Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/01328**

27 October 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 2 October. You wrote:

[redacted]*Please treat this as a request under the Freedom of Information Act 2000.*

*For Medicines and Healthcare products Regulatory Agency: This request concerns MHRA's response to reports of botulism or suspected botulism associated with cosmetic botulinum toxin injections during 1 January to 31 December 2025.*

1. *Please provide the existing incident chronology or decision log recording the first relevant notifications, referrals between agencies and decisions to issue public or professional safety communications. Dates, agency names and redacted decision summaries are sufficient.*
2. *Please provide the completed incident review or latest assurance report, including any recorded assessment of whether earlier complaints or product intelligence were linked to these incidents.*
3. *Please provide the associated action tracker and any existing aggregate table distinguishing suspected unlicensed/falsified products from licensed products in the incidents reviewed. I am not requesting complainant identities, individual Yellow Card records or operational details of live investigations.*

*Please reply electronically, supplying tables in their existing spreadsheet/CSV format where held. I am requesting existing records, not a new investigation or identifiable personal information. Please distinguish information not held from a recorded zero. A direct link is fine for published information. If part would exceed the applicable cost limit or require an unreasonable search, please advise how to narrow it, prioritising the first two items. Please disclose the remaining material with any necessary redactions.*

**MHRA Response**

Thank you for your request for information relating to incidents of botulism associated with botulinum toxin products.
The MHRA does not hold the information in the formats requested such as an incident chronology, completed incident review, action tracker or aggregate table distinguishing licensed from unlicensed or falsified products. However, we can provide the following

information regarding the MHRA's consideration of the risks associated with botulinum toxin products.
The MHRA has undertaken regulatory consideration of the risks associated with botulinum toxin products over a number of years. This includes routine pharmacovigilance activities, international safety monitoring and consideration of emerging safety concerns.

In October 2007, the MHRA published a Drug Safety Update (DSU) highlighting the rare but serious risks associated with botulinum toxin products.This communication is publicly available here: www.gov.uk/drug-safety-update/botulinum-toxin-products-rare-but-serious-risks.In June 2023, reports of botulism associated with the use of botulinum toxin for intragastric injection in Turkey were raised through the MHRA's international post-market surveillance processes. More recently, following reports of botulism associated with cosmetic procedures in the UK during 2025, the MHRA worked alongside other relevant agencies in responding to the emerging safety concerns.The UK Health Security Agency (UKHSA) published a warning regarding botulism in August 2025 which can be found here: www.gov.uk/government/news/ukhsa-issues-warning-over-botulism.

The MHRA subsequently published a press release in September 2025 outlining enforcement activity relating to illegal botulinum toxin products: www.gov.uk/government/news/mhra-crackdown-on-illegal-botox-after-victims-left-seriously-ill.

The MHRA routinely considers safety information from a range of sources, including UK Yellow Card reports, international regulatory assessments, published literature and other emerging safety intelligence.
The MHRA has also received and considered European Union Periodic Safety Update Report (PSUR) assessments relating to botulinum toxin-containing products.The assessments identified that serious adverse reactions have occurred following the administration of botulinum toxin products outside their authorised indications, including administration at unapproved injection sites, use of higher than recommended doses and administration by individuals who are not suitably qualified healthcare professionals.

Importantly, the assessments acknowledged that although some reported cases involved counterfeit or unauthorised products, reports of iatrogenic botulism were not limited to these products.
The recommendations included strengthening warnings in the Summary of Product Characteristics and associated Patient Information Leaflets regarding the potential for iatrogenic botulism, recognition of symptoms and the need to seek medical attention.

The MHRA does not hold a consolidated action tracker or aggregate table in the format described in your request.

Suspected adverse reactions associated with botulinum toxin products are monitored through the Yellow Card scheme. However, it is important to note that Yellow Card reports do not establish a causal relationship between a product and a reported adverse reaction. Information concerning product authenticity or authorisation status may not be included in every report.
Consequently, Yellow Card reporting data should not be interpreted as providing a definitive breakdown of incidents attributable to licensed products compared with unlicensed or falsified products.
The MHRA's Criminal Enforcement Unit also undertakes investigations into the unlawful supply and use of medicinal products, including unlicensed botulinum toxin products, as outlined in the September 2025 press release referenced above.

The MHRA continues to monitor the safety of botulinum toxin-containing products and considers whether further regulatory action or safety communications are warranted as new evidence becomes available.

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

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**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.

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