Medicines & Healthcare products
Regulatory Agency

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Mr Martin D Fleming
His Majesty's Senior Coroner for West Yorkshire
By Email: [redacted]

Reference: [redacted]

13 February 2025

Dear Mr Fleming,

Regulation 28 report relating to the death of Angela Stacey Carney (DOD 26/09/2023)

Thank you for your Regulation 28 report relating to the death of Ms Angela Stacey Carney (DOD 26/09/2023) which was received on 13 January 2025. I would like to offer my sincere condolences to Ms Carney's family on their tragic loss.

I am writing in relation to your request that the Medicines and Healthcare products Regulatory Agency (MHRA) takes action to prevent similar events of this kind occurring in the future. I have provided some background information below, which I hope will offer some useful context regarding our role, followed by our response to your matters of concern.

Introduction and regulation of medical devices in the UK

The 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. We take all reasonable steps to protect public 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 prior to placing new medical devices on the market and during the intended service life of the device.

While the MHRA does not regulate the sale of second-hand medical devices, 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 their devices are compliant with relevant requirements of the Regulations. Manufacturers of wheelchairs and scooters can self-certify compliance with the regulations as these are Class I medical devices.

As part of the requirements, manufacturers must identify potential hazards and risks associated with use of their device and establish mitigations for each of the identified risks, this is an ongoing process throughout the lifecycle of any medical device. The risk mitigations related to use of the device can include but are not limited to, warnings in user manual, labelling and educational material.

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 the MHRA through our Yellow Card scheme. Additionally, it is mandatory for manufacturers of medical devices to report certain incidents to the MHRA. In general, where an adverse incident occurs, the manufacturer of a medical device is responsible for carrying out any investigation required and informing the MHRA of their findings directly or through the appointed UK Responsible Person. 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 first informed of the incident leading to the death of Ms Carney by the Regulation 28 report received by the MHRA on 13 January 2025. Prior to this notification, we had not received any information regarding this tragic incident. A search conducted on the MHRA adverse incident database did not yield any results that corresponded with the specific event described in the report.

We initiated an investigation focusing on identification of the specific device and its manufacturer. Following the provision of additional information by the Coroner's Officer, it was determined that the device involved in this tragic accident was Sterling Sapphire mobility scooter, manufactured by Sunrise Medical Ltd. The manufacturer initially was not aware of the extent of the device involvement in the accident, however, subsequently to being informed on the circumstances concerning the tragic accident in October 2024, the manufacturer failed to report it to the MHRA. Further information was provided to the MHRA by the manufacturer, indicating that at the time of the accident, the device was 19 years old and had a flat battery.

This model of the scooter has a service life of five years and has been discontinued since 2010.

As indicated in the Regulation 28 report, Ms Carney purchased the scooter second hand from her neighbour, and it was noted in the report that this model of the scooter did not have secondary (independent) braking mechanism. At the time of the tragic accident, Ms Carney's mobility scooter was in freewheel mode, as it descended a road with a 4.7% downward gradient. The engine was disengaged, thereby preventing the activation of the primary brakes. The scooter proceeded down the footpath at speed towards the junction and directly into the path of a vehicle. Regrettably, Ms. Carney succumbed to her severe injuries at the hospital following the collision.

Matters of concern

You have expressed the following as matters of concern:

1) While more recently designed and manufactured mobility scooters are manufactured with secondary braking system by way of a fitted hand brake mechanism, other manufacturers may be producing scooters without such independent braking mechanism.

2) There may be other second-hand mobility scooter models being used without secondary brakes.

3) Summary of the concern: To review the adequacy of the existing guidelines and regulations and to consider the feasibility of fitting secondary braking systems by way of a fitted hand brake mechanism to all mobility scooters.

Prevalence of the problem

A search of our database over the last five years (January 2020 – January 2025) yielded five potentially relevant reports involving mobility scooters and powered wheelchairs, with three of these reports having inconclusive link to the freewheel mode. The remaining two reports appear to have relevance to the freewheel mode and reported issues with functionality of brakes. Notably, no injuries were reported as a result of these two events.

Comments

The initial concerns around the risk of unintended movement of mobility scooter in freewheel mode were raised by the MHRA (previously known as Medical Device Agency) in 1999. The Agency issued a safety notification (MDA SN1999 (15)) indicating that the manufacturers of mobility scooters should include appropriate warnings in the instructions for use to ensure the users are aware of the risks and should be advised to use the freewheel device only when it is essential and that it should be re-engaged as soon as manoeuvre is completed.

Following this, changes were introduced to the next iteration of the standard 'BS EN 12184 Electrically powered wheelchairs, scooters and their chargers. Requirements and test methods'. The introduced changes included requirements of having brakes which, when operated after the scooter has been put into freewheel mode, shall bring the device to a stop.

Actions taken in response to the matters of concern

1. We are working with the manufacturer of Sterling Sapphire mobility scooter to address the failure to report this serious incident to the MHRA in October 2024, in accordance with vigilance reporting requirements. To address this, the manufacturer has been requested to review their internal processes related to reportability and provide the MHRA with the outcomes of this review by 17 March 2025, indicating whether any improvements have been implemented.

2. We have reviewed the current version of the standard BS EN 12184:2022 'Electrically powered wheelchairs, scooters and their chargers'. Requirements and test methods and the following provisions related to freewheel mode / device are included in the standard:

- Subclause 10.2 Braking function, 10.2.1 Requirements states the following: *10.2.1. b) The wheelchair shall have a running brake which, when operated after the wheelchair has been put into freewheel mode, shall bring the wheelchair to a stop. NOTE 1 This requirement can be met by a brake which operates when freewheel mode is ended, if that brake provides the required function.*

- Subclause 10.2.2 Test methods, 10.2.2.1 Determination of the effectiveness of running brakes specifies the conditions of testing.

- Subclause 10.3 Freewheel device states the requirements for the freewheel, including the following: *An audible alarm activated when the freewheel device is in operation and deactivated when the drive and braking systems are fully operational can assist the occupant and/or assistant. Freewheel devices shall be protected against activation caused by accidental contact. Example: A suitable shape and location for the means for disengagement.*

- Subclause 12.6 Emergency stop states the following: *The wheelchair shall be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.*

  The emergency stop function shall be available and operational at all times, regardless of the operating mode. Emergency stop devices shall be a back-up to other safeguarding measures and not a substitute for them.

- Annex B, Recommended design features, subclause B.3.4 Freewheel alarm indicates: *When the freewheel device is operated, an auditory warning and/or a visual warning should be made until the freewheel device is deactivated, and the drive and braking system is fully operational.*

- Annex E, Recommendations for safety in freewheel mode, subclause E1 provides recommendations to limit the speed of the device and to allow safe re-engagement following the manually re-engaging the drive and / brakes to exit freewheel mode.

- Subclause E.2 indicating the following recommendation: *When in freewheel mode, the wheelchair should be prevented from travelling faster than 0,5 m/s on the rated slope.*

  The provisions listed in the BS EN 12184:2022 standard comprehensively outline safety requirements for mobility scooters when in freewheel mode, with additional recommendations for the manufacturer to limit the speed of the scooter when in freewheel mode. BS EN 12184:2022 is a harmonised standard in the EU. The requirements for brakes that enable the device to stop once in freewheel mode were also reflected in BS EN 12184:2009, which is the designated standard in the UK. Designated standards (harmonised in the EU) can help manufacturers demonstrate their products, services or processes comply with the relevant regulations. By following designated standards for UKCA marking (or harmonised standards for CE marking), manufacturers can claim, 'presumption of conformity' with the corresponding requirement.

3. Using the data from our Registration Database, we have identified manufacturers who have registered with the MHRA as manufacturers of powered mobility scooters. We will sample a number of these manufacturers to evaluate the extent to which mobility scooters placed on the market in the UK are equipped with adequate safety features to mitigate the risk of unintended and uncontrolled movement while in freewheel mode. Following this initial review and based on its findings, we will undertake appropriate regulatory actions.

4. We are aware of complexities associated with the use and purchase of mobility scooters, including the use of devices beyond their intended service life, purchase of second-hand devices from unauthorised retailers, and use of devices that are not safe. In addition to the existing guidance on the safe use of assistive technology devices[1], the MHRA is working on updating Medical devices: information for users and patients guidance to raise awareness on important considerations prior to purchasing a mobility scooter. The updated guidance will include key points for potential users to be aware of before purchasing their mobility scooter, including links to documents produced from other organisations to further strengthen the advice. The update is expected to be published by June 2025. We will inform you once the guidance is updated.

5. To further promote the guidance, once published, we will collaborate with relevant stakeholders to disseminate this information and emphasize the importance of safety features in mobility scooters when operating in freewheel mode.

Conclusions

While we have received a relatively low number of reports potentially related to braking issues when in freewheel mode, we acknowledge the severity of harm that can occur if the device is not equipped with appropriate stopping mechanisms. We will therefore take the necessary steps to try and address the concerns raised. We will continue to monitor reports concerning

[1] Assistive technology: definitions, examples and safe use - GOV.UK

braking mechanisms in mobility scooters when in freewheel mode, work on analysing any emerging safety patterns and act on identified safety signals.

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

Yours sincerely

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