Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

14th July 2023

Dear [redacted]

FOI 23/423 - RE: Details on adverse incidents related to scanning of fixed orthopaedic implants.

Thank you for your request dated 16 June 2023 where you asked for the following information under the FOIA:

"Please can you send me the details of all adverse incidents reported to you within the last 15 years which related to the MRI scanning of fixed orthopaedic implants? If possible, I would like this to include the manufacturer and model of the implant(s) and the scanner, the immediate/short term adverse effects, any actions taken, and the details of any long-term follow up with the patient".

I can confirm we hold the majority of the information you have requested; however, we have also determined that some of the information such as details of the manufacturer, make or model of a device, is exempt from disclosure under Section 44 (Prohibitions on disclosure). The release of information is exempt as its disclosure is prohibited by other legislation. In this case, section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions, and which relates to the affairs of an individual or business.

Additionally, details from adverse incident reports such as patient and reporter details are exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOIA. Supplying you with this information could lead to patient identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.

Further to this, we can provide you with the number of adverse incidents reported to us for orthopaedic implants within the last 15 years and any adverse effect reported to us that suggest MRI scanning has caused interference. Please can you confirm that this is the

correct interpretation of your request? Additionally, to assist us with your request, please can you provide a list of the orthopaedic devices you are interested in? We can provide this information per year received.

To note, it is not within our remit to carry out long term follow-up of patients who experience adverse incidents to medical devices. Ultimately any treatment and long-term health outcomes as a result of a medical device adverse incident is the responsibility of the healthcare professional. We may however provide recommendations for long-term follow-up of patients after seeking expert advice from our expert advisory groups which may be included in any relevant alerts, recalls and safety information published on our website. To note we do not have any oversight of how this follow-up is carried out in clinical practice. This published information includes any regulatory actions taken by the MHRA in response to medical devices safety issues.

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