Medicines & Healthcare products Regulatory Agency

Insulin pumps and continuous glucose monitoring (CGM) equipment: guidance for users on reporting suspected adverse incidents and safety concerns to the Yellow Card scheme

Contents:

This guidance is aimed at users of diabetes management equipment, their families, care givers and representatives. It explains how to report your concerns to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card scheme and the information we need from you to support a thorough investigation. The Yellow Card scheme collects and monitors information on safety concerns involving healthcare products, like problems with medical devices or suspected side effects with a medicine.

You can report safety issues with all medical devices, medicines, vaccines and e-cigarettes, as well as defective or falsified (fake) products via the Yellow Card scheme.

This guidance has been written to assist you in submitting reports involving products within the diabetes management system, but does not cover blood glucose meters and strips and insulin medications. Reporting your concerns with any device via the Yellow Card scheme helps the MHRA to identify problems and work with manufacturers to take action so that people living with diabetes can access safe treatments with devices that fail less often.

Diabetes management systems

Continuous glucose monitors (CGM) are used to check your glucose levels. They let you see patterns in your levels and check if your glucose is too high or low. They can help you control your blood glucose levels, as you'll be able to act on patterns before they go too high or low.

Insulin pumps deliver insulin into the body, reducing events of high blood sugar (hyperglycaemia). The pump may be tethered to the body by an infusion set (tethered pump) or attached to the skin (patch pump). Insulin flows into the body through a tiny tube, known as a cannula, under the skin.

Insulin pumps and CGMs may be used together in different configurations, for example closed loop feedback systems, requiring varying amounts of manual input.

Insulin can also be given via a reuseable or single use insulin pen. Reuseable insulin pens, into which an insulin cartridge is inserted, a needle attached and then the insulin injected under the skin, are covered by this guidance. New smart pens can link with CGM apps to download when and how much insulin has been given, so that this is automatically added to the CGM record.

People using these medical devices should familiarise themselves with the instructions for use and follow any clinical guidance or training which may have been provided.

What should be reported to the MHRA

If you are concerned that there is an issue with any device in your diabetes management system, please complete a Yellow Card report online using the Yellow Card website or via the free Yellow Card app.

We are aware that incidents occur which do not result in injury or harm due to actions taken by the user. Your report will be valuable to us regardless of whether or not the issue led to an injury or harm. If injury or harm was avoided by action being taken, please let us know in your report.

We are also aware that some incidents are not reported to us as they are considered to be a result of user error. Please report these to us – a pattern in these reports may indicate a usability issue which requires investigation.

If you have reported a problem once and it happens again, we need you to submit another report so that we can understand the scale of the problem.

Please speak to a healthcare professional if you are worried about your health as the MHRA is unable to provide you with medical advice. The MHRA will not contact your GP or diabetes clinic when we receive your report so it is important that you inform your healthcare professional directly if you have concerns.

You can also report problems with medical devices directly to the manufacturer of the equipment. Manufacturers are obliged to inform the MHRA of specific types of adverse events reported to them by users, but not all. It is therefore important that we hear from you to get the full picture around how these devices are being used, and the problems you are experiencing.

Problems we would like to hear about from you include:

- any failure of a device to perform as expected, or in line with the information provided by the manufacturer
- concerns with accuracy of results from your CGM
    - *as part of your report, please tell us what the readings were on both the CGM and the approved blood glucose meter (see page 6) including the length of time between when the 2 readings were taken*
- concerns with accuracy of delivery from the insulin pump (for example, suspected underdose or overdose, unexpected bolus doses, non-delivery of insulin)
- connectivity issues between the various parts of the diabetes management system
- failure of a device to perform as intended throughout the expected lifespan
- concerns with the touchscreen, display or buttons, particularly following software updates
- physical failures, including leaks and cracks
- failure of adhesive and reaction to adhesive. If a patch test was carried out, please let us know
- display issues
- power issues or unexpected shutdown
- concerns around device documentation (such as the instructions for use, or the technical/operation manual). For example, this may include:
    - missing or confusing information
    - lack of information on compatibility with other products, including consequences of using an incompatible product
    - documents missing on receipt of a device

The Yellow Card scheme

Yellow Card

The MHRA runs the Yellow Card scheme, which collects and monitors information on safety concerns involving medicines and healthcare products. The scheme relies on voluntary reporting of problems involving a healthcare product by the public (including patients, parents and care givers) as well as from healthcare professionals. It is important for people to report problems experienced with healthcare products as these are used to identify issues which might not have been previously known about.

The Yellow Card system helps us to monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and users.

What will we do with the information in your report?

Your report will feed into the Yellow Card database which we monitor to pick up safety concerns that are only detected following widespread use by way of reviewing patterns of reporting and observing changes. We also use supporting evidence taken from the database in our work with device manufacturers and other stakeholders where our review indicates that action is required to reduce risk. We may contact you to request further information where it would be helpful in our assessment.

With your consent, we send your report to the relevant device manufacturer for their investigation and device specific signal detection activities. The manufacturer may contact you for further information to aid their investigation. Please note that the MHRA and manufacturer reference numbers for your report may not be identical.

We will not update you on the outcome of the manufacturer's investigation into your report. We ask the manufacturer to do this when we send them your report.

Who will have access to your report

All reports where consent was provided are sent to the manufacturer for their investigation. We may also share anonymised reports with other government departments or public health bodies, for example where the report is relevant to the work of the department for patient safety learning or if they have been commissioned by the MHRA. Details about who will have access to your information can be found here.

Case study: glucose sensors used with CGM system

The MHRA observed a large increase in reports from professional users and the public regarding skin sensitivity reactions to CGM sensors. These reactions ranged from minor irritation to serious allergic reactions with users seeking medical treatment or medication to self-treat symptoms.

We identified that patients were using creams or patches to reduce skin reactions and found numerous social media/Facebook pages recommending the use of such skin barrier products. Use of these skin barriers was not advised by the manufacturer of the CGM sensors. Through our investigation, we identified that use of these skin barrier products was having an impact on the overall device performance.

The MHRA arranged meetings with stakeholders such as Diabetes UK and NHS England to follow up on this reporting trend.

We also requested a review by the manufacturer of the CGM sensors of all available global safety and clinical data. This was assessed alongside all Yellow Cards and other safety information.

The MHRA worked with the CGM sensor manufacturer to improve safety reporting of this issue and to ensure that reported details were captured, assessed and acted upon adequately. Subsequently, we published a safety communication and press release to increase awareness of this safety concern, to advise that the manufacturer was making changes to the adhesive and to encourage users to seek advice from their healthcare professional. Following these safety communications and the action taken by the manufacturer, the number of reported allergic skin reactions with CGMs from this manufacturer reduced.

- **Reporting problems with the use of medical devices helps to provide a clearer picture about their safe use to protect users – if you suspect something is wrong, please submit a Yellow Card report**
- **The MHRA works closely with other organisations including NHS England and patient groups to encourage the safe use of medical devices, encourage Yellow Card reporting, and for both, local and national learning from incidents and device use issues**
- **If you have any concerns that the device you are using is causing you adverse reactions, ask your doctor or pharmacist for advice**

Read further examples of how Yellow Card reports have contributed to patient safety here.