's specification.
6. Performance Verification-is testing conducted to verify that the device functions properly and meets the performance specifications; such testing is normally conducted during the device's initial acceptance testing.
7. Preventive Maintenance is the inspection, cleaning, lubricating, adjustment or replacement of a devices nondurable parts. Nondurable parts are those components of the device that have been identified either by the device manufacturer or by general industry experience as needing periodic attention, or being subject to functional deterioration and having a useful lifetime less than that of the complete device. Examples include filters, batteries, cables, bearings, gaskets, and flexible tubing.
8. Remarketing-is the act of facilitating the transfer of ownership of a medical device by sale, gift, or lease.
9. Repair is the restoration of the device to its original level of functional performance and safety after it has malfunctioned or sustained damage.
10. Safety Testing-is testing conducted to verify that the device meets the safety specifications; such testing is normally conducted during the device's initial acceptance testing.
11. Scheduled (Planned) Maintenance -consists of some or all of the following activities: cleaning; decontamination; preventive maintenance; calibration; performance verification; and safety testing.
12. Service-consists of some or all of the following activities: installation; cleaning and/or decontamination; preventative maintenance; calibration; performance verification; safety testing; the repair of performance defects; repairs of safety defects; and cosmetic restoration. This does not include activities that would result in remanufacturing as that term is used in the FDA's Quality System/Good Manufacturing Practices regulation.

Two Device Condition codes were defined for use on the label:

DC 1-Device may have received cosmetic restoration but otherwise is in as is/unknown condition. Prior to use, device must be checked for proper performance and safety.

DC 2-Device is performing properly and safely and is ready for clinical use. If installation is required, the device must be checked again after installation. For devices labeled DC 2, users and purchasers should refer to the service documentation for additional information on the service (s) performed.

Another key element of the voluntary regulations included the establishment of a registry operated by a third party. The purpose of this third-party registry was to make hazard, recall, and safety related service notices available to all participants. Remarketers would have been obliged to make information on FDA and manufacturer hazard, recall, and safety related service notices available to their customers.