IRISH MEDICINES BOARD

MEDICAL DEVICE
SAFETY NOTICE

The "Intended Purpose" of a Medical Device
IMB Safety Notice: SN2004(04)

SAFETY NOTICE

MANUFACTURER/SUPPLIER

Various

TARGET GROUPS

All Medical and Nursing Staff
Medical Directors
Nursing Directors
Risk Managers
Purchasing Officers

ISSUE

The use medical devices outside the intended purpose, as defined by the manufacturer in the instructions for use of the device, can have serious clinical consequences. The aim of this IMB Safety Notice is to enhance awareness of the need to use medical devices within the intended use specified by the manufacturer of the medical device. It should be read in association with the recently published MHRA Medical Device Alert MDA/2004/006: Medical devices in general and non-medical products.

BACKGROUND

The Irish Medicines Board (IMB) has been advised of several instances where medical devices have not been used as intended by the manufacturer. The term used to describe this is "off label use". Devices have been:

- Used for a purpose, which differs from that intended by the manufacturer.
- Used in a configuration, which differs from that outlined by the manufacturer.

- Used in combination with accessories, which have not been validated for use by the manufacturer.
- Sterilised by products or procedures not validated by the manufacturer.
- Used by staff that have not had the recommended level of training.

The manufacturer of a medical device is responsible for defining the "intended purpose" of the device. To establish this, the manufacturer implements appropriate controls on the device design and manufacture, and evaluates the safety and performance of the device in its intended use.

This involves:

(a) an analysis of risks that could arise during use

(b) an assessment of relevant pre-clinical and clinical data

(c) an assessment of the compliance of the device with recognised international standards

(d) an assessment of the compliance with relevant European and national medical device legislation.

The outcome of the above evaluation by a manufacturer is the preparation of appropriate instructions for use and, if necessary, specific training schemes for the medical device in question. From such activities, manufacturers are able to verify that risks have been eliminated or minimised and are judged acceptable when weighed against the anticipated benefits to patients.

When a user of a medical device decides to use the device in a manner that is outside the intended use as defined by the manufacturer, this is regarded as "off label" use of the device. The user should be aware that the manufacturer has not considered this new use in his risk analysis of the device and hence the safety and performance of the device has not been assessed and cannot be guaranteed for this new use by the manufacturer.

Under these circumstances the liability for "off label" use rests with the user and not the manufacturer of the device. The user should be aware that the consequence of using medical devices outside the intended purpose can be serious and requires careful consideration and you assume the responsibilities of the manufacturer under the legislation.

ACTION OR RECOMMENDATIONS

- Ensure that those responsible for the choice and purchase of medical devices are made aware of this notice.

- Ensure that all medical devices that are purchased are used within the scope of the "intended purpose" as defined by the manufacturer in its instruction for use and labelling.

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- Ensure that all medical devices which are used are CE marked and are designed / validated for the specific application you require. e.g. the clinical application, the population or the environment.

- Ensure that all medical devices are only used in combination with other devices and or accessories that have been proven to be “mutually compatible” by the manufacturer.

- Ensure that all training and support documentation are provided with the device e.g. the instructions for use (IFU).

- Ensure that all relevant staff are identified and trained in the use and intended purpose of the device.

The manufacturer should be able to provide sufficient data; instructions for use, data sheets, certificate of conformity, scientific data, etc, to allow the user determine the best product to meet his needs.

ENQUIRIES

All adverse incidents relating to a Medical Device should be reported to the:

Irish Medicines Board
Medical Devices Department
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries regarding Safety Notices, you may contact the Medical Devices Department at:

Telephone: +353-1-6764971
Fax: +353-1-6767836
Email: medicaldevices@imb.ie
Website: www.imb.ie

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