



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk

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

Our Ref: **FOI2026/00969**

23 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 28 August 2026. You wrote:

We have reviewed the MHRA's updated warning about the risk of botulism following botulinum toxin treatment. Could you please advise whether you can share:

- *The latest aggregated Yellow Card data relating to botulinum toxin, ideally showing annual trends since 2021*
- *Whether cosmetic treatments can be separated from therapeutic use*
- *The main reactions reported, including serious or fatal outcomes*
- *Any themes involving unlicensed, counterfeit or imported products*
- *Important limitations when interpreting the figures*
- *The main warnings and advice that should be communicated to the public*
- *Any existing MHRA communication materials that we could use*

MHRA Response

I can confirm that we hold the information you have requested. However, some of this information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain. The MHRA publishes reported side effects of a drug in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed using this website: <https://yellowcard.mhra.gov.uk/idaps>. The iDAPs will provide all reactions reported, including serious or fatal outcomes.

You can view the idaps for clostridium botulinum here, [CLOSTRIDIUM BOTULINUM | Making medicines and medical devices safer](#). The profile provides the data you have requested in points 1 and 3 of your request. You can use the filters on the left hand column to view the data of interest including the number of reports by year, a complete list of all suspected adverse reactions as well as whether the report was classified as serious.

When considering the spontaneous adverse drug reaction (ADR) data, it is important to be aware of the following points:

- The number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction. ADR reporting rates may be influenced by multiple factors including the seriousness of ADRs and their ease of recognition.
- A reported reaction does not necessarily mean it has been caused by the drug or vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a drug or vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug or vaccine. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- The MHRA continuously monitors the safety of medicines and vaccines through a variety of pharmacovigilance processes, including the Yellow Card scheme. As part of our signal detection processes, all adverse reaction reports received by the Yellow Card scheme are assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

Please note, indication for use of a suspect medicine is not a mandatory field when completing a Yellow Card report and is all free text. It would be difficult to categorise whether a reported indication is either cosmetic or therapeutic, as this would require subjective assessment, especially taking into account the format. Under the FOIa we are not obliged to assess information we hold in order to provide information relevant to the request. Please be assured that we do take into account all information including indication for use as part of our routine safety assessment procedures.

The Criminal Enforcement Unit (CEU) holds information relating to intelligence and enforcement activity concerning unlicensed, counterfeit and illegally imported botulinum toxin products. This information is exempt from disclosure under section 31(1)(a) and (b) of the Freedom of Information Act 2000, as disclosure would be likely to prejudice the prevention and detection of crime and the apprehension or prosecution of offenders. Disclosure of information concerning intelligence holdings, identified themes, enforcement priorities or investigative activity could provide those involved in the illegal supply of medicines with insight into MHRA's operational interests and capabilities, increasing the risk that they could evade detection and undermine future enforcement action. We recognise the public interest in transparency regarding the regulation of botulinum toxin products; however, there is a stronger public interest in protecting the MHRA's ability to prevent and detect crime and safeguard public health. We have therefore concluded that the public interest in maintaining the exemption outweighs the public interest in disclosure.

The MHRA recently published a Drug Safety Update following reports of rare cases of iatrogenic botulism associated with the therapeutic and cosmetic use of botulinum toxin-containing products. Iatrogenic botulism can occur where the effects of botulinum toxin spread beyond the site of administration. Although this is rare, it can be serious and potentially life-threatening. Symptoms typically occur 4 to 8 days following treatment but may take up to 4 weeks to develop, and can include difficulty swallowing, slurred speech, breathing difficulties, severe drooping of the upper eyelids and muscle weakness. Individuals experiencing symptoms suggestive of botulism following treatment should seek immediate medical attention.

The MHRA advises that the risk may be increased where high doses are used, where botulinum toxin is used off-label or at unapproved administration sites, in individuals with certain underlying conditions (including neurological disorders or a history of dysphagia or aspiration), and particularly where unauthorised or counterfeit products are used.

Following these reports, the MHRA is strengthening the product information for UK-authorized botulinum toxin type A products to more clearly highlight the risk of iatrogenic botulism and the action patients should take if symptoms occur. Serious adverse reactions associated with distant spread of toxin were already reflected in product information prior to this update.

Further information is available in the MHRA Drug Safety Update published on 15 July 2026: [Botulinum toxin type A products: updated warnings regarding risk of iatrogenic botulism – MHRA Drug Safety Update](#)

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

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/>