Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2026/01094**

16 October 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 19 September. You wrote:

> *I am writing to make a Freedom of Information request regarding adverse reactions, specifically allergic and hypersensitivity reactions, associated with botulinum toxin products used in the UK.*
>
> *I would like the MHRA to provide the most complete and up-to-date data held by the agency, preferably from the Yellow Card reporting system and any other relevant pharmacovigilance databases.*
>
> *Please provide the following:*
> *The total number of UK Yellow Card reports associated with botulinum toxin products, broken down by individual product/brand where possible (for example, Botox/Vistabel, Azzalure, Bocouture, Nuceiva and other authorised botulinum toxin products).*
> *Of these reports, the number specifically classified or coded as:*
> *• allergic reaction*
> *• hypersensitivity*
> *• anaphylaxis*
> *• anaphylactic shock*
> *• angioedema*
> *• urticaria/hives*
> *•facial swelling*
> *• swelling of the lips, tongue or throat bronchospasm or breathing difficulty where recorded as an allergic/hypersensitivity reaction other suspected immune-mediated reactions.*
>
> *Please provide the number of reports involving serious reactions, including those resulting in:*
> *hospitalisation*
> *emergency treatment*
> *life-threatening events*
> *intensive care admission*
> *disability*
> *death.*

Please provide the data broken down by:
botulinum toxin product/brand &
year of report.
therapeutic versus cosmetic use, where this information is available age group, where disclosure is possible.
sex, where disclosure is possible.
Please provide the number of reports where the reaction occurred after a cosmetic administration of botulinum toxin.
Please provide any data held by the MHRA concerning suspected allergic or hypersensitivity reactions following repeat exposure to botulinum toxin, including cases where the individual had previously received the same or another botulinum toxin product without an apparent reaction.

Please state whether the MHRA holds information concerning the time between administration of botulinum toxin and onset of an allergic or hypersensitivity reaction. If so, please provide aggregated data showing the reported time to onset.

Please provide the number of reports in which the botulinum toxin product was considered the suspected medicine, as opposed to a concomitant medicine or another suspected cause.

Please provide any information held regarding the number of these reports that were subsequently assessed by the MHRA as potentially related to the botulinum toxin product.
Please provide the reporting period covered by the data and the date on which the data were extracted.

I would also like clarification regarding under-reporting.
The MHRA has previously stated that Yellow Card reporting is a spontaneous reporting system and that the indication for use is not necessarily recorded on every report. I would therefore like to know:
• Whether the MHRA has made any assessment of the likely level of under-reporting of allergic or hypersensitivity reactions to botulinum toxin.
• Whether the MHRA has any estimated figures for the true number of allergic reactions compared with the number reported through Yellow Card.
• Whether the MHRA has identified any particular limitations in using Yellow Card data to establish the incidence or prevalence of allergic reactions to cosmetic botulinum toxin.
Please provide the information electronically, preferably in spreadsheet/CSV format where possible.
I am specifically requesting aggregated statistical information and am not requesting personal information relating to individual patients.
If any part of this request is considered exempt from disclosure, please provide the remainder of the information and identify the specific exemption being relied upon.
I would also be grateful if you could distinguish between:
(a) the number of reports received,
(b) the number of individual suspected reactions/events recorded within those reports, and
(c) any cases that have subsequently been medically assessed or investigated by the MHRA.
I understand that a Yellow Card report represents a suspected adverse reaction and does not necessarily establish that the medicine caused the reaction. I am therefore requesting the underlying reported data and any available MHRA assessment rather than assuming causation.
Please treat this correspondence as a formal Freedom of Information request.

MHRA Response

We confirm that we hold the information you have requested.

You can view all our Yellow Card data for medicines and vaccines, including reports of clostridium botulinum, on our Interactive Drug Analysis Profiles (iDAPs) from our Yellow Card website: (https://yellowcard.mhra.gov.uk/idaps). iDAPs contain complete listings for all medicines and vaccines of all UK spontaneous suspected adverse reactions received by the MHRA. On this platform, you will be able to search for the specified medicine or vaccine and find the reported suspected adverse reactions associated with them. The graphs and tables within the 'Total Report Profile' and 'Total Reaction Profile' tabs are dynamic for all products. The filters on the left-hand side allow you to interact and filter the data as you wish. Please refer to the guidance included in the iDAP page to ensure appropriate interpretation of the information presented.

We can confirm that the MHRA has received a total number of 1,975 UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with Clostridium Botulinum products up to and including the 09/10/2026.

Please find attached Annex 1 containing breakdowns of the reports for Clostridium Botulinum products as requested. The Annex contains:

- Table 1 - Total number of UK spontaneous ADR reports associated with Clostridium Botulinum products broken down by product name and year up to and including 09/10/2026.
- Table 2 - Total number of UK spontaneous ADR reports associated with Clostridium Botulinum products and the requested reaction terms up to and including 09/10/2026.
- Table 3 - Total number of UK spontaneous ADR reports associated with Clostridium Botulinum products broken down by seriousness up to and including 09/10/2026.
- Table 4 - Total number of UK spontaneous ADR reports associated with Clostridium Botulinum products broken down by patient age bands up to and including 09/10/2026.
- Table 5 - Total number of UK spontaneous ADR reports associated with Clostridium Botulinum products broken down by patient sex up to and including 09/10/2026.
- Table 6 - Total number of UK spontaneous ADR reports associated with Clostridium Botulinum products and hypersensitivity reactions broken down by time to onset (days between treatment initiation and reaction onset) up to and including 09/10/2026.

Please note that the above data only includes reports in which clostridium botulinum was reported as a suspect or interacting drug and does not include reports in which clostridium botulinum was reported solely as a concomitant medicine. A single Yellow Card report may also contain more than one suspect or interacting drug. As a result, where data is presented by brand name, the combined sum of reports in the tables provided may exceed the total number of unique reports.

Please be aware that patient age, sex, drug start date, and reaction start date are optional fields within a Yellow Card report and are not required for a report to be considered valid. The Yellow Card scheme relies on voluntary reporting to monitor the safety of all healthcare products in the UK and by not making all report fields mandatory, we aim to maximise the number of reports we receive. As such, this data may not be available for all reports. Consequently, the number of reports identified through searches based on these criteria may be lower than the total number of reports received, as the relevant information may not have been provided in some cases.

Additionally, in the case of hypersensitivity reactions, the onset of the reaction may occur within minutes or hours of drug administration. As Yellow Card reports record drug start dates and reaction onset dates in date format only, the interval between administration and reaction onset, where provided, can only be determined in days.

For reference, a Yellow Card 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 according to 6 criteria[1].

The above data is also not specific to use for cosmetic, aesthetic or therapeutic indications. Indication is not a mandatory field on a Yellow Card Report, and as such, reports might not include any data on indication. Additionally, “use for cosmetic/ therapeutic indications” does not map to one specific term on our internal dictionary: the information in the field will depend on how the reporter has entered this information. As such, reviewing indication data would require manual review, introducing possible subjectivity. Therefore, we cannot provide you with the number of reports that occurred after therapeutic/cosmetic administrations.

Similarly, we are unable to provide data specifically concerning suspected allergic or hypersensitivity reactions following repeat exposure to botulinum toxin, including cases where an individual had previously received the same or another botulinum toxin product without an apparent reaction. Information relating to previous exposure, prior treatment history and the absence of a reaction following earlier administrations is not held in a structured, searchable field within the Yellow Card database. Where such information is available, it would typically be contained within the free-text narrative of individual reports and may not be reported consistently. Identifying and extracting this information would therefore require a manual review of individual case reports and the application of subjective judgement. As a result, we are unable to provide a reliable count of reports meeting these criteria.

Patient safety is our highest priority and the MHRA takes all reports very seriously. While the MHRA carefully assesses Yellow Card reports to facilitate assessment of the link between a medicine and the reported adverse event, we do not verify reports or assign causality (i.e., whether the patient’s reaction was caused by the medicinal product) at the level of individual reports. As such we do not hold information on whether the product was the cause of the reported reaction in these reports.

The MHRA does not currently have an open safety signal specifically relating to allergic or hypersensitivity reactions associated with botulinum toxin products. The MHRA continually monitors the safety of medicines and undertakes safety assessments as potential signals emerge. In July 2026, the MHRA published a Drug Safety Update highlighting the risk of iatrogenic botulism associated with botulinum toxin type A products, including the potential for the effects of the toxin to spread beyond the site of administration. The update also outlined strengthened safety warnings and advice for healthcare professionals and patients. This can be accessed here: Botulinum toxin type A products: updated warnings regarding risk of iatrogenic botulism - GOV.UK. The MHRA continues to monitor the safety of botulinum toxin products.

Please be assured that should any significant safety concerns relating to clostridium botulinum products be identified, the MHRA will take appropriate regulatory action and communicate to healthcare professionals and patients alike.

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[1] The seriousness criteria for adverse event reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS). 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.

The MHRA does not hold an assessment of the level of under-reporting of allergic or hypersensitivity reactions associated with botulinum toxin products and does not hold any estimates of the number of such reactions compared with the number reported through the Yellow Card scheme.

It is important to note that the reporting rate for spontaneous adverse drug reactions (ADRs) is variable and can depend on a multitude of factors. The actual rate of reporting is unknown and likely to be highly variable as it will be influenced by public awareness and seriousness of events as well as publicity around the use of medicines and vaccines. Based on this, it is not possible for the estimated rate of under-reporting to be calculated for any medicines or vaccines, including botulinum toxin products, nor is it possible to provide estimates relating specifically to allergic or hypersensitivity reactions. Please be assured we evaluate all aspects of the data including potential variability in levels of reporting for Yellow Card data as part of our ongoing monitoring procedures.

All spontaneous ADR reporting systems worldwide, like the Yellow Card scheme, are known to be subject to underreporting. Underreporting of ADRs is thought to occur less frequently with serious and unlabelled reactions (those reactions which are not yet on the product information). The disproportionality statistical analysis which we use to routinely review the whole Yellow Card database are purposefully designed to minimise the impact of under reporting by comparing between drugs or vaccines rather than with unexposed patients further the MHRA can also apply additional sensitivity analysis into its statistical evaluation of a potential safety concern which takes into account a range of levels of possible reporting. Additionally, the MHRA does not rely solely on spontaneous reporting when assessing any potential safety issues and reviews the totality of evidence available.

Yellow Card data cannot be used to determine the incidence or prevalence of a suspected adverse reaction. In relation to cosmetic botulinum toxin specifically, the indication for use is not a mandatory field on a Yellow Card report and may therefore be absent. Where an indication is provided, cosmetic or therapeutic use is not recorded using a single standardised term, as mentioned above. It is therefore not possible to reliably identify all reports relating to cosmetic use. In addition, Yellow Card reports represent suspected adverse reactions and do not necessarily establish that the medicine caused the reported reaction. These limitations, together with an unknown and variable level of reporting, mean that Yellow Card data cannot be used to establish the incidence or prevalence of allergic or hypersensitivity reactions following cosmetic use of botulinum toxin.

When considering spontaneous data for medicinal products, it is important to be aware of the following points:

- As these data do not necessarily refer to proven side effects, you should refer to the relevant product information for details on the possible side effects of these medicines and vaccines. The product information can be found by searching for the name of the medicine or vaccine of interest on: MHRA Products | Home.
- A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a medicine, 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 may be responsible and such events can also be coincidental.
- It is also important to note that 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 or compare the safety profile of different medicinal products. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine,

and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

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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