Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00952**

16 September 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 24 August. You wrote:

I am requesting recorded information concerning cases of iatrogenic botulism associated with cosmetic botulinum toxin treatment, and evidence or statistics supplied to the MHRA by Save Face and the Joint Council for Cosmetic Practitioners.

This request follows public statements about the 2025 outbreak and the MHRA's subsequent Drug Safety Update of 15 July 2026.

The JCCP has published the following statement concerning the 2025 cases:

"Between 4 June and 14 July 2025, the UK Health Security Agency (UKHSA) confirmed 38 cases of iatrogenic botulism in England, which were traced to unlicensed or counterfeit botulinum toxin injections in nonclinical settings."

Save Face has separately stated publicly that the number of Botox-related complaints it received increased by more than 350% between 2019 and 2024. It has also stated that, across its reporting years, more than 80% of complainants were treated by a non-healthcare practitioner and that recent complaints commonly concerned products not approved for use in the UK.

The MHRA Drug Safety Update published on 15 July 2026 describes iatrogenic botulism following botulinum toxin treatment as rarely reported. It also identifies JCCP and Save Face among the organisations involved in stakeholder engagement.

Against that background, please provide the following recorded information.

For the period 1 January 2025 to the date of this request:

The number of reports received by the MHRA concerning suspected iatrogenic botulism following cosmetic use of botulinum toxin, broken down by calendar year.
Where held, the number of those reports that were subsequently:
a. clinically confirmed as iatrogenic botulism; b. considered probable or suspected; c. not confirmed.
For those cases, where recorded, the number involving:
a. a botulinum toxin product authorised for use in the UK; b. an unlicensed or

unauthorised product; c. a counterfeit product; d. a product whose identity or regulatory status could not be established.
Where recorded, the name or brand of the product involved in each case, together with whether it was licensed, unlicensed, suspected counterfeit or unidentified. Personal information about patients is not requested.
The number of relevant Yellow Card reports received during 2025 and 2026.
The number of cases referred to, investigated by, or otherwise considered by the MHRA Criminal Enforcement Unit.
Where this information is recorded, the professional status of the person who administered the product, including whether they were a doctor, dentist, nurse, pharmacist, other regulated healthcare professional, independent aesthetic practitioner, beautician, other practitioner category, or unknown.
Where recorded, the treatment setting, including clinic, salon, home, mobile setting, other premises or unknown.
Any statistical information, datasets, case summaries, complaint figures, briefings or other evidence supplied to the MHRA by Save Face concerning botulinum toxin, Botox-related complaints, unlicensed products, counterfeit products or iatrogenic botulism from 1 January 2024 onwards.
Any equivalent statistical information, datasets, case summaries, complaint figures, briefings or other evidence supplied by the JCCP during the same period.
Any recorded assessment, verification, checking or discussion by the MHRA concerning the methodology, provenance, reliability or evidential status of figures supplied by Save Face or JCCP.
Correspondence between the MHRA and Save Face or JCCP concerning iatrogenic botulism, the 2025 outbreak, unlicensed or counterfeit botulinum toxin, or the July 2026 Drug Safety Update.
Any recorded information showing what evidence led the MHRA to include Save Face and JCCP in the stakeholder engagement identified in the Drug Safety Update of 15 July 2026.

Electronic copies are preferred.

I am not requesting patient-identifiable information. Where records contain personal information, please redact that material and disclose the remainder rather than withholding documents in their entirety.

If any part of this request would exceed the appropriate cost limit, please provide advice and assistance under section 16 of the Freedom of Information Act 2000 so that the request can be narrowed while preserving the principal questions concerning case numbers, product status and evidence supplied by Save Face and JCCP.

MHRA Response

We have considered your request under the Freedom of Information Act 2000 (FOIA).

We can confirm that the MHRA holds information within the scope of your request. Information available from the Yellow Card scheme is provided below. However, we are unable to disclose certain additional information because exemptions under FOIA apply.

It may be helpful to first provide some background information to assist with interpretation of the data.

The Yellow Card scheme is the UK's system for collecting and monitoring suspected adverse drug reactions (ADRs). The scheme is operated by the MHRA and receives reports from healthcare professionals, patients and pharmaceutical companies. All reports are reviewed

as part of MHRA's pharmacovigilance activities to monitor the safety of medicines and identify potential safety concerns.

The MHRA uses the Medical Dictionary for Regulatory Activities (MedDRA), an internationally recognised medical terminology, to code suspected adverse reactions reported through the Yellow Card scheme.

The Yellow Card scheme received a total of 11 UK spontaneous suspected ADR reports between 1 January 2025 and 24 August 2026 associated with Clostridium botulinum and the MedDRA Preferred Term "Botulism".

Table 1: Number of UK spontaneous suspected ADR reports received between 1 January 2025 and 24 August 2026 associated with Clostridium botulinum and the MedDRA Preferred Term "Botulism"

Year	Brand Name	Number of Reports
2025	BOCOUTURE	1
2025	BOTOX	2
2025	BOTULINUM TOXIN TYPE A	2
2026 (to 24/08/2026)	BOTOX	3
2026 (to 24/08/2026)	BOTULINUM TOXIN TYPE A	3
Total		**11**

Please note that provision of a product brand name is not mandatory when submitting a Yellow Card report and may therefore be unavailable in some cases.

It is also important to note that these data are not specific to cosmetic or aesthetic use. The indication for treatment is not a mandatory field within a Yellow Card report and, where provided, may be recorded in a variety of ways. As such, MHRA cannot reliably identify all reports relating specifically to cosmetic treatments from Yellow Card data alone.

The Yellow Card scheme collects reports of suspected adverse reactions. It does not routinely record:

- whether an individual case was clinically confirmed as iatrogenic botulism;
- whether a case was considered probable, suspected or not confirmed;
- whether a product was licensed, unlicensed, unauthorised, counterfeit or otherwise;
- the professional status of the individual who administered the product; or
- the treatment setting in which the product was administered.

Accordingly, this information is not held within the relevant Yellow Card dataset for the purposes of section 1(1)(a) of FOIA.

You have also requested information concerning:

- products that may be unauthorised, unlicensed or counterfeit;
- information identifying manufacturers, suppliers, distributors, practitioners or premises;
- the number of cases referred to, investigated by, or otherwise considered by the MHRA Criminal Enforcement Unit (CEU);

- case summaries, intelligence reports, investigation records and enforcement material;
- information concerning the source and status of products associated with specific cases; and
- correspondence or information which has informed ongoing MHRA investigations.

The MHRA is withholding this information under sections 30 and 31 of FOIA.

Section 30 applies to information held for the purposes of investigations that may lead to criminal proceedings.

Some of the information requested forms part of ongoing investigations into potential breaches of medicines legislation. Disclosure of information held within active investigation files could prejudice current or future enforcement action and undermine the integrity of those investigations.

The MHRA has also applied section 31(1)(g), with subsections 31(2)(a), (b), (c) and (j).

Disclosure would be likely to prejudice the MHRA's law enforcement functions by revealing information about:

- the scope and focus of ongoing investigations;
- intelligence received by the MHRA;
- investigative methods and priorities;
- enforcement activity relating to specific products or individuals; and
- information that could assist those seeking to evade regulatory or criminal scrutiny.

Sections 30 and 31 are qualified exemptions and require consideration of the public interest.

The MHRA recognises the public interest in transparency regarding patient safety, reports of suspected iatrogenic botulism and the regulation of cosmetic botulinum toxin products.

However, there is a stronger public interest in ensuring that criminal and regulatory investigations can be conducted effectively and without prejudice. Disclosure of information relating to active investigations could compromise enforcement activity, undermine the MHRA's ability to investigate suspected offences and reduce its ability to protect public health.

Having considered the competing public interest arguments, the MHRA has concluded that the public interest favours maintaining the exemptions.

Some information falling within the scope of your request was provided to the MHRA by third parties, including external organisations and individuals.

Where applicable, this information is exempt under:

Some information was supplied in circumstances giving rise to an obligation of confidence. Disclosure could constitute an actionable breach of confidence and is therefore exempt from disclosure.

When considering the Yellow Card data disclosed above, please note:

- A reported reaction does not necessarily mean that the medicine caused the event. Reports reflect the suspicions of the reporter and further assessment may be required.

- Reports may relate to underlying medical conditions, other medicines, coincidental events or other contributing factors.
- Yellow Card data cannot be used to calculate the incidence of adverse reactions or directly compare the safety profiles of different medicines.
- Reporting rates may be influenced by publicity, awareness of safety concerns, patterns of medicine use and other factors.

As noted in the Summary of Product Characteristics (SmPC) for BOTOX:

"Cases of iatrogenic botulism have been reported following injection of botulinum toxin products. Patients and caregivers should be advised to seek immediate medical advice if they experience any signs or symptoms consistent with the spread of botulinum toxin effect or if swallowing, speech or respiratory disorders arise."

The BOTOX SmPC is publicly available via the Electronic Medicines Compendium website.

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 FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
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