Medicines & Healthcare products Regulatory Agency

[redacted]

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Our Ref: **FOI2025/01068**

24 October 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 3 October. You wrote:

I am writing to request clarification under the Freedom of Information Act regarding the regulatory framework and clinical responsibilities related to botulinum toxin in the UK.

1. I have reviewed the MHRA Drug Safety Update (December 2014) titled "Botulinum toxin products: rare but serious risks", which highlights spread reactions including muscle weakness, dysphagia and aspiration https://www.gov.uk/drug-safety-update/botulinum-toxin-products-rare-but-serious-risks

1. I have also noted the UKHSA 2025 public health warning regarding botulism following cosmetic botulinum toxin procedures https://www.gov.uk/government/news/ukhsa-issues-warning-over-botulism

1. The "Botulism: clinical and public health management" guidance explicitly states that botulinum antitoxin should not be delayed pending laboratory confirmation https://www.gov.uk/government/publications/botulism-clinical-and-public-health-management/botulism-clinical-and-public-health-management

1. Furthermore, I am aware of FOI disclosures (FOI 22/774) confirming that MHRA maintains records of reported adverse reactions relating to botulinum toxin.

In light of these documents, I kindly request clarification on the following points:

* *Which authority or body is responsible for updating official safety warnings and product information regarding botulinum toxin (MHRA, UKHSA, or another)?*
* *From July 2014 to December 2015, which clinical authority (GP, hospital trust, Public Health England at that time, or another) held responsibility for ensuring appropriate diagnosis and administration of botulinum antitoxin in cases where patients presented with suspected systemic botulinum toxin reactions?*
* *On what date were the above-mentioned warnings formally integrated into UK clinical guidance and/or product labelling?*
* *Could you please provide a list of all adverse events reported in relation to botulinum*

toxin products since 2010, with particular reference to neurological, muscular, or autoimmune outcomes (including but not limited to myositis)?

MHRA Response

We confirm that we hold the information you have requested.

It may be helpful to clarify the role of the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA regulates medicines, medical devices and blood components for transfusion in the UK. We ensure that medicines, medical devices and blood components for transfusion meet the applicable standards of safety, quality and efficacy (effectiveness).

Botulinum toxin products are prescription only medicines in the UK. In the UK there are a number of authorised products containing botulinum toxin which have been granted a marketing authorisation by the MHRA based on safety, quality and efficacy data. The MHRA is responsible for the whole of the medicine's lifecycle and changes to the marketing authorisation must be approved by the MHRA. The product information which contains information about how to use the medicine and safety warnings such as potential adverse reactions and warnings and precautions for use. The product information is approved at the time of authorisation and can be varied (for example to include new safety information) as part of the lifecycle management of the product. Therefore, the MHRA is responsible for the safety warnings and product information for authorised botulinum toxin products in the UK.

As you are aware, adverse reactions for botulinum toxin including the distant spread are listed in the product information for authorised botulinum toxin products. The product information can be found here: https://products.mhra.gov.uk/. Table 1 below shows the brand of botulinum toxin product authorised for use in the UK and the date in which warnings related to distant spread of toxin were added to the product information.

Table 1:

Brand	**Authorised**	**Date of warnings regarding distant spread of toxin**
Alluzience	16/07/2021	Since first authorisation
Relfydess	23/12/2024	Since first authorisation
Azzalure	26/02/2009	Since first authorisation
Letybo	23/02/2022	Since first authorisation
Xeomin	07/01/2008	Since first authorisation
Bocouture	29/06/2010	Since first authorisation
Dysport	26/10/1995	26/06/2007
Botulinum toxin type A 500 units powder for solution for injection	26/10/1995	05/07/2007
Botox	17/05/1994	07/06/2007
Neurobloc	18/05/2001	28/03/2007
Nuceiva	27/09/2019	Since first authorisation

It is important to note that the MHRA does not regulate clinical practice. The diagnosis and clinical management of patients with suspected botulism from the use of botulinum toxin adverse reactions is outside of the remit of the MHRA. As you are aware, the UK Health Security Agency (UKHSA) have published guidance on the clinical and public health management of botulism. The UKHSA would be best placed to provide further guidance on your second point.

All suspected adverse reactions to botulinum toxin containing products, including suspected botulism, can be reported to the MHRA via the Yellow Card Scheme. The scheme allows the MHRA to monitor suspected safety concerns from routine use and acts as an early warning system for new or emerging safety concerns. The MHRA can take regulatory action, where necessary, to minimise the risks to patients. This includes communicating safety information to patients, the public and healthcare professionals. You can find the information on the reported reactions to Botulinum Toxin at https://yellowcard.mhra.gov.uk/idaps/CLOSTRIDIUM%20BOTULINUM. This interactive Drug Analysis Profile (iDAP) contains a complete listing of all the suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme. The filters in the report will allow you to filter the data by year of receipt and specific adverse reaction system organ class (e.g. Musculoskeletal and connective tissue disorders). It is important to note that reported adverse reactions have not been proven to be related to the drug and should not be interpreted as a list of known side effects. Please read the essential context at the bottom of the iDAP for additional information to help understand the report.

The MHRA works collaboratively with the UKHSA, where necessary, to help investigate a potential outbreak of an infectious disease that may be linked to a medical product. The UKHSA published a health warning on the 18 July 2025 related to botulism following cosmetic procedures involving botulinum toxin. You may be aware, that the MHRA have also issued a press release on the 30 August 2025 in related to investigations being conducted by our Criminal Enforcement Unit following the spike in hospital admissions believed to be linked to the use of unlicensed botulinum toxin products.
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.

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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/