FOI 23/725

Dear

Thank you for your email of 1 October where you have asked

"*I would like to request all information held by the agency with regards to the impact assessment of the proposed amendments to requirements for 'in-house' manufactured medical devices outlined in the "Government response to consultation on the future regulation of medical devices in the United Kingdom" dated 26th June 2022 page 27/page 28. In particular, I would like to request:*

1. *assessment of the impact to the NHS in general and anticipated potential cost implications.*

2. *number of NHS institutions impacted.*

3. *number of devices that are currently put into service by NHS trusts using the in-house exemption."*

For your request for all information held by the agency regarding the impact assessment of the proposed amendments to requirements for 'in-house' manufactured medical devices, except for point 3 above, we confirm we hold some information relevant to the request. However, this information consists of preliminary discussions on this matter of policy development, and as these discussions are not yet concluded, we are refusing to provide the information at this time as section 35 of the FOI Act applies.

Section 35(1)(a) applies when the information relates to the formulation or development of government policy. The purpose of this exemption is to protect the integrity of the policymaking process, and to prevent disclosures that would undermine this process and result in less robust, well-considered or effective policies. In particular, it ensures a safe space to consider policy options in private.

Section 35 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. In this case, we consider that, while there is always a public interest in the disclosure of information where this would show transparency and inform the public, we strongest public interest favours maintaining the exemption at this time in order to allow policy discussions to take place in a safe space. We can also explain that when regulatory changes relating to the "Government response to consultation on the future regulation of medical devices in the United Kingdom" are laid in Parliament, the accompanying impact assessment(s) will be published, as appropriate; we consider that this factor also favours the public interest in maintaining the exemption for the information held at this time.

For point 3, which asks for the number of devices that are currently put into service by NHS trusts using the in-house exemption, we advise that because exempted devices are not subject to the requirements that apply to other devices, MHRA does not hold data for devices put into service by NHS trusts using the in-house exemption.

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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