IRISH MEDICINES BOARD
SAFETY NOTICE

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Counterfeit Medical Devices

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Note: Revision 2 update to add Biomedical / Clinical Engineers to the target group listing. There are no other content changes to the safety notice.

MANUFACTURER/SUPPLIER
General medical device (GMD), active implantable medical device (AIMD) and *in-vitro* diagnostic medical device (IVD) manufacturers and/or suppliers.

TARGET GROUPS
This safety notice has been written as a guide for medical device manufacturers, distributors, purchasing managers, prescribers and users of medical devices in hospital, community and home settings including:

General Surgeons
Theatre and Nursing Staff
Procurement Managers
Nursing Managers
Consultant General Surgeons
Hospital Managers / CEOs
Clinical Directors
Risk Managers
Medical Device Distributors
Pharmacists
Diabetic Clinics
General Public
Biomedical / Clinical Engineers

ISSUE
In recent years there has been increased global activity in relation to the production and supply of counterfeit / illegal medical devices, which are not in conformity with the essential requirements of the medical devices legislation. As a result, members of the public or healthcare professionals may inadvertently use counterfeit and other medical devices that should not be on the Irish market.

The safety and quality of counterfeit medical devices cannot be guaranteed as they may not be manufactured to the required standards or conform to the requirements of the medical devices legislation. Therefore counterfeit medical devices pose a risk to public health and safety.

BACKGROUND
The counterfeit products that have been identified to date do not suggest that there is a particular focus on any specific categories of medical devices. Low cost, over the counter products such as condoms and injection needles and more specialised products

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used and prescribed by healthcare professionals, such as surgical meshes and contact lenses have been the subject of counterfeiting.

The consequences of using counterfeit products can vary. In some instances the user may suffer direct harm or in the case of a diagnostic medical device, the use of counterfeit product may result in the patient not being diagnosed or treated appropriately.

Counterfeit medical devices may enter the supply chain at any point. The counterfeit product may be supplied to a distributor, wholesaler or directly to a hospital or a retail outlet. In some cases, counterfeit medical devices may be available for purchase over the internet. The source of these counterfeit medical devices is often difficult to trace. Such devices can only reach the end user when a weakness or poor governance has occurred in one or several parts of the supply chain.

With increasing financial pressures, users of medical devices are keen to seek the best value for money and as a result, consumers may now be exploring new routes of acquiring medical devices. Access to global markets, global suppliers at trade fairs and the internet has increased the accessibility and range of products available to the consumer. However, vigilance is required to ensure that the medical device that is being offered / purchased is a genuine CE-marked product from the authentic manufacturer, which complies with the EU medical devices legislative requirements.

While many genuine medical devices are available for purchase online, a large number of internet sites are unauthorised, unregulated and may offer non-compliant products. Buying medical devices online may appear to be an attractive alternative due to the perceived convenience, lower price and the privacy afforded to individuals, however, the potential risk to users who purchase medical devices over the internet may be relatively high.

ACTION OR RECOMMENDATIONS

The IMB advises:

Hospital / healthcare professionals:

- Ensure that all medical devices purchased are CE marked. Devices that are CE marked and sold on the European market must have a European registered business premises. Look for a European address on the packaging and labelling of the device.
- Ensure that the labelling and instructions for use (*if applicable*) have been provided in English. It is a requirement of the medical devices legislation that the labelling and instructions for medical devices placed on the Irish market are provided in the English language.
- Buy directly from the manufacturer or an authorised dealer / distributor. Complete the warranty form (*if provided*) so that the manufacturer can contact you if they need to (e.g. in the event of a field safety corrective action / recall).
- Do not buy medical devices from websites that you have not verified by good governance.
- Verify that the CE mark on the device or packaging is authentic and is supported by the appropriate certification from the stated manufacturer.

Members of the public:

- Talk to a health care professional, such as your GP, before buying a medical device.
- Make sure the device that you are planning to buy has a CE mark.

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- Ensure that the labelling and instructions for use (*if applicable*) have been provided in English. It is a requirement of the medical devices legislation that the labelling and instructions for medical devices placed on the Irish market are provided in the English language.
- Consider buying directly from the manufacturer or authorised distributor.
- Complete the warranty form (*if provided*) so that the manufacturer can contact you if they need to (e.g. if they need to recall the product).
- Do not buy medical devices from websites that you have not verified.

Distributors:

- Where possible, purchase directly from the genuine manufacturer. If purchasing from another distributor, verify the validity of the distribution chain.
- Do not buy medical devices from websites that you have not verified by good governance.
- Ensure the device is CE marked and has the appropriate certification.
- If the manufacturer of the device is based outside of Europe, confirm that the manufacturer has a European authorised representative.
- Be particularly vigilant at trade fairs and where possible do not purchase from extended supply chains with multiple distributors. In addition to the counterfeit risk, this could also introduce traceability issues.

Manufacturers of medical devices:

- Be vigilant for potential counterfeit items when buying components / materials from subcontractors.
- Seek and confirm that the material or subcontractor has the appropriate certification where applicable.
- Conduct appropriate and effective supplier / vendor evaluation.
- Conduct an audit of the subcontractor's manufacturing facility.
- Develop and manage a robust system for product distribution to minimise the potential for counterfeit product.

REFERENCES

Further information may be obtained from the following:

- Council Directive 93/42/EEC of 14th June 1993 concerning medical devices.
- Directive 98/79/EC of the European Parliament and of the Council of 27th October 1998 on *in vitro* diagnostic medical devices.
- Council Directive 90/385/EEC of 20th June 1990 on the approximation of the laws of the Member States relating to Active Implantable Medical Devices.
- IMB Safety Notice SN2006(03) The Procurement and Commissioning of Medical Equipment for Hospitals.
- IMB Safety Notice SN2010(09) Effective Traceability of Medical Devices.
- IMB Medical Devices Information Leaflet – Buying Medical Devices Online.

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ENQUIRIES

If you suspect that you may have purchased a counterfeit medical device or you suspect that counterfeit medical devices are available for sale in Ireland, please contact the IMB.

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