MHRA asks public to check for faulty blood glucose meters

Thursday 11 April, 2013

The Medical devices regulator has asked members of the public with diabetes to perform a check on their blood glucose meters to rule out a software fault effecting around two models. The faulty glucose devices are either giving a false reading of levels which can result a health risk to the user.

The OneTouch Verio Pro (serial numbers that start with RA, RB, RC, RD or RE) and the OneTouch Verio IQ (serial numbers that start with TA or TB) manufactured by LifeScan are blood glucose meter models that are used by people with diabetes at home. The OneTouch Verio meters are used by approximately 22,000 active users.

The manufacturer is recalling both models because the faulty software causes the OneTouch Verio Pro to give falsely low readings and the OneTouch Verio IQ to turn off in the unlikely event a person has an extremely high blood glucose level of 56.8 mmol/L and above.

This software issue affects all OneTouch Verio meters, including the OneTouch Verio Pro+ models that are used only in healthcare settings. The manufacturer has issued an alert to healthcare professionals about this issue.

The software fault in the specific meters could mean diagnosis and treatment are delayed. The MHRA wants people with diabetes to check if they have these meters at home and if they do, to contact LifeScan who will provide a fully-working replacement meter free of charge. OneTouch Verio strips and other models of Lifescan meters are not affected by the fault or recall.

John Wilkinson, the MHRA's Director of Medical Devices, said:

"Extremely high blood glucose levels in people are rare, but if they do occur the person will require immediate medical attention.

"Protecting public health is our priority. If you have a Lifescan OneTouch Verio blood glucose meter, please telephone LifeScan on 0800 279 9118 (UK) or 1800 535 676 (Ireland) for a replacement."

Simon O'Neill, Director of Health Intelligence at Diabetes UK, said:

"Blood glucose testing is an important part of diabetes management. People using these meters should contact the manufacturer for a replacement but if they are concerned about their blood glucose readings, they should consult with their diabetes care team."

Notes to Editor

1. Diabetes UK's Careline is available Monday-Friday, 9am-5pm on 0845 120 2960 for all general diabetes related enquiries.

2. The MHRA's Medical Device Alert can be viewed here:
Home use blood glucose meters: Lifescan OneTouch Verio Pro; Lifescan OneTouch Verio IQ (MDA/2013/022)

3. The manufacturer LifeScan issued an alert to healthcare professionals on 25 March about their voluntary recall. This alert can be accessed on the link below:
LifeScan Announces Voluntary Recall for Certain OneTouch® Verio® Blood Glucose Meters (external link)

4. Link to Diabetes UK warning about these faulty meters:
Lifescan recalls certain OneTouch Verio blood glucose meters (external link)

5. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there

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is a problem. We encourage everyone – the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action.

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