



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2024/00589**

28th October 2024

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 1 October. You wrote:

- 1. For each of the last ten calendar years, 2014 to 2023 inclusive please state (i) how many reports you received relating to adverse reaction relating to breast implants, and (ii) how many suspected adverse reactions these reports were connected with?*
- 2. For the 2023 calendar year could you please state the number of Adverse Reactions reported relating to breast implants used in breast enlargement surgery.*
- 3. For the 2023 calendar year's Adverse Reactions to breast implants used in breast enlargement surgery please could you give me a complete breakdown of the side effects that the reporter has claimed.*

Note. If it is possible to isolate reports that relate to cosmetic surgery rather than reconstructive surgery following a different medical procedure then please provide separate answers for both types of surgical implant. Also I would be grateful if the response could be supplied on the same basis as that which was supplied to me in a similar request for 2013 data [Ref: FOI 14/378]

MHRA Response

We can confirm that we hold the information falling within the description specified in your request.

Section 12(4) of the FoI Act and also the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 provides that requests can be aggregated for the purpose of estimating whether the cost limit applies, providing they relate to any extent to the same or similar information and the requests are received from the same individual or different persons who appear to the public authority to be acting in concert or in pursuance of a campaign.

This is where more than one request has been made within 60 consecutive working days relating to the same or similar information and the requests have been made by the same person. This includes adding to the estimated costs of complying with a later request, the cost of complying with a request that has already been answered. We have therefore aggregated the following requests under this provision:

- FOI2024/00588 - submitted 1st October 2024
- FOI2024/00589 - submitted 1st October 2024

We estimate that the cost of complying with your aggregated requests would exceed the appropriate limit for central Government, set by regulations at £600. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(4) of the Freedom of Information Act the Agency is not therefore obliged to comply with your requests as we have aggregated the cost of processing them together and as such we will not be processing them any further. In order to process your request and respond fully, for accurate adverse incident data retrieval specifically for breast implants we would need to search through and conduct a manual review of incident reports to identify the adverse incident or health consequences reported. This manual review will need to be applied for all reports received by the MHRA prior to 2015. Reports received after 2015 have information on the device problem and also reported clinical effects in the patient, captured within structured database fields. Additionally in all breast implant reports the indication of the device is not captured in a structured field and therefore manual review would be required to identify if breast implants have been used in breast enlargement surgery.

Based on a sample exercise, manual review of each report for the intended purpose of surgery took 45 seconds and, in some instances, longer. Between 2015 and 2023 the MHRA have received 4266 incident reports under the breast implant GMDN CT code. As such, review of these reports for the intended purpose of surgery would equate to 53 hours and 20 minutes. Based on a sample exercise for reports received in 2014, manual review of each report took 4 minutes. The MHRA received 368 incident reports under the breast implant GMDN CT code in 2014 and as such review of these reports would equate to 24 hours and 30 minutes.

Under section 16 of the FoI Act we should help you narrow your requests so that they may fall beneath the cost limit.

As the information you seek will require a very high degree of manual processing you should look to limit your request. You may wish to limit your request to breast implant reports received between 2015 and 2023 inclusive, regardless of the intended purpose of surgery.

We will consider afresh any revised request however we cannot guarantee that any revised request will fall within the cost limit.

If you have any queries about this letter, please contact us quoting the reference numbers above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website [ICO FOI and EIR complaints](#) or telephone 0303 123 1113

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>