Medicines & Healthcare products
Regulatory Agency

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[redacted]

29 November 2023

FOI 23/840

Dear [redacted]

Thank you for your information request, dated 2 November 2023, where you asked 6 questions. I have stated each question in full and the answer is below each question.

1. Did the adverse wheelchair incident which took place on 12 March 2019 in The Red House Welfare & Housing Society (care home, with dementia care), give rise to a MHRA Yellow Card Report? F.Y.I. the tragic incident in 2019, described in Issue 13 on the CQC website is related to life-changing fractures sustained by a resident in the said care home, due to inappropriate footplates on a standard wheelchair. The resident's foot fell from the wheelchair's footplate, while being pushed down a slope, and became caught underneath fracturing her thigh bone and damaging her knee joint:

   https://www.cqc.org.uk/press-release/suffolk-care-provider-fined-exposing-woman-risk-avoidable-harm

   https://www.cqc.org.uk/guidance-providers/learning-safety-incidents/issue-13-protecting-people-using-wheelchairs

The MHRA carried out a search of our database using the search terms "wheelchair" and "Red House" or "Sudbury" or "bone" or "femur", in the date range 12 March 2019 to 30 November 2022. These searches did not identify any relevant Yellow Card report for this incident.

2. Did MHRA and/or the manufacturer of the wheelchair investigate the potential problem with the design of the footplates or the wheelchair itself?

We have checked our records and the MHRA did not investigate as this incident was not reported to us. The MHRA does not hold information on whether the manufacturer investigated any design issues.

3. What was the make and model of the wheelchair involved in this tragic adverse incident?

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The MHRA does not hold this information as the incident was not reported to us.

> 4. Does MHRA intend to publish a safety medical device alert on the safety risks generated by improper use, improper adjustment, inadequate prescription by untrained care home staff of: wheelchairs, footplates, heel loops, leg straps, calf support/calf straps etc? Today, on the Facebook pages of many care homes, including many run by CQC's best-rated providers, one can observe multiple instances of feet improperly and unsafely positioned on ill-adjusted or inappropriate footplates (outdoors & indoors, photos & videos).

This request is asking for the MHRA's view, which we are not required to provide under the Freedom of Information Act. However, we are are providing our view on this in order to assist you and to be transparent.

The MHRA no longer publishes Medical Device Alerts, however, we have other methods for publishing important safety information, such as Device Safety Information or National Patient Safety Alerts. The decision on whether to publish safety information is based on evidence from signal detection on adverse incidents, engagement from our stakeholders, or evidence from other sources as appropriate. You can find further information on these alerts here.

At this time, the MHRA does not believe additional safety information on this issue is required, as the CQC has already recently published information (which you linked to in your first question) on the risks of improper use of wheelchairs, as you are aware from the links from your first question. After your initial report in November 2022, we raised this at a National Wheelchair Managers Forum meeting, and no concerns were raised, and our regular signal detection work has also raised no concerns. Guidance on how to ensure safe use, adjustment and prescription of medical devices is provided in the MHRA's Managing Medical Devices guidance document, which as you know from FOI 23/714 is currently in the initial stages of being updated.

> 5. How does MHRA encourage care home staff and nurses to systematically file MHRA Yellow Card Reports, when an adverse incident involving wheelchairs takes place?

- As an agency, we are always trying to improve healthcare professionals' awareness and understanding of the Yellow Card scheme to increase the frequency of reporting. To achieve this, we conduct a range of educational and outreach activities such as:
    - engagement via social media channels;
    - sharing case studies;
    - exhibiting at healthcare conferences; and
    - running campaigns.

  You can find out more about the resources mentioned above on the Yellow Card scheme website: www.mhra.gov.uk/yellowcard
- We also have 6 Yellow Card Centres across the UK that are commissioned by MHRA to educate and promote the reporting of suspected adverse events to the

Yellow Card scheme in their local regions: 1) Northern and Yorkshire, 2) North West, 3) West Midlands, 4) Scotland, 5) Wales and 6) Northern Ireland.

- Additionally, MHRA work closely with the Medical Device Safety Officer (MDSO) Network to alert members to safety issues that they need to be vigilant of in their organisation and to encourage reporting of adverse incidents concerning medical devices to us.
- Any guidance or safety communications issued by MHRA will always signpost to the Yellow Card scheme to further encourage reporting.

6. In 2015 MHRA published a Medical Device Alert MDA/2015/0018 related to safety/posture belts improperly adjusted or fitted to wheelchairs and the associated risks of strangulation, asphyxia and injuries, which is now archived https://webarchive.nationalarchives.gov.uk/ukgwa/20170209035403/https:/assets.publishing.service.gov.uk/media/55361b37ed915d15d8000011/MDA-2015-018.pdf

Does MHRA intend to issue a new MDA related to the issue of wheelchair seat/pelvic belts, due to multiple FB care home photos, showing residents sliding dangerously in wheelchairs due to inappropriate belts or seat belts too loose, migrating up to abdomen or chest level? F.Y.I many wheelchairs in care homes are allocated by inadequately trained care home staff and/or nurses without any OT or PT input, resulting in multiple falls from wheelchairs, practically all recorded as "unwitnessed", with no relevant detail about the make, model and setting of the wheelchair.

This request is asking for the MHRA's view, which we are not required to provide under the Freedom of Information Act. However, we are are providing our view on this in order to assist you and to be transparent.

MDA/2015/0018 was archived as our regular signal detection activities had shown that we were receiving no further incidents of asphyxiation due to wheelchair belts, and we received no further concerns from stakeholders. We have not received any further reports of serious injury or deaths relating to wheelchair belts. After your initial report in November 2022, we raised this at a National Wheelchair Managers Forum meeting, and no concerns were raised. Based on the current evidence, the MHRA is not planning on issuing any further alerts on this issue.

If you have a query about the information provided, please reply to this email.

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our

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handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

Safety & Surveillance