Medicines & Healthcare products Regulatory Agency

[redacted]

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United Kingdom
gov.uk/mhra

9th August 2023

Dear [redacted]

FOI 23/450 - Freedom of Information request - Flash Glucose sensor failure rates?

Thank you for your Freedom of Information request dated 24th June 2023 where you asked:

- Please could you tell me if the number of reported issues has increased with flash glucose sensors in the last 3 months compared to the rate a year ago?

In response to your request, we should advise that we cannot share information about specific manufacturers, makes or models of devices, or who has reported problems to us. This is because there are confidentiality clauses in the legislation that we work under and the agreements under which information is provided to us which limit disclosure in some circumstances. As the Abbott Freestyle Libre 2 is the only flash glucose system currently available in the UK, we also consider that the information you have asked for is exempt from disclosure under section 43 of the Freedom of Information Act (FOIA) as disclosure of the requested information may prejudice the commercial interests of a third party ; while we appreciate that there is a public interest in disclosure in this case, there is also a strong public interest in maintaining the confidentiality of our agreements in such cases.

We can however provide some broader information about the wider category of generic types of devices, and we are providing this information below. Using the Global Medical Device Nomenclature, we searched our adverse event database for 'Glucose monitoring systems and associated devices' and 'Glucose monitoring systems'.

As of 3rd August 2023, the MHRA have received 1245 adverse incidents between 1st April 2022 - 30th June 2022, and 2144 adverse incidents with the same search between 1st April 2023 - 30th June 2023. This includes reports received from manufacturers, healthcare professionals and members of the public.

We should advise that these figures need to be interpreted with caution as they are not the same as complication rates.

Please also note the following considerations in relation to the data provided:

- this information is accurate at the time we conduct the search on our database, changes in the number of adverse events can occur following receipt of additional information.
- reports do not necessarily represent an individual patient and incident. Individuals may report an incident at any time after the event and people can make multiple reports at any time after the use of device and on the same issue. Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate when interpreting the data, it is important to note that the number of reports received should not be used as a basis for determining the incidence of a health/clinical effect as neither the total number of effects occurring, nor the number of patients using the device is known.
- the inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device.

- adverse incident reports by members of the public are voluntary but play a substantial part in the successful operation of the vigilance system. All reports received via Yellow Card are sent to the relevant manufacturer (if known and anonymised as appropriate) to feed into the vigilance system.
- in addition, the use of our Yellow Card scheme by healthcare professionals and members of the public are voluntary and therefore do not provide absolute adverse event figures.

As with all medical devices, MHRA continues to monitor their safety and performance and encourages reporting of any adverse incidents through its Yellow Card scheme on https://yellowcard.mhra.gov.uk/. Any emerging evidence relating to possible risks associated with these devices will be carefully reviewed and, if appropriate, regulatory action will be taken if any serious risks are confirmed.
We hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency