IRISH MEDICINES BOARD
SAFETY NOTICE

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SynchroMed® II Implantable Drug Pumps

IMB Safety Notice: SN2014(14)
Circulation Date: 27 March 2014

MANUFACTURER/SUPPLIER
Medtronic Limited

TARGET GROUPS
Medical directors
Anaesthetists
Neurologists
Neurosurgeons
Pain Consultants
Spinal Surgeons
Chronic Pain teams
Theatre teams
Risk managers
Emergency Medicine Departments

ISSUE
Medtronic has detected an upward shift in reports of occurrence for overinfusion associated with the SynchroMed® II Implantable Pump. Overinfusion can result in a life-threatening overdose and can also result in drug withdrawal due to premature emptying of the pump.

BACKGROUND
Medtronic has recently issued a Field Safety Notice (FSN) related to the SynchroMed II (attached). The FSN advised health care professionals of the upward shift in reports of occurrence for overinfusion. The cause(s) for pump malfunction leading to overinfusion remains under investigation and has not been linked to any specific pump lot, drug used, or geographical area.

Based on current data from Medtronic's prospective, long-term multi-center registry study (ISPR), the occurrence rate or overinfusion is less than 0.16%.

As of November 18, 2013**,** 76 pumps have been confirmed for overinfusion through returned product analysis since the introduction of the device in 2003, 14 of which related to a life threatening overdose.

At this time, due to the low reported rate of occurrence of this issue and the inability to predict which pumps may be at risk, Medtronic is not recommending prophylactic replacement of pumps. Medtronic, in collaboration with clinical experts, has developed specific recommendations that are outlined in the attached FSN.

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The information outlined in the FSN should be considered in the management of existing patients and in the selection of devices for new patients.

The IMB is continuing to monitor the performance of this device with other European Colleagues and the manufacturer (Medtronic) and will provide an updated safety notice as necessary.

ACTION OR RECOMMENDATIONS

The IMB recommends that:

1. Relevant personnel in your organisation are made aware of these potential issues.
2. The device and patient management advice outlined in the Medtronic Communications is considered and followed as appropriate.
3. This IMB Safety Notice and the attached FSN are passed on to any organisation or end user where the potentially affected devices have been transferred.

ENQUIRIES

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

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Medtronic Ireland Ltd,
Unit G
Swords Business Campus
Balheary Road
Swords
Co. Dublin

Telephone: 01 511 1400
Fax: 01 807 7220
Contact person: Lezlie Bridge
E-mail: lezlie.j.bridge@medtronic.com