FOI 23/496

Dear

Thank you for your information request, dated 6 July 2023, in which you requested

> ***copies of all records associated with the lifting of UK restrictions on the LifeVac device by the MHRA, including all reviews, reports and correspondence***.

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. The requested records have been produced within the context and remit of a compliance investigation undertaken by MHRA, and we have determined that wholesale disclosure of these records could prejudice any potential legal action taken or considered by the Agency in future. We do recognise that there is considerable interest in these types of devices and their appropriate use in the UK, and the work that MHRA undertakes to ensure that medical devices placed on the UK market are compliant with the applicable regulations. MHRA does intend to publish guidance in due course specifically concerning these devices, MHRA's position concerning their availability and use, and how this regulatory position has been reached.

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 disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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
10 South Colonnade, Canary Wharf, London E14 4PU