Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Dr [redacted]
[redacted]

MHRA

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www.gov.uk/mhra

10th January 2024

Dear [redacted]

FOI 23/961 - Request for information: Adverse incidents reported to the MHRA relating to wheelchair tipping in the last 5 years.

Thank you for your Freedom of Information (FOI) request dated 7th December 2023. Please accept my sincerest apologies for the delay in providing you with a response to your FOI.

In your email request you asked for:

- **Information regarding the number of adverse incidents referring to wheelchair tipping in the last 5 years. Specifically, the type of instability, type of wheelchair (manual or powered) and the age group of the user.**

In response to your request, we have widened our search criteria to cover all adverse incidents reported to the MHRA in relation to manual and powered type wheelchairs, focussing on any reports that included the Annex A IMDRF (International Medical Device Regulators Forum) code A051202 (Device tipped over), and mentioned the words '*tip*', '*tipping*' and '*tipped*' within the failure description, from January 2018 to December 2023 inclusive. Please see tables 1a and 2a below for all tipping incident reports broken down by year received, for manual and powered wheelchairs respectively. Tables 1b and 2b outline the number of tipping incidents reported, broken down by age of the patient, for manual and powered wheelchairs respectively. It is important to note, patient age is not a mandatory field when submitting a Yellow Card report concerning a medical device to the MHRA. As a result, the majority of device Yellow Card reports we receive do not include this information.

Unfortunately, we are unable to provide you with details on the type of stability incidents (i.e. forward, reverse, and sideways) as 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 manual wheelchairs containing *Annex A IMDRF code A051202 or* words '*tip', 'tipping'* or *'tipped' within the failure description.*

Year	Number of device incident reports
2018	28
2019	9
2020	23
2021	22
2022	16
2023	9

Table 1b: The number of adverse incident reports received by age for manual wheelchairs.

Patient Age Group	Number of Adverse Incident Reports
0-9	2
10-19	3
20-29	1
30-39	1
40-49	0
50-59	0
60-69	0
70-79	0
80-89	1
90-99	1
Unknown	98

Table 2a: The number of adverse incident reports received for powered wheelchairs containing *Annex A IMDRF code A051202 or* words '*tip', 'tipping'* or *'tipped' within the failure description.*

Year	Number of device incident reports
2018	22
2019	12
2020	12
2021	19
2022	13
2023	2

Table 2b: The number of adverse incident reports received by age range for powered wheelchairs.

Patient Age Group	Number of Adverse Incident Reports
0-9	0
10-19	0
20-29	1
30-39	1
40-49	1
50-59	1
60-69	0
70-79	0
80-89	0
90-99	0
Unknown	76

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,

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MHRA
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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
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