



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI 2026/00888**

10 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 12 August. You wrote:

You asked for a specific list of the substances to respond to my request.

Could you please send me the details I requested for the following substances:

BOTOX:

Azzalure
Bocouture
Alluzience
Letybo
Dysport
Nuceiva

FILLERS:

Juvéderm
Restylane
Revolax
Belotero
Teosyal

STEROIDS:

Testosterone (Enanthate / Cypionate / Propionate)
Nandrolone Decanoate (Deca-Durabolin)
Trenbolone
Sustanon 250
Stanozolol (Winstrol)

PEPTIDES:

Reta(Retatrutide)

GHK-Cu

MOTs-C

BPC157

TB500

MHRA Response

We confirm that we hold some of the information you have requested.

I can confirm that the MHRA received a total 6 UK spontaneous suspected adverse drug reaction (ADR) reports from Northern Ireland between 1 March 2021 and 31 March 2026 associated with the botox, steroid and peptide products specified in your request.

Of these:

- 3 reports were associated with Azzalure
- 1 report was associated with Dysport
- 2 reports were associated with testosterone (enanthate / cypionate / propionate)

The MHRA has not received any UK spontaneous ADR reports associated with the other botox, steroid and peptide products listed in your request, including Bocouture, Alluzience, Letybo, Nuceiva, Nandrolone, Trenbolone, Sustanon, Stanozolol, Retatrutide, GHK-Cu, MOTs-C, BPC-157, or TB-500.

Please note Retatrutide, GHK-Cu, MOTs-C, BPC157 and TB500 are not licensed products in the UK.

Please be aware that data by region is based on the postcode provided by the reporter in their Yellow Card submission. While reporters are encouraged to provide contact details to facilitate potential follow-up, a postal address is not required for a report to be considered valid. As postcode is an optional free-text field, it may not always be provided and, where it is, the information may vary depending on how it has been entered by the reporter.

Please find attached Annex 1 containing breakdowns of the ADR reports as previously requested in FOI2026/00470. The annex includes:

- **Table 1** - The total number of UK spontaneous ADR reports received from Northern Ireland between 01/03/2021 and 31/03/2026 associated with Azzalure, Dysport and Testosterone broken down by product name and seriousness
- **Table 2** - The total number of UK spontaneous ADR reports received from Northern Ireland between 01/03/2021 and 31/03/2026 associated with Azzalure, Dysport and Testosterone broken down by year received and seriousness
- **Table 3** - The total number of UK spontaneous ADR reports received from Northern Ireland between 01/03/2021 and 31/03/2026 associated with

Azzalure, Dysport and Testosterone broken down by patient sex and seriousness

- **Table 4** - The total number of UK spontaneous ADR reports received from Northern Ireland between 01/03/2021 and 31/03/2026 associated with Azzalure, Dysport and Testosterone broken down by patient age group and seriousness
- **Table 5** - The total number of UK spontaneous ADR reports received from Northern Ireland between 01/03/2021 and 31/03/2026 associated with Azzalure, Dysport and Testosterone broken down by primary reporter
- **Table 6** - The total number of UK spontaneous ADR reports received from Northern Ireland between 01/03/2021 and 31/03/2026 associated with Azzalure, Dysport and Testosterone broken down by reaction MedDRA SOC and seriousness
- **Table 7** - The total number of UK spontaneous adverse incident reports received from Northern Ireland between 01/03/2021 and 31/03/2026 associated with dermal fillers broken down by IMDRF Annex E code

Please note for Tables 6 and 7, the total number of reactions will not be equal to the total number of unique reports as one report may contain more than one reaction. Furthermore, we have not received any fatal ADR reports associated with the botox, steroid and peptide products listed in your request.

For reference, an ADR report is considered serious according to two criteria; firstly, a reported reaction can be considered serious according to our medical dictionary. Secondly, whether the original reporter considers the report to be serious whereby they can select based on the six serious criteria¹ available. It is important to note that the aggregated number of reports within the seriousness tables provided will not equal the overall number of reports, given that reporters are able to select more than one of the six serious criteria.

In the UK, dermal fillers are regulated as medical devices where the manufacturer makes medical claims. This means that they must be UKCA or CE marked and meet the requirements of the medical devices regulations. Where dermal fillers have no medical claims and are intended only for aesthetic purposes, they are not considered to be medical devices. Products indicated only for an aesthetic purpose, but which contain lidocaine are a medicinal product and therefore subject to the medicines regulations.

The information you have requested on brands associated with dermal fillers is considered commercially sensitive and is therefore exempt from release under Section 43(2) of the FOI Act. Section 43(2) of the FOI Act exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person, including a public authority. It protects not only the commercial interests of third parties but also those of the Agency itself.

¹ The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.

Under Section 17(1) of the FOIA, when refusing any part of a request, we must specify the relevant exemption and explain why it applies. Section 43(2) is a prejudice-based exemption, which applies where disclosure would, or would be likely to, prejudice the commercial interests of any legal person (including the public authority holding it). In this case, disclosure of brand-specific incident data could negatively affect the commercial standing of individual suppliers. It may lead to misinterpretation of safety data without appropriate clinical context, potentially distorting public perception and procurement decisions.

The MHRA holds commercially sensitive information to support its regulatory functions. For this exemption to apply, we must demonstrate that the risk of prejudice is real and significant, and that there is a causal link between disclosure and the harm identified. We consider that disclosure of this data could be used by competitors to cause reputational damage and influence market dynamics unfairly.

The MHRA codes medical devices within adverse incident reports using the Global Medical Device Nomenclature (GMDN). The GMDN is the leading global standard for the naming, classification and categorisation of medical devices. Further information on GMDN codes can be found [here](#).

Further to your query, we have conducted a search of our database for all UK adverse incident reports for dermal fillers. The GMDN CT code used to filter out these reports was CT2341: Dermal tissue reconstructive materials. I can confirm that we have received a total of 4 UK spontaneous adverse incident reports from Northern Ireland associated with dermal fillers between 1 March 2021 and 31 March 2025.

Of these:

- All 4 reports reported patient sex as unknown
- All 4 reports reported patient age as unknown
- All 4 reports were submitted by healthcare professionals
- All 4 reports were classified as non-serious
- 2 reports were received in 2023 and 2 reports were received in 2025

Under MHRA criteria, an adverse incident is considered serious if it caused, or could have caused, death or a serious deterioration in health. This includes life-threatening illness or injury, permanent impairment, hospitalisation or prolonged hospitalisation, medical or surgical intervention to prevent permanent harm, or fatal injury, death, or abnormality. Incidents with no actual harm may still be considered serious if recurrence could result in significant patient harm.

Furthermore, Table 7 provides the total number of reports for dermal fillers respective to International Medical Device Regulators Forum (IMDRF) Annex E (Health Effects - Clinical Signs and Symptoms or Conditions) codes and terms. Further information on IMDRF codes can be located [here](#).

Please note that when considering the spontaneous data within this response, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine or device, only that the reporter had a suspicion it may have been.

The fact that reactions occur after use of a medicine or device, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses, user or patient factors or recognised complications may be responsible and such events can also be coincidental.

- The number of reports received cannot be used to determine the incidence, frequency or likelihood of an adverse reaction or incident, nor to compare the safety profiles of different medicines or devices. This is because neither the total number of adverse events occurring nor the total number of individuals exposed to the product is known. Reporting rates are influenced by the seriousness of the reaction, their ease of recognition, the extent of use and may be stimulated by promotion and publicity. Reporting is often higher for newly introduced products and may decline over time.
- Reports do not necessarily represent unique individuals or events. A single individual may submit multiple reports relating to the same issue, and some reports may relate to follow-up information concerning an earlier report. Where possible, duplicate reports are identified and linked; however, this cannot always be achieved because some information fields are optional.
- Reports submitted by healthcare professionals and members of the public are voluntary and form an important part of the MHRA's post-market safety monitoring activities. All adverse incident reports received via Yellow Card are sent to the relevant manufacturer (if known and anonymised as appropriate) to feed into the vigilance system. In addition, certain adverse incidents involving medical devices are subject to mandatory manufacturer reporting requirements under the vigilance system.
- All reports contribute to the MHRA's ongoing safety monitoring and vigilance activities, the purpose of which is to identify potential safety concerns and, where appropriate, support actions to protect public health and reduce the risk of similar events occurring in the future.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: <https://products.mhra.gov.uk/> for details on the possible side effects.

As with all medical devices MHRA continues to monitor the safety and performance and encourages reporting of any adverse incidents through its Yellow Card scheme on <https://yellowcard.mhra.gov.uk/>

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.

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

Yours sincerely,

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/>