Medicines & Healthcare products Regulatory Agency

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

[redacted]

25 October 2023

FOI 23/715

Dear [redacted]

Thank you for your information request, dated 27 September 2023, where you requested: *"Following your release of the document NatPSA/2023/010/MHRA can you please send me information of the 18 reports of deaths related to beds and the 54 reports of serious injuries."*

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.

With this in mind, it would be appreciated if you can let us know if there is any specific information you require, and we will do our upmost to provide you with this information while still maintaining that the requirements of data protection are met. When we receive this clarification from you, we will be able to deal with query as a new request.

Medicines & Healthcare products
Regulatory Agency

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.

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

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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