Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

16th February 2024

Dear [redacted]

FOI 24/082 - Request for information: Adverse incidents reported to the MHRA relating to the presence of a sling remaining in between the patient and wheelchair.

Thank you for your Freedom of Information (FOI) request dated 24th January 2024.

In your email 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.**
- **More specifically, the nature of the adverse event or incident, the severity of injury, the causative/contributory factors, type of sling (in-situ or not), whether complex seating was involved, and whether the incident occurred whilst travelling in a vehicle.**

In response to your request, we have widened our search criteria to cover all adverse incidents reported to the MHRA in relation to wheelchairs and hoist slings. We focussed 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 see tables 1a and 1b below which outline the number of adverse incident reports received for all types of hoist slings containing the word '*wheelchair*' within the failure description, broken down by year and injury status respectively. Tables 2a and 2b outline the number of adverse incident reports received for all types of wheelchairs containing the words '*hoist*' or '*sling*' within the failure description, broken down by year and injury status respectively. We have also manually reviewed these incidents to remove those which do not fit the scenario you have described.

Further to your request regarding contributory factors, tables 1c and 2c outline the number of adverse incident reports where injury status is not 'none' or 'unknown' (see Tables 1b and 2b), broken down by International Medical Device Regulators Forum (IMDRF) Annex A Terms. The IMDRF Annex A terms are used to describe the medical device problem that occurred such as malfunctions and deterioration

in function of the medical device. You can find further information on IMDRF Annex A codes and corresponding terms here. This should provide some context around the cause or contributory factors of the incident. It's important to note that not all reports have an IMDRF Annex A term coded and therefore the number of reports is less than the total number of reports identified.

In regard to the details requested concerning the type of sling, unfortunately, this information is exempt from disclosure under section 44 (prohibition on disclosure) of the FOI Act, as it 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. Furthermore, there was no information in the reports regarding, complex seating or whether the incident occurred whilst travelling in vehicle, this information is not always provided by the reporter and is not an essential requirement to submit a report.

Table 1a: The number of adverse incident reports received for all types of hoist slings containing the word 'wheelchair' within the failure description, broken down by year. *

Year	Number of device incident reports
2017	23
2018	13
2019	5
2020	3
2021	13
2022	7
2023	2

Table 1b: The number of adverse incident reports received for all types of hoist slings containing the word 'wheelchair' within the failure description, broken down by reported injury status. *

Injury Status	Number of reports
None	36
Minor	15
Serious	10
Death	1
Unknown	4

Table 1c: The number of adverse incident reports received for all types of hoist slings containing the word 'wheelchair' within the failure description, and the injury status of 'Minor', 'Serious' or 'Death' broken down by reported IMDRF Annex A terms.

Type of severity	IMDRF Annex A Terms	Number of reports
Minor	Material Split, Cut or Torn	1
Minor	Activation failure	1
Minor	Material Separation	1

Minor	Collapse	1
Serious	Improper or Incorrect Procedure or Method	1
Serious	Detachment of Device or Device Component	2
Serious	Device Handling Problem	1
Death	Device Tipped Over	1

Table 2a: The number of adverse incident reports received for all types of wheelchairs containing the words 'hoist' or 'sling' within the failure description, broken down by year. *

Year	Number of device incident reports
2017	3
2018	8
2019	9
2020	5
2021	6
2022	6
2023	0

Table 2b: The number of adverse incident reports received for all types of wheelchairs containing the words 'hoist' or 'sling' within the failure description, broken down by reported injury status. *

Injury Status	Number of reports
None	20
Minor	6
Serious	9
Death	1
Unknown	1

Table 2c: The number of adverse incident reports received for all types of wheelchairs containing the words 'hoist' or 'sling' within the failure description, and the injury status of 'Minor', 'Serious' or 'Death' broken down by reported IMDRF Annex A terms.

Type of severity	IMDRF Annex A Terms	Number of reports
Minor	Device Tipped Over	1
Minor	Break	1
Minor	Detachment of Device or Device Component	1
Minor	Defective Component	1
Serious	Detachment of Device or Device Component	2
Serious	Improper or Incorrect Procedure or Method	1

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Serious	Unintended Movement	1
Serious	Adverse Event Without Identified Device or Use Problem	1
Death	Improper or Incorrect Procedure or Method	1

**It's important to note that incidents that do not fit the requested scenario have been removed for the purpose of this request.*

Please also note the following considerations in relation to the data provided in the tables 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 adverse incident figure is for all reports received within the time period specified.
- Individuals may report an incident at any time after the event and people can make multiple reports at any time. Where possible, multiple reports for the same event are linked, however as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate.
- 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.
- The inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device.

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