IRISH MEDICINES BOARD

MEDICAL DEVICE

SAFETY NOTICE

K- Series, Competition, Compact, Compact – Hemi Combi Drive, Kid and Ultra Light Wheelchairs

IMB Safety Notice: SN2006(08)

SAFETY NOTICE

MANUFACTURER/SUPPLIER

Invacare

TARGET GROUPS

Occupational Therapists
Physiotherapists
Public Health Nurses
Risk Managers
Nursing Home Managers

ISSUE

The wheelchair seat covers manufactured by Invacare between February and October 2003 were supplied with a covering material, which did not meet the requirements for flammability defined by the manufacturer.

BACKGROUND

In November 2003, a recall of the above product was initiated by Invacare following the discovery that seat covers manufactured, for the following list of devices, between February 2003 and October 2003 did not comply with the flammability requirements.

- The K-series
- Competition
- Compact
- Compact – hemi drive
- Kid
- Ultra Light

Invacare have had no reported incidents relating to this flammability issue. The manufacturer has confirmed that when the chair is used with a cushion, the risk is reduced.

The affected product was supplied to the Irish market by Lifestyle Mobility and Irish Wheelchair Association. Since this time the supply of Invacare products has changed from the Irish Wheelchair Association to Invacare Ireland.

The IMB has not been able to obtain confirmation from the manufacturer indicating that all affected product in Ireland have been checked and new covers provided and fitted.

ACTION OR RECOMMENDATIONS

Ensure that the purchaser and prescribers of these devices within your healthcare institution:

1. Identify all K-series, competition, compact, compact-hemi drive, kid and Ultra light seat covers that were supplied to your healthcare institution in 2003

2. Arrange with your supplier (Invacare Ireland or Lifestyle Mobility) to check the seat cover material. The inside of the non-flame retardant cover is black while the inside of the flame retardant cover is grey.

3. Ensure that all affected seat covers are replaced with new covers.

ENQUIRIES

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

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

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

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: medicaldevices@imb.ie
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Declan Services
Invacare Ireland

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Telephone: 087-6894940
Fax: dservices@invacare.com

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