Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

30th November 2023

Dear [redacted]

FOI 23/896

Thank you for your FOI request dated 2nd November 2023, where you requested:

"Information on the failure reports for the following devices.

Corpuls CPR - https://corpuls.world/en/products/corpuls-cpr/
Zoll Autopulse - https://www.zoll.com/uk/products/automated-cpr/autopulse-for-ems
LUCAS 2 - https://www.lucas-cpr.com/product_specifications/#lucas_2
LUCAS 3 - https://www.stryker.com/gb/en/emergency-care/products/lucas-3/index-eu-eemea.html".

I can confirm that while we do hold information on failure reports regarding the above devices, this information is exempt from disclosure under Section 44 of the Freedom of Information Act 2000 (FOIA).

Section 44 – Prohibitions on disclosure: the release of information is exempt as its disclosure is prohibited by other legislation. In this case, section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions, and which relates to the affairs of an individual or business.

The MHRA is satisfied that the information you have requested constitutes information which came to us in connection with the exercise of the Agency's functions. The MHRA has a duty of consumer protection under the Consumer Protection Act 1987 which is listed as a specified function under Schedule 14 of the Enterprise Act 2002 and receives information while exercising consumer protection functions in its role as the regulator of medicines and healthcare products.

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Whilst we cannot provide information for a specific device, we are able to provide higher level information. For instance, we are able provide the medical device problems reported for mechanical CPR devices generally. If this would be appropriate, please can you state this in a reply and we will be able to deal with this as a new request.

I hope that the explanation provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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