

Draft

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

Complete text of the current version of this annual report  
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[www.ita.doc.gov/td/mdequip](http://www.ita.doc.gov/td/mdequip)

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# Draft

## Executive Summary

### *Findings*

Information on import regulations for pre-owned medical devices was available for 99 markets.<sup>1</sup>

Of these 99 markets, 78 markets appear to permit the unrestricted importation of used or refurbished medical equipment on the same terms as new.<sup>2</sup> 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 condition;
- 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—the U.S. Food and Drug Administration does not regulate the resale of medical devices.

Unrestricted importation of pre-owned devices does not mean that a country allows the importation of devices that were never approved by regulators. For example, to import a medical device 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. This applies to both new and pre-owned devices.<sup>3</sup> 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.

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 78 markets that permit the unrestricted importation of pre-owned medical devices, 22 have laws or policies that prevent or discourage public healthcare institutions from purchasing pre-owned

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<sup>1</sup> 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 99 includes the EU as a whole plus 13 of its member countries.

<sup>2</sup> 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.

<sup>3</sup> 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 can not 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.

equipment. Although private healthcare facilities in these countries, can buy pre-owned equipment, the private healthcare sector often represent a relatively small share of the market.

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

Australia	France	Malawi	Senegal
Austria	Gabon	Malaysia	Singapore
Bahamas	Germany	Mexico*	Slovenia
Barbados	Ghana	Morocco	Spain
Belgium	Greece	Mozambique	Sri Lanka
Belize	Guatemala	Nepal	Sweden
Bolivia	Guinea	Netherlands	Switzerland
Botswana	Haiti	New Zealand	Taiwan
Cameroon	Honduras	Nicaragua	Tanzania
Chad	Hong Kong	Nigeria	Trinidad & Tobago
Chile	Hungary	Oman	Tunisia
Costa Rica	Iceland	Panama	Turkmenistan
Czech Republic	Indonesia	Paraguay	Ukraine
Denmark	Israel & Palestinian Auth.	Philippines	United Arab Emirates
Dominican Republic	Italy	Poland	United Kingdom
Ecuador	Jamaica	Portugal	Venezuela
El Salvador	Jordan	Romania	Yemen
Ethiopia	Kazakhstan	Russia	Zambia
European Union	Kyrgyzstan	Saudi Arabia	
Finland	Liberia	Serbia and Montenegro	

\* 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	Venezuela
Ecuador	Mexico	Romania	
El Salvador	Nicaragua	Saudi Arabia	

*Source: U.S. Department of Commerce*

Sixteen countries—Argentina, Brazil, Canada, Colombia, Croatia, India, 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.<sup>4</sup>

### **Countries that Restrict the Importation of Pre-Owned Medical Equipment**

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

*Source: U.S. Department of Commerce*

<sup>4</sup> 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**

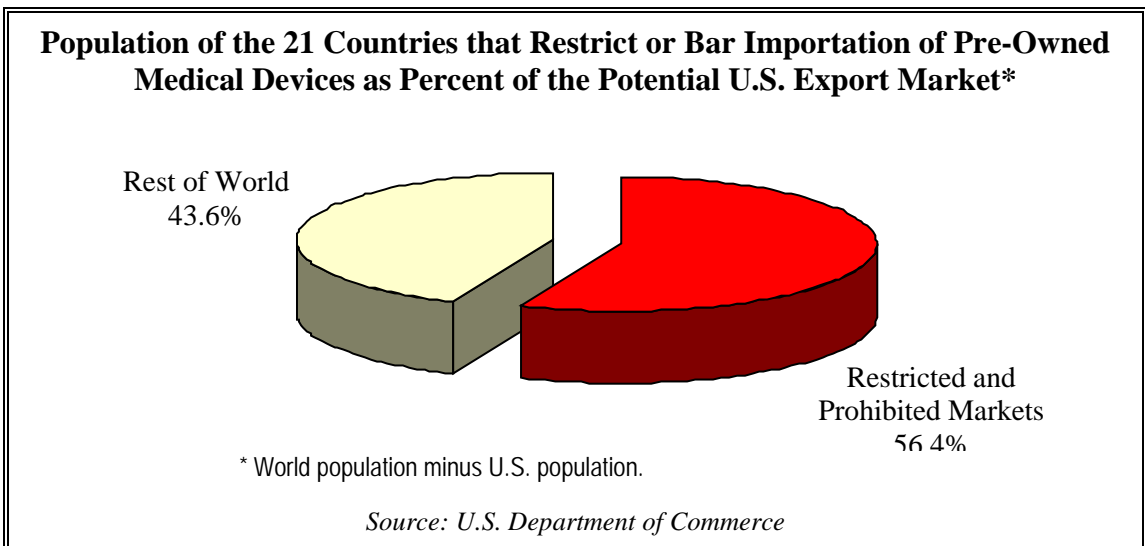
China	Syria
Egypt	Thailand
Kuwait	

*Source: U.S. Department of Commerce*

The countries included in this report are not an exhaustive listing of the world’s markets. No information about import policies for pre-owned medical equipment was available for the markets not listed in this report.

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

Although only 21 countries are known to bar or restrict the importation of pre-owned medical devices, these 21 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 21 countries (approximately 3.3 billion people) represents 56.4 percent of the total population of the U.S. export market.<sup>5</sup>



<sup>5</sup> 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.

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## **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 includes voluntary labeling that tracks the pre-owned equipment, registration of medical device resellers, and mandatory FDA review of medical devices when original specifications are modified in any way. The draft agreement also foresees a system for distributing recall and hazard notices.

### ***Status of the Proposal***

Approval of the draft agreement by FDA has been pending since Fall 1999. In June 2001, a spokesperson for the FDA indicated that review of the proposal was delayed by consideration of guidance for the re-use of single-use devices. Because the FDA desired to maintain a clear distinction between used capital equipment and re-use of single-use devices, the agency delayed consideration of the proposed self-regulatory system for pre-owned capital equipment until guidance had been issued on the re-use of single use devices.

On 14 August 2000, the FDA released a document entitled 'Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.' This document provides guidance to third-party and hospitals reprocessors about their responsibilities as manufacturers engaged in reprocessing devices labeled for single use. Issuance of that document has enabled the FDA to renew consideration of the voluntary regulatory system to pre-owned capital equipment.

According to the FDA spokesperson, the FDA does 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 would 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 under the voluntary regulatory system.

As of May 2002, the FDA had not issued this proposed document, but a spokesperson indicated that it would be forthcoming later in the year.

### ***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:

*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.

*Cleaning*—is the removal of ordinary dirt or debris.

*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.

*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.

*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.

*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.

*Preventive Maintenance*—is the inspection, cleaning, lubricating, adjustment or replacement of a device’s 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.

*Remarketing*—is the act of facilitating the transfer of ownership of a medical device by sale, gift, or lease.

*Repair*—is the restoration of the device to its original level of functional performance and safety after it has malfunctioned or sustained damage.

*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.

*Scheduled (Planned) Maintenance*—consists of some or all of the following activities: cleaning; decontamination; preventive maintenance; calibration; performance verification; and safety testing.

*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.