Medicines & Healthcare products Regulatory Agency

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United Kingdom
www.gov.uk/mhra

[redacted]

31st October 2023

[redacted]

[redacted]

Thank you for your Freedom of Information (FOI) request dated 04th October 2023 where you asked:

- **If there have been any adverse incidents reported to the MHRA in relation to these devices (loop recorders/internal cardiac monitors) and MRI?**

In response to your request, we have broadened our adverse event database search for the above criteria to cover all adverse incidents reported to the MHRA containing the device type loop recorders, implantable cardiac monitor or internal cardiac monitor and magnetic resonance imaging (MRI) systems. As of 24th October 2023, MHRA have received a total of 5 adverse incidents for the above search criteria. This includes reports received from manufacturers, healthcare professionals and members of the public. Out of the 5 reports, 3 of them provided the reason for failure, which included over-sensing, failure to interrogate, reset problem, failure to capture, and a high capture threshold.

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.

I 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