Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
E14 4PU
United Kingdom
www.gov.uk/mhra

[redacted]

5th February 2024

Dear [redacted]

FOI 24/059 – FOI about hoisting deaths

Thank you for your Freedom of Information (FOI) request dated 19th January 2024 where you asked for:

> The number of deaths attributed to a hoisting incident in the years 2023, 2022, 2021.
> The attributing factors for those deaths would also be very helpful to establish trends.

In response to your request, we have widened our search criteria to cover all adverse incidents reported to the MHRA of, patient lifting systems, patient lifting/ transfer devices and mobile patient lifting systems and any reports that included the Annex F IMDRF (International Medical Device Regulators Forum) code F02 (death) or where the injury status flag was death. As of the 23rd January 2024, the MHRA have received a total of 6 adverse incidents using the above-mentioned search of our database. One report was received in 2021, 3 reports were received in 2022 and 2 reports were received in 2023.

With regards to your question on the attributing factors for these deaths, for one of the incidents the cause was not established. For another incident an installation problem and issue with the user of device was concluded and another incident concluded a maintenance issue and user error following investigation. For the remaining three incidents we do not hold information on the attributing factors.

Please also note the following considerations in relation to the data provided:

- 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.
- Reports do not necessarily represent an individual patient and incident. Individuals may report an incident at any time after the event and people can make multiple reports at any time after the use of device and on the same issue. 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 when interpreting the data, it is important to note that 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.
- Adverse incident reports by members of the public are voluntary but play a substantial part in the successful operation of the vigilance system. All reports received via Yellow Card are sent to the relevant manufacturer (if known and anonymised as appropriate) to feed into the vigilance system.

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- In addition, the use of our Yellow Card scheme by healthcare professionals and members of the public are voluntary and therefore do not provide absolute adverse event figures.

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