Medicines & Healthcare products Regulatory Agency

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

[redacted]

02 November 2023

FOI 23/745

Dear [redacted]

Thank you for your information request, dated 6th October 2023, where you requested: *"a database query for any adverse events involving patients with penile implants during MRI scans covering the period 01/10/22 to today (06/10/23) for me please?"*

Further to your request, we have searched our database for reports which concern both MRIs and penile implants for the period 01/10/2022 to 06/10/2023. I can confirm that the MHRA has not received any adverse incident reports which match these criteria.

It is important to note that the number of reports received, or lack thereof does not directly equate to the number of people who suffer adverse incidents and therefore cannot be used to determine incidence rates. Reporting rates are influenced by incident seriousness, their ease of recognition, the extent of use of a particular device, and may be stimulated by promotion and publicity about a device. For these reasons any data should not be used as a basis for determining incidence rates or the proportion of people effected.

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

Yours sincerely,

FOI Team,
Safety and Surveillance

Medicines & 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, 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
Wilmslow
Cheshire
SK9 5AF