Medicines & Healthcare products Regulatory Agency

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[redacted]
Guy's and St Thomas' NHS Foundation Trust
King's College London
[redacted]

12th January 2024

Dear [redacted],

FOI 23/966 - MRI Safety: heart valves, annuloplasty rings and cardiac occluders

Thank you for your Freedom of Information (FOI) request dated 11th December 2023 where you asked:

- **I have noticed that there was an incident reported in the MHRA databased for cardiac occluders and MRI. Would it be possible to get further details about it?**

As mentioned in the updated response letter to the original FOI 23/825, the information provided in this response will be regarding the heart valve and MRI adverse incident report rather than the cardiac occluders and MRI. Therefore, in response to your request based on the updated FOI response letter, I can confirm that we do hold the majority of the information you have requested. Unfortunately, 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 of the FOI Act due to Prohibitions on disclosure.

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.

We can however provide a summary of the failure description for the adverse incident involving the heart valve device and MRI. It was reported that there was an issue with the MRI safe/conditional details on the instruction for use (IFU), package inserts and patient information cards for the heart valve device.

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

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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, 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
Wilmslow
Cheshire
SK9 5AF