Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2024/00630**

5 November 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 9 October. You wrote:

> *I was wondering if you could provide further information regarding the number of deaths and injuries specifically related to bed grab bars rather than the combined with the figures including bed rails as is detailed in the guidance document.*

MHRA Response

I can confirm that we do hold the requested information falling within the description specified in your request. However, we have determined that the information is exempt under Section 12 of the Freedom of Information Act, and we cannot process your request any further.

This is because we estimate the cost of gathering the requested information would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Bed grab bars are medical devices which fall under the Global Medical Device Nomenclature (GMDN) Collective Term codes 102 Beds and associated devices and 1896 Rails. Upon review of the data held, there are 1054 adverse incidents on the MHRA database containing these GMDN CT codes. To be able to provide this information would require manual review of all 1054 cases potentially relating to bed grab bars on our database. Based on a sampling exercise this step took approximately 4 minutes for each case and in some instances longer, totalling 70 hours and 15 minutes for the 1054 cases which we would need to review in this request. After this is complete the cases would then need to be analysed to identify those associated with deaths and patient harm. It is estimated that this will take a minimum of 1 hour to complete.

Under Section 16 of the FoI Act we should help you narrow your request so that it may fall beneath the cost limit. We would suggest specifying a date limit in your request, such as the number of deaths and injuries related to bed grab bars in 2024.

Further information can be accessed on the ICO website here:

- ICO Section 12 Guidance
- ICO Section 16 Guidance

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO Contact Information or telephone 0303 123 1113.

Re-use of our information