Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

[redacted]

22 September 2023

Dear [redacted]

FOI 23/678 - Kimel CVC pre- packs reference number K67129/SUB/P1 for CVC insertion

Thank you for your Freedom of Information request dated 13 September 2023 where you requested any information available about any reported incidents for the Kimel CVC pre-packs reference number K67129/SUB/P1 for CVC insertion.

In response to your request, we should advise that we cannot share information about specific manufacturers, makes or models of devices, or who has reported problems to us. This is because there are confidentiality clauses in the legislation that we work under and the agreements under which information is provided to us which limit disclosure in some circumstances. Therefore, we consider that the information you have asked for is exempt from disclosure under Section 43 of the Freedom of Information Act (FOIA) as disclosure of the requested information may prejudice the commercial interests of a third party; while we appreciate that there is a public interest in disclosure in this case, there is also a strong public interest in maintaining the confidentiality of our agreements in such cases.

We can provide some broader information about the wider category of generic types of devices. If this is something that would be useful to you, please email MHRACustomerServices@mhra.gov.uk with details of your request.

As with all medical devices, MHRA continues to monitor their safety and performance and encourages reporting of any adverse incidents through its Yellow Card scheme on https://yellowcard.mhra.gov.uk/. Any emerging evidence relating to possible risks associated with these devices will be carefully reviewed and, if appropriate, regulatory action will be taken if any serious risks are confirmed.

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