

Why Capsules Could Be the Future of Inhalation

Why the Next-Generation Capsule Inhaler (NGCI) creates a third strategic choice

The industry is asking the wrong question.

The choice is not simply pMDI or MDPI. It is which delivery architecture best serves the molecule, the patient and the market — without importing avoidable complexity.

Three architectures. Three different burdens.

	pMDI	MDPI	NGCI
WHAT IT DOES WELL	Familiar, compact and capable of reliable delivery without high inspiratory effort.	Propellant-free, breath-actuated and well established across major respiratory classes.	A visible capsule, potentially simpler device architecture and a reusable route across selected molecules.
PRESSURE POINT	Low-GWP reformulation, component change, filling capacity, supply continuity and market-by-market approval.	Device-formulation coupling, flow dependence, engineered powders, moisture control, strips/blisters and replication burden.	Must prove dose suitability, robust aerosol performance across realistic flow profiles, usability, stability and scalable manufacture.
STRATEGIC READ	Essential format — but the transition is a portfolio and capital-allocation problem, not a propellant swap.	Strong format — but propellant-free does not automatically mean simple, low-cost or easy to genericise.	Not a universal replacement. A third option where capsule delivery removes more complexity than it creates.

The slips and trips already visible

Treating low-GWP as a formulation exercise. It also changes components, capacity, validation, supply agreements, economics and regulatory sequencing.

Assuming every market moves together. Evidence expectations and approval timing will diverge; portfolio gaps may appear before replacements are ready.

Calling every dry-powder solution simple. MDPIs can exchange propellant complexity for powder, strip, device and human-factors complexity.

Ignoring the patient in an architecture debate. Technique, inspiratory flow, handling and switching support remain decisive; no single format suits everyone.

Confusing an in-vitro result with a product. Equivalence, stability, usability, IP, manufacture, scale-up and market access still have to converge.

Overclaiming the platform. NGCI should win candidate by candidate — where it can demonstrate a better total system, not merely a different device.

Regulatory context: EU F-gas Regulation 2024/573 · EMA draft OIP therapeutic-equivalence guideline · FDA MDI/DPI quality considerations

OUR PREDICTION

pMDIs will remain. MDPIs will remain. But the assumption that they are the only sensible reference architectures will not. The next winners will match delivery technology to patient need and total-system economics. For selected products, NGCI could turn forced transition into strategic choice.

The capsule as a strategic choice

The Mirai™ platform puts this thinking into practice — a non-piercing capsule architecture that makes the opened capsule an active part of the aerosol pathway.