

## Medicines & Healthcare products Regulatory Agency

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London
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United Kingdom
gov.uk/mhra



17<sup>th</sup> November 2023

Dear

## FOI 23/798 – Adverse Reactions relating to Breast Implants

Thank you for your email dated 20<sup>th</sup> October 2023, where you asked for information on the following:

- 1. For the 2022 calendar year could you please state the number of Adverse Reactions reported relating to breast implants used in breast enlargement surgery.
- 2. For the 2022 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.

The MHRA received a total of 727 adverse reaction reports related to breast implants for the 2022 calendar year.

A breakdown of the reported adverse reactions can be found in the table attached. Please note one report can contain multiple suspected adverse reactions. It is important to note that inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the implant. Therefore, reports submitted to MHRA may be adverse reactions to the implant or they may be purely coincidental events that would have occurred anyway in the absence of the device (e.g., events due to underlying medical conditions). The table therefore is not a summary of known or proven adverse reactions to the implant and must not be interpreted and used as such.

I hope the information provided is helpful, but 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,

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

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