

Review

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Review

Hyaluronidase Access in 2025: When Regulatory Reality Undermines Clinical Safety in Aesthetic Medicine

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Abstract

Background: Hyaluronic acid (HA) fillers are among the most commonly performed aesthetic procedures worldwide. Hyaluronidase is the sole enzymatic antidote capable of reversing HA filler-related vascular occlusion, a rare but potentially vision- and tissue-threatening complication. Established international guidelines uniformly endorse immediate hyaluronidase availability as a non-negotiable safety requirement. **Objective:** This evidence-informed narrative and perspective review examines the mismatch between clinical standards mandating hyaluronidase availability and the real-world access constraints facing practitioners in 2025, with focus on the European and German regulatory environment. **Methods:** A review of peer-reviewed literature, clinical guidelines, regulatory documentation, and expert consensus statements was conducted. Grey-literature sources and institutional notifications are incorporated where they constitute the most current available evidence. AI-assisted language tools were used in the preparation of this manuscript for drafting and editorial refinement. All content was reviewed, verified, and approved by the authors, who take full responsibility for the accuracy and integrity of the final text. **Results:** Access barriers documented in official shortage registers, professional society notifications, and regulatory reports include restrictive prescription frameworks, fragmented supply chains, and regulatory classifications that do not reflect hyaluronidase's emergency rescue function. These barriers are particularly pronounced in Germany: BfArM officially documented Hylase® Dessau shortages across 2023, and in June 2025 the DGHO notified clinicians that the manufacturer had ceased production entirely. The clinical consequence is a safety paradox: advances in filler technology have not been matched by equivalent improvements in reversal agent accessibility, with direct implications for patient safety, practitioner liability, and the reversibility principle underpinning modern aesthetic medicine. **Conclusions:** Regulatory frameworks governing hyaluronidase must be re-evaluated in light of its life-saving function. Targeted policy reform, structured access models, and mandatory training integration are needed to align regulatory structures with clinical standards of care.

Keywords: hyaluronidase; dermal fillers; hyaluronic acid; vascular occlusion; aesthetic complications; regulatory access

1. Introduction

Injectable hyaluronic acid (HA) fillers are among the most widely performed aesthetic procedures globally, with an estimated 5–6 million treatments administered annually in Europe alone. Their popularity reflects a favorable combination of immediate results, biocompatibility, and reversibility. Yet this reversibility is not an inherent property of the filler itself—it depends entirely on the availability of a single enzymatic agent: hyaluronidase.

Hyaluronidase is an endoglycosidase capable of degrading HA by cleaving glucosaminidic bonds. It is the only pharmacological intervention capable of dissolving HA filler deposits rapidly and predictably, with its most critical application in the management of filler-induced vascular occlusion—a complication that, while uncommon, can result in tissue necrosis, permanent visual impairment, or blindness if not treated urgently.

The centrality of hyaluronidase to safe filler practice has been recognized and codified in guidelines issued by major aesthetic medicine societies over the past decade. These guidelines, alongside expert consensus statements, are unambiguous: hyaluronidase must be immediately available at any site where HA filler injections are performed. This is not a recommendation to be balanced against logistical convenience—it is a fundamental safety prerequisite. Against this background, a troubling mismatch has begun to emerge. Across multiple practice settings, particularly in Germany and parts of continental Europe, access difficulties have been documented in professional society communications, regulatory reports, and practitioner surveys, reflecting documented failure to meet emergency preparedness requirements. This difficulty reflects a combination of changes to prescription frameworks, supply chain fragility, and regulatory classifications that treat the agent according to its routine dermatological indications rather than its emergency rescue function. In practical terms, the reversibility of HA fillers, long considered an unconditional safety feature, has become a conditional one—contingent on whether hyaluronidase happens to be available at the moment it is needed. This review examines the clinical role of hyaluronidase, characterizes the emerging access landscape in 2025, explores the safety paradox this situation creates, and proposes a framework for addressing the gap between regulatory structures and clinical necessity.

2. Standard of Care: Hyaluronidase in Complication Management

DeLorenzi (2014) established the mechanistic basis of filler-induced vascular events and identified hyaluronidase as the primary therapeutic response. Beleznyay and colleagues (2015, updated 2019) catalogued HA-related occlusive events and reinforced that hyaluronidase administration at high doses and without delay is the single most consequential intervention available. Vascular occlusion arises from either direct intravascular injection or extrinsic vessel compression by surrounding filler material. The internal carotid artery's ophthalmic branch and its terminal tributaries—in particular the central retinal artery—are of special clinical concern: retinal ischemia may produce irreversible damage within 60–90 minutes, and any administrative or logistical delay in obtaining hyaluronidase directly reduces the probability of a favorable outcome. In cases of suspected vascular compromise, the agent must be physically present at the point of treatment; access via a distant pharmacy is not clinically adequate.

International guidelines reflect this urgency with notable consistency. The British College of Aesthetic Medicine (BCAM) and the British Association of Dermatologists have published guidance mandating on-site hyaluronidase availability for all HA filler practitioners. The ACE Group has further detailed emergency management protocols in which immediate hyaluronidase injection—often at doses of 1,500 IU or more at the site of occlusion, with repeat dosing if required—constitutes first-line intervention. The European Dermatology Forum (EDF) similarly endorses hyaluronidase preparedness as a standard of care requirement rather than an optional enhancement. Expert consensus statements published in the *Journal of Cosmetic Dermatology and Aesthetic Surgery Journal* have reinforced these positions repeatedly. This consensus is further substantiated by converging recent evidence: Kroumpouzou and Treacy (2024) confirmed that immediate treatment is essential for emergent complications and identified persistent dosing variability as a patient safety concern, while the scoping review by Borzabadi-Farahani et al. (2024) mapped the controlled evidence base across the full spectrum of filler complications—including vascular occlusion, blindness, and delayed nodules—and identified significant gaps in standardised dosing protocols that underscore the need for structured practitioner preparedness.

Beyond vascular emergencies, hyaluronidase plays an important secondary role in managing delayed hypersensitivity reactions, biofilm-associated nodules, filler migration, and overcorrection—indications that collectively reinforce the paradigm of reversible aesthetic medicine, which assumes that the means of reversal are reliably obtainable.

3. Clinical Reality in 2025: Emerging Access Barriers

Despite the clarity of clinical guidance, the real-world accessibility of hyaluronidase in 2025 does not uniformly reflect the standards described above. Access barriers have been documented in professional society communications, practitioner surveys, and regulatory notifications across Europe, with particular prominence in Germany, reflecting a documented failure to meet emergency preparedness requirements. These observations are as yet incompletely represented in indexed peer-reviewed literature, which itself reflects the speed with which this issue has emerged, but the convergent signals from multiple institutional and regulatory sources point to a coherent set of systemic problems.

3.1. Prescription Status and Regulatory Classification

In Germany, hyaluronidase preparations (most commonly Hylase® Dessau) require a physician's prescription. This requirement is not inherently problematic where prescribing practitioners treat their own patients in an ambulatory setting. However, complications arise at the regulatory and institutional margins. Non-physician aesthetic practitioners operating in supervised settings, or performing HA filler procedures under delegated models, face structural difficulties in maintaining an independent hyaluronidase stock. More significantly, the increasingly strict interpretation of prescription dispensing in Germany, combined with periodic pharmacy shortages, has introduced delays that are incompatible with the emergency timeline required for vascular occlusion management. The situation is further complicated by the German Apothekenpflicht (pharmacy obligation), which mandates exclusive dispensing through licensed pharmacies, preventing prospective on-site emergency stock in the manner used for other antidotes. While exemptions and workarounds exist in practice, the regulatory framework does not explicitly accommodate the emergency-preparedness function of hyaluronidase, creating a gray zone that practitioners must navigate without formal regulatory guidance.

The broader regulatory deficit is increasingly acknowledged by professional societies. The DGÄPC, in its 2025 annual statistics report, documented rising domestic complication rates and a marked market shift toward less qualified providers, prompting formal calls for a statutory Facharztvorbehalt (specialist reservation) for injectable treatments. The GÄCD has similarly advocated for stricter qualification requirements and discussed prescription-only status for dermal fillers—a step that would further affect hyaluronidase access architecture.

3.2. Supply Chain Fragility

Independent of regulatory classification, hyaluronidase has been subject to intermittent supply shortages across European markets, attributed to manufacturing consolidation and the product's small commercial footprint. Supply disruptions in Germany, Austria, and Switzerland have been documented in pharmacy databases and official shortage registers. The situation escalated critically in mid-2025: in June 2025, the DGHO formally notified its members that the manufacturer of Hylase® Dessau—the sole commercially available hyaluronidase preparation in Germany—had ceased production, with remaining stocks limited and no information available on future supply. The BfArM had already recorded official shortage notifications for Hylase® Dessau 150 IU and 300 IU across 2023, confirming that supply instability is an escalating structural problem rather than an isolated event. A practitioner who discovers an expired or unsupplied stock may have no mechanism to remedy this before a scheduled procedure.

3.3. Comparative International Landscape

Access conditions vary significantly across jurisdictions. In the United States, multiple preparations (Vitrase®, Amphadase®, Hylenex®) are supported by standardised emergency preparedness protocols integrated into training curricula. In South Korea, one of the world's highest-volume injectable markets, hyaluronidase preparedness is explicitly addressed in professional training frameworks, including mandatory simulation training for filler practitioners. This model provides a template for integrating emergency agent availability into the regulatory fabric of aesthetic practice. In the United Kingdom, following a public consultation in 2023, the Department of Health and Social Care published its response in August 2025, explicitly proposing that any cosmetic procedure involving a prescription-only medicine (POM)—including the adjunctive use of hyaluronidase for managing filler complications—must be overseen by a qualified and regulated healthcare professional. The scheme, with implementation expected through 2025 and 2026, formally anchors hyaluronidase access within the practitioner licensing framework and treats emergency preparedness as a regulatory obligation rather than a professional recommendation.

By contrast, Germany and several other continental European jurisdictions have not yet integrated hyaluronidase availability into any formal regulatory framework for aesthetic practice. The result is a system that relies entirely on voluntary guideline adherence, without enforcement mechanisms or structured access pathways. Given the documented fragility of supply chains and the complexity of prescription frameworks, voluntary adherence is an insufficient guarantee of emergency preparedness. This regulatory gap is particularly consequential because it is asymmetric: the procedures that create the risk of vascular occlusion are commercially promoted and widely performed, while the agent required to manage that risk has no comparable regulatory or commercial infrastructure supporting its availability.

4. The Safety Paradox: Safer Fillers, Less Safe Practice

The past decade has witnessed genuine advances in filler safety. Improvements in product formulation—including lidocaine-containing HA gels, cross-linking technologies that reduce migration risk, and an expanded understanding of optimal injection planes and volumes—have contributed to a progressive reduction in acute complication rates. Practitioner training has improved, anatomical education has become more sophisticated, and the culture of complication awareness within the aesthetic community has matured substantially. This progress, however, creates a potentially dangerous assumption: that safer products translate directly into safer outcomes.

The clinical safety architecture of HA filler medicine rests on two distinct pillars. The first is prevention: product quality, technique, training, and anatomical knowledge. The second is rescue: the ability to reverse a complication when it occurs. No advance in prevention eliminates the residual risk of vascular occlusion; the incidence may decrease, but it does not reach zero. Belezny et al. (2019) document continued cases of vision loss and blindness associated with HA filler injection across all practitioner experience levels. The safety paradox can be stated precisely: if the probability of a vascular occlusion event is 1 in 10,000 procedures, and 500,000 procedures are performed annually in Germany alone, the expected number of such events is approximately 50 per year—each requiring immediate hyaluronidase access for optimal management. If that access is unreliable, the statistical improvement in complication rates achieved through better products and training is partially negated by a preventable increase in outcome severity when complications do occur.

This logic is not novel; it is precisely the reasoning that underlies the requirement to maintain emergency medications in any setting where acute adverse events are a recognized risk. Emergency pharmacies maintain epinephrine; dental practices maintain atropine; anaesthetic suites maintain specific reversal agents for neuromuscular blockade. The principle that the availability of reversal agents is a non-negotiable component of procedural safety is consistent across medicine. Aesthetic medicine is not exempt from this principle, yet its regulatory framework in many European jurisdictions does not yet reflect it.

5. Clinical Consequences of Restricted Access

5.1. Patient Safety

The most immediate consequence of restricted hyaluronidase access is delayed treatment of vascular occlusion. Time is the critical variable in filler-induced arterial and venous occlusion management. Every minute between the onset of occlusion and hyaluronidase administration represents additional ischemic damage. In cases involving the ophthalmic artery or its tributaries, the therapeutic window may be as short as 60–90 minutes for complete visual recovery. Where this window passes without treatment—due to an unavailable supply, a delayed prescription, or logistical barriers to emergency dispensing—the clinical outcome will be permanently worse than with timely access. For soft tissue necrosis, the consequences of delayed treatment are similarly severe, though the timeframe is somewhat longer. Delayed hyaluronidase administration in cases of skin ischemia (characterized by livedo reticularis, blanching, or dusky discoloration at the injection site) increases the probability of full-thickness necrosis, scarring, and long-term deformity. These outcomes represent serious and, in principle, preventable treatment failures.

5.2. Medicolegal Implications

The medicolegal dimensions of inadequate hyaluronidase preparedness are substantial and are becoming more clearly defined as case law and regulatory guidance evolve. In jurisdictions where guidelines explicitly mandate hyaluronidase availability, a practitioner who administers HA filler without on-site access to the reversal agent may be found to have practiced below the accepted standard of care. Even where no explicit regulatory mandate exists, the consistent international guideline consensus constitutes a body of expert opinion that courts and medical regulatory bodies are likely to treat as determinative. The burden of proof in such cases may effectively shift to the practitioner to demonstrate that unavailability was genuinely beyond their control—a difficult argument to sustain when guidelines are clear and the product is commercially available.

5.3. The Reversibility Principle

If reversibility is contingent on an agent that is not reliably accessible, the informed consent process becomes ethically compromised. Patients consent to a procedure marketed as reversible; if hyaluronidase is unavailable at the time of treatment, that consent may be materially flawed. This is not merely an academic concern: legal and ethical grounds may exist for patients to argue misrepresentation of a key safety feature.

6. Why This Gap Exists: Regulatory Logic Versus Clinical Reality

Understanding why the access gap exists requires examining the logic by which regulatory frameworks classify and control pharmaceutical agents. Regulatory systems are designed primarily around product safety—the prevention of harm arising from inappropriate or unsupervised use of medicinal substances. For prescription-only medications, the central concern is that the prescribing physician exercises clinical judgment and bears responsibility for therapeutic decisions. This logic is appropriate and well-founded for the overwhelming majority of clinical contexts. The problem arises when this logic of prescribing control is applied uniformly to agents whose primary function is emergency reversal rather than elective therapy. Hyaluronidase in aesthetic medicine is not prescribed for its direct therapeutic effect; it is maintained as an emergency antidote. Its mode of use in vascular occlusion is analogous to epinephrine in anaphylaxis: the prescribing decision has effectively been made in advance, the clinical threshold for use is clear, and the only variable is whether the agent is physically present at the moment it is needed. Regulatory frameworks that do not distinguish between elective prescribing and emergency preparedness will predictably create access barriers that are clinically irrational. The classification of hyaluronidase as a routine prescription medication—subject to standard pharmacy dispensing requirements without

emergency-stock exemptions or streamlined access pathways—reflects a regulatory logic that was not designed with its emergency function in mind.

A secondary factor is the commercial structure of the hyaluronidase market. Unlike HA fillers, which represent a major commercial enterprise with substantial industry investment in practitioner education and regulatory engagement, hyaluronidase is a low-volume, low-margin product with limited commercial advocacy. This asymmetry means that when regulatory frameworks are developed or revised, the interests of filler manufacturers are well-represented, while the clinical need for hyaluronidase access receives comparatively little attention. The structural consequences are now documented in professional society data: the DGÄPC 2025 statistics report a growing shift of filler treatments toward less qualified providers, rising domestic complication rates, and an explicit call for statutory regulation. In a market where a growing proportion of procedures are performed by practitioners without formal emergency management competency, the probability of absent or delayed hyaluronidase use in the event of a vascular complication is correspondingly elevated.

7. What Needs to Change: Practical Solutions

7.1. Regulatory Reclassification of Emergency-Use Access

The most impactful single change would be the formal recognition, within national pharmaceutical and healthcare frameworks, that hyaluronidase serves an emergency rescue function in aesthetic medicine. This recognition should translate into practical mechanisms: explicit exemptions permitting licensed aesthetic medicine practitioners to maintain pre-stocked emergency supplies without individual prescription requirements for each patient; expedited dispensing pathways through pharmacy networks; and clear regulatory guidance on what constitutes adequate emergency preparedness in filler practice. Models exist within medicine for managing emergency medications in non-hospital settings. The analogy to epinephrine auto-injectors in schools, or to glucagon in diabetic management, is instructive: emergency agents can be maintained outside hospital pharmacies, with appropriate training and oversight, when the clinical case is clear. A similar framework for hyaluronidase in aesthetic medicine settings is technically achievable and operationally necessary.

7.2. Integration into Licensing and Credentialing

Following the UK model, hyaluronidase preparedness should be an explicit criterion for aesthetic practice authorization. As licensing frameworks develop across Europe, mandatory on-site availability should be an enforceable standard rather than a professional recommendation.

7.3. Training Integration

Mandatory training in filler complication recognition and emergency management—including hyaluronidase administration techniques, dosing protocols, and the anatomical basis of occlusion events—should be a requirement for all practitioners performing HA filler injections. Such training exists and is delivered by several professional societies, but it is not universally required. Embedding emergency preparedness competency into training frameworks ensures that practitioners understand not only that hyaluronidase is needed, but how to obtain and use it effectively under pressure.

7.4. Supply Chain Resilience

Professional societies, regulatory bodies, and healthcare authorities should engage with hyaluronidase manufacturers and distributors to address the structural fragility of the supply chain. Given the small commercial volume but high clinical stakes associated with this product, there may be a case for strategic stock maintenance arrangements analogous to those used for other low-volume, high-criticality medications. At a minimum, practitioners should be advised to maintain a sufficient

on-site supply buffer, and regulatory frameworks should be revised to permit this without placing practitioners at legal risk.

8. Discussion

The argument presented in this review rests on a convergence of well-established clinical evidence, consistent guideline consensus, and access difficulties documented in official shortage registers, professional society notifications, and regulatory reports. Its principal limitation is the same as its principal motivation: the access problem described here is recent, rapidly evolving, and as yet incompletely represented in indexed peer-reviewed literature. Many of the relevant regulatory developments—including the cessation of Hylase® Dessau production and the UK licensing consultation response—have occurred within the past two years, a timeframe in which indexed literature cannot reasonably be expected to have caught up. The evidence base is therefore fragmented, drawing substantially on grey literature—professional society publications, BfArM notifications, and institutional communications—where these constitute the most current available evidence.

This pattern is not without precedent. Regulatory and safety issues in medicine have consistently generated institutional responses before indexed literature catches up; early warning systems for hospital deterioration offer a comparable example. The core clinical argument—that immediate hyaluronidase availability is essential for safe filler practice—is itself established beyond reasonable scientific dispute, as affirmed by Borzabadi-Farahani et al. (2024) and Kroumpouzou and Treacy (2024). What remains inadequately addressed is the regulatory and supply infrastructure required to give that principle practical effect.

The international comparisons presented are illustrative rather than systematic. A rigorous comparative analysis of hyaluronidase regulatory frameworks across EU member states, the UK, the US, and Asia-Pacific markets would provide the empirical foundation for targeted policy recommendations; this represents an important priority for researchers and professional societies. The medicolegal dimensions of this issue warrant particular attention. As guideline frameworks become increasingly explicit about hyaluronidase requirements, and as regulatory licensing models in some jurisdictions move toward enforceable preparedness standards, the gap between best practice and common practice creates a liability landscape that is unfavorable for practitioners and ultimately for patients. Professional indemnity organizations and medical defense bodies should consider whether existing guidance on hyaluronidase preparedness is adequate. Finally, the argument presented here has implications beyond hyaluronidase specifically. It raises the broader question of how emergency preparedness requirements should be structured for any procedure carrying a risk of acute-onset, irreversible adverse events. Filler-induced vascular occlusion is not the only such risk in aesthetic medicine: vasovagal syncope, systemic allergic reactions, and local anaesthetic toxicity all require immediate pharmacological responses. The framework of emergency preparedness as a regulatory requirement—not merely a guideline recommendation—is one whose time has come in aesthetic medicine more broadly.

9. Conclusions

Hyaluronidase is not merely a useful adjunct in the management of HA filler complications; it is the singular pharmacological agent capable of reversing potentially catastrophic vascular events in a time-critical context. The clinical evidence for its essential role is consistent and well-established. The international guideline consensus mandating its immediate availability is clear and unambiguous, and is now corroborated by converging independent reviews.

The emergence of access barriers in 2025—arising from regulatory classification frameworks, supply chain fragility, and the absence of emergency-preparedness mandates across much of Europe—creates a genuine safety paradox. Advances in filler technology do not compensate for the

inability to reverse a complication when it occurs. A treatment marketed and consented to as reversible must be reversible in practice, not merely in principle.

Addressing this gap requires coordinated action from regulatory authorities, professional societies, practitioners, and the pharmaceutical supply chain. The models exist and have been implemented in analogous procedural contexts. The aesthetic medicine community in Europe, and in Germany specifically, would benefit from engaging with these models proactively. The reversibility of HA fillers must be substantiated in practice—available, immediate, and reliably maintained—rather than remaining practically constrained by supply and regulatory conditions at the time of treatment.

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