IRISH MEDICINES BOARD
SAFETY NOTICE

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Unsafe Hand-held Dental X-Ray Units

IMB Safety Notice: SN2012(08)
Circulation Date: 17 July 2012

MANUFACTURER/SUPPLIER
Various

TARGET GROUPS
Orthodontists
Dentists
Dental Council of Ireland
Irish Dental Association
The Society of Chief and Principal Dental Surgeons
Dental Hospitals

Please bring this safety notice to the attention of all who need to be aware of it.

ISSUE
Non-compliant and unsafe hand-held dental X-ray units could potentially expose the operator and patient to unnecessary and potentially harmful X-rays.

BACKGROUND
The Irish Medicines Board (IMB) is issuing this Safety Notice to alert healthcare providers, dentists and dental care professionals to the sale of non-compliant and potentially unsafe hand-held dental X-ray units, particularly those sold via internet websites. The IMB is concerned that devices which may not meet the essential requirements of the European Medical Devices Directive are being made available for sale.

All compliant dental X-ray devices sold within Europe must bear a legitimate CE mark accompanied by a 4-digit notified body number. Labeling must also include the name or trade name and address of the manufacturer and the authorised representative. Appropriate warnings, cautions and instructions for use should also accompany the unit.

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The IMB is urging dentists and dental care providers to be vigilant of non-compliant

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and potentially unsafe hand-held dental X-ray units that are being made available for sale; particularly through internet websites. Use of non-compliant hand-held dental X-ray units could lead to unsafe levels of radiation exposure to the operator and the patient. The operator may be more susceptible to unsafe radiation dose levels when using one of these unsafe and non-compliant hand-held dental X-ray units, particularly when dealing with a high turnover of patients per week. If you have any concerns in relation to suspicious hand-held dental X-ray units, please highlight your concerns to the IMB.

ACTION OR RECOMMENDATIONS

The IMB recommends that:

1. Relevant personnel in your organisation are made aware of this potential safety issue.
2. Dental professionals should ensure that verification of the labelling and CE certification is carried out to ensure all details are genuine and compliant.
3. If you have any concerns about the CE Certification and labelling of a device, please contact the IMB using the contact details below.
4. This IMB Safety Notice is passed on to any organisation or end user where potentially non-compliant hand-held dental X-ray units have been transferred.

ENQUIRIES

If you have any queries or concerns in relation to these devices or wish to report a potential non-compliance with a device, please do not hesitate to contact the IMB using the contact details below.

All adverse incidents relating to a medical device should be reported to the:

Human Products Monitoring Department
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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