FOI 23/314 - investigational review into the LifeVac and Dechoker medical devices

MHRA RESPONSE
5 May 2023

Dear

Thank you for your information request, dated 27 April 2023, **in which you requested a copy of the review and all related records concerning an investigational review into the LifeVac and Dechoker medical devices** referred to in an April 2022 MHRA Board meeting.

Having reviewed your request we can confirm that the agency holds the requested information. However, we have determined that the specific information you have requested is exempt from disclosure under Sections 22(1) and 30(1) of the Freedom of Information Act 2000 and we cannot process your request any further.

Section 22(1) states:
22 –(1) Information is exempt information if—
(a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not),
(b) the information was already held with a view to such publication at the time when the request for information was made, and
(c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in paragraph (a).

Section 30(1) states:
30 –(1) Information held by a public authority is exempt information if it has at any time been held by the authority for the purpose of –
(a) any investigation which the public authority has a duty to conduct with a view to it being ascertained –
(i) whether a person should be charged with an offence, or
(ii) whether a person charged with an offence is guilty of it,

Sections 22 and 30 are qualified exemptions, which means that we have considered whether there is public interest in releasing the information. We do recognise that there is considerable interest in the work which we undertake to ensure that medical devices placed onto the UK market are compliant with the applicable regulations. That said, the investigational review of the LifeVac and Dechoker devices has taken place within the context of a compliance investigation conducted by MHRA and therefore wholesale disclosure of information or relevant records held for this investigation could prejudice any potential legal action taken or considered by the Agency in future. In addition, the Agency Board Meeting minutes of 19 April referred to in your request indicates that the Agency does intend to publish the outcome of this review in due course, which we confirm remains to be the case.

For more context on our regulatory role, the MHRA is the designated authority that administers and enforces the law on medical devices in the UK, as established in the Medical Device Regulations 2002. Our investigatory and enforcement powers and

responsibilities are drawn from multiple pieces of legislation, including the Consumer Protection Act 1987, Consumer Rights Act 2015, the Medicines and Medical Devices Act 2021 as well the Medical Devices Regulations 2002 (as amended) itself.

In the majority of circumstances, where our investigations identify breaches of the regulations, we shall engage with the relevant parties to bring them into compliance and prevent dangerous products being made available to the public. Where parties fail to cooperate or a serious risk to public health is identified, MHRA may exercise its enforcement powers and investigations may lead to prosecution.

Further information on how MHRA enforce the Medical Devices Regulations 2002 can be found here.

Patient Safety is our priority and where we identify any products on the market that pose a risk will take appropriate regulatory action to protect UK patients.

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

If you remain dissatisfied following any internal review, you may ask the Information Commissioner (ICO) to decide on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. 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 ICO's address is:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

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