IRISH MEDICINES BOARD

Notice Information: - Advisory
24 July 2012

Part 1. Product Information

a)	Title:	Blood glucose meters and Test Strips
b)	Product Name/Type:	Blood glucose meters and Test Strips
c)	Reference:	SN2012(10)
d)	Manufacturer/Supplier:	Various

Part 2. Target Audience

a) Target Audience:

Pharmacists supplying these devices

General Practitioners

Healthcare professionals who use these devices

Healthcare professionals managing patients who use these devices

General public

Risk Managers

Procurement Managers

Carers

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

Part 3. Problem/Issue

a) Problem/Issue:

The correct unit of measurement for blood glucose monitoring in Ireland is mmol/L. The IMB is aware that some Test Strips being procured from outside Ireland and placed on the Irish market have the control solution range stated in the unit of measurement mg/dL instead of mmol/L.

Part 4. Background Information

a) Background Information:

The correct unit of measurement for blood glucose monitoring in Ireland is mmol/L. The IMB is concerned that the unit of measurement for the control solution range provided with some blood glucose test strips being procured from outside Ireland and supplied to the Irish market, is mg/dL instead of mmol/L. In this scenario, although the values for the control solution range provided are correct, for the unit of measurement mg/dL, blood glucose meters in Ireland may provide a result outside the range because they read in the mmol/L unit of measurement. Users may reject the test strips which may result in a delay in treatment or users making a treatment decision in the absence of a glucose result.

The instructions for use that are provided with blood glucose test strips and the operator manuals provided with blood glucose meters clearly outline the importance of checking the unit of measurement.

Part 5. Action to be taken

a) Action to be taken:

Procurement Managers

• If you purchase glucose Test Strips which originate from outside Ireland,

ensure that the control solution range stated on the label is in mmol/L.

Healthcare professionals:

• If you prescribe / supply or use these devices ensure that the correct unit of

measurement for blood glucose monitoring in Ireland is used (mmol/L).

• Advise patients that the correct unit of measurement for blood glucose

monitoring in Ireland is mmol/L.

General public:

• The correct unit of measurement for blood glucose monitoring in Ireland is

mmol/L.

The IMB has also published an Information leaflet on safety tips for blood glucose meters. Please see the Information leaflets section on the Publications page of the IMB website.

Medical devices information leaflet - safety tips for blood glucose meters

Part 6. Enquiries

a)	All enquiries should be made to:	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 Please click here to view PDF version of this Safety Notice