Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
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London
E14 4PU

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MHRA Website

Our Ref: **FOI2026/00436**

19 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 21 April. You wrote:

I am writing to formally escalate concerns regarding the adequacy of the investigation into my reported CPAP-related incident involving:

Löwenstein Prisma SMART Max (WM090TD)
Serial number: 26739107

This escalation is made in light of MHRA's internal review outcome (IR2026/00392), which raises significant concerns regarding the framework applied to my case.

1. Regulatory position confirmed by MHRA

The internal review confirms that:

"MHRA does not hold any current internal guidance, SOPs, templates, or decision-support material addressing how investigation boundaries should be defined in cases involving multiple components within a medical-device therapy pathway."

My case is precisely such a scenario, involving a therapy pathway comprising:

* *the primary device;*
* *tubing and inlet filters;*
* *a patient interface (mask) supplied by another manufacturer.*

2. Concern regarding investigation boundary

Given the absence of a defined framework, I am concerned that:

* *there was no consistent or standardised method for determining which components of the therapy pathway should be included within the investigation;*
* *key components (including the patient interface and associated pathway elements) may not have been fully assessed;*
* *the investigation may have relied on a narrowed scope without a clearly defined methodological basis.*

3. Evidence handling and verification

In addition, concerns arise regarding:

* *whether the full breathing pathway (device, tubing, filters, and mask) was preserved and assessed as a single system;*
* *whether chain-of-custody and handling of returned components were sufficiently documented and verified;*
* *the extent to which MHRA independently verified the manufacturer's conclusions in the absence of a defined mixed-pathway investigation framework.*

4. Clinical context

This matter is not purely theoretical. Following the incident, I have experienced ongoing symptoms and subsequent medical findings, and it is therefore essential that any investigation into potential exposure pathways is robust, complete, and evidence-based.

5. Request for clarification

I would be grateful if MHRA could provide a substantive response addressing the following:

1. *What methodological basis was used to define the investigation boundary in my case?*
2. *Whether MHRA requires or verifies an assessment of the full therapy pathway, including patient-interface components;*
3. *How MHRA assured itself that the manufacturer's investigation and conclusions were sufficient, given the absence of a defined framework for mixed-component systems;*
4. *Whether MHRA considers that the absence of internal guidance in this area presents a regulatory gap, and if so, what steps are being taken to address it.*

6. Request for handling

Please treat this as a formal escalation.

I request:

* *confirmation of receipt;*
* *identification of the named officer responsible for responding;*
* *a substantive response addressing the points above.*

This request is made in order to understand the basis on which safety conclusions were reached, and to ensure that all relevant components of the therapy pathway have been appropriately considered.

MHRA Response

It may be helpful if we explain the role of the FoI Act. It provides a legal right of access to recorded information held by a public authority like the MHRA, subject to certain exemptions that may apply. The Act does not oblige a public authority to create new information to answer questions; nor does it require a public authority to give an opinion or explanation, generate answers to questions, or create or obtain information it does not hold.

If you ask a question, rather than requesting recorded information, we will provide you with the recorded information that best answers the question. Once we have provided the

recorded information, we have met our obligations under the Act; interpreting the information provided is up to you.

Your request asks questions and seeks to engage us in debate which you want us to respond to. This would need new information to be created.

We do not hold any recorded information to answer your request and will therefore not be progressing your request any further.

However, you may find the following explanation useful. We have provided this outside our obligations under the FoI Act.

Explanation

The regulation of medical devices in the UK is governed by the UK Medical Devices Regulations 2002 (as amended) (UK MDR 2002), supported by publicly available guidance on vigilance and post-market surveillance.

Under the UK MDR 2002, the manufacturer is legally responsible for investigating incidents involving their devices. This includes establishing and maintaining an appropriate post-market surveillance system, conducting investigations into incidents and complaints, and determining the scope, methodology and extent of such investigations.

Accordingly, the investigation boundary in individual cases is determined by the manufacturer, in line with its regulatory obligations. The MHRA, as the UK competent authority, does not prescribe investigation boundaries but instead reviews and oversees the adequacy of the manufacturer's investigation.

Manufacturers are required to follow publicly available vigilance guidance, which outlines expectations for incident investigation and risk assessment. Within this framework, manufacturers determine the scope of their investigations, including whether consideration is given to the wider therapy pathway and relevant system components, such as patient-interface elements, where appropriate.

Manufacturers will also have their own policies and procedures for returned medical devices and investigations, which may vary depending on the device type. Further information is available in the public domain, including:

> https://www.gov.uk/government/publications/medical-devices-post-market-surveillance-requirements/vigilance-reporting-requirements#f-investigation-of-incidents-regulations-44zi-44zo-and-44zp

In the case referenced, the manufacturer conducted an investigation in accordance with its obligations under the UK MDR 2002. The MHRA was provided with the relevant outputs of that investigation, which included a final Manufacturer's Incident Report (MIR), responses to regulatory queries, and supporting evidence (for example, technical, clinical, and/or biological data, where relevant).

While detailed documentation is not publicly disclosable (exempted under Section 41 – Information provided in confidence), the MHRA undertook a regulatory assessment of the information provided. This assessment considered whether the investigation methodology was appropriate, whether the scope was proportionate to the reported issue, and whether the conclusions were supported by the available evidence.

Regulatory assessments are conducted on a case-by-case basis, applying the general principles set out in the UK MDR 2002 and associated guidance. Although there is no single prescriptive framework for “mixed-component systems”, the MHRA assesses whether all relevant aspects of device safety and performance have been appropriately considered.

On this basis, the MHRA was satisfied that the manufacturer had adequately investigated the issue and provided sufficient justification for its conclusions, in line with its regulatory obligations.

If you want a bespoke response to your correspondence outside of the FOI provisions, please write to MHRACustomerServices@mhra.gov.uk.

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 freedom-of-information-request@MHRA.gov.uk or by writing to: MHRA Central FoI 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
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