Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

[redacted]

14th November 2023

[redacted]

Thank you for your Freedom of Information request dated 17th October 2023, where you asked:

- If there have been any reports for the EasyChamber spacer device?

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. As EasyChamber is a manufacturer, we consider 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 however provide some broader information about the wider category of generic types of devices, if you would like this information, please let us know and we can log this request.

Please be assured that the MHRA keeps the safety of all medicines, vaccines, and devices under close and continual review. Any emerging evidence relating to possible risks associated with of these products would be carefully reviewed and, if appropriate, regulatory action would be taken, and communicated to healthcare professionals and patients alike.

If you are aware of any adverse incidents relating to the spacer within your trust, we would advise you report this via the Yellow Card scheme.

Yours sincerely,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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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