



Medicines & Healthcare products
Regulatory Agency

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[REDACTED]

10 October 2023

FOI 23/714

Dear [REDACTED]

Thank you for your information request, dated 27 September 2023, where you asked 8 questions. I have stated each question in full and the answer is below each question.

1. Does MHRA consider portering wheelchairs to be Class I Medical devices, when used for self-propulsion with the feet by disabled care home residents who can no longer walk?

I am pleased to provide you with the information requested. On MHRA's interpretation database for borderline medical devices there is the query: Are porter's chairs (attendant -pushed wheelchairs) medical devices?

The answer provided on 14/08/2002 was that of "the opinion that the chairs as described by the manufacturer do not appear to be medical devices, this judgement is based on the intended purpose the manufacturer has assigned to the product, which is to transport patients more quickly and easily around the hospital."

2. Does MHRA require the manufacturers of portering wheelchairs to clearly stipulate that portering wheelchairs are not intended for long-term use, for self-propulsion with the feet, for outdoor use, or for use occupied in minibuses during outings?

We do not hold the information that you have requested as MHRA doesn't stipulate.

3. In the third scenario I described in the background, who is responsible for monitoring and acting on improper and unsafe use of portering wheelchairs in care homes?

The local Council or the CQC is responsible.



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4. When will the stakeholder consultation start and finish and who are the stakeholders who will be consulted in order to update Managing Medical Devices - Guidance for health and social care organisation – January 2021?

The consultation has not started. We do not hold a formal planning document. There have been informal initial discussions about the possible process and stakeholders with notes taken and we are disclosing these notes in the attachment with this letter. These will be subject to change and have not been approved.

5. When do MHRA intend to publish the updated version of the above guidance?

A specific timeline has not yet been defined for the publishing of the updated version of the Managing Medical Devices guidance document. Therefore, we do not hold this information.

6. Who is responsible in MHRA for the clarity and absence of ambiguity in published MHRA guidance on medical devices, notably wheelchairs?

No such post exists. Guidance goes through a consultation process and then an internal sign-off process. Currently, the Chief Safety Officer of MHRA is the final approver.

7. Kindly release information on how MHRA works with CQC and NMC to promote safe and effective use of medical devices, notably wheelchairs, in nursing and residential homes.

I am pleased to provide you with some of the information requested. The memorandum of understanding that MHRA has with CQC is available on the CQC website: https://www.cqc.org.uk/sites/default/files/20170929_cqc_mhra_mou.pdf. MHRA does not hold information on how MHRA works with the NMC.

8. Please provide the MHRA email address to which the public should address FOIA requests.

I am pleased to provide you with the information requested; the email address is: info@mhra.gov.uk.

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.



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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
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

Safety & Surveillance