Medicines & Healthcare products Regulatory Agency

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United Kingdom
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[redacted]

18th September 2023

FOI **23/623**

Dear [redacted]

Thank you for your information request, dated 18th August 2023, where you asked for clarity on the information previously provided to you regarding cyanoacrylate glue (CAG). We also note your previous FOI requests: FOI 23/552, which we responded to on 17th August 2023; and FOI 23/431, which we responded to on 19th July 2023.

We first note that your new request follows on from the responses previously provided to you. We would therefore remind you that if you disagree with the response given to a request, you may ask for an internal review of that decision, and we would then conduct a review of the request handling for you.

Your email of 18 August 2023 was:

Further to my previous FOI requests FOI 23/431 and FOI 23/552, I would like to ask:

1. There are three products registered in the UK- Venaseal, Venablockl and Veinoff. As far as I can see the report does not specify which product has caused which incident. Is it possible to have the data broken down by product?

2. Can I address a point of confusion in the data provided? Under “Infection” the description reads: “the device has not been identified as the root cause of death.” In the same letter (last paragraph), the text reads: “To our knowledge, none of these reported injuries have resulted in a patient death”. However, in the previous letter the text stated that there has been a case of death following CAG usage. Therefore, in addition to the case of death associated with infection, has there been another case of death?

3. Can I ask why a search by three medical practitioners of the Yellow Card system could not retrieve these adverse incidents and necessitated a FOI

request? Are they classified differently or are they maintained on a separate database?

Please see our response below to your questions, further to the data we previously provided.

1. *There are three products registered in the UK- Venaseal, Venablockl and Veinoff. As far as I can see the report does not specify which product has caused which incident. Is it possible to have the data broken down by product?*

In response to your request, we consider that several exemptions in the FOI Act apply to information about specific manufacturers, makes or models of devices. 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.

This information is exempt from disclosure under sections 41(1) and 43(2) of the FOI:

> Section 41 – (Information provided in confidence): information provided to us in confidence, with the expectation that it will not be further disseminated, is exempt from disclosure under the Freedom Of Information Act (FOIA). Information will be covered by Section 41 if: it was obtained by the authority from any other person; its disclosure would constitute a breach of confidence; a person or organisation could bring a court action for that breach of confidence; and that court action would be likely to succeed. In this case, we consider that the information has the necessary quality of confidence and is not trivial or otherwise available in the public domain.
>
> Section 43 – (prejudice to commercial interests): information where disclosure would be likely to prejudice the commercial interests of any person, including third parties or the public authority that holds the information. Section 43 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. In favour of disclosure, we consider that there is a general public benefit from knowing which product has caused which incident. However, we consider that the public interest will be better served by not releasing the information as it is not in its complete form, and the public interest is better served by our continued investigations into these incidents and the MHRA taking appropriate regulatory action as needed. Releasing the information would also prejudice the Agency's commercial interests in this case and in future. As a market regulator, it is vital that the Agency can freely engage in dialogue with organisations about commercial activities.

To summarise, whilst we hold the data requested, we consider the information you have asked for to be exempt from disclosure under section 41 of the FOIA as this information was provided in confidence and disclosure would constitute a breach of

confidence; and section 43 of the 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.

2. *Can I address a point of confusion in the data provided? Under "Infection" the description reads: "the device has not been identified as the root cause of death." In the same letter (last paragraph), the text reads: "To our knowledge, none of these reported injuries have resulted in a patient death". However, in the previous letter the text stated that there has been a case of death following CAG usage. Therefore, in addition to the case of death associated with infection, has there been another case of death?*

Please accept our apologies for the confusion regarding the information previously provided.

To clarify the information regarding "Infection", although there was a reported death, the device has not been identified as the root cause of death and there were other factors in this report that were considered likely causes of death instead. This was the only case of death identified.

3. *Can I ask why a search by three medical practitioners of the Yellow Card system could not retrieve these adverse incidents and necessitated a FOI request? Are they classified differently or are they maintained on a separate database?"*

It is not clear what circumstances this part of your request is referring to; we are not sure if you mean that you had asked for this information prior to your initial request FOI 23/431, or if this refers to the handling of your two previous FOI requests. At present, this question does not meet the criteria for a valid request in section 8 of the FOI Act.

If you would like to provide further details of your concern here, we will be able to determine if your concern would be best dealt with as a request for recorded information or as an internal review of a previous response issued to you. Details of your appeal rights are below.

Yours sincerely,

Safety and Surveillance Group

Medicines & Healthcare products Regulatory Agency

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Appeal rights

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you are dissatisfied with the outcome of the internal review, you may apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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