Medicines & Healthcare products
Regulatory Agency

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

[redacted]

10th January 2023

Dear [redacted]

FOI 23/967

Thank you for your Freedom of Information request dated 8h December 2023, where you asked:

> *Is it possible that you can share the csv files or dataset relating to medical devices with me please (if this information is available yet)?*

Further to your request as explained in our previous response dated 7th December over the next year we are working on being able to make devices incident data available on our website like medicines data. However, as this is not yet available, neither are the CSV files, you can request information such as the number of reports for particular types of devices and some details such as the patient harm for example can be included.

We should also advise that we cannot share information about specific manufacturers, makes or models of devices, or who has reported problems to us. This is because there are confidentiality clauses in the legislation that we work under and the agreements under which information is provided to us which limit disclosure in some circumstances. This type of information is exempt from disclosure under section 43 of the Freedom of Information Act (FOIA) as disclosure may prejudice the commercial interests of a third party.

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 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

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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