Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

15th March 2024

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

Dear [redacted],

FOI 24/180 - Request for information: Adverse incidents reported to the MHRA relating to the presence of a sling remaining in between the patient and wheelchair whilst travelling in a vehicle.

Thank you for your follow-up Freedom of Information (FOI) request, dated 21st February 2024, regarding your previous request FOI 24/082. Please accept my apologies if our response to FOI 24/082 did not sufficiently answer your question.

In your initial request, you asked for:

- **The number of adverse incidents occurring each year over the past 7 years where an incident to a wheelchair user was related to the presence of a sling remaining between the occupant and the wheelchair/seating surface and whether the incident occurred whilst travelling in a vehicle.**

In response to your follow-up request, we have again searched the failure description field of each individual report for any information on incidents that occurred whilst travelling in a vehicle. I can confirm that we did not identify any reports where an incident occurred relating to the presence of a sling between the occupant and a wheelchair, specifically whilst travelling in vehicle. I feel it is important to reiterate that this information is not always provided by the reporter and is not an essential requirement to submit a report. The failure description is a free-text field and therefore the information provided is determined by what the reporter has included.

Please be assured that the same search criteria as your previous FOI (FOI 24/084) was used. This focused on any reports that included the word *'wheelchair'* within the failure description in association with all hoist sling devices using the Global Medical Device Nomenclature (GMDN) Clinical Terminology (CT) codes CT3038, CT2861, CT2096 and CT2898. Similarly, we searched for any reports that include the words *'hoist'* or *'sling'* within the failure description in association with all wheelchair devices using the GMDN CT codes CT1200, CT2045, CT1196 and CT1193, from January 2017 to December 2023 inclusive.

Please also note the following considerations in relation to the above:

- This information is accurate at the time we conduct the search on our database, changes in the number of adverse events can occur following receipt of additional information.
- Use of our Yellow Card scheme by the healthcare sector and members of the public is voluntary and it does not provide absolute adverse incident figures.
- The number of reports received should not be used as a basis for determining the incidence of a health/clinical effect as neither the total number of effects occurring, nor the number of patients using the device is known.

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 on 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

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, 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

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