Medicines & Healthcare products
Regulatory Agency

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

[redacted]

Our Ref: **FOI 23/493**

Dear [redacted]

Thank you for your Freedom of Information request dated 9th July 2023, where you requested for the calendar year 2022:

*i) the number of Adverse Reactions reported relating to dermal fillers*

*ii) could you please provide a complete breakdown of the side effects that the reporters have claimed relating to dermal fillers*

Further to your request, I can confirm that we have received a total of 86 UK, spontaneous adverse incident reports for dermal fillers in the year 2022. Please also see a breakdown of the reported clinical effects for the adverse incidents reported in the calendar year 2022, in Table 1. Please be aware that where less than 5 reports have been received reporting a specific clinical effect the number has not been included within the table. This is in compliance with data protection laws and to protect patient/reporter confidentiality.

As previously stated, the inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. In addition, details of the reports may have changed since the report was submitted. When incidents are recorded on MHRA's adverse incidents database, each incident is reviewed and then the reported clinical effects are recorded by selecting the respective term from a list of predetermined clinical effects.

*Table 1. The number of adverse incidents included in UK reports received in 2022 for dermal fillers.*

| Reported Clinical Effect | Number of Reports Received in 2022 |
|---|---|
| Abscess | <5 |
| Anxiety | 11 |
| Bacterial Infection | <5 |
| Blister | 5 |

| | |
|---|---|
| Bruise/Contusion | <5 |
| Erythema | 7 |
| Foreign Body Embolism | <5 |
| Granuloma | <5 |
| Headache | <5 |
| Hypersensitivity/Allergic reaction | <5 |
| Increased sensitivity | <5 |
| Infections | <5 |
| Inflammation | 14 |
| Local Reaction | 18 |
| Necrosis | <5 |
| Neuralgia | <5 |
| Nodule | <5 |
| Numbness | <5 |
| Obstruction/Occlusion | <5 |
| Pain | 13 |
| Scar Tissue | <5 |
| Skin Discoloration | <5 |
| Skin Infection | <5 |
| Skin Inflammation/ Irritation | <5 |
| Subcutaneous Nodule | 37 |
| Swelling/ Edema | 34 |
| Unspecified Infection | 5 |
| Viral Infection | <5 |
| No Clinical Signs, Symptoms or Conditions | <5 |

The data must be read together with the following explanations:

- The majority of reports indicate an issue experienced by a single user. However, some cases may represent the same user experiencing further issues.
- Reports do not necessarily represent an individual patient. Individuals may report an incident at any time after the event and people can make multiple reports at any time after the use of dermal fillers and on the same issue. Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate.
- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with any particular device.
- When interpreting the above data it is important to note that the number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the dermal filler is known.
- The numbers may include reports where the incident has been taken from published literature.
- These numbers of reports are accurate at the time they are extracted from our database and minor changes in the numbers can occur if the reporter of the incident gives us more details later.
- Adverse incident reports by members of the public are voluntary but play a substantial part in the successful operation of the vigilance system. All reports received via Yellow Card are sent to the relevant manufacturer (if known and anonymised as appropriate) to feed into the vigilance system.

- Adverse incident reports 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.

I hope the information provided is helpful. The MHRA encourages the use of Yellow Card data however wishes to ensure that the data is studied and applied appropriately, and any conclusions/interpretations take into account the above information. For this reason, if you wish to use this information for a publication, we request that you engage with the MHRA during this process and provide a copy of the report.

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,
Vigilance and Risk Management of Medicines Division

The MHRA information supplied in response to your request is subject to Crown copyright. The FOIA only entitles you to access to MHRA information.

For information on the reproduction or re-use of MHRA information, please visit https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information

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:

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

Copyright notice
The information supplied in response to your request is the copyright of MHRA and/or a third party or parties, and has been supplied for your personal use only. You may not sell, resell or otherwise use any information provided without prior agreement from the copyright holder.