



# Medicines & Healthcare products Regulatory Agency

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Our Ref: **FOI2025/00192**

28<sup>th</sup> March 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request dated 28th February 2025 where you asked,

- 1. The total number of deaths reported under the Yellow Card scheme in relation to botulinum toxin (Botox) from 1998 to the present.*
- 2. A breakdown of these reports, including:*

- \* The year each report was submitted*
- \* The suspected cause of death (if available)*
- \* Whether the cases involved medical or cosmetic use of Botox*

- 1. Any internal reviews or assessments conducted by the MHRA regarding the safety of botulinum toxin based on Yellow Card data.*

## **MHRA Response**

We confirm that we hold the information you have requested.

Further to your initial request, I can confirm between 01/01/1998 to 25/03/2025 the MHRA has received 1,535 UK spontaneous suspected adverse reaction reports for the substance clostridium botulinum, 23 reports of which were associated with a fatal outcome. Please see attached the Drug Analysis Print (DAP) which lists all the reactions that have been reported to us associated with clostridium botulinum. The DAP also lists which reactions had a fatal outcome. You will also see enclosed an information sheet for guidelines on how to interpret the DAP. Please note, the total number of reactions in the table will not be equal to the total number of unique reports as one report may contain more than one reaction.



## Medicines & Healthcare products Regulatory Agency

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

- A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have been. The fact that symptoms occur after use of a vaccine or 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. I hope the information provided is helpful. If you have any queries about this letter, please contact us quoting the reference number above.

Please be aware that the DAP provided should not be used as a list of side effects. All established adverse reactions for any drug can be found within the Patient Information Leaflets (PIL), available here <https://www.medicines.org.uk/emc>.

In response to your second request please see Figure 1 below which displays the number of fatal reports received each year with clostridium botulinum from 01/01/1998 up to and including 25/03/2025.

**Figure 1. Number of fatal UK spontaneous suspected reports of clostridium botulinum received each year between 01/01/1998 up to and including 25/03/2025.**

Year received	Number of reports
2001	1
2004	2
2006	1
2007	1
2008	3
2010	1
2011	2
2012	1
2015	2
2016	1
2017	3
2020	1
2022	1
2023	1
2024	1
2025 up to and including 25/03/2025	1
<b>Total number or reports</b>	<b>23</b>



## Medicines & Healthcare products Regulatory Agency

In terms of how many fatal reports are associated with medical or cosmetic use, it's important to note that on a Yellow Card report, indication is an optional field therefore, this information may not always be provided by the reporter. When this information is provided, entries will vary between reports depending on how the reporter has entered this information. However, I can confirm that of the 23 fatal reports, none of the cases reported that they were indicated for cosmetic use.

The MHRA assessed 2 safety concerns for clostridium botulinum based on potential signals from Yellow Card data. These included a signal raised regarding a potential discrepancy in product information in the warnings of use during pregnancy in the SPC section 4.6. It was concluded after a review of the different brands, that the warnings of use in pregnancy was sufficient. The second was a signal on joint dislocation. The conclusion was that there was insufficient evidence to support a causal association between the formation of joint subluxation/dislocation and botulinum toxin, however this is continually being monitored via routine pharmacovigilance.

I would like to reassure you that once a product is on the market, the MHRA continues to monitor its safety through various mechanisms. This monitoring strategy is continuous, proactive, and based on a wide range of information sources. A dedicated team of assessors and scientists' review information to look for suspected safety issues or unexpected, rare events. The MHRA's ongoing vigilance helps to ensure that the benefits of approved products consistently outweigh any potential risks, thereby safeguarding public health.

I hope the information provided is helpful. If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team  
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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.



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Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

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