Medicines & Healthcare products
Regulatory Agency

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United Kingdom
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[redacted]

15 December 2023

FOI 23/951

Dear [redacted]

Thank you for your follow up questions to FOI 23/840 received 29 November and 30 November 2023. We appreciate the issue is of great concern to you. We have copied the questions below and answered each one below.

1) On 02.11.23, I posted three (3) additional but related questions (nos.7-9). When can I expect a response from MHRA?

This enquiry was received on 6th November 2023 and logged as FOI/23/847. It was replied to on 4 December 2023.

2) Did an MHRA clinician review the MHRA Safety and Surveillance team's public FOI response ref. 23/840 dated 29.11.23 before it was posted?

No. This is not part of the procedure.

3) My question is were care homes represented at the National Wheelchair Managers Forum?

No.

4) Are care homes represented in the Medical Device Safety Officer (MDSO) Network, with whom MHRA work closely?

Yes.

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In reference to your request for clarification of FOI 23/840 which you sent on Friday, December 15, 2023, we can provide the following responses:

5) "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." (see MHRA response attached, points 4 & 6).

   Does this mean that the NWMF is not aware of any similar concerns, or does this mean that the NWMF deemed the improper use of wheelchairs in care homes that I reported, and which was in disregard of manufacturer's instructions and best practices guidance, to be acceptable and recommendable?

It means that the NWMF is not aware of any similar concerns.

6) Does this mean that MHRA's "regular signal detection work", which apparently also raised no concerns, is based on the incomplete database of the optional (non-compulsory) Yellow Card Reports, rarely used by care homes, even in serious cases with fractures and hospitalisation?

The MHRA uses the YellowCard database as the main source of regular signal detection work. Literature and stakeholders are examples of other sources of signals.

If you have a query about the information provided, please reply to this email. However, we are also conscious that you are submitting numerous requests and correspondence to us at this time, and we therefore suggest that you may wish to consider Information Commissioner's Office on making effective FOI requests prior to submitting further requests.

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 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

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Regulatory Agency

Wilmslow
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Yours sincerely,

Safety & Surveillance