Medicines & Healthcare products
Regulatory Agency

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[redacted]

17th August 2023

[redacted]

Thank you for your information request, dated 10th July 2023, where you asked for information regarding cyanoacrylate glue (CAG). We also note your previous FOI request, FOI 23/431, which we responded to on 19th July 2023.

Further to your request, please see our response below to your questions, further to the data we previously provided.

1. Confirm which of the 8 events were directly related to the cyanoacrylate glue

It is not possible to definitively ascribe causality based on spontaneous data and instead we would review the available evidence as a whole and make a judgement based on that.

We should explain that the Medicines and Healthcare products Regulatory Agency (MHRA) conducts safety analyses which include adverse events with a fatal outcome. You have requested disclosure of studies and analyses carried out by the MHRA to examine causes of deaths however, this is not part of the MHRA's role.

The MHRA evaluates a range of safety data to assess the likelihood of an overall association between a medicinal product and an adverse event, regardless of whether the event has a fatal outcome or not. As part of these assessments, reports with a fatal outcome would be carefully evaluated in relation to determination of the public health impact of the safety concern. It is not the MHRA's role to assign cause of death in relation to suspected adverse events following any medicinal product. This is the case for both individual reports and aggregated data.

The Yellow Card Scheme is the UK system for collecting and monitoring information on suspected incidents associated with medical devices, as well as adverse drug reactions (ADRs) to medicines and vaccines. The Scheme is run by the (MHRA) on

behalf of the Commission on Human Medicines (CHM), and currently relies on voluntary reporting of adverse incidents by healthcare professionals and patients. There is also a legal obligation for companies to report serious adverse events for their products. The MHRA then performs market surveillance of medical devices on the UK market and is able to take decisions over the marketing and supply of devices in the UK. Important safety risks will be assessed, and regulatory action will be taken if deemed necessary, this can include product recalls where the overall risks outweigh the benefits.

Adverse Incident Reports (AIRs) include mandatory reporting by manufacturers to MHRA for certain types of incidents that occurred in the UK as part of the regulatory post market surveillance 'vigilance' system. The principal purpose of this system is to improve the protection of health and safety of patients. This is to be achieved by the evaluation of reported AIRs and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such adverse events.

2. If you could provide the result of the reviews of each of the 8 reports.

Unfortunately, the information is exempt from release under sections:

Section 40 – Personal information:. Section 40 protects personal data, the disclosure of which would breach one or more of the data protection principles. The Agency is satisfied that disclosure here would breach the first data protection principle, in particular the requirement of fairness on the basis that disclosure would not be reasonably expected by the people mentioned in the information.

Section 41 – Information provided in confidence: information provided to us in confidence, with the expectation that it will not be released, is exempt from disclosure under the FOI Act. 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.

However, I am pleased to provide you with further details of the reports to assist you, please see below.

Please note, one of the reports was found to be a duplicate report. Therefore, 7 reports were reviewed and their outcome provided for you below.

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Incident Type	Number of Incidences	Outcome
Granuloma	1	Device not returned. A foreign material/granuloma post procedure was confirmed based on the images received.
Multiple: thrombophlebitis/ pulmonary embolism/ leg ulcer/ high tie venectomy/ seroma/ seroma infected.	1	Samples not returned. The root cause of the reported reaction could not be determined at this time.
Pulmonary embolism	1	The device has not been identified as the root cause of the event.
Infection	3	The root cause of the of the observed clinical complications could not be determined.
		The root cause of the of the observed clinical complications could not be determined.
		Device not returned for evaluation. Unable to confirm reported fault. The device has not been identified as the root cause of patient death.
Hypersensitivity	1	The device has not been identified as the root cause of the event. The most probable cause of this issue is patient cyanoacrylate allergy.

The data must be read together with the following explanations:

- These numbers are accurate at the time they are extracted from our database, however as this is a dynamic database minor changes in the numbers can occur if the reporter gives us more details later.

- A report does not necessarily represent an individual incident – people may report an incident at any time after the event and people can make multiple reports. Where possible, multiple reports for the same event are linked, however as reporters are not required to complete all fields, every duplicate report cannot always be linked.

- These figures include a range of reported adverse events and do not necessarily indicate a fault with any particular device.

To our knowledge, none of these reported injuries have resulted in a patient death. We would like to reiterate that at this time none of these reported injuries have been confirmed as having been caused by the use of CAG, investigations into these

incidents are still ongoing and the MHRA will take appropriate regulatory action as needed once this is concluded.

Please be assured that patient safety is of paramount importance to the MHRA and we keep the safety of medicines and medical devices under close review.

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If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

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 were to remain dissatisfied with the outcome of the internal review, you would have the right to 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

Yours sincerely,

Safety and Surveillance Group