

Statement re:

Dysport

Statement Regarding the Use of Dysport® at Elements Medical

At Elements Medical, client safety and trust are at the heart of everything we do. We want to address the concerns raised regarding the use of Dysport® sourced directly from an approved pharmaceutical supplier in Turkey and provide reassurance about the actions we have taken to ensure full compliance of all regulations.

About Dysport®

Dysport® is a prescription medication derived from botulinum toxin type A, used widely for therapeutic and aesthetic purposes. It works by relaxing muscles through temporarily blocking nerve signals.

Dysport® is manufactured by Ipsen, a trusted pharmaceutical company, at its primary production facility in Wrexham, United Kingdom. This state-of-the-art facility supplies Dysport® to global markets, **including Turkey**, under strict quality and safety protocols. Follow this **link** for more details.

While Dysport® is licensed for use in over 90 countries worldwide, we were unaware that Dysport® manufactured here in the UK but intended for use in clinics/hospitals in Turkey, is not licensed for use in this country.

Procurement Background, Licensing and Regulatory Oversight

Historically, we sourced Dysport® intended for the Turkish market through a UK aesthetic pharmacy, ensuring compliance with all regulations. However, when this supplier faced procurement challenges, we sourced the product <u>directly</u> from an authorised pharmaceutical supplier in Turkey. This decision was made in good faith, based on our prior experience of the use of this product, and we did not appreciate that sourcing Dysport® directly (instead of going through a UK pharmacy) required a specific import licence.

MHRA Regulatory Compliance and Current Practice

Upon receiving an enquiry from the Medicines and Healthcare products Regulatory Agency (MHRA), we immediately implemented robust measures to ensure strict adherence to all regulations. To guarantee full compliance, the remaining Turkish Dysport was taken to a local pharmacy on 11th October 2024 for destruction, and we can confirm that all botulinum toxin since then, has been sourced exclusively from UK aesthetic pharmacies. The MHRA has confirmed that, as a result of these actions, they consider the matter now closed.

Assurances About Safety and Quality

We want to reassure our clients that the Dysport® in question was a genuine, high-quality product manufactured by Ipsen, the same company responsible for producing Dysport® for the UK market, and at no point was their safety compromised.

Additionally, the integrity of the Dysport® product itself was never in question. Ipsen's manufacturing processes guarantee consistency and quality across all markets, and there was no difference in the formulation or safety of the product provided.

Commitment to Excellence

Client safety and regulatory compliance remain our highest priorities. We deeply regret any concerns this situation may have caused and are committed to maintaining the highest standards of care and transparency. Your trust in us is invaluable, and we are grateful for the opportunity to serve you.

Should you have any further questions or concerns, our team is here to provide personalised reassurance and information. Please do not hesitate to contact us at info@elements.org.uk