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

Our Ref: **FOI2026/00176**

17 March 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 18 February. You wrote:

I shall be grateful if you will provide information as follows:

- 1) Is Dysport licensed for use in hernia surgery in the UK?*
- 2) In the event it is licensed please outline the conditions for its use in hospitals.*
- 3) Are all hospitals able to use it? In the event the use is limited which ones are allowed to do so?*
- 4) Has the MHRA been notified of any side effects it has? Have any patients deaths been reported following use of Dysport?*

MHRA Response

We confirm that we hold the information you have requested and have provided it below and in the attached Product Analysis Print.

Dysport is a brand of Clostridium botulinum toxin type A which is authorised by the MHRA. As you may be aware, the licensed indications of a medicinal product are listed in the accompanying product information which includes the Summary of Medicinal Products Characteristics (SmPC) and Patient Information Leaflet (PIL). These documents can be found on our website via the following link: <https://products.mhra.gov.uk/>

The authorised indications for Dysport include:

For the symptomatic treatment of focal spasticity of:

- Upper limbs in adults*
- Lower limbs in adults affecting the ankle joint*
- Dynamic equinus foot deformity in ambulant paediatric cerebral palsy patients, two years of age or older*
- Upper limbs in paediatric cerebral palsy patients, two years of age or older*

Dysport is indicated for the management of urinary incontinence in adults with

neurogenic detrusor overactivity due to spinal cord injury (traumatic or nontraumatic) or multiple sclerosis, who are regularly performing clean intermittent catheterisation.

Dysport is indicated in adults for symptomatic treatment of:

- Spasmodic torticollis*
- Blepharospasm*
- Hemifacial spasm*
- Severe primary hyperhidrosis of the axillae, which does not respond to topical treatment with antiperspirants or antihidrotics.*

Dysport does not have a licensed indication for the use in hernia surgery in the UK. The use of a medicine outside of its authorised indications is known as off-label use. A prescribing healthcare professional is able to choose to use a medicinal product off-label when judged by the prescriber to be in the best interest of the patient and the responsibility of use of the product in this way lies with the prescriber. Further information on the off-label or unlicensed use of medicines and prescribers responsibilities can be found at the following link: <https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities>

Following a search of our database, we can confirm that the MHRA have received a total of 277 UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with Dysport up to and including 19/02/2026. Of these reports, 8 reported a fatal outcome.

Please find attached a Product Analysis Print (PAP) containing information on all the reports received through the Yellow Card Scheme associated with Dysport. Please note that the PAP contains reports where Dysport has been used for all indications. The attached Drug Analysis Print guidance sheet provides you with further information on how to interpret the print.

Conclusions on the safety and risks of the medicinal product cannot be made on the data shown in the PAP. When considering the attached 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 or vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after treatment with a medicine or vaccine, 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine or vaccine, and may be stimulated by promotion and publicity about a drug or vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.
- 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 individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

- As spontaneous data do not necessarily refer to proven side effects, you should refer to the product information for the medicine which can be found here: [MHRA Products | Home](#) for details on the possible side effects.

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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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>