



# Global hub for Botox! Why Ireland is leading the way

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Ireland develops and produces approximately 80% of the world's Botox, our Corporate team explain why Ireland is a destination of choice for Botox production worldwide.

## What is Botox?

'Botox' is a trademarked brand name which has become the catch-all term for a biological product, made from botulinum neurotoxin type A. While Botox is primarily known for its use in non-surgical anti-aging treatments, the majority of Botox sales are for therapeutic medical treatments including for cerebral palsy, spinal injuries, multiple sclerosis and chronic migraines. Two newer botulinum products, Dysport and Xeomin, are starting to gain popularity, though Botox still leads with 70% market share.

Ireland develops approximately 80% of the world's Botox through the company Allergan. Allergan's Westport, Co. Mayo site gives the town (population approximately 7,000) the title of 'Botox capital of the world'. The pharmaceutical firm first opened in Westport in 1977 and employs approximately 1,700 people. Allergan was acquired by pharma giant Abbvie in 2020 for €58 billion, the same year it opened a new €145 million research and development plant.

In 2023 it was reported that sales of Botox from this plant rose to US\$4.88 billion. Botox from Westport ultimately reaches 96 countries around the world.

## Regulatory framework

The Health Products Regulatory Authority (HPRA) is central to Ireland's regulatory environment, ensuring that pharmaceutical products meet stringent safety, efficacy, and quality standards. The HPRA's mandate includes the approval of manufacturing facilities, oversight of clinical trials, and monitoring of adverse reaction reporting, among other responsibilities.

## Legislation governing Botox administration

In Ireland, the administration of Botox for both cosmetic and therapeutic purposes is tightly regulated. The Irish Medicines Board Act 1995 (the Act), along with its subsequent amendments and regulations, outlines the legal framework for the prescription, sale, and administration of medicines that are available by prescription-only. Under the Act, Botox is classified as a prescription-only medication. Specific provisions ensure that only qualified healthcare professionals can administer Botox, aiming to protect patients from potential harm and ensure treatments' efficacy and quality standards.

## Challenges in regulation and enforcement

Despite the robust regulatory framework, challenges persist, particularly in the cosmetic sector. The rise of non-surgical cosmetic procedures has outpaced specific regulatory provisions, leading to instances of unauthorised individuals administering treatments.

In recent enforcement actions within Ireland's cosmetic treatment sector, a beautician based in Dublin was fined €10,000 for illegally administering Botox-like treatments. The case revealed the risks associated with unauthorised treatments, specifically adverse patient reactions.

The debate over who should administer Botox and fillers is ongoing. Some argue for expanded eligibility beyond medical professionals, citing the need for broader access to treatments. Others, noting the influx of non-FDA approved products, call for tighter regulations to safeguard patient safety and maintain treatment integrity. These instances underscore the challenges and complexities of regulating cosmetic treatments in Ireland, which require balancing accessibility and safety.

## Future directions in regulation

The evolving landscape of cosmetic treatments, including Botox and dermal fillers, has prompted calls for tighter regulation. Proposed legislative changes, such as the Patient Safety (Licensing) Bill, 2016, aim to address these challenges by establishing clearer guidelines and stricter oversight mechanisms. Yet, eight years following its introduction, it has yet to be enacted. In March of this year, former Taoiseach, Leo Varadkar, stated there was a need for further regulation in the area, revealing that tighter legislative frameworks are currently being drafted to address these concerns.

## Ireland's competitive advantage

Ireland's attractiveness to multinational pharmaceutical companies is multifaceted, encompassing a favourable corporate tax regime, a skilled workforce, and a strong educational emphasis on science and engineering. The country's membership in the European Union further facilitates the free movement of skilled professionals, augmenting its talent pool.

These factors, combined with a reputable regulatory system, have made Ireland a global hub for pharmaceutical manufacturing, including Botox. In the past 10 years, investments of some €10 billion have been made into biopharmaceutical facilities across the country. There are more than 75

biopharmaceutical companies located in Ireland, many of which have multiple sites. This sector accounts for 60% of the country's exports.

Ireland's legal and regulatory frameworks play a critical role in its prominence in the global Botox market. The country's comprehensive approach to pharmaceutical regulation, coupled with its strategic advantages, positions it as the key player in the industry. For more information about these developments in the pharmaceutical market contact a member of our team via their contact details below.

## About Ogier

Ogier is a professional services firm with the knowledge and expertise to handle the most demanding and complex transactions and provide expert, efficient and cost-effective services to all our clients. We regularly win awards for the quality of our client service, our work and our people.

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