

The Distribution and Refurbishment of Used Medical Devices

15 May 2002

JFMDA

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Change of Medical Environments

A circulatory society for effective use of resources is being developed. This trend is also extending to medical economic environments.

Increasing containment of healthcare expenses is pressing a number of medical sectors. This situation has an impact on users in purchasing less expensive refurbished medical devices.

Various Quality Issues (1/4)

1. Lack of distribution information

- a. Manufacturers and their affiliated distributors are unable to identify their device users.
- b. Distribution information of used medical devices is not forwarded to manufacturers.
- c. Manufacturers are not aware of device transfers between users.

Various Quality Issues (2/4)

2. Insufficient quality information

- a. Instructions for use and warning labels are not attached to used medical devices.
- b. Distributors and repairers do not provide users with an adequate explanation of safety operation and contraindications.
- c. History records (which represent use conditions, maintenance and repairs) do not accompany used medical devices. Devices are also distributed without a clear indication of a durable period of time.

Various Quality Issues (3/4)

- d. Used medical devices are distributed overly beyond a durable period of time.
- e. Devices are not properly repaired since they use inadequate parts and similar boards.
- f. Used medical devices are distributed without a designated label, which should identify manufacturer, product type and serial number.
- g. Product liability is not clear between manufacturers and repairers.

Various Quality Issues (4/4)

3. Exports without prior notice to manufacturers

- a. Exporting channels of used medical devices are unclear to manufacturers.
- b. Medical devices for domestic use are exported to the other countries. In this case, it is difficult to repair them since adequate parts are not available in those countries.

4. Unqualified distributors and repairers

- a. Unqualified distributors resell refurbished medical devices.
- b. Unqualified repairers refurbish used medical devices.

JFMDA Review Procedures (1/3)

A used medical device has appeared!

1. Did PAL and other laws qualify the distributor?
2. Do all documents accompany the device? These documents should include instructions for use and maintenance manual. Similarly, do important accessories accompany it?
3. Doesn't a durable period of time supersede one as designated in instructions for use?
4. Are there any labels on the device? These labels should identify manufacturer and importer, sales name, product type and serial number. In addition, are there any warning labels on it? Is it possible to collect any history records of use conditions, maintenance and repairs?

JFMDA Review Procedures (2/3)

5. Is there any record of software/hardware up-grade? Or, is the version updated?
6. Did the manufacturer overhaul or repair the device? Or, did the repairer (which has been recognized by the manufacturer) overhaul or repair it?
7. Did the repairer deal with the device properly (by means of maintenance, repairs, overhaul or inspections)? Did the repairer report to the manufacturer in writing? Then, did the manufacturer confirm the report?
8. Did the installer confirm installation environments (temperature, electric supply, earth and breaker)? Is the confirmation based on the installation plan or installation control procedures?

JFMDA Review Procedures (3/3)

9. Did the distributor and repairer notify the manufacturer and importer of resale and repairs?
10. Did the distributor and repairer receive agreement from the manufacturer and importer?
11. Does the distributor comply with regulatory requirements under PAL and other laws?
12. Is there any label for the proof of repairs? This label should identify repairer, its address and repairs dates. It is recommended that a distributor place its name on the label.
13. Is the distributor ready to provide the user with cautions of operation and maintenance?
14. End of procedures

Japanese Regulatory Framework (1/3)

1. Distributor's requirements

- a. Distributors are required to get licenses from local Governors when they intend to sell high risk devices (Class III, IV) and specific maintenance control devices (which need professional expertise/skills for maintenance, repairs and other control). It is noted that specific maintenance control devices could include other risk class devices (Class II and perhaps Class I).
- b. Before reselling any used medical devices, distributors are required to notify manufacturers and importers thereof. Distributors are required to adhere to warnings and cautions indicated by manufacturers and importers.

Japanese Regulatory Framework (2/3)

2. Repairer's requirements

- a. Repairers are required to get licenses from local Governors when they intend to repair specific and non-specific maintenance control devices.
- b. Before repairing any used medical devices, repairers are required to notify manufacturers and importers thereof. Repairers are required to adhere to warnings and cautions indicated by manufacturers and importers.

Japanese Regulatory Framework (3/3)

3. Manufacturer's and importer's requirements

- a. Manufacturers and importers are required to get licenses from local Governors. These licenses give them a status of 'Marketing Authorization Holder'.
- b. Manufacturers and importers are required to assure the quality of any used medical device when they have received notification from distributors and repairers.
- c. As required, manufacturers and importers should indicate warnings and cautions to distributors and repairers.