Medicines & Healthcare products Regulatory Agency

[redacted]

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MHRA Website

Our Ref:
FOI2026/00732

27 July 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 28 June 2026. You wrote:

5. Requests for PIP-Specific Surveillance Data

Please provide the following PIP-specific statistics from the current surveillance frameworks:

a. *The total number of PIP-specific adverse incident reports received by the MHRA to date, broken down by year and type of adverse event.*
b. *The exact number of these reports that specifically involve rupture, gel leakage, silicone migration, lymph-node involvement, or systemic inflammatory/autoimmune symptoms, BIA-ALCL, other implant cancer, or malignancy, including BIA-SCC.*
c. *The total headcount of historically PIP-exposed women currently recorded within the BCIR.*
d. *d. The specific data fields held for those PIP-exposed entries in the BCIR (e.g., original batch, model numbers, current rupture status).*
e. *A statement clarifying whether the current BCIR contains historical PIP records from before 2016/2017, does if it hold data from later revision surgeries? If it cannot map the historic PIP cohort, please clarify the answer to Question 7(a).*

6. Clarification on "Multiple Exposure" and BIA-ALCL Tracking
An MHRA presentation regarding Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) note that as of December 2023, 48 out of 117 confirmed UK cases occurred in women who had "previous breast implants".

Please disclose how the MHRA records and evaluates these sequential histories:

- What is the MHRA's official operational definition of "multiple exposure" in its adverse event tracking?
- If a woman had a PIP implant, underwent explantation, and later received a different textured brand (e.g., PIP > explant > Allergan), does the MHRA record this complete sequence? If the Agency only records the specific brand present at the time of cancer diagnosis, explain how multiple exposure risk is accurately assessed.

- Out of the confirmed UK BIA-ALCL reports, how many of those patients had a documented history of prior PIP exposure?

MHRA Response:

We can confirm that the MHRA does hold some of the information that you have requested in your enquiry. However, the element of your request seeking details of all PIP implant related adverse events received to date falls within the scope of Section 12 (2) of the Freedom of Information Act (FOI), as complying with this request would exceed the appropriate cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. 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, and we are therefore unable to process it further.

Under Section 12(2) of the FoI Act, the Agency is not therefore obliged to comply with your request and will not be processing it further. This is because device problems and clinical effects are not consistently captured within structured database fields for reports received before 2015. Additionally, in 2019, the MHRA adopted the International Medical Device Regulators Forum codes for Health Effects (IMDRF), coding method. Prior to this, a different mapping system was applied, which was not as exhaustive as the current. As a result, identifying and retrieving the information requested would require a manual review of individual incident reports to determine the adverse incidents and health consequences reported in relation to PIP implants.

As of 23 July 2026, the MHRA has received over 2,500 adverse incident reports related to PIP implants, of which, over 2,200 were between 2000 and 2014. Based on a previous sample exercise of 10 reports this exercise took 4 mins per report, totalling over 167 hours to conduct just the review. This is therefore exempt under Section 12 of the Freedom of Information Act.

Advice and assistance

In line with our obligations under Section 16 of the FoI Act, we can provide advice and assistance to help you obtain the information you are seeking. We recommend narrowing the scope of your request by specifying a particular time period. We will consider afresh any revised request however we cannot guarantee that any revised request will fall within the cost limit

I can confirm that the MHRA does hold the information for the second part of your request, '*6. Clarification on "Multiple Exposure" and BIA-ALCL Tracking*' regarding information on BIA-ALCL and can provide this within the refined request.

If you have any queries about this letter, please contact us quoting the reference number 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 Contact Information 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/