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Navigating Different Regulatory Pathways For Your Health Product

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The Global Regulatory Maze: Your Product's Claims vs. Its Path to Market

- A product's intended use and claims directly determine its regulatory classification and the evidence required for approval.

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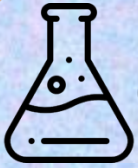
The Regulatory Conundrum: What Pathway to Choose?



Your product
(e.g. Hyaluronic Acid Serum)

Are you making a therapeutic claim to affect the body's structure, function, or to treat/prevent a disease?

YES

Medicine

NO

Device

NO

Complementary medicine/NHP

NO

Cosmetics

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The Drug Pathway: The Highest Bar for Entry

- **Intended Use & Claims:** Products that claim to cure, mitigate, or prevent a disease (e.g., "Hyaluronic Acid heals joint damage").
- **Required Evidence:** Full, multi-phase human clinical trials. This includes proving both safety and efficacy in a defined patient population.
- **Mode of Action (MoA):** The product must have a pharmacological, metabolic, or immunological MoA.
- **Verdict:** This path offers the strongest claims but is a massive investment of time and capital.

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The Medical Device & NHP Pathways: The Middle Ground

Medical Device:

- **Intended Use & Claims :** To achieve a therapeutic purpose through a physical or mechanical mode of action, such as a dermal filler to correct facial wrinkles (e.g. " Hyaluronic Acid adds volume to correct nasolabial folds")
- **Required Evidence:** Demonstrating safety and performance through technical documentation and biocompatibility data.

Natural Health Product (NHP, CA) / Complementary Medicine (AU):

- **Intended Use:** For low-level health claims, often based on traditional use or pre-existing scientific data (e.g. "Helps support overall skin health.")
- **Required Evidence:** Listed as a NHP in Canada. Submission of a dossier to a regulatory body (like Health Canada) with data on safety, quality, and efficacy, which can be a combination of scientific literature and traditional use evidence.

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The Cosmetic & Wellness Pathways: The Lowest Regulatory Burden

Cosmetics:

- **Intended Use & Claims:** For beautifying, cleansing, or altering the appearance (e.g., a serum that visibly plumps skin or reduces the appearance of fine lines).
- **Required Evidence:** Does not require pre-market approval, but needs a registration. Claims must be supported by scientific substantiation but not allowed to make therapeutic claims about a disease or altering the body's structure or function.

Wellness (US):

- **Intended Use & Claims:** To promote a healthy lifestyle without any therapeutic purpose (e.g. "Supports your wellness journey")
- **Required Evidence:** Not a regulated category. No pre-market approval, and no mandatory registration.

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Strategic Choice: The Commercial Trade-Off

There is a direct trade-off between the strength of your claims and the regulatory burden you will face:

- For strong therapeutic claims, the only path is a full drug development program.
- For faster market entry, the best path is to carefully craft low-level claims that fit the cosmetic (non-therapeutic), NHP (general health), or medical device (physical mode of action) categories.

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Your Market Access Partner: Bridging the Regulatory and Access Strategy

- **Integrated Strategy:** We provide a unified approach that connects regulatory strategy directly to your market access and commercial goals.
- **Early-Stage Insight:** Our expertise in regulatory pathways helps you identify and mitigate risks at the earliest stages of product development, avoiding costly delays and ensuring a more efficient path to market.
- **Maximizing Value:** We translate approved claims and evidence into a compelling value proposition for payers and customers, ensuring your product is positioned for success.
- **The Path Forward:** Let's discuss how a smart regulatory strategy can build a foundation for a powerful and profitable market access plan.
- **And more:** www.sur-access.com

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