Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
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United Kingdom

www.gov.uk/mhra

20 March 2024

Dear [redacted]

RE: FOI 24/226

Thank you for your information request, dated 4 March 2024, where you asked:

"I am an NHS Doctor and Academic Researcher in AI Bias and Medical Technology (profile here). I am currently researching errors and malfunctions in medical devices and am seeking datasets for this research. Previously I have used the FDA Maude Dataset for identifying trends in medical device issues in the USA, and I would like to look at similar data for the UK.

I could not find anything on the Gov UK website for the past few years. Do you have any datasets that I can access that describe the prevalence and trends in medical device malfunctions? I am particularly interested in implanted and connected medical technologies (e.g. pacemakers, deep brain stimulators)".

The MHRA holds information on suspected adverse incidents and runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products. The scheme relies on voluntary reporting from the public as well as from healthcare professionals. There are also legal requirements for manufacturers to report problems with their healthcare products to the MHRA.

As you will be aware we do not publish this information in a similar way to the FDA Maude Dataset currently. Instead, we are able to provide some of this information upon request.

As per your request, unfortunately, we cannot provide individual case information. Some of the information held in a case, 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.

In accordance with Section 16 of the FOIA, concerning the provision of advice and assistance to those requesting information under FOI we have provided some explanations below which may help you narrow your request or provide some further clarification on the information you are interested in. When we receive this clarification from you, we will be able take this forward in a new request.

For your reference, types of aggregated data we may be able to provide include device type, medical device problem, clinical signs and symptoms or conditions, and health impact.

The MHRA codes medical devices within adverse incident reports using the Global Medical Device Nomenclature (GMDN) Clinical Terminology (CT) codes. GMDN is a system of internationally agreed generic descriptors used to identify medical device products. If possible, please could you provide a list of GMDN or CT codes for the devices you are interested in.

The MHRA codes adverse events within adverse incident reports using the International Medical Device Forum (IMDRF) terminology. IMDRF terminology is a system of internationally agreed codes used to describe the medical device problem as well as clinical signs, symptoms, and conditions of the affected patient concerning the medical device adverse event. In your request you mentioned that you are interested specifically in malfunctions. As I am sure you are aware malfunctions covers a large range of possible issues. If you would like we can provide all reported medical device problems associated with the device types you are interested in, however we would suggest you narrow this data request to particular IMDRF codes of interest in order to comply with the appropriate limit under section 12 of the FOIA.

In addition, if there is a specific timeframe which you would like to receive this information for, please specify this in your request.

I hope you have found this response helpful and look forward to your future request. 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,

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

FOI Team,
Safety and Surveillance

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If you have a query about the information provided, please reply to this email

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

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF