Medicines & Healthcare products
Regulatory Agency

Medicines & Healthcare products Regulatory Agency
10 South Colonnade
Canary Wharf
London
E14 4PU

Ms Susan Ridge
H.M. Assistant Coroner for Surrey
By Email: [redacted]

Reference: [redacted]

25 October 2024

Dear Ms Ridge,

Investigation into an Invacare Portugal Lda, Medley Ergo bed with an extension and its relation to the circumstances surrounding the death of Paul Rodney Batchelor (DOD 28/06/2023).

Thank you for your email of 16 September 2024 attaching the Regulation 28 letter following the inquest into the sad death of Mr Paul Rodney Batchelor. I would like to offer my sincere condolences to the family of Mr Batchelor on their loss.

In your letter, you requested that action should be taken to prevent similar events of this kind occurring in the future. I would like to take the opportunity to provide relevant background before responding to your matters of concern.

Introduction and regulation of medical devices in the UK

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care and is responsible for the regulation of medical devices, blood components for transfusion and medicinal products in the UK.

The MHRA takes all reasonable steps to protect the public's health and safeguard the interests of patients, public and users. We ensure manufacturers of medical devices comply with the UK Medical Devices Regulations 2002 (as amended) to demonstrate that they meet appropriate standards of safety, quality, and performance for the expected lifetime of the device. Where possible, we work with a range of stakeholders, including patients and the public, to work towards the promotion of safer medical devices and their safe use.

Manufacturers must demonstrate compliance with the Regulations before a medical device can be UKCA or CE marked and placed on the UK market. Although not

mandatory, device manufacturers can use designated standards to demonstrate that they are compliant with relevant requirements of the Regulations.

One major area of the MHRA's responsibilities is to collect, analyse, monitor, and act on information relating to safety concerns from a range of data sources including reports of adverse incidents. An adverse incident is an event involving a medical device, which produces, or has the potential to produce, unwanted effects involving the safety of patients, users, and other persons. These effects may arise from shortcomings in the device, its operating instructions, user practice or conditions of use. Adverse incidents may also occur due to patient factors, as not all interventions are suitable for all patients and their condition may change over time, requiring a different approach.

Patient safety is our highest priority and we encourage everyone to report safety concerns to MHRA through our Yellow Card scheme. However, it is mandatory for manufacturers of medical devices to report certain incidents to MHRA.

In general, where an adverse incident occurs the manufacturer of a medical device is responsible for carrying out any investigation required and informing MHRA of their findings. We regularly review our database of incidents to detect safety signals and consider whether additional action is required. Where necessary we will issue safety messages to health and care organisations, patients, and the public. These types of actions help to reduce the risk of similar incidents happening again.

Synopsis of incident

The MHRA was initially informed of Mr Batchelor's death involving a Medley Ergo bed by Invacare Portugal Lda on 14 February 2024. Invacare first became aware of the incident on 5 February 2024 and reported within the regulatory timeframes.

From the details within your report, Mr Batchelor was using a Medley Ergo bed with an extension frame manufactured by Invacare Portugal Lda. On 27 June 2023, Mr Batchelor was found trapped in the gap between the standard mattress and the footboard, after the extension section of the mattress fell through the gap. His death was formally recorded by paramedics on 28 June 2023. It was found that there was no deck in place to support the mattress extension.

Matters of concern

You expressed to the MHRA as a matter of concern that there may be a lack of awareness of the need to ensure adequate support for the mattress extension or bolster when using nursing care beds with an extension frame fitted.

Prevalence of the problem

A search of the MHRA's database over the last 5 years (20 September 2019 to 20 September 2024) yielded no similar incidents involving a patient becoming trapped between the mattress and footboard when a bed was extended, apart from this incident reported to the MHRA on 14 February 2024. This search was conducted for any bed, and not just the Medley Ergo.

Invacare Portugal Lda has searched their database of complaints and not found any similar complaints for the Medley Ergo bed.

The wider issue of entrapment with medical beds is well known. A search of the MHRA's database over the last 5 years (20 September 2019 to 20 September 2024) yielded 32 reports of entrapment involving beds and associated devices such as mattresses, bed rails and bed grab handles. This includes reports of entrapment of caregivers as well as with bed occupants.

MHRA response

The MHRA reviewed the manufacturer's User Manual. The User Manual provides general warnings regarding the risk of entrapment. The User Manual also includes instructions on how to install the mattress support extension, which includes the step "Attach mattress deck extender to the mattress deck". These instructions are also accompanied by diagrams. There are also instructions on the need for regular servicing and maintenance, and that these activities should only be conducted by "personnel who have received the necessary instructions or training".

The MHRA carried out a review of deaths and serious injuries involving beds and bed rails in October 2022. In January 2023, the MHRA hosted a round table to discuss updating the Guidance on safe use and management of bed rails and how to raise awareness of the risks of death and serious injury with beds, bed rails, and other associated devices. As a result of these discussions, a National Patient Safety Alert on the risk of death from entrapment or falls with medical beds, trolleys, bed rails, bed grab handles and lateral turning devices was published in August 2023, two months after the sad death of Mr Batchelor.

The Alert requires that relevant staff receive device training suitable to their roles, organisations have an up-to-date medical device management system in place, and that regular servicing and maintenance of these medical devices is implemented in line with the manufacturer's instructions. It also requires regular risk assessments for patients using bed rails or handles, including entrapment risks.

This Alert was directed towards care home staff, among others, and was sent to relevant organisations via the MHRA's Central Alerting System on 30 August 2023 and was also highlighted in the CQC's Adult Social Care Bulletin on 28 September 2023. The MHRA attended meetings with Medical Device Safety Officer (MDSO) network on implementation of the Alert and provided input into the MDSO network's FAQs for this Alert. The is available both on the MDSO network (restricted access) and also on the National Association of Medical Device Educators and Trainers (NAMDET) webpage (public access). The MHRA has also provided advice on the Alert wherever requested, including from various NHS organisations, local councils, care homes and manufacturers.

The MHRA also published in 2014 'Devices in Practice' which is intended to provide a practical guide for health and social care professionals on using medical devices.

Ongoing Work

The MHRA has discussed with the NAMDET the possibility of producing training materials for users of beds and bed rails, and the risks relating to entrapment, and this is currently being drafted, with a view to be available in the coming months.

Conclusions

We suggest that the above list of actions detailed in the National Patient Safety Alert, published two months after Mr Batchelor's death, are relevant to this case. Neither the MHRA nor the manufacturer have received any similar reports with the Medley Ergo bed, and the MHRA does not have any similar reports for other beds either, relating to the bed extension. The MHRA has published a National Patient Safety Alert with general requirements to prevent entrapment with beds and associated devices and based on the lack of similar reports relating to bed extensions, we believe these requirements are sufficient, and we therefore do not intend to take further action.

The MHRA will continue to monitor reports of entrapments in beds and associated devices very carefully, and if any adverse signals are detected in the future, we will take further action.

Should you have any further questions, please do not hesitate to contact my office: [redacted].

Yours sincerely,

[redacted]

[redacted]
Chief Executive
Medicines and Healthcare products Regulatory Agency
E: [redacted]