Technical Paper

INHALED PHARMACEUTICAL PRODUCTS

The Next-Generation Capsule Inhaler

Capsules Were Never the Problem. The Device Was.

Respiratory delivery platforms were optimised for yesterday's constraints. The market is now asking different questions.

Russell F. Spencer, Chief Commercial Officer, Knightpoint Group

In an era where respiratory products may generate billions in value while simultaneously facing procurement pressure, environmental scrutiny and generic erosion, platform economics can no longer be treated as secondary engineering consequences.

For decades, respiratory delivery innovation has largely moved in one direction: toward greater integration, greater complexity and tighter coupling between device, dose and proprietary ecosystem.

That evolution was rational.

It solved important technical, commercial and regulatory problems. It enabled highly successful respiratory franchises. It improved convenience, strengthened IP positions, reinforced originator lifecycle control and delivered clinically robust platforms at scale.

But optimisation is always contextual.

Markets change. Technologies evolve. Constraints shift.

The question is whether respiratory delivery strategy has evolved with them.

Because many of the assumptions that shaped today's inhalation platforms were built for a different era.

And increasingly, the pressures now shaping respiratory markets are not the same ones that originally drove platform selection.

The Platforms We Built Made Sense

Modern inhaled pharmaceutical delivery did not emerge by accident.

Nebulised systems solved obvious clinical problems. Metered dose inhalers brought speed, portability and mass-market usability. Multi-dose dry powder inhalers introduced convenience, integration and increasingly sophisticated proprietary device ecosystems.

Each generation solved something important.

But each generation also embedded assumptions.

Nebulised delivery assumed time, cleaning burden and workflow inefficiency were acceptable trade-offs for reliable administration.

pMDIs assumed propellant-based delivery remained strategically acceptable in exchange for clinical familiarity and scalable manufacturability.

Multi-dose dry powder inhalers assumed increasing device complexity was a rational price for proprietary control, convenience and lifecycle defensibility.

For many years, those assumptions held.

Today, some look less secure.

The Market Changed

Respiratory delivery platforms are now being evaluated under pressures that barely existed in their current form when many incumbent systems were conceived.

Those pressures are cumulative.

- ✓ Payer pressure
- ✓ Generic erosion
- ✓ Environmental scrutiny
- ✓ Supply chain fragility
- ✓ Capital discipline
- ✓ Reshoring and resilience agendas
- ✓ Active lifecycle management

- Healthcare affordability
- Strategic flexibility

This matters because respiratory delivery platforms are not neutral technical choices.

They define:

- manufacturing complexity
- capital burden
- supply chain architecture
- transfer friction
- generic accessibility
- environmental profile
- lifecycle economics
- strategic optionality

And increasingly, these second-order consequences matter as much as clinical performance.

Because some platforms that solved yesterday's problems may now be creating today's.

Nebules: Clinically Important, Operationally Burdensome

Nebulised delivery remains clinically relevant.

In acute care settings, specialist environments and specific patient populations, it continues to serve important purposes.

That is not in dispute.

The strategic question is whether nebulised delivery represents an efficient mainstream respiratory platform in a market increasingly shaped by convenience, adherence, workflow efficiency and cost discipline.

Here, the structural limitations are obvious.

- Administration times remain lengthy.
- Cleaning introduces friction and compliance burden.
- Portability remains compromised.

- Real-world patient adherence is imperfect.
- Workflow inefficiencies create hidden system costs.

Nebulised delivery remains clinically useful. But as a scalable mainstream respiratory architecture, it is increasingly difficult to argue it represents the strategic future.

pMDIs: Technically Excellent, Strategically Constrained

Few pharmaceutical delivery platforms have been as commercially and clinically successful as the pMDI.

The reasons are obvious.

- Fast
- Portable
- Clinically familiar
- Scalable
- Manufacturing ecosystems are mature
- Rescue-compatible
- Deeply embedded in physician and patient behaviour

That is real strategic strength.

But the platform now carries structural baggage.

The environmental challenge is obvious.

The move toward greener propellants is a meaningful response.

But it should be viewed honestly.

It is an adaptation—not necessarily a full strategic reset.

Because while GWPP addresses the propellant challenge, it does not fundamentally simplify the broader industrial architecture of the pMDI ecosystem.

The platform remains dependent on:

- specialist fill-finish infrastructure
- high qualification burden
- specialised manufacturing ecosystems

- capital-intensive supply chains
- technology transfer friction
- industrial complexity

GWPP may improve environmental positioning.

It does not automatically create a simpler respiratory future.

And simplification increasingly matters.

MDPIs: Elegant Originator Strategy, Difficult Lifecycle Inheritance

Multi-dose dry powder inhalers may represent one of the most sophisticated originator platform strategies pharma has ever developed.

They solved multiple challenges simultaneously:

- patient convenience
- dose certainty
- integrated user experience
- strong differentiation
- proprietary ecosystem control
- technical defensibility

For originators, this was strategically brilliant.

But lifecycle economics tell a different story.

Because once exclusivity erodes and 505 pathways emerge, the strategic equation changes.

The same complexity that once protected value becomes inherited burden.

- High component counts
- Complex tooling
- Assembly burden
- Manufacturing rigidity
- Tech transfer difficulty

- Elevated COGS
- Difficult generic replication
- Slow lifecycle flexibility

In effect, many MDPIs solved the originator problem exceptionally well.

They solved the lifecycle economics problem far less elegantly.

That distinction deserves more attention.

The Regulatory Misconception

A common objection is that moving away from incumbent multi-dose architectures automatically makes regulatory pathways harder or commercially impractical.

That is too simplistic.

For inhaled products, the critical question is not whether a future product visually or mechanically reproduces the incumbent device. The real question is whether the development programme can define, control and bridge the relevant performance and quality vectors.

That means understanding and demonstrating the relationship between:

- delivered dose
- aerodynamic particle size distribution
- MMAD and fine particle performance
- critical material attributes
- critical quality attributes
- device–formulation interaction
- patient-use and airflow behaviour

If those vectors can be properly mapped, justified and controlled, then differentiated respiratory architectures should not be dismissed simply because they do not replicate yesterday's device format.

This is especially important because capsule-based delivery was not an exotic exception to DPI development. Capsules were part of the original DPI foundation, and even today

important inhaled products continue to launch in capsule-based formats using first-generation piercing devices.

The strategic question is therefore not whether capsules are “regulatory impossible.”

They are not.

The strategic question is whether modern device engineering can remove the historical limitations of capsule systems while preserving or improving the performance vectors that matter.

The Capsule Misconception

This is where industry assumptions deserve challenge.

Capsule-based respiratory delivery has long been positioned as transitional, primitive or strategically inferior.

Historically, that criticism was understandable.

Traditional capsule inhalers often depended on destructive puncture systems.

- ✓ Capsules spun, rattled and behaved unpredictably
- ✓ Residual powder performance could be inconsistent
- ✓ Airway contamination concerns existed
- ✓ Patient usability could be suboptimal
- ✓ Airflow performance was often limiting

Taken together, the industry conclusion was straightforward: move beyond capsules.

But this may have been the wrong conclusion.

Because many of those limitations were not intrinsic failures of the capsule itself.

They were failures of the device systems built around the capsule.

That is not the same thing.

The industry may have concluded that capsules were the limitation when the true limitation was the delivery mechanism interacting with them.

That distinction is strategically significant.

If The Device Problem Changes, The Strategic Equation Changes

If historical capsule constraints can be materially addressed through modern device design, the strategic question changes completely.

Because capsules then stop being viewed as passive packaging constraints.

And start being reconsidered as active components of the delivery solution.

That changes everything.

- ✓ Manufacturability
- ✓ Capital burden
- ✓ Supply chain architecture
- ✓ Lifecycle flexibility
- ✓ Environmental logic
- ✓ Strategic optionality

A reimagined capsule-enabled respiratory platform could theoretically offer:

- ✓ simplified manufacturing
- ✓ lower capital intensity
- ✓ reusable platform models
- ✓ dose-device decoupling
- ✓ shorter supply chains
- ✓ greater lifecycle flexibility
- ✓ more credible generic economics
- ✓ higher payload potential
- ✓ improved sustainability logic

This does not mean capsules automatically become superior.

It means the category deserves strategic re-evaluation.

Beyond Cheap Generics

This is where the discussion becomes more interesting.

Capsule reconsideration should not be reduced to low-cost rescue economics.

That is far too narrow.

The more compelling strategic opportunity may lie in bridging segments that incumbent platforms increasingly handle imperfectly.

- ✓ Complex generics
- ✓ Lifecycle transition products
- ✓ Combination maintenance therapies
- ✓ Differentiated respiratory value products
- ✓ Higher payload concepts
- ✓ Potential future respiratory modalities

The strategic question is not whether capsules replace everything.

They will not.

The strategic question is whether the industry prematurely abandoned a category that may now solve problems its more complex successors increasingly struggle with.

That is a different conversation entirely.

Complexity Is Not Always Sophistication

Pharma often equates engineering complexity with strategic sophistication.

Sometimes that is justified.

Sometimes it is not.

Complexity can create:

- ✓ IP protection
- ✓ technical defensibility
- ✓ user differentiation
- ✓ barriers to competition

But complexity also creates:

- ✓ cost

- ✓ industrial fragility
- ✓ transfer burden
- ✓ environmental burden
- ✓ capital lock-in
- ✓ generic barriers
- ✓ strategic inertia

The question is not whether complex platforms are impressive.

Many are.

The question is whether they remain economically and strategically optimal under today's constraints.

That deserves honest examination.

A Bridge, Not A Replacement

The strongest strategic role for reimagined capsule-enabled respiratory delivery may not be wholesale replacement.

It may be strategic bridging.

- ✓ Between legacy small-molecule economics and next-generation respiratory innovation
- ✓ Between affordability and differentiation
- ✓ Between sustainability pressure and industrial practicality
- ✓ Between proprietary ecosystems and viable lifecycle competition
- ✓ Between historical respiratory assumptions and future platform flexibility

That is where the opportunity becomes most compelling.

Not nostalgia.

Not simplification for its own sake.

But adaptation to a fundamentally changed market.

The Real Question

The question is not whether historical capsule inhalers were imperfect.

They were.

The question is whether the industry incorrectly generalised from those imperfections.

If yesterday's device limitations no longer define what capsule-enabled respiratory delivery can become, then an important strategic assumption may deserve revision.

Respiratory delivery platforms were optimised for yesterday's constraints.

Today's market is asking different questions.

Perhaps respiratory strategy should too.

Reconsidering the capsule platform?

The Mirai™ platform puts this thinking into practice — a non-piercing capsule architecture that treats the opened capsule as part of the airflow pathway.