Medicines & Healthcare products
Regulatory Agency

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

[redacted]

[redacted]

30th April 2024

FOI 24/316

Dear [redacted]

Thank you for your Freedom of Information request, dated 2nd April 2024, where you asked:

> *I am writing in connection with the afore mentioned press article and its significance to women with GC Aesthetic implants. Kindly provide safety updates with full details of the protections provided for women under the MDR and details for Irish UK and EU women with GC Aesthetic implant warranties.*
>
> *Please also provide details of PIP implant adverse event reports and deaths.*

I can confirm that the MHRA does hold some of the information that you have requested. However, we have also determined that the information requested on the details of all the PIP implant reports we have received to date is exempt under Section 12 of the Freedom of Information Act and we cannot process your request any further.

Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

In order to process your request and respond fully, for accurate adverse incident data retrieval 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.

Based on a review of the data held we have 2,637 adverse incident reports related to PIP implants, 2,259 of which were received between 2000 and 2014, and 378 were received between 2015 and 25/04/2024.

Medicines & Healthcare products
Regulatory Agency

To be able to provide the information requested, all reports received prior to 2015 would need to be manually reviewed in order to identify the adverse incident and health consequences in the free text fields. Based on a sample exercise of 10 reports this exercise took 4 mins per report. Therefore, for all reports received prior to 2015 this would take a total of 133 hours to conduct.

Secondly, for reports received after 2015 a table can be created on our data extraction software which will display the health effects and the number of reports received for each. In total this step would take 10 minutes only.

Lastly for all reports received prior to 2015, once manual review has been completed, will then need to be collated into the table produced as above for reports received after 2015. This would be done manually, and based on the sampling exercise takes on average 1 min for each report resulting in a total of 33 hours for this step.

Overall, this part of the request would take 166 hours and 10 mins to complete. In accordance with Section 16 of the FOI, concerning the provision of advice and assistance to those requesting information under FOI, we would advise you to refine your request by restricting to a particular time period or by requesting adverse health effects that you are specifically interested in.

For the first part of your request regarding safety updates and relevant protections in place, I can confirm the MHRA does hold this information and can provide this within a refined request as detailed above.

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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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:

Medicines & Healthcare products
Regulatory Agency

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