

FOI 23/523

Dear

Thank you for your request of 14 July 2023 under the Freedom of Information Act. Please accept our apologies for the delay in this response. You requested:

"Can you please seek, find and release any internal information in minutes of MHRA meetings, internal & external correspondence etc. that contributed to placing the paragraph below in the MHRA Guidance for health & social care organisation, including care homes, and published in January 2021 (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf).

The paragraph in question (below) had a specific meaning and purpose and was not randomly placed in the MHRA guidance, and the persons who contributed to this update in 2021 must have discussed and agreed on the wording before publishing.

"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."

We confirm that we hold information which may be in scope of your request. However, we consider that Section 12 of the Freedom of Information Act applies to your request. Section 12 allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

We will provide some context before setting out how we have arrived at applying the Section 12 exemption. In late 2020 and early 2021, when this document would have been going through drafting, reviewing and finalising for publication, the MHRA had a different operating structure, with different teams in place. A number of individuals that would have been likely to have been involved in this process have since left the organisation, which means we have need to ask our IT team to conduct a search of all our electronic records for anything that may be in scope of your request. That search has returned 1107 items. To note that for a request like this, which asks about all internal and external correspondence, it is the usual practice that we need to request a search such as this to ensure we can identify any material that may be in scope.

The search conducted was to look for the specific quote you asked about, however, as you will appreciate, that quote will appear in any versions of that document, even

if that specific section is not being discussed in the correspondence. We would therefore need to review the 1107 items to determine which, if any, are specifically discussing the quoted section and as such would be in scope of your request. We judge we would need at least 2 minutes on average to review each item, which would bring us to approximately 37 hours.

When applying Section 12 we look at any suggestions we can make as to how a requestor could refine their request to bring it within the 24 hour limit. In this case you may wish to consider refining the request to internal correspondence / emails only for example.

Whilst we will be very happy to consider any new request you may wish to make, we do not know whether any results in scope will be returned. We would like to draw your attention, via the National Archives website at the link below, to an earlier version of this document, published in April 2014. If you follow the link below and navigate to page 7, you will find the exact same quote as the one you have asked about from the 2021 document:

<https://webarchive.nationalarchives.gov.uk/ukgwa/20141206200229mp/http://www.mhra.gov.uk/home/groups/dts-bs/documents/publication/con2025143.pdf>

Our expectation is that the process to review and update the 'Managing Medical Devices' publication, which was published in 2021, would have been to start from the 2014 version and make amendments and updates where these were considered appropriate. It is therefore possible that there may not have been any discussion or comment passed on the quote you have asked about.

We will be happy to consider any refined request, should you wish to make one. We'd also like to apologise once again for the delay in this 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

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