Point of view: A proposed roadmap for sustainable inhaler use in the UK that could support the NHS net zero ambition

A conversation with Alex Wilkinson and Gregor Anderson about a multi-faceted program aimed at developing sustainability and circularity for inhalers

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In this opinion article, *Inhalation* talks with Alex Wilkinson and Gregor Anderson about aspects of a potential sustainability roadmap for inhalation platforms that could lead to reaching the UK's National Health Service net zero goal.

Alex Wilkinson is an NHS consultant in respiratory medicine with a specialist interest in sustainable respiratory care. He serves on sustainability committees with the British Thoracic Society and NHS England inhalers working group. He is a member of the United Nations Medical Technical Chemical Options Committee as an expert on inhalers and has published widely on this topic.

Gregor Anderson founded Pharmacentric Solutions, Ltd. in 2017 and provides consultant services for the pharma Industry. Prior to this, Gregor was Design Director at GSK, working as a device and packaging specialist with over 35 years of experience and is a named inventor on more than 60 patents. He has presented widely on topics such as digital, sustainability, patient-centric design and road mapping. He also authored the UK Pharma road map for the Medicines Manufacturing Industry Partnership in 2017.

Vicki Schuman, Editor and Publisher, Inhalation: Gregor and Alex, please begin by giving us some context.

Gregor and Alex: With the world facing an environmental crisis from human-derived global warming, every industry must meet increasing demands from governments, regulators, payors and customers. The inhalation industry is no different and has an accountability to reduce its carbon footprint. With an estimated 262 million people suffering from asthma and 212 million suffering from chronic obstructive pulmonary disease (COPD) globally [1], the volume of inhalers used is in the billions. The resultant environmental impact of inhalers is substantial. For instance, metered dose inhalers (MDIs) prescribed within the United Kingdom's National Health Service (NHS) account for approximately 3.5% of the NHS total carbon footprint [2]. In addition, the NHS has set forward-looking targets to reach "net zero" by 2040. Beginning in April 2027, all NHS suppliers will have to publicly announce their carbon reduction plans that align with the NHS's net zero target.

Inhalation: Then what is a "roadmap?"

Gregor: A roadmap sets out challenges and opportunities, essentially making a series of aligned recommendations, defining *why* something must be done,

what is needed (and *what* are the benefits), *when* it is to be delivered, *how* much it will cost and *how* it will be implemented. Roadmaps can cover various topics such as skills, technology and sustainability. They are understood by key stakeholders (such as government, academia and industry) and used when challenges and opportunities are industry-wide and require alignment and consensus.

Today, our focus is inhaler sustainability. We believe the respiratory industry needs a sustainability roadmap to build on its recent advances with new propellants. While these propellants are a major step forward toward a net zero target, they are not a "silver bullet" or single solution; others will be needed. Much more work must be done to meet this challenge. A roadmap can capture these initiatives and be a template for the whole respiratory industry to work around.

Inhalation: What would an inhaler sustainability roadmap include?

Gregor: We believe it should cover the "total product," which would include the active pharmaceutical ingredients (APIs), the device, packaging, transportation and other factors. The roadmap should consider eliminating (or at least reducing) waste throughout the "cradle to grave" lifecycle. It should also have clear targets. Some would be expressed as CO_2e or "CO_2 equivalent," which is the way carbon footprints are measured. These initial baselines of CO_2e are vital to then setting up sustainability key performance indicators (KPIs) to be compared against. These commitments and KPIs would ideally be shared and actively integrated into company corporate sustainability reporting (CSR).

Alex: In the UK, the NHS has started setting expectations for suppliers regarding the scope for sustainability expectations. Beginning earlier this year, in April 2023, for all contracts above £5 million per annum, the NHS has required suppliers to publish a Carbon Reduction Plan for their UK emissions. As of April 2024, this will extend to all procurements, and as of April 2027, all suppliers will be required to publicly report targets, emissions and a Carbon Reduction Plan for global emissions aligned to the NHS net zero target. Without this, they will be unable to supply the NHS [3].

Inhalation: What is driving the need for a roadmap? For instance, what typically happens to used inhalers now?

Gregor: Net zero initiatives from healthcare providers are becoming more prevalent and inhalers have been identified as a target for improved sustainability. MDIs with HFA-134a or HFA-227ea propellants have a much higher carbon footprint than dry powder inhalers (DPIs), mainly because of the propellants currently used. But DPIs and MDIs have material content and a core challenge is addressing what happens to inhalers after use. Although there is no specific data, the unfortunate truth is most inhalers end up in landfill. In the more controlled healthcare environment, such as hospitals, waste is typically incinerated. However, in the home/domestic environment—where most inhalers are prevalent—they end up in the general waste, which is ultimately either incinerated or more often sent to landfill.

We believe inhalers should be more "circular" to meet sustainability expectations of customers, meaning they should be returned after use then recycled/recovered. There is a growing expectation for this. However, at present, the industry has no unified plan for more sustainable inhaled platforms or managing "end of life" disposal. So now is the time to set new, aligned initiatives for *all* inhalers, with the intent of meeting the net zero challenge. The roadmap could be the ideal place to capture these initiatives.

Alex: I agree. Suppliers are key to supporting the NHS sustainability targets. While the NHS can modify how it consumes products and services, a large part of the environmental impact can only be reduced by the suppliers themselves. The NHS recognizes this in its procurement decisions and has embedded social value into those decisions, but environmental factors will become more important in the future and that is why a roadmap is needed now.

Inhalation: This intent is admirable. But aren't there historic parameters or constraints such as quality, performance and cost?

Alex: I think it's wrong to see quality as a constraint. Healthcare organizations recognize sustainability as a key aspect of quality care because it considers impacts on the environment and future generations. With asthma, we know that patients who have the largest carbon footprint of care are those with poorly controlled disease. Most of that carbon footprint comes from reliever MDI inhalers. But by appropriately escalating treatment for patients who have poor disease control and are over-reliant on relievers, disease control and patient outcomes can be improved in cost-effective ways while also reducing the carbon footprint of treatment.

Gregor: If managed effectively, nothing would change regarding quality, performance or even cost. For instance, the roadmap would build on the MDI propellant changes currently under evaluation. Opportunities include adding layers of enhancements and strategies to improve the eventual goal of a net zero target. As mentioned, there is no single silver bullet here. This will require a range of approaches, changes in our current methods of working and changes in the ways we involve healthcare providers and patients as part of the solution.

Inhalation: What types of initiatives would be included?

Gregor: There are many initiatives, such as patient adherence. We know that 30-50% of medicines are not taken properly and inhalers are no different; in fact, up to 80% of patients do not use inhalers properly [4]. Poor adherence is never green. So the industry must do more to engage and educate patients and enhance inhaler adherence. There are opportunities to use better, simpler, reusable training aids and we should stop using placebo MDIs containing HFA propellants. And I would always advocate a device trainer be available when launching a new inhaler.

Alex: I believe training inhalers are urgently needed for effective treatment. Healthcare professional education is a major challenge and we've known for a long time that, unfortunately, the staff who prescribe inhalers may not know how to use them. However, I think all the interest in the environmental impact of inhalers is helping to drive more education.

New ways of treating asthma, in particular the use of as-needed combination inhalers for asthma or maintenance and reliever therapy (MART), could have a huge impact.

More accurate diagnostics could definitely play a role in reducing waste. Preventative measures, such as improving air quality and supporting smoking cessation, are the most environmentally friendly interventions. Also, non-pharmacological approaches, like pulmonary rehabilitation, need to be promoted more. Biologic therapy for asthma would also be a vital tool for reducing propellant emissions while getting the disease under control.

Gregor: We believe pharma companies should use a device and packaging "Green Guide." This is a common document that sets out "rules" to follow when developing devices. These guides should be shared across teams within a business, as well as with suppliers, and include initiatives such as the "7R's," which are reduce/remove/refill/renew/reward/respect/recycle. I'll describe these briefly:

- Reduce: minimize the materials in inhalers.
- Remove: Remove materials that have a higher CO_2e or environmental concerns. Simplify the range of materials used in inhalers to make them easier to recycle. Also, the pharma industry could learn a wide range of small enhancements from the packaging industry. [5].
- Refill: Where feasible, consider offering a refillable inhaler.
- Renew: This considers that energy used to manufacture the product comes from renewable sources (which in many countries, it does already). Plastics used in inhalers are mandated virgin materials and typically fossil-fuel based. Although the weight of plastic used in each inhaler is low, the material is of the highest quality and, as such, has a potential recyclate value.
- Reward: This is an interesting consideration. How does the industry get a reward for being sustainable? Logically, if a company follows the 7R's, they would not only achieve CO_2e savings, but also (by default) get real, measurable cost savings.
- Respect: In other words, responsible selection of suppliers. Those suppliers make the inhalers and should have input into the sustainability roadmap. At the same time, the pharma industry should understand the sustainability initiatives that suppliers work with and build on them.
- Recycle: I'm listing this initiative last because it's the one that has considerable opportunity and could enable the pharma industry to become circular. In the UK, recycling schemes have been implemented in the past, but unfortunately failed, for several reasons that are now known.

Alex: It is evident that patients want more environmentally friendly products too. A major survey conducted by Asthma + Lung UK was presented at the European Respiratory Society (ERS) Congress in 2021. It showed that most patients who have asthma would want to switch to a more environmentally friendly inhaler [6]. There is a lot of support for recycling as well, but it does need to be well-promoted and easily accessible.

Inhalation: Let's continue discussing what currently happens to used inhalers.

Gregor: Building on those earlier comments, I'm going to focus on the UK because the market is familiar to Alex and me. But other countries are similar when it comes to inhaler post-use. Disposal is through either landfill or controlled incineration (and specifically as a waste product in healthcare environments). Incineration has a cost but it does capture inherent material energy. I believe that all pharmacies should offer the collection of used inhalers but at present, this is not enforced in the UK. Currently, any collected inhalers are "bundled" with other medicinal packaging waste and then incinerated. This strategy is applied inconsistently across the UK and needs wider understanding (and enforcement), in partnership with pharmacies, about ways to optimize inhaler collection.

In the home environment (where most inhalers are used), they are typically disposed of in the general waste bin, which is then landfilled. Overall, landfill is worse than incineration, but incineration is not as good as recycling. The ideal opportunity is recycling, which would be a key roadmap target.

Alex: I think there is still considerable uncertainty about what happens to inhalers after use. Previous small surveys suggested patients mainly put them in domestic waste. The amount of waste that is incin-

erated has increased in the UK in recent years. But if the waste is crushed first and MDI canisters are pierced, then the propellant gases will be released before incineration. If the temperatures in the incinerator are not high enough, the propellants will not be thermally degraded. Some inhalers are also inappropriately put into recycling bins.

Incineration of medicines waste is currently the best of the poor options, but community pharmacies are not supported to do this. They pay for medicines waste disposal, so why would they want patients to return inhalers to them? Although I would encourage incineration in medicines waste now, ultimately, it is a barrier to recycling. Instead, I believe the circular economy that Gregor has described is where we should be aiming.

Inhalation: If recycling is the ideal, why do you believe previous UK inhaler recycling schemes failed?

Gregor: Great question. The most successful inhaler recycling scheme was initiated by GSK and ran for nine years (2011-2020). GSK funded the program and collected used inhalers from any manufacturer. Because MDIs are the main inhaler platform used by patients in the UK, those were separated, any residual propellant was extracted, then the aluminum was recovered from the canister and valve. Plastic components were also recovered. Although the scheme collected approximately two million inhalers, this was a very small percentage of inhalers used. The main challenges were:

- Ongoing messaging and awareness. Following an excellent launch, any scheme needs continual communication.
- Industry support. GSK funded the scheme but, although it was open to all inhalers, no other inhaler manufacturer joined in the initiative. This was a real shame. For a scheme to be successful, it must be funded and have clear, unified alignment with all manufacturers. Subsequent, smaller, very localized schemes have been initiated by other pharma companies and they have suffered the same fate. Scale is key to getting the volume of returned devices necessary to make a recycling program cost effective.
- Timing. Sustainability has always been a driver for positive change but a decade ago, it possibly had less of a focus. Sustainability is now much more of an expectation and patients are increasingly asking questions about their inhaler sustainability and disposal.

Alex: The time feels right for a national recycling scheme in the UK. Importantly, the NHS is firmly behind it now, with their new inhaler waste management policy. By the end of March 2024, pharmacies must show they have spoken to all their patients who use inhalers regarding the environmental benefits of returning used inhalers to a community pharmacy for disposal. "Please return your inhaler so we can recycle it" is a much clearer and more powerful message than "Please return your inhaler so we can set fire to it." We urgently need to get the infrastructure and industry support in place for such a recycling scheme [7].

Inhalation: What do you suggest will be needed for a successful inhaler recycling scheme?

Gregor: Building on what the industry has learned in the past and looking to the future, I see some clearly defined aims: Anyone supplying inhalers of any type, including companies who supply inhaler components, would join the recycling scheme. In addition, the NHS would be a key stakeholder and help educate the public about the scheme. They would continue to collect used inhalers in healthcare settings but also at pharmacies. Patients would bring them in when picking up repeat prescriptions (as asthma and COPD are chronic diseases). This would also create opportunities for pharmacies to reinforce correct inhaler use with patients.

Alex: Looking at several past schemes for recycling inhalers, it appears the hardest aspects are firstly making the program sustainable and secondly getting patients to return their inhalers. Instead of relying on one company initiative, we need a consortium to make this effort sustainable. Then I agree that community NHS pharmacies, where most patients get their inhalers, are key to collecting used inhalers.

Gregor: The scheme would need a small, independent team to manage it. In turn, the team would be accountable to a steering group, which could include industry and NHS stakeholders, recyclers and patient groups such as Asthma UK. The team's responsibilities would include communicating about the scheme, leading negotiations with recyclers and reverse logistics suppliers, answering day-to-day questions, supporting government and regulators regarding recycling and building relationships with industry representatives.

Inhalation: How would it be funded?

Gregor: That's always a fundamental question. From previous experience, I believe that the annual funding would be less than £1 million. Overheads such as staff would be a part of this. Having patients return used inhalers when picking up new prescriptions would be the most efficient way to minimize reverse logistics and specifically designed boxes would be the only additional requirement in pharmacies. These would be picked up, along with other medicines waste, when deliveries are made in order to simplify logistics This concept has already

been tried and tested by GSK (and Teva), and the outcome had risks mitigated.

Alex: Storage is one of the technical challenges. Because these are prescribed medicines, they need to be stored securely, but we know how to do that. However, the NHS would not be able to fund this.

Gregor: Funding would naturally come from the pharma industry because they are already providing inhalers (on a pro rata volume basis). Inhaler manufacturers could also pay to support the scheme. Splitting the required funding among all players would be fair and likely the only way this scheme could ever work. Still, each member of the scheme could benefit from this investment and could include it in their annual sustainability reporting.

Inhalation: And you are not envisioning large financial investments?

Gregor: No, as the scheme grows, more staff may be needed. But there are precedents from past programs and there has been previous investment in MDI propellant extraction equipment. Also, let's not forget that HFA-152a does have a global warming potential (GWP) so why wouldn't we continue to collect residue left in MDI devices? MDIs are fantastic devices but the sustainability "elephant in the room" are the current propellants. So let's take the opportunity to set up a scheme now that is ready for the imminent changes and again drive towards circularity for inhalers. Recycled materials would be sold, as would collected propellants, and these would offset some of the scheme's costs. It could also be argued that if you have a recycling scheme in place, it could protect the industry from future mandated taxing of materials. So why not shape our future, as opposed to being forced to follow it?

Alex: We know from previous recycling schemes that "used" MDIs are typically still half-full of propellant. This is particularly problematic for MDIs without dose counters, where there is considerable wastage. HFA-152a has a global warming potential of 164, so a typical "used" MDI with 6 grams of HFA-152a propellant remaining would contain one kilogram of CO_2e. That's less than the 9 kg CO_2e from 6 g of HFA134a or 21 kg CO_2e from 6 g of HFA227ea, but still well worth saving.

Inhalation: What about DPIs and recycling?

Gregor: With most of the volume coming from MDIs in the UK, the focus would obviously be on them. However, DPIs would be very much part of the scheme. They would need to be disassembled in a controlled environment, as there will be the potential risk of drug residue. Simple disassembly equipment has been used historically and such use would be accelerated as feedstock increases. Incineration could be used as a secondary overflow option and, as volumes became known for DPIs, appropriate equipment could then put in place. In summary, the plastic and metal components of DPIs would be recycled, along with soft mist inhalers (SMIs) and spacers.

Inhalation: Healthcare strategies and situations will vary by country. But could a successful recycling scheme—or aspects of it—be extended to at least some other countries?

Gregor: Absolutely. If the UK can refine the scheme and enhance it over several years, I see no reason why it could not be repeated in other countries. But I cannot emphasise enough that stakeholder commitment and involvement are needed from the beginning. Much de-risking was done by GSK and other lessons have been learned from smaller localized schemes. On a side note, a scheme could also involve injectors and the most obvious platform is products for anaphylactic shock, where most injectors are, hopefully, never needed so they often expire before use.

Alex: That's a good point. Injectors for diabetes are also another large, potential volume of waste. The NHS is currently leading in its ambitions for net zero. I believe it should be leading on recycling as part of that process, as well as in its commitment to reducing other aspects of environmental waste.

Inhalation: Ultimately, is recycling the key to getting inhalers towards net zero?

Alex: It's not a panacea but it's a vital piece of the overall puzzle.

Gregor: Recycling would enable the industry to "complete the circle," making inhaled platforms truly circular. As mentioned, this approach enables the pharma industry to continue to manufacture inhalers of the highest quality, in high volumes and still meeting regulatory requirements—such as the use of virgin plastics. It has no apparent downside and could be a real win/win for the industry, patients and ultimately healthcare providers, who are key stakeholders in its success too.

Inhalation: Now that you've detailed inhaler recycling, what else would you include in the roadmap?

Gregor: There are quite a few concepts and could include standards. Having an agreed-upon standard for life cycle analysis (LCA) measurement is a must. Healthcare providers are asking for these as part of procurement requirements and having a known baseline is the only way to prioritize sustainability projects. Work has been initiated on setting standards through the Sustainable Markets Initiative Health

Systems Taskforce and this will ensure a robust LCA calculator for pharma devices and packaging.

Also connected "smart" devices. These have been available more recently and have gained some traction in the market. They are more expensive than existing inhalers and typically contain batteries. If a battery is sealed in the inhaler, it will require a specific, mandated recycling strategy, if that inhaler is to be marketed in the EU. Connected devices can be a useful tool during clinical trials where data is "live" and owned and managed by the pharma company. Smart inhalers can enhance these trials, but the challenge is moving from the clinic to commercial scale. Additional challenges include battery and electronics recycling as well as scale-up complexity and data ownership moving to the healthcare provider.

Alex: Smart devices have yet to take off in respiratory medicine; they're still mainly confined to research, where they are a very helpful tool. Healthcare professionals would need to be convinced of the clinical benefits before paying the additional financial and environmental cost for these devices.

Gregor: Leaflets. These are currently included in every single inhaler package. They are mandated but add substantially to the overall package size. There is a future opportunity to make these digital, which has been an ongoing topic of discussion for years. With the advent of serialization (which is the use of a unique product code on each package), mobile phone use and many other industries moving their instructions to digital formats, now is the time to mobilize this technology leap. Better visuals and training could be accessed with a QR code and information made available and easily searchable. In the case of an adverse event, important information could be added to the digital leaflet immediately, offering a considerable safety advantage. And before you ask, for those without mobile phone access, leaflets could be printed at the pharmacy.

Alex: I absolutely agree. We already add digital QR codes to clinic letters so patients can access videos on the Asthma UK website. They generally find this far more helpful than the leaflet in the package.

Gregor: Packaging material technology. Medicine packaging must provide an adequate shelf life, ideally a minimum of 18-24 months. Although this may seem reasonable, supply chains in the pharma industry are very long and inhaler supply chains are no exception. If the shelf life has been reduced by the time the inhalers reach the distributor, there is a risk of the pharmacy rejecting them so that stock may be written off. This is not a green situation. Therefore, consider extending shelf life through new developments that fully maximize shelf life.

Bioplastics. This is an interesting area. Inhalers use plastics made from fossil fuels. These plastic materials have mandated provenance, have been tested thoroughly and are cost competitive. Given they are virgin material, they would also have a value post-use, if they were recycled. This is why recycling inhalers is the best solution for circularity. Incineration is less ideal, but energy is recovered. Landfill is the worst scenario, as plastics typically take hundreds of years to break down.

Bioplastics are typically plant-based. They can be recycled or incinerated but cannot (and should not) be landfilled. Given they are biomaterials, there is the risk of these materials in landfill creating methane gas, which is 23 times more harmful than CO_2 as a greenhouse gas. This is a considerable "red flag" for me. Among other challenges, there are only so many bioplastic materials available and they are typically two to four times more expensive than conventional plastics. Currently, bioplastics account for approximately 1% of the total plastics market and biomaterial supply can vary, depending of factors such as the weather and market forces, in regions like South America and Asia. I'm sure that switching to a bioplastic would involve re-testing/re-validation as well as stability evaluation for an inhaler. For these reasons (and the cost of moving to bioplastics), surely it would be better to invest a fraction of this funding into recycling the inhalers that we currently have.

Inhalation: What are your final thoughts about new sustainable innovations and approaches?

Alex: Thinking more broadly, we need radical changes to prevent respiratory diseases in the first place. Action on air pollution, promoting healthy, active lifestyles and tobacco control are vital. Secondly, early and accurate diagnosis can help greatly to reduce waste. Thirdly, optimizing disease management. The main driver here is inhaler technique training and assessment, though that problem has been around for decades. Greater use of combination inhalers as needed in asthma, appropriate use of biologics, avoiding unnecessary inhaled steroids in COPD and greater use of non-pharmacological treatments are important too. Fourthly, lean service delivery that harnesses digital technologies where appropriate. Finally, and probably the most significant in terms of impact on greenhouse gas emissions, is the adoption of low-carbon inhalers. That means using currently available DPIs and SMIs, and moving forward, developing MDIs containing novel propellants, assuming they become available.

Gregor: Regarding approaches: When inhaler designers and developers are undertaking new inhaler programs, they use methodologies such as "Design for Manufacture (DfM)" and "Design for Assembly (DfA)." The DfM and DfA are important as inhalers are mass-marketed, high-volume products assembled at high speed by assembly machines and robots. What we should also add is "DfS," Design for Sus-

tainability and "DfD," Design for Disassembly. With innovations: Because we expect to change MDI propellants, let's, for example, improve the actuator too.

Alex and I had a brainstorm about this and made a range of proposals that could be factored into what is essentially a simple component [8]. These included offering the option to add a lever to make actuation easier, making the actuator molding in clear plastic, reducing change-over time when molding and using a colored label on the canister to indicate the drug, etc. I've also heard recently about an innovation where the carton in which the MDI is supplied is designed so it can be used also as a "spacer." For emerging markets, where spacers often must be bought by patients, this is a genius idea that offers access *and* sustainability. Now is the ideal time to integrate ideas and innovations such as these, in parallel, when we have to re-evaluate existing MDI enhancements due to the propellant change.

Inhalation: It's great to hear these innovative ideas and see there are real opportunities for change in the inhaled market. Thank you both for your thoughts and recommendations.

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