Medicines & Healthcare products Regulatory Agency

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

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2024/00801**

14 January 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 11 December 2024. You wrote:

> *I refer to your National Safety Alert on bed rails and bed levers. As you rightly identify there are significant risks relating to the provision of these pieces of equipment.*
>
> *My understanding is there are 18 deaths over four years relating to bed levers and bed rails.*
>
> *These cases would have been heard at inquests which are open hearings that could be reported on. I want to review these cases as a learning exercise for our clinical team. Would you be able to provide me with the case report details so I can read the cases and understand how the equipment contributed to patient mortality. I used to work as a solicitor so I would understand the caselaw and how to apply it to clinical practice.*
>
> *We want to do our best for patients and understanding the risks identified by the inquest would help especially with bed levers where mortality seems less clear cut.*

MHRA Response

We can confirm that the Agency holds the information you are seeking.

We can confirm that from 1 January 2018 to 31 December 2022, the MHRA received 18 reports of deaths related to medical beds, bed rails, trolleys, bariatric beds, lateral turning devices and bed grab handles.

However, we are engaging an exemption from disclosure under Section 41(1) and Section 40(2) of the Freedom of Information Act.

The information you have requested relates to device incident reports which were obtained by the Agency from another person and the Agency believes that if this information would be released it would breach the confidence of the person(s) the information pertains to, actionable by them or any other person. Therefore, we are not going to be releasing the requested information under Section 41(1).

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

MHRA maintains the following policy on disclosure of personal information:

"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

In accordance with Section 16 of the FOIA, concerning the provision of advice and assistance to those requesting information under FOI I can confirm that we are able to anonymised and aggregated information on the 18 reports. Examples of what we can provide includes patient age by 10-year age band, gender, clinical events and medical device problems.

If any of this information would be of use, please reply to this email specifying what you require, and this will be logged as a new request.

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 FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information