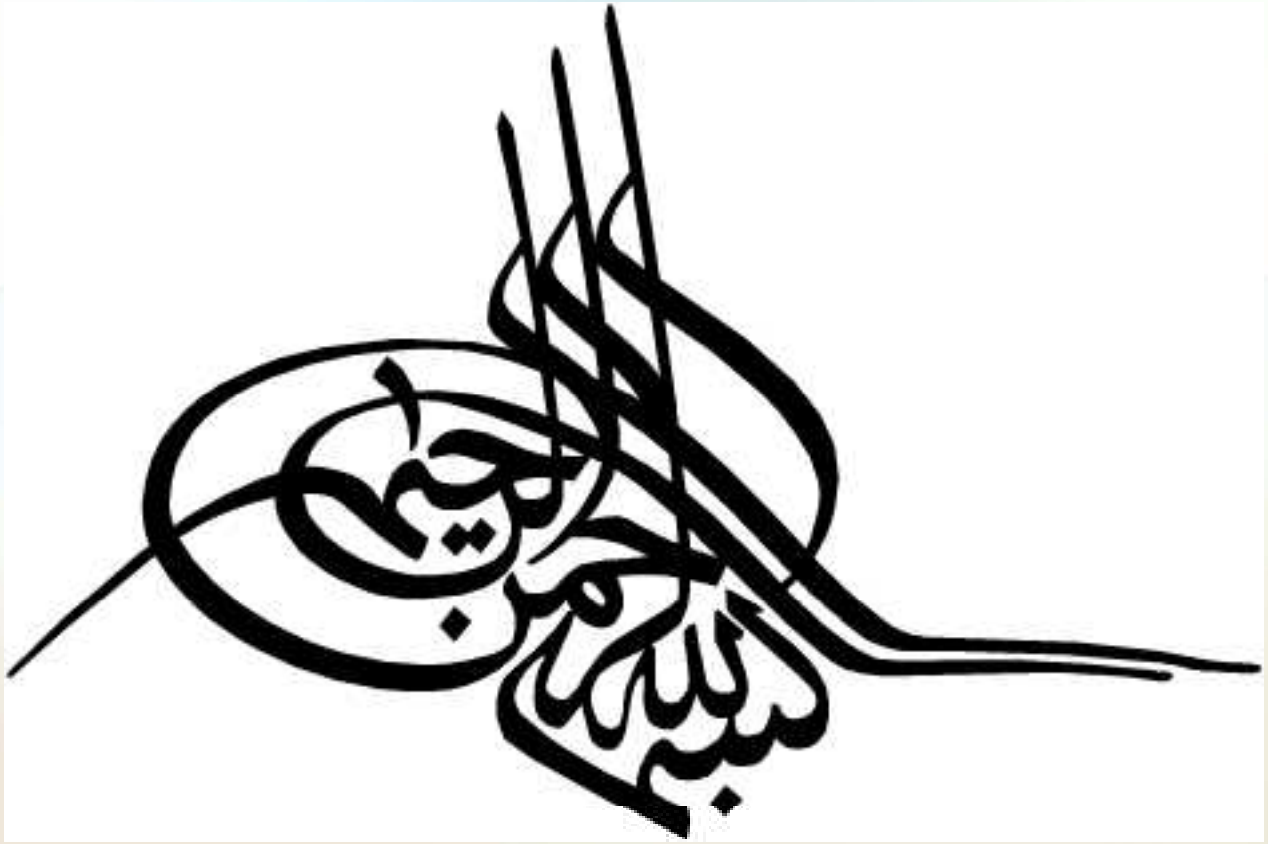
بسم الله الرحمن الرحيم

Using Refurbished Medical Equipment And Importation Requirments

اداره کل تجهیزات پزشکی - اداره تجهیزات آزمایشگاهی

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

Findings

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

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.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.

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

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

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

Only five countries—China, Egypt, Kuwait, Syria, and Thailand—appear to ban the importation of preowned 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.

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.

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.
- The date the work was performed and/or the date the transaction was completed; and The appropriate Device Condition code.

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.

CONCLUSIONS AND NEXT STEPS

The 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 preowned 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 preowned devices is largely unregulated and no FDA approval is generally required for pre-owned medical devices exported from the United States.

Refrence:

- Global Import Regulations for Pre-Owned (Used and Refurbished) Medical Devices,2006 Edition, Published by “U.S. DEPARTMENT OF COMMERCE, International Trade Administration”

The End