Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2025/00327**

24 April 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 31 March. You wrote:

> *This is a request for information filed under the FOI Act. Please confirm receipt.*
>
> *1) According to: https://imedconsultancy.com/lifevac-europe-ltd/*
> *In 2017, the MHRA imposed a temporary restriction on LifeVac, limiting its sales to the care sector, which required LifeVac Europe to meet stringent regulatory demands and reporting requirements for an innovative device intended for an unmet medical need. During this period, Matthew Burton worked tirelessly to help LifeVac Europe meet rigorous regulatory demands, including the preparation of detailed Post-Market Surveillance (PMS) and Post-Market Clinical Follow-up (PMCF) reports on a quarterly basis until significant sufficient data was generated to allow the restrictions to be lifted in June 2023. After this point the device could now be used as intended.*
>
> *Please provide me with copies of all quarterly Post-Market Surveillance (PMS) and Post-Market Clinical Follow-up (PMCF) reports submitted by or on behalf of LifeVac Europe Ltd from August 2017 through June 2023 including all related correspondence. Please redact any confidential and/or proprietary company information, and identify the appropriate statutes justifying each redaction.*
>
> *2) From*
> *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/667136/Item_07__2017-OB-14__CEOs_Report_Nov_17.pdf*
>
> *LifeVac - We took a number of enquiries about MHRA's regulation of LifeVac, an antichoking device. After liaising with colleagues in Devices, we sent a statement to Huffington Post, Daily Mail, Cambrian News and Sunday Times Ireland.*
>
> *Re: all of the above inquiries (Huffington Post, Daily Mail, Cambrian News and Sunday Times Ireland), please provide me with copies of all related correspondence.*
>
> *Please provide the records in digital format via e-mail if possible.*
>
> *I'm requesting these records for an article I'm reporting on my blog and I have no financial interest in the requested information, therefore this is to request that any fees be*

waived.

If the fee for completing my request exceeds 5 pounds, please obtain my written approval prior to completing this request.

Please send the requested records as ready rather than accumulated in a single response.

Finally, please include instructions on how I may appeal your response.

Thank you for your attention and I look forward to your confirmation of receipt and to receiving the requested records.

MHRA Response

We can confirm that we hold the information you have requested but are withholding some of it from disclosure.

For ease will address each of your 2 questions separately.

Question 1

Under Section 14(2) of the FoI Act, public authorities are not obliged to comply with a repeat request.

Where a public authority (in this case MHRA) has previously responded to a request for information which was made by any person, it is not obliged to comply with a subsequent identical or substantially similar request from that person unless a reasonable interval has elapsed between compliance with the previous request and the making of the current request.

In this case, the Agency has already responded to a similar request from you, FOI/2024/00252 on 24 July 2024 and so, under section 14(2) of the FoI Act will not be responding further. This response was also addressed through an Internal Review on 30 August 2024 and an ICO investigation IC-3330169-Y3R2 on 14 March 2025.

In your previous request you sought *“any reviews and reports of the LifeVac and Dechoker devices that determined that those devices did not pose such risks.”*

This element of your previous request is where we have determined the repeated request for information to arise from.

Question 2

We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

Please refer to the documents sent with this response for what we are able to provide.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/