# 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<sup>®</sup> sourced from Turkey and provide reassurance about the actions we have taken to ensure full compliance and maintain the highest standards of care.

## About Dysport®

Dysport<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> to global markets, including Turkey, under strict quality and safety protocols.

## Licensing and Regulatory Oversight

While Dysport<sup>®</sup> is licensed for use in over 90 countries worldwide, we were unaware that Dysport<sup>®</sup> manufactured in the UK but intended for the Turkish market is not licensed for use in this country. Additionally, we did not appreciate that sourcing Dysport<sup>®</sup> directly from an authorised pharmaceutical supplier in Turkey required a specific import licence.

#### **Procurement Background**

Historically, we sourced Dysport<sup>®</sup> 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 directly from an authorised supplier in Turkey. This decision was made in good faith, based on prior experience of the use of this product, but we were not aware of the specific licensing requirements for this process.

#### **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, all remaining Turkish Dysport was taken to a local pharmacy on 11<sup>th</sup> October 2024 for destruction, and we now source all botulinum toxin products, including Dysport<sup>®</sup>, exclusively from UK-licensed 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<sup>®</sup> in question was a genuine, high-quality product manufactured by Ipsen, the same company responsible for producing Dysport<sup>®</sup> for the UK market, and at no point was their safety compromised.

Additionally, the integrity of the Dysport<sup>®</sup> 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 <u>info@elements.org.uk</u>