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IN HOUSE SERVICE AND REFURBISHMENT OF MEDICAL EQUIPMENT – UNDERSTANDING REGULATORY RISK

In-house servicing or refurbishment of medical devices is increasingly common practice, as is the use of spare parts from third-party providers. This is understandable as users seek to get the most value from health care budgets. However, the supply and maintenance of medical devices is strictly controlled by the TGA. Persons and organizations seeking to contain costs by means of in-house service, refurbishment or modification of medical devices can place themselves in the position of manufacturer or supplier of that device and are therefore:

- legally liable for the safety and performance of the device and
- exposed to criminal and civil penalty provisions for breaches of the Therapeutic Goods Act if the service or refurbishment do not meet TGA requirements.

This guide explores the requirements of the Therapeutic Goods Act which apply to in house service and refurbishment, and the risks of non-compliance.

The Role of the TGA and the Therapeutic Goods Act

Medical devices are strictly regulated in Australia – and for good reason. Even a small issue with a medical device can cause serious harm to the patient or user of the medical device. The Commonwealth *Therapeutic Goods Act (1989)* and the associated *Therapeutic Goods (Medical Devices) Regulations, (2002)*, include broad based definitions of *manufacturer* and *sponsor* (supplier), and sets out detailed requirements for control over their activities. Relevant extracts from the Act and Regulations are provided in the Appendix to this Guide.

All medical devices supplied in Australia must be included in the Australian Register of Therapeutic Goods (ARTG) and it is a criminal offence to supply Medical devices which have not been included in the Register. Inclusion in the ARTG can only be obtained by application to TGA.

The Act also defines and prohibits *counterfeiting* as supply of device manufactured by one person which is labeled as manufactured by another.

The Act includes criminal penalties for breaches – including substantial fines and jail penalties for serious offences.

What is a Medical Device – and what about accessories?

The Therapeutic Goods act has a very broad definition of a medical device, which also includes items such as accessories and associated software. Large capital equipment (e.g. MRI, CAT scanners, Linear Accelerators) usually comprises a number of separate medical devices which have all been approved by TGA. TGA regulatory approval includes review and approval of all accessories.

Who is a Manufacturer?

A manufacturer is not only the person who originally "makes" the medical device, but can also be anyone who assembles, refurbishes, re-labels, or processes a device that is already supplied.

Manufacturers:

- **Assume Legal Liability:** The manufacturer takes full responsibility for the safety and performance of the device and must ensure that device complies with Australian regulations.
- **Must be assessed by TGA:** Manufacturers must be certified as competent. For Australian based manufacturers certification usually requires on site audit by TGA as well as review of test data which prove that the device is safe and effective.

Manufacturers must:

- Establish and maintain a Technical File which provides evidence of device compliance with the Australian Medical Device Regulations.
- Sign a legal "Declaration of Conformity" that the device meets Australian regulations.
- Implement ISO 13485 Quality systems to control design, production and service activities and including arrangements for qualification of all parts and materials and training of personnel (for all except Class I devices).
- Apply to TGA for assessment, pay TGA fees and undergo on-site audit and document review.
- Notify TGA of substantial changes to the design, production or intended performance of the device.
- Notify TGA and provide required information in the case of adverse events or product recalls.

WHO IS A SPONSOR, AND WHAT CONSTITUTES "SUPPLY"?

A sponsor is a person who, in Australia, is legally responsible for the compliance of a medical device and arranges for its supply. Supply *does not require sale*. Exchange, loan, rental, or gift are all considered acts of supply, as is "administration" - the use on a patient by the person or organization doing the manufacturer.

So if a device is modified or refurbished in house in a way that causes the hospital to become the manufacturer, then the hospital also automatically becomes the supplier or "sponsor" of the device.

Similar to a manufacturer, a sponsor has responsibilities defined in the Act. Sponsors must:

- Apply to TGA for permission to supply in Australia, by means of inclusion of the device on the Australian Register of Therapeutic Goods (ARTG).
- Ensure suitable evidence is available to demonstrate that the device meets the Australian regulations (typically a TGA conformity assessment certificate).
- Make adverse event reports to TGA and manage product recalls.
- Hold records of product distribution in Australia.

WHAT ABOUT SPARE PARTS AND ACCESSORIES?

Accessories are themselves considered independently to be medical devices. If an accessory to a system is supplied separately from the system, it will need to be separately approved by TGA for supply. Accessories include any item sold specifically for use in the medical equipment – which would include most service parts.

Be very careful when sourcing accessories from third party suppliers (i.e., a supplier who is not the original manufacturer of the device). In the event that a spare part or accessory does not already have TGA approval, it is illegal to supply that item in Australia for use in the medical equipment.

If you obtain the accessory internationally – e.g. by direct order from a foreign supplier, then you become the Sponsor of the accessory. If you import without TGA approval and inclusion on the ARTG then you have committed a criminal offence under Section 41MK of the Therapeutic Goods Act.

In the case of use of general purpose components (e.g. electrical components, lights, cables) which are then incorporated in the medical device, the person who uses these components in the medical device is

CASE STUDY – THIRD PARTY ACCESSORIES

We use accessories bought from an overseas supplier and install the devices ourselves in the hospital.

Consequences

In Australia, all medical devices and their accessories have to be approved by the TGA and included in the ARTG before being used or supplied. In this case – as you are arranging for the import yourself, you become the sponsor and are responsible for obtaining TGA approval directly.

This presents two problems:

1. The act of import of the accessory is a criminal offence if no approval has been obtained from TGA
2. TGA approval will not be granted if the third-party manufacturer is not assessed either directly by a TGA or the device is CE certified *in the name of the third party supplier*.

If the parts are used to upgrade the device or in a substantial refurbishment. The person installing the spare parts into a medical device also becomes manufacturer and assumes responsibility for the safety and performance of the entire device.

likely to be considered the manufacturer, particularly if the use goes beyond simple replacement of a single part – e.g. if a hospital biomedical engineer prepares a replacement circuit board or modifies a device by adding extra switching or controls not provided by the original manufacturer.

Even replacement of single components with spare parts not specified by the manufacturer carries legal liability risk. If the unapproved component fails or causes incorrect operation then the person or hospital which installed the part may be considered legally liable for the consequences of the failure.

What about upgrading or refurbishment?

Upgrading a medical device by a party other than the original supplier would in most cases be considered refurbishment. Therefore by default the person or hospital upgrading the medical device becomes the manufacturer and sponsor. The upgrade activity must be audited by TGA and the upgraded device must be entered onto the Australian Register of Therapeutic Goods. Supply (including in house use) of an upgraded or refurbished device without a TGA approval is also a criminal offence under the Act.

CASE STUDY – REFURBISHMENT

An old medical device has been retired but used for its spare parts.

Consequences

The Act considers the act of assembling a device from the reconditioned parts of one or more old devices to be "refurbishment" – which is an act of manufacture.

The reassembled medical device requires approval from the TGA and listed on the ARTG by undergoing process of conformity assessment. In the event the TGA approval is not sought, or is not granted, clinical use of the refurbished device would be illegal.

What about Software upgrades?

Software that is supplied with the device or upgraded by the original supplier is considered part of the device and is subject to the full controls over design and production involved in manufacturer assessment.

However software supplied independently is considered a medical device in its own right and is subject to separate manufacturer certification and separate ARTG inclusion. This means that if a hospital chooses to obtain software from a third party supplier then that supplier must have TGA approval and ARTG inclusion for the software. If the hospital independently imports software from an overseas supplier, for example by downloading from an international Internet site, then the hospital becomes the sponsor and must apply to TGA for approval to supply in Australia. Installation and use of that software in Australia is a criminal offence if it is not included on the ARTG.

Other provisions of the Therapeutic Goods Act – counterfeit devices

If a hospital chooses to refurbish a device, then the refurbishment provisions to the Act make it an offense to supply (including in house use of) that device carrying the branding of the original manufacturer. It is a requirement that the device be clearly identified as refurbished and the labeling and manuals must correctly identify the party which refurbished the device. Failure to do so risks contravention of both the medical device labeling requirements and the anti-counterfeiting provisions of the Act.

PENALTIES UNDER THE ACT

Breaches of the Therapeutic Goods Act are criminal offences and attract heavy fines and even jail terms for serious offences. TGA has a number of enforcement powers including search and seizure powers. **The penalty for manufacturer or supply without the required TGA manufacturer assessment and device registration is up to $840,000 fine or 5 years imprisonment, or both for criminal offences and up to $1,050,000 fine and $10,500,000 fine for individual and corporate body civil offences, respectively.**

WHAT DOES IT ALL MEAN?

If a hospital chooses to service, obtain parts or refurbish medical equipment, then in many cases they place themselves in the position of ***manufacturer*** or ***supplier*** and become subject to the Commonwealth *Therapeutic Goods Act*. This means that TGA approval is required for these activities. There are severe criminal penalties in the Act for unapproved manufacture or supply.

The hospital, once it becomes manufacturer, takes on full civil responsibility for the device, including all legal liability for any harm to patients or operators arising out of subsequent malfunction. Hence the hospital must ensure that the refurbished, upgraded or serviced device continues to meet the Essential Requirements of safety and performance specifications as defined in the *Therapeutic Goods Act.*

Need Advice?

Brandwood CKC is an independent advisory firm supporting regulatory compliance for medical devices, diagnostics and pharmaceuticals. If you have questions or need advice about your responsibilities when servicing or refurbishing a medical device, we can provide help.

Please contact us directly:
Tel: (02) 9906 2984
Email: help@brandwoodckc.com
or visit www.brandwoodckc.com

CASE STUDY – MODIFYING THE DEVICE

A hospital modifies a device purchased from the original manufacturer.

Consequences

Any significant modifications to a medical device which are carried out by someone other than the original manufacturer constitute manufacture of a new device. Once the modified device is used it is considered supplied by means of administration to a patient. In this case the hospital is the new manufacturer and must meet the full range of manufacturer ad sponsor obligations under the act including:

- Documenting the new design to include the modifications
- Conducting technical risk assessment
- Testing the modified device to show that it conforms to Australian requirements
- Performing Clinical Evaluation (signed by a clinician) to show the modified device is safe and effective in clinical use.
- Maintenance of A Technical File documenting compliance with Australian regulations
- Implementing Quality Systems controls over the design and manufacture of the modified device
- Relabeling the device under their own name.
- Submitting to TGA manufacturer assessment, on site audit
- Obtaining ARTG inclusion for the device

APPENDIX: THERAPEUTIC GOODS ACT, 1989: RELEVANT EXTRACTS

DEFINITION OF MEDICAL DEVICE [ACT S41BD] AND ACCESSORY (ACT S3(1)]

(1) A ***medical device*** is:

(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for [therapy or diagnosis] or

(b) an **accessory** to an instrument, apparatus, appliance, material or other article covered by paragraph (a).

accessory … means a thing that the manufacturer of the thing specifically intended to be used together with the device to enable the device to be used as the manufacturer of the device intended.

DEFINITION OF MANUFACTURER [ACT S41BG]

(1) The *manufacturer* of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.

(2) If subsection (1) does not apply to a medical device, the *manufacturer* of the device is the person who, with a view to supplying the device under the person's name, does one or more of the following using ready-made products:

(a) assembles the device;

(b) packages the device;

(c) processes the device;

(d) fully refurbishes the device;

(e) labels the device;

(f) assigns to the device its purpose by means of information supplied [e.g. in labeling, instructions for use or technical documentation].

DEFINITION OF MANUFACTURING SITE [ACT S3 (1)]

Manufacturing site means premises:

(a) that are for use in [manufacture]; and

(b) at which the same persons have control of the management of the production of the goods and the procedures for quality control.

DEFINITION OF SPONSOR [ACT S3 (1)]

sponsor, in relation to therapeutic goods, means: …

(a) a person who exports, or arranges the exportation of, the goods from Australia; or

(b) a person who imports, or arranges the importation of, the goods into Australia; or

(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

DEFINITION OF SUPPLY [ACT S3 (1)]

supply includes:

(a) supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and

(b) supply, whether free of charge or otherwise, by way of sample or advertisement; and …

(d) supply by way of administration to, or application in the treatment of, a person.

DEFINITION OF REFURBISHMENT [REGULATION 1.5]

(1) A ***refurbishment*** of a medical device is taken to have occurred if the medical device, or a part of the device, is substantially rebuilt from one or more used medical devices of that kind so as to create a medical device that is able to be used for the purpose originally intended by the manufacturer of the original device.

(2) Without limiting subregulation (1), a ***refurbishment*** of a medical device may involve the following actions:

(a) stripping the device into component parts or sub-assemblies;
(b) checking parts of the device for suitability for reuse;
(c) replacing component parts or sub-assemblies of the device that are not suitable for reuse;
(d) assembling reclaimed or replacement component parts or sub-assemblies of the device or another used device;
(e) testing a reassembled device against the specifications of the original device or, if the manufacturer has revised those specifications, the revised specifications;
(f) identifying an assembled device as a refurbished device.

COUNTERFEIT GOODS [ACT S42E]

(1) A person commits an offence if:
  (a) the person intentionally:
    (i) manufactures goods in Australia; or
    (ii) supplies goods in Australia; or
    (iii) imports goods into Australia; … and
  (b) the goods are therapeutic goods; and
  (c) the goods are counterfeit and the person knows that fact or is reckless as to whether that fact exists.

Penalty: 7 years imprisonment or $420,000, or both.

(2) Goods are counterfeit if any of the following contain a false representation of a matter listed in subsection (3):
  (a) the label or presentation of the goods;
  (b) any document or record relating to the goods or their manufacture; …

(3) The matters are as follows:
  (a) the identity or name of the goods;
  (b) the … design specification of the goods or of any … component of them;
  (c) the presence or absence of any … component of the goods; ...
  (f) the sponsor, source, manufacturer or place of manufacture of the goods.