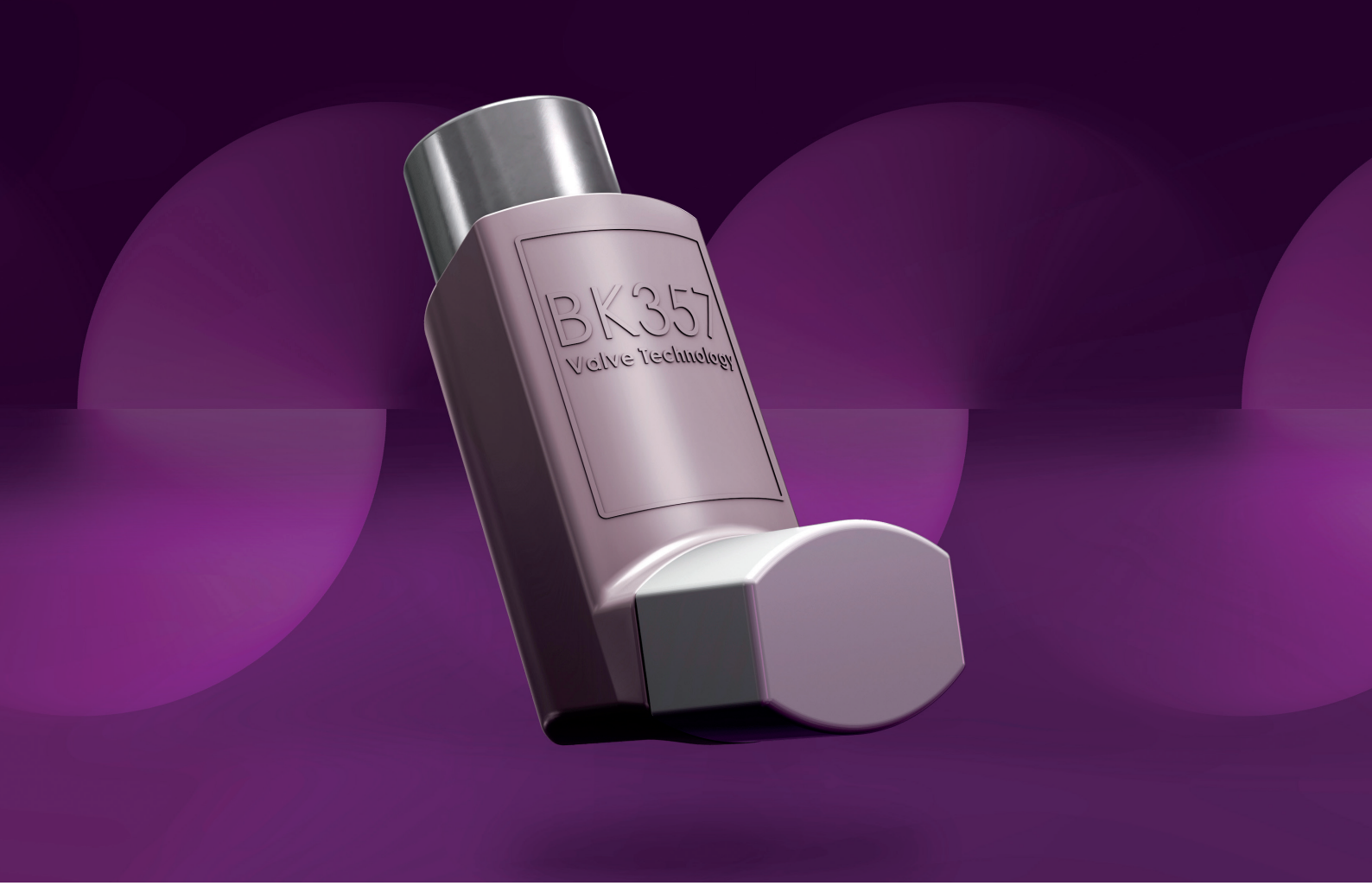

SHORTENING AND DECARBONISING THE INHALATION SUPPLY CHAIN

Louise Righton of **Bespak** examines the potential for reducing emissions across the pMDI supply chain, considering the localisation of suppliers to shorten supply chains as well as strong partnerships for developing novel, low-carbon alternatives to current high-emission pMDI manufacturing processes.

Maintaining the supply of critical medicines in the face of a changing world poses a growing challenge. From natural disasters and geopolitical events that disrupt supply chains to the increasing pressure to reduce greenhouse gas emissions, there is a clear need to optimise the production and supply of life-saving drugs and devices. Localising supply chains where the option exists, reducing emissions throughout the process and supporting the development of lower carbon products and drug delivery devices, are the key steps that Bespak, a specialist CDMO in the inhalation space, is already taking.

THE TEMPESTUOUS CLIMATE-HEALTHCARE FEEDBACK LOOP

When considering the future of drug delivery, the interplay between healthcare and the environment cannot be ignored. There are clear negative impacts of climate change on health – a key example being the impact of pollution on respiratory conditions – and yet, healthcare itself contributes significantly to pollution and greenhouse gas emissions.[1]

> "WHEN CONSIDERING THE FUTURE OF DRUG DELIVERY, THE INTERPLAY BETWEEN HEALTHCARE AND THE ENVIRONMENT CANNOT BE IGNORED."

The ever-evolving supply of vital medicines is enormously complicated and is therefore also vulnerable to disruption. For instance, there have been significant increases in the number of potential supply issue alerts raised in the UK between 2021 and 2023 due to various geopolitical factors.[2] Taking this into account, factors such as extreme weather events – increasing in severity and frequency due to climate change – pose an even greater threat to supply security.

With the health of the planet so inextricably linked with the health of the population, there is a clear and urgent need to decarbonise the value chains within healthcare systems. To this end, in the UK, the NHS has committed to becoming "carbon net zero" – a significant step given that it currently accounts for 4–5% of the UK's total carbon emissions.[3] Approximately 60–70% of this total is from supply chains across all operations – highlighting the importance of considering the full ecosystem, including aspects such as raw materials sourcing, processing, packaging and transportation.

Therefore, by working to shorten these supply chains – through more local sourcing rather than global value chains – emissions can be limited, while simultaneously building up more resilience to extreme climate-induced weather events and other disruptions. The scope of these changes is significant and different sectors must approach this in different ways. Within the pharma industry, CDMOs have a central role to play because of their connections across all stages of drug development and commercialisation, and their deep, often niche, industry expertise.

CONSIDERING THE INHALATION SUPPLY CHAIN

In the UK, around 25% of NHS carbon emissions are from medicines. Whilst the majority of these emissions result from the manufacture, distribution and use of medicines (20%), pressurised metered dose inhalers (pMDIs) alone are responsible for 3%.[4] This is due to the high global warming potential (GWP) of the propellant gases currently used in these devices. Reducing these emissions is not just a moral obligation for producers – evolving regulations have highlighted pMDIs as an area of focus, putting pressure on the inhalation supply chain to decarbonise.

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In fact, due to the evolving regulations impacting high-GWP propellant gases used across various industries, the supply chain will likely shrink, resulting in propellant scarcity and price increases before phasedown targets are close to being met for pMDIs. With this in mind, it is key to establish the capabilities and processes for manufacturing with the next generation of propellants and, in so doing, take opportunities to strengthen and decarbonise the entire supply chain. This will allow the industry to continue to provide patients with access to their familiar and trusted medicines whilst minimising harm to the planet.

Achieving this will require concerted efforts from manufacturers and suppliers, with collaborations and consortiums offering a promising approach to bringing about large-scale, industry-wide improvements. As a specialist inhalation CDMO, Bespak is well positioned to foster these collaborations and make a significant contribution to consortiums – such as through membership of the International Pharmaceutical Aerosol Consortium (IPAC) and associated group IPAC-RS (on Regulation and Science). These connections can help to drive wider efforts towards carbon reduction and engage players from across the value chain, both for pMDIs specifically and for other inhaled drug-device combination products going forward.

STRATEGIC LOCAL COLLABORATIONS TO SHORTEN THE SUPPLY CHAIN

Partnering with suppliers that are working towards the same goals, or have the capabilities needed to enable these goals, can accelerate progress – for example, streamlining the transition to low-GWP propellants in pMDIs. Prioritising working with local suppliers adds further benefits of shortening the supply chain and increasing resilience of supply.

With this goal in mind, Bespak has collaborated with several local partners in the UK to streamline its processes for developing and manufacturing with both of the new, low-GWP propellants:

- Drawing on a longstanding partnership, Bespak worked with DH Industries (Basildon, UK) – expert pMDI processing and packaging engineers – to optimise manufacturing equipment for the new propellants.
- Valuable insights and guidance on safe propellant handling have been developed through close collaboration with Orbia Fluor & Energy Materials (Runcorn, UK), a global provider of fluoroproducts and technologies, and supplier of low-GWP propellant, HFA-152a. Likewise, Bespak partnered early with Honeywell, a company driving decarbonisation in refrigerants, and supplier of HFO-1234ze, to facilitate early adoption of this near-zero GWP solution for its customers.
- Canisters for pMDIs are supplied by H&T Presspart (Blackburn, UK), a specialist in devices and components. Through collaboration, Bespak and H&T Presspart accelerated the development of a GMP clinical-scale facility for supplying pMDIs manufactured with HFA-152a, closing a gap in the global supply chain for the adoption of low-GWP propellants in pMDIs.

These collaborations have focused on enabling the transition to low-carbon pMDIs, so bringing all the suppliers into the conversation is hugely beneficial for optimising the components and manufacturing processes needed to succeed in the propellant switch. Harnessing the collective technical expertise of all key

players drives faster progress in product development and manufacturing readiness. Furthermore, because the majority of these businesses are based in the northwest of England, this creates a strong cluster of expertise in the region and supports local sourcing, minimising transport-related emissions. And, because they are aligned with the ultimate goal of enabling low-carbon pMDIs, the various constituents of the supply chain work together more cohesively.

Similarly, Bespak has partnered with other specialist businesses in the region to support the full drug-device development pathway. This includes collaborations with contract research organisations (CROs) such as OzUK (Chippenham, UK), whose independent laboratory supports an efficient formulation feasibility and development pathway for pMDIs, and the Medicines Evaluation Unit (Manchester, UK), which is working to accelerate clinical trials of products using the new generation of propellants.

These collaborations enable knowledge sharing of low-carbon pMDI technology and processes, helping to increase the pace at which new low-carbon pMDIs can be developed and clinically evaluated. Accelerating this pathway can allow the industry to adopt low-GWP propellants more quickly, whilst also bolstering regional expertise, bringing the entire process – from formulation through to commercial supply – into the UK and ultimately shortening the supply chain.

Work is already ongoing towards the low-GWP pMDI transition. Additionally, the partnerships and principles built here will help to inform best practices for inhaled and nasal drug-device combination product development and manufacturing more widely.

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ESG PRINCIPLES ACROSS THE SUPPLY CHAIN

As outlined above, strategic partnerships and co-location can help to foster a supply chain that works together to bring low-carbon drug-device combination products to patients efficiently. For many drug developers and manufacturers operating in the pMDI space, current propellant gases make up a significant proportion of their total emissions, and therefore transitioning to low-GWP alternatives is likely to be the most significant opportunity to reduce operational emissions. However, there will always be room to go further.

Bespak has recently shared its inaugural ESG Update which sets out its holistic environmental, social and governance (ESG) strategy. This considers, amongst other issues, the lifecycles of its products – identifying opportunities for improvement at all points in the value chain. This means consideration of Bespak's internal processing operations, as well as those of its raw material suppliers and service providers.

To achieve reductions in carbon impacts, Bespak is partnering with its suppliers to determine how to use more sustainable materials and identify opportunities to minimise resource consumption and waste from the earliest stages of product development. For example, Bespak has recently investigated the reductions in emissions associated with a switch from synthetic to bioethanol in production processes.

Another approach is lifecycle assessments (LCAs), which are useful tools for understanding the cumulative environmental impacts of the energy and materials that go into products and identifying key areas for improvement. Bespak has recently conducted its first LCA on its BK357 pMDI valve platform, which has been independently verified by expert sustainability scientists from Tunley Environmental (Leeds, UK) in line with ISO 14067:2018 standards. Steps such as this are key parts of Bespak's work towards designing products with full lifecycle considerations in mind.

Taking a full business-level view of environmental impact is also critical

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for effecting sustainable change. Bespak has committed to fully and transparently mapping and communicating its environmental footprint across Scope 1–3 emissions and will submit its Science Based Targets initiative (SBTi) targets for validation in 2025, working with expert sustainability advisors at The Carbon Trust (London, UK).

Additionally, in Bespak's first year as a standalone company, a double materiality assessment (DMA), in alignment with the requirements of the European Sustainability Reporting Standards (ESRS), was conducted. To gain a full picture of all potential impacts, risks and opportunities (IROs) associated with business operations, this was followed by value chain mapping from upstream raw material sourcing to downstream patient use, identifying key segments, activities and stakeholders at each stage. Stakeholders were then engaged to consider the detailed insights collected across various sustainability topics. Each sustainability matter was reviewed with a focus on identifying relevant IROs before being scored to arrive at the final DMA. The results of the 2024 DMA assessment were used to define Bespak's key ESG focus areas and form the foundation of its sustainability strategy.

With all of these sustainability initiatives in mind, co-ordinating change across the supply chain requires commitment and leadership. Having ESG principles built in from the start, Bespak is well placed to drive this change and to help encourage and enable decarbonisation across the inhalation industry.

CONCLUSION

Shortening and decarbonising the supply chains of medicines will be vital activities in achieving the long-term sustainability of healthcare – particularly in inhaled drug delivery. Taking steps to reduce emissions through process optimisation, the development of lower carbon options and more local sourcing and collaboration will be an important approach for pharma. In the inhalation sector, Bespak is working to lead this approach, with collaborative partnerships that span the value chain, helping to streamline the path to low-carbon pMDIs for its partners. In a world of change, a willingness to collaborate has never been more important and Bespak is proud to lead the way.

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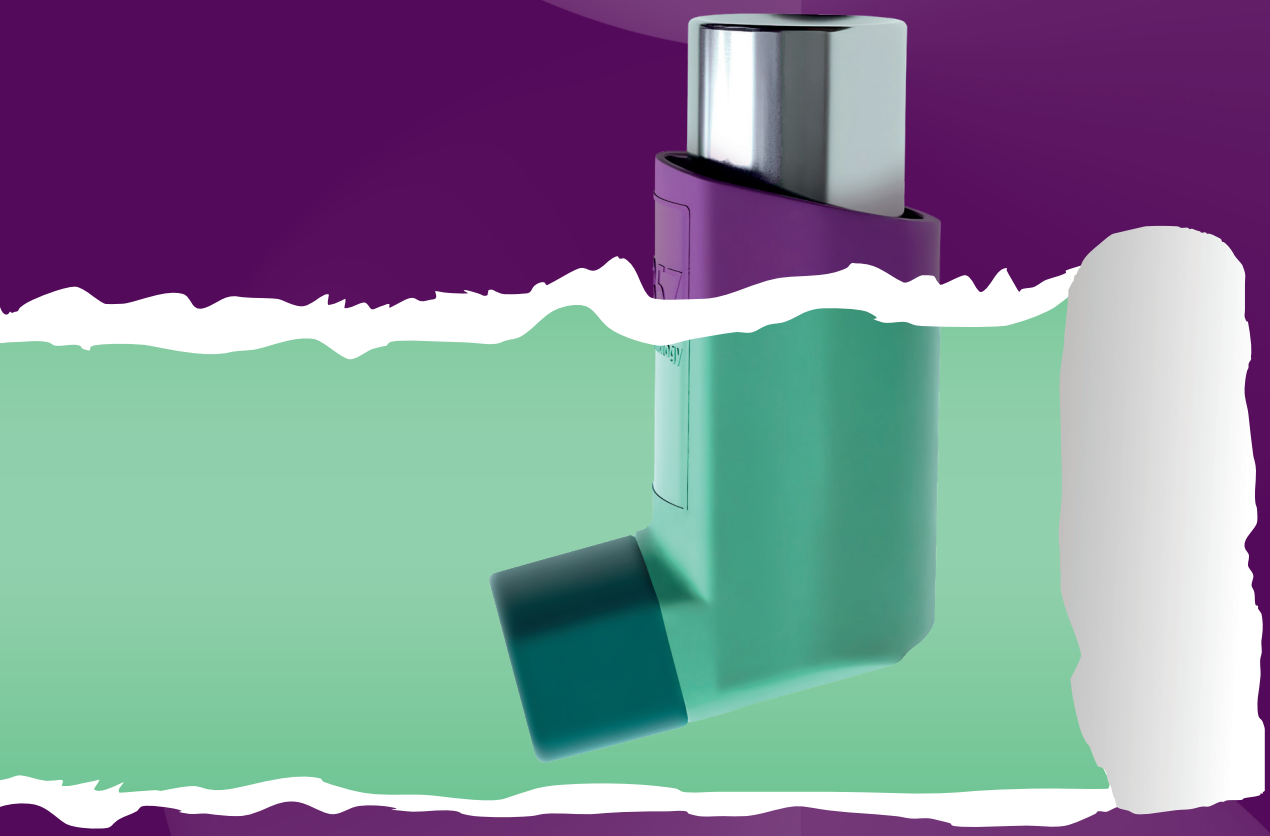

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