Device-specific guidance for manufacturers on reporting adverse incidents under the vigilance system

IVD blood glucose meters – POCT or home use

To be read in conjunction with the guidelines on a medical devices vigilance system MEDDEV 2.12/1 which sets out the general adverse incident reporting obligations on all manufacturers of medical devices including IVDs.

1 What should be reported?

Examples of adverse and near incidents include, but are not limited to, the following:

1.1 Display issues

Incidents which resulted from missing segments of the screen, failure of the screen to display the result, or a complete failure of the screen to display at all, are considered reportable.

1.2 Performance issues

An incident resulting from the failure to perform according to the performance characteristics specified in the information provided by the manufacturer is reportable.

Any incorrect test results that caused, or contributed to, an incorrect or missed patient diagnosis and/or treatment are reportable; these may result from imprecision, falsely high results, falsely low results, inadequate quality control or inadequate calibration.

Tools for determining the clinical significance of reported results may be useful (Parkes JL, Pardo, S, Slatin SL, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. Diabetes Care, 23:1143-1148, 2000).

1.3 Use error

Adverse incidents resulting from use error are considered reportable (guidelines on a medical device vigilance system, MEDDEV 2.12-1).

1.4 Inadequate labelling and instructions for use

Any incident which has resulted from inadequate or misleading labelling is reportable; this includes any incident which results from incorrect packaging due to product mix up.

Additionally, any adverse incident resulting from confusing or inadequate instructions for use is reportable.

1.5 Design/manufacturing

Incidents resulting from defective product design, or faulty manufacturing of the product, are reportable. Faulty manufacturing processes include, but are not limited to, contamination issues, stability problems with quality control solutions or test strips, issues resulting in failure to power-on, and reversion to incorrect units of measurement.

1.6 Unknown aetiology

In some cases, the reason for an incident may not be well defined, may involve a number of aetiologies, or may present novel or previously unrecognized factors; under these circumstances, the incident is reportable.

2 Report information

The MHRA would expect the following information to be included, if applicable, on each individual adverse incident report submitted by the manufacturer:

- test strip model, lot number and expiry date
- meter model name and serial number
- description of failure (e.g. imprecise reading, missing segment, incorrect unit)
- blood glucose meter readings
- patient's symptoms including any resultant injury
- description of patient's testing technique (e.g. use of alcohol wipe before testing)
- patient and/or carer's immediate actions (e.g. immediate treatment, ambulance called)
- healthcare worker's immediate actions (e.g. immediate treatments initiated)
- manufacturer's actions (e.g. actions taken to obtain meter and\or test strips)
- any other relevant information

The manufacturer's investigation should include, as applicable, an analysis of the manufacturing records, a post-market surveillance review, stability studies, analysis of the returned product, use of control solutions on retained strips and retained meters, and a presentation of the results. In addition, the manufacturer should have in place a standard operating procedure describing the actions taken when either no blood glucose meter or no blood glucose meter test strip is returned.

3 Final vigilance report

The final vigilance report should include, as a minimum, the following information:

- details of any clinical assessment where the patient's condition may have contributed to the adverse incident
- manufacturer's final assessment, including root cause and details of further follow up with timescales as appropriate
- corrective actions taken by the manufacturer