Medicines & Healthcare products
Regulatory Agency

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United Kingdom
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[redacted]

28 December 2023

FOI 23/926

Dear [redacted]

Thank you for your updated Freedom of Information request dated 28th November 2023 after our clarification of your original request on 16th June 2023 (FOI 23/423). You clarified that:

"my request only relates to adverse incidents for which adverse effects suggest that MRI scanning has caused interference, and does not cover non-MRI related incidents.
I would like the information for all orthopaedic devices if possible".

Further to your request, a search of our database was performed for all cases involving orthopaedic devices (GMDN CT1006), where the terms MRI or Magnetic were present in the event description text, between 27/12/2008 – 27/12/2023. These results were then further reviewed by a trained signal assessor to determine any adverse incidents for which the adverse effects suggest the possibility that MRI scanning caused interference. From this search, 3 reports were identified which have been summarised below.

Please note that the inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. In addition, details of the reports may have changed since the report was submitted.

1. A patient with a non-bioabsorbable, orthopaedic bone screw experienced pain, stiffness and clicking after an MRI scan. The reactions were continuing at the time of the report.
2. A patient with a bioabsorbable tendon/ligament bone anchor "felt something ping in his shoulder" during an MRI scan. Computed tomography scan/X-rays revealed that the bone anchor appeared to have become detached. No outcome was provided by the reporter.

3. A patient with a non-bioabsorbable tendon/ligament bone anchor “felt a pop mid MRI”. It was reported that a metal object was left in anchor from previous labral repair. The patient was reported to be well and recovering at the time of the report.

The reports must be read together with the following explanations:

- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with any particular device.
- When interpreting the above 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 reaction as neither the total number of reactions occurring, nor the number of patients using the delivery device is known.
- The numbers may include reports where the incident has been taken from published literature.
- These numbers of reports are accurate at the time they are extracted from our database and minor changes in the numbers can occur if the reporter of the incident gives us more details later.
- Adverse incident reports include mandatory reporting by manufacturers to the MHRA and voluntary reports by members of the public. All reports received via Yellow Card are sent to the relevant manufacturer (if known and anonymised as appropriate) to feed into the vigilance system. The principal purpose of this system is to improve the protection of health and safety of patients. This is to be achieved by the evaluation of reported AIRs and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such adverse events.

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

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner’s Office
Wycliffe House
Water Lane
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