**FOI 23/218 - MHRA Managing Medical Devices - Guidance for health and social care organisations – January 2021**

**REQUEST**
**20 March 2023**

MHRA Managing Medical Devices - Guidance for health and social care organisations - January 2021

On p.5 of the above mentioned MHRA guidance for health & social care organisations, downloadable on GOV.UK at the address below:

https://www.gov.uk/government/publications/managing-medical-devices

it is stated: “The management structure for medical devices should have clear lines of accountability up to board level. These lines of accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community-based services, independent hospitals providing services for NHS patients, managed care providers, Private Finance Initiative (PFI) organisations and other independent contractors. It is important to establish who is accountable, and where there is a need for joint accountability arrangements.”

Can you please provide clear and complete information as to how and when, and in which cases, it is deemed appropriate for the said lines of accountability to be extended to include residential and care homes.

**MHRA RESPONSE**
**22 May 2023**

Dear

Thank you for your request under the Freedom of Information Act, we apologise for the delay in response.

You have asked about the paragraph on page 5 of our Managing Medical Devices publication which states:

*The management structure for medical devices should have clear lines of accountability up to board level. These lines of accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community-based services, independent hospitals providing services for NHS patients, managed care providers, Private Finance Initiative (PFI) organisations and other independent contractors. It is important to establish who is accountable, and where there is a need for joint accountability arrangements.*

By this statement, we have an expectation that someone would be able to take responsibility/accountability for the medical devices which are in use within their organisation, this could fall, for example to a Medical Director.

We do not hold any information that covers “how and when, and in which cases, it is deemed appropriate for the said lines of accountability to be extended to include residential and care homes.”

We apologise once more for the delay in response.

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
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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