Designing inhalers for reuse, remanufacture and recycling:

Circularity in medical devices

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Part of Capgemini Invent

Contents

This whitepaper was originally written and published as a peer reviewed article for Respiratory Drug Delivery (RDD).

The content was delivered as a podium talk at RDD Europe 2023 by Henry Blower and Dan Cowen

Summary

Management of medical waste is a significant challenge for the healthcare industry, particularly for inhaled therapies. With most waste still being incinerated or sent to landfill, there is an ever-increasing pressure on the industry to divert waste to more sustainable end-of-life processing options. This paper explores the various options, such as reuse, remanufacture, recycling, and biodegrading, and selection of the appropriate option for a given product. We explore the role of product design and development in minimising the burden on the environment, and ensuring waste management methods are commercially viable and feasible from a technical and regulatory perspective.

1 Background

Sustainability is at the forefront of current affairs, and the United Nations Sustainable Development Goals [1] have provided clarity on what sustainability involves. Medical technology development should align to these 17 goals, particularly in ensuring good health and well-being. Medical product developers often focus solely on treatment efficacy and rarely consider or prioritise environmental sustainability. However, healthcare produces 4.4% of global net emissions [2] and it is time for the sector to take on additional goals such as 'responsible consumption and production' and 'climate action'.

A change in attitude in the medical sector is gaining momentum with pressure growing from legislation, patients, and organisational commitments. There are currently few examples of legislation mandating that medical devices must be designed to a sustainability standard, however several proposals could soon change this picture. In March 2022, the European Commission published a proposal for regulation that creates a framework for designing products with reduced environmental impact [3]. If this is approved, medical devices will likely be included within the scope of this regulation and there will be a requirement to factor sustainability into their design. In addition, the European Climate Law [4] is a legally binding regulation that requires all member states to reduce net greenhouse gas (GHG) emissions by 55% by 2030 and achieve economy-wide climate neutrality by 2050. To achieve this, every sector will have to play its part, the medical device industry included.

Many groups are aligning themselves to this type of legislation, including major purchasing and distribution organisations such as the UK National Health Service (NHS). The NHS is the first health system to embed a net zero target into legislation; with the Health and Care Act 2022 [5] the NHS formalised its ambition to be net zero on all emissions by 2045. This is a major commitment and by including all Scope 3 emissions the burden of responsibility is on suppliers and manufacturers as well as the NHS itself.

In addition to change being driven from the top down, there is a trend from product manufacturers and pharmaceutical companies to set their own targets. This is seen in many inhalation-focused companies who have announced challenging goals; for example Chiesi launched its eco-friendly products challenge in 2021 and set a target of being carbon neutral by 2035 [6]. Changes in legislation and company policy are positive news, but there is still a question about the most effective way of actually tackling the environmental impact of the industry.

Inhalers are frequently referenced in sustainability discussions. This is largely due to the high global warming potential (GWP) propellants that are used in pressurised metered dose inhalers (pMDIs). This is an important area to tackle as propellants are a significant part of the reason that inhalers lead to ~3% of NHS emissions [7] and must be a priority. The good news is that low GWP alternatives are already being developed. AstraZeneca, in partnership with Honeywell, are developing HFO-1234ze-based pMDIs that will reduce the GWP by 99.9% [8]. Transitioning patients to lower impact propellant-free devices such as dry powder inhalers (DPIs) and soft mist inhalers (SMIs) has also been advocated [9]. However, issues remain with low GWP pMDIs, DPIs, SMIs, and all devices in general, regarding the vast amount of waste material generated, compounded by the requirement to use virgin plastics in the manufacture of medical devices. The NHS prescribes around 60 million inhalers each year, and these disposable devices create significant amounts of material that go to landfill or to incineration. Even if the upstream impact of the propellants is reduced, the downstream waste remains and must be addressed. In fact, the National Institute for Health and Care Excellence (NICE) in the UK has pledged to reduce the amount of waste going to landfill to <5% of overall waste [10].

When assessing the environmental burden of products, a standard method of estimating the impact is to use life cycle assessment (LCA), for which there are defined and measurable impact categories. It is important to look across a spectrum of these categories to fully understand the harm that a device causes and to determine how to mitigate that effect. For example, a high GWP propellant may have a large impact on ozone depletion but less effect on water usage, or a DPI may have higher impact on ecotoxicity but lower climate impact. As with many optimisation goals there are trade-offs to be made. Looking into these impact categories reveals that there are potential improvements to a product's design both upstream and downstream of the in-use period. Upstream changes may include using biopolymers or energy from carbon neutral sources. Downstream changes may aim to keep raw materials in service for longer and extend product life as far as possible. Products should be designed with end-of-life in mind and the aim to minimise the amount of waste generated. This paper sets out the options for downstream processing of medical devices to promote circularity and to design away from landfill and incineration, whilst being mindful of medical device requirements and regulations.

2 Product end-of-life strategies

The concept of a 'waste hierarchy' was introduced in 1975 with the European Waste Directive [11] which communicated the importance of minimising the impact of waste on the environment. Often simplified to the three Rs, 'reduce, reuse, recycle', the waste directive is actually a five-tiered funnel (Figure 1), where prevention, or 'reduce', acts as the first line of defence, the idea being that the best waste management strategy is to avoid creating waste in the first place.

Consequently, preventing waste generation has fast become a core objective in healthcare systems and medical product development, for example, minimising waste medicine, optimising packaging formats, ensuring patients are diagnosed accurately and prescribed the optimal therapies. While prevention is the first and most impactful tier, there are four remaining tiers within the hierarchy: reuse, recycling, recovery, and disposal. This paper aims to outline sustainable strategies for each of these avenues.

Figure 1: Waste hierarchy from the European Waste Directive [11]

These waste options are shown and expanded upon in Figure 2 in the context of the life cycle of a medical device.

The following product end-of-life processes are considered:

- **Reuse:** A product's lifetime is extended so that less waste is produced per dose delivered. This may involve replacement of a consumable part by the patient (e.g., drug cartridge).
- **Reprocess:** Used products are collected, inspected, and cleaned before being redistributed to a new patient.
- **Refurbish/recondition:** Used products are collected, disassembled, cleaned, and serviced, and parts repaired/replaced (if necessary).
- **Remanufacture:** Used products are collected and disassembled into parts which are then assessed, cleaned, and requalified (if necessary). New products that meet the original specification and intended use are then built using a mix of old and new parts.
- **Recycle:** Used products are collected and disassembled, then separated into waste streams that are turned back into material feedstock (for medical use or otherwise).
- **Dispose:** A product is made using biodegradable/ compostable materials that will decompose safely in landfill or at home, or turned into energy or fuel.

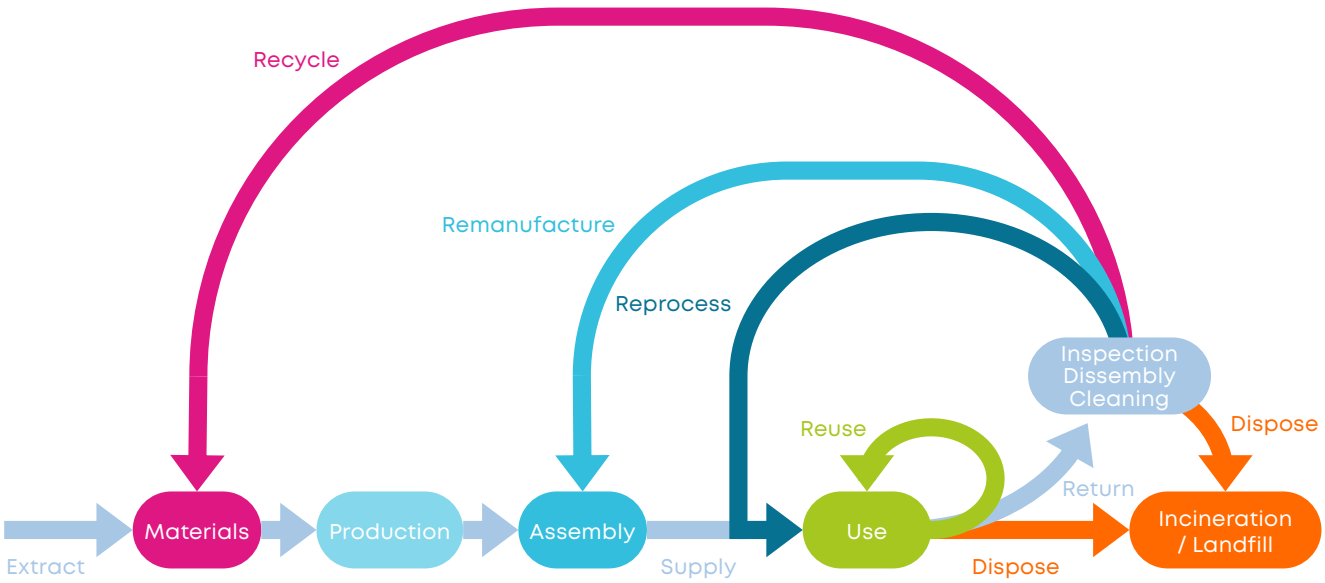

Figure 2: Overview of product end of life options and crucial steps

3 Reuse

Developing reusable inhalers is a core pillar of bolstering a circular economy in the healthcare sector. A reusable inhaler can significantly alleviate environmental burden with impacts reduced both upstream and downstream of patient use as fewer devices are produced and disposed.

Moving from a single- or low-use disposable product to a highly reusable product presents challenges because additional risks can be introduced. For example, using a device for longer may increase delivered dose variability, or may incur a size and complexity increase that adversely affects usability. These challenges may prohibit reusability as a viable route for certain products; nevertheless, it is valuable to consider the potential to reuse early in development when the system architecture is most flexible.

A study of the Breezhaler® (Novartis Pharmaceuticals) comparing the impact of a 30-day pack with a 90-day pack [12] (Figure 3) found a 50-60% reduction per 30 days of use across several impact categories including climate change, resource depletion, and eco-health metrics. Even though the same number of capsules and blister packs were used and disposed of in a 30-day period, the environmental harm associated with the device, shipping and outer packaging was reduced by a factor of three.

When designing a multidose device, consideration should be given to maximising the number of doses included at the start of life (providing the reliability of the device is sufficiently maintained). This may involve a size, and therefore usability, trade-off that should be carefully considered.

An alternative approach is to enable drug replenishment through a user-replaceable consumable subsystem, such as a replacement pMDI canister or a multidose cartridge system. For example, the Spiriva® Respimat® (Boehringer Ingelheim) is available as either a one-month disposable or a six-month reusable device. The reusable device has been shown to have a 71% reduction in cradle-to-grave climate change impact compared on a per month basis to the disposable Respimat [13]. Considerations here include the effect on usability of splitting the device into durable and consumable elements which may increase device size and/or complexity, and how much this increased device size and/or complexity may offset environmental gains.

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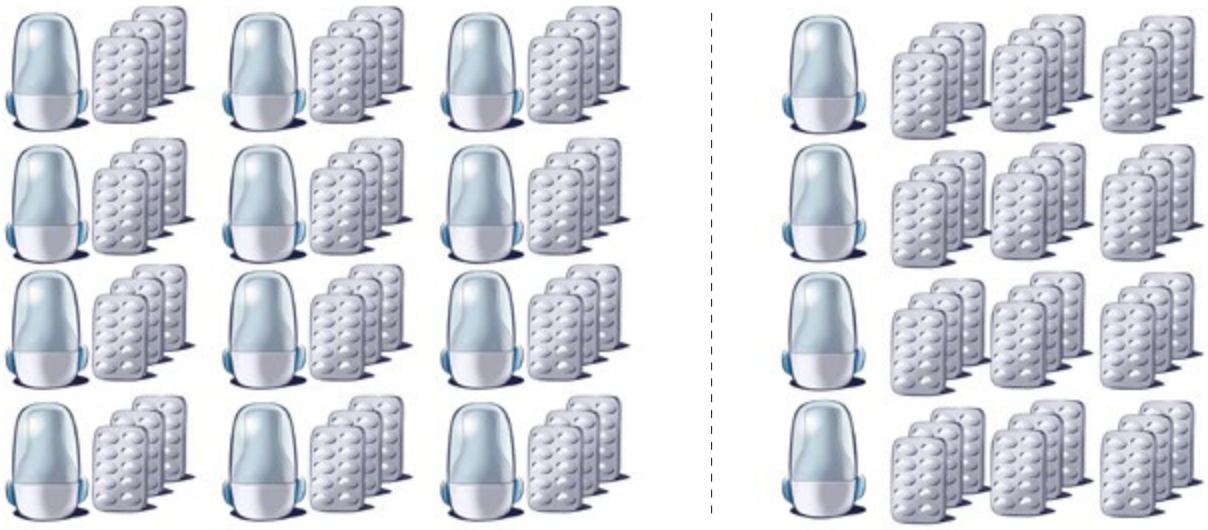

Figure 3: Illustration of the effect of extending use life for a capsule inhaler (1 year of use)

To improve reliability, patients may be encouraged to clean and maintain parts of the device to prolong the life, although this may create risks such as moisture ingress in DPIs. Alternatively, it may be possible for patients to swap out parts with limited lifetimes using a modular arrangement. This carries risks of tracking and adherence, as well as potential usability issues and increased size and/or complexity.

Increasing the level of reuse reduces the overall environmental impact in a given time due to the fact the durable element is now operating over a longer period. This reduces both production impacts such as raw material extraction, and end-of-life impacts such as disposal. However, as the use life extends further, the impact of the durable element becomes increasingly less significant compared to the consumable. Therefore, it does not make sense to extend the durable life indefinitely if this creates risks to reliability or additional user steps such as cleaning. Further analysing the Respimat data [13] (Figure 4), a significant reduction in climate change impact is made when extending the life from one to six months, but little further benefit would be derived from extending to 12 months. An optimal durable life exists that balances environmental benefit with performance and risk profile.

To achieve effective environmental burden reduction via reuse, the following design principles should be followed:

- Focus on minimising the environmental impact of any consumable elements.
- Balance the number of reuses with reliability – diminishing returns mean an extreme use life is unlikely to be worth the design challenge and compromises needed to achieve performance.
- Reuse process should be low friction for patients – it requires user engagement and adherence.
- Improve the reliability of the weakest part of the system, enabling effective use life extension.

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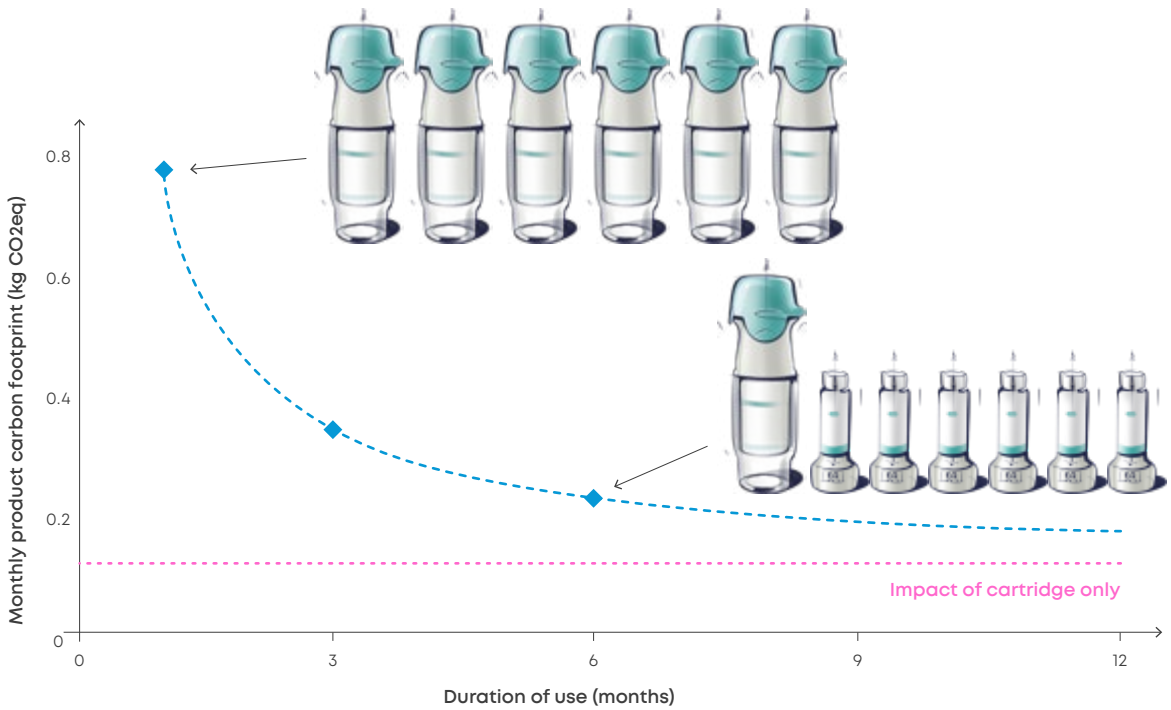

Figure 4: Diminishing returns for reusable Spiriva Respimat, with monthly impact for different use periods. Data from [13] extrapolated based on calculated durable and consumable impacts

4 Reprocess

Closely aligned with reuse, reprocessing puts the act of cleaning and refilling into the hands of an approved third party who may or may not be the original equipment manufacturer. Devices are collected at the end of life and sent to a processing facility where they are inspected, cleaned, and redistributed to a different user. Like reuse, service life of a device is extended, and the number of devices produced and disposed can be greatly reduced. This time, however, additional processes are involved which must be carefully specified to avoid eroding the benefit.

A common pattern seen with the reprocessing model is a significant reduction in solid waste and a modest reduction in other impact categories (e.g., a study of hospital gowns reused 1000 times vs. single-use disposables [14] found a 93% reduction in solid waste generation vs. 30-40% reduction categories such as energy consumption, water consumption, and GHG emissions). While solid waste is successfully diverted from landfill to be used again, putting products back into service takes energy and resources, and thus generates environmental harms which must be considered. A good rule of thumb is that the impact of the full reprocessing stage must be less than the cradle-to-grave impact of an equivalent disposable device across impact categories of interest.

Cleaning is critical in restoring technical and functional safety to used products prior to return to service. The level of cleanliness/sterility required can have a significant bearing on the impact of the reprocessing step, with sterilisation often representing high impact for both climate change and key environmental harms such as ecotoxicity. In one extreme case, a study of single-use disposable vs. reusable cystoscopes found that the reprocessing step alone had a far greater impact than the entire cradle-to-grave life cycle of the single-use product [15]. This was due to the use of peracetic acid as a disinfectant and highlights the importance of choosing an appropriate cleaning strategy and assessing its impact. Other studies of different device types have found significant benefits to reprocessing, for example, single-use vs. reprocessed blood pressure cuffs [16] (up to 40× reduction in kg CO_2eq) and laparoscopic tools [17] (70-80% reduction in GHG, damage to human health, damage to ecosystems and resource depletion). Reprocessed respiratory products would need to achieve the same level of cleanliness and bioburden as the original device. For inhalers, sterility may not be as burdensome as for a surgical tool, so it is expected that gains can be made from a well-designed reprocessing setup.

Reverse logistics must also be considered – how are the used devices collected and brought to a processing centre? There are several problems that must be overcome, such as how to incentivise patients to engage with the collection, or how to minimise the burden of shipping and sorting.

In order to ensure devices remain safe and effective for patient use throughout the entire product life (which may involve many iterations), systems must be in place to prevent issues associated with overuse, such as wear, fatigue and degradation of materials. Importantly, this must be demonstrated to the regulator when seeking approval for a medical device with reprocessing.

Drug refill for a reprocessed device must also be defined. Depending on the exact approach implemented this could be considered reprocessing, refurbishment, or remanufacturing, and covers a spectrum from straightforward reservoir filling through medication cartridge replacement to full pMDI canister remanufacture. The approach is subject to many of the same considerations as the broader reprocessing or remanufacturing of the device.

To achieve effective reprocessing, the following design principles should be followed:

- Devices should be easily and thoroughly cleanable without complex disassembly using a low-impact cleaning method that ensures patient safety.
- Effective tracking and/or assessment processes should be established that ensures products returned to service perform to the same specification as a new device. This must also be proved to the regulator.
- Reverse logistics should have minimal impact, with a good balance of local and centralised processing facilities.
- Used-product collection should be low friction for the patient – this should be streamlined, easy, and well-advertised to ensure adherence.
- Patients should be educated that a reprocessed product is clean, safe, and effective to overcome potential reluctance regarding ‘used’ medical devices.

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5 Remanufacture

Product use life is usually dictated by a single factor. For inhalation products this may be the quantity of medication provided, or could be reliability or robustness of a component or subsystem. Remanufacturing takes advantage of the fact that most components within a used device are viable for continued use (perhaps hundreds of times over) but are nonetheless discarded once the defined end-of-life is reached. With remanufacturing, devices could instead be collected, disassembled into their constituent parts or subsystems which can then be cleaned, inspected, and assessed, before being rebuilt into new devices using a mix of old and new parts. This approach has much crossover with reprocessing, but the degree of handling is greater, as is the burden of testing and tracking.

Inhalers, particularly DPIs, are often made of many components. Remanufacturing offers the opportunity to recover those with long lifetimes such as springs and performance plastics. These do not need to be manufactured again and the environmental burden of the product can be reduced.

As with reprocessing, care should be applied when considering remanufacturing; collection, disassembly, cleaning, evaluation, reassembly, and redistribution all have environmental impacts and can undo some or all the expected gains. Evaluating a remanufacturing cycle can be very complicated given the variable makeup of a 'device' over time, with a mix of parts of different ages and the variable lifetime of any given component. Large gains are possible though, for example a study of electrophysiology catheters [18] reported a reduction in emissions of up to 60% per remanufacturing loop and 57% per catheter life (when the full life cycle is accounted).

Once disassembled, parts are processed individually, which is likely to improve the ability to clean (although the impact of cleaning must be considered) but will complicate the task of assessing their suitability for reuse as this must now happen at component, assembly, and system level, rather than just at system level as for reprocessing.

Remanufacturing has been successfully demonstrated in other industries, for example remanufacturing of printers by Canon [19]. In the case of one of their leading multi-functional printers, this approach results in an 80% reduction in the use of raw materials compared with a like-for-like new model, reducing impacts across the raw material extraction, manufacturing, and logistics stages of the life cycle. This approach has allowed the company to achieve a 36% reduction in carbon emissions per product over the complete life cycle.

Another potential benefit of remanufacturing is moving environmental burden from one impact category to another. This will be more and more relevant as power grids decarbonize and reserves of natural resources deplete.

To implement remanufacturing effectively, the following design principles should be followed:

- Devices should be easy to disassemble into individual components which can be used again (non-destructive separation). This runs counter to the need for medical devices which prevent tampering, and care must be taken to achieve this without compromising usability or function.
- Use a manageable number of parts or subsystems.
- Facilitate tracking of number of remanufacturing loops at the part level (individual serial numbers etc.), or have robust testing procedures in place to allow out-of-spec parts to be identified and removed from service.
- Used product collection should be low friction for the patient – this should be streamlined, easy, and well-advertised to ensure adherence.
- Patients should be educated that a remanufactured product is clean, safe, and effective. This will help to overcome potential reluctance regarding 'used' medical devices.

"Remanufacturing takes advantage of the fact that most components within a used device are viable for continued use (perhaps hundreds of times over) but are nonetheless discarded once the defined end-of-life is reached."

6 Recycle

Recycling is widely used in waste management. Once a product has reached the end of its useful life, it is sent to a processing facility via some form of collection scheme, where it is disassembled and separated into waste streams. By recycling inhaler materials there is potential for a twofold benefit: first, there is a reduction of harmful waste entering the environment; second there is a reduction in the raw material consumption and energy involved in the production of virgin material.

Recycling is an end-of-life option which requires energy to turn waste into a material that can be used in a subsequent manufacturing process. This means that for a given product it is often hard to quantify its wider effect. It is possible to measure some of the impact, however other benefits, such as reduced raw material consumption, require an expansion of the system boundary and would not often be considered in the LCA of a given device. Some advantages of recycling are therefore hidden, and benefits are likely to extend beyond the impact that is calculated for the product being assessed.

The exact details of processing determine both the impact of the recycling process and the usefulness of the output material feedstock.

For plastics there are several grades of recycling available [20]:

- **Primary recycling** takes a single plastic and returns a feedstock of the same grade as the input. This can have the most benefit but requires the input material to be of a single resin and free of contaminants to guarantee the integrity of the output. Processing costs are higher but there is the possibility of returning plastic for use in medical devices.
- **Secondary recycling** takes plastic and recycles it to provide a lower value plastic that can be used in new applications. This is lower cost than primary recycling as it does not require such strict separation of material and is currently the most common approach. Medical devices could be recycled in this way, but the material could not be used for manufacturing more medical devices as medical devices require virgin plastic.
- **Tertiary recycling** extracts useful material, but the polymer is not kept intact. This requires a lot of energy and processing, but the output can be used to synthesise high quality polymers which may be suitable for medical devices.
- Finally **quaternary recycling** involves incineration of plastic material with energy recovered.

The impact must be carefully assessed using techniques such as LCA to identify which process creates a positive outcome. To optimise impact reduction, recycling should focus on quality and quantity of avoided product production.

Recycling can be conducted through either a mechanical or chemical process. The choice of which approach to use will also have an effect, for example chemical recycling may involve materials which have a high ecotoxicity [21] but can return more useful and valuable output feedstock.

One of the main impacts from pMDIs is the amount of propellant emitted into the environment, and this does not just occur during the use life of the device. A study for GSK by the Carbon Trust reported that 18% of the climate change impact of a Seretide pMDI over the entire product life cycle was from propellant released during disposal [22]. Therefore, there is also an opportunity to recapture the propellant and recycle it, possibly for use in refrigerants and air conditioning, if appropriate processing is available.

While there are several examples of medical recycling schemes for inhalers and other medical devices, these have not shown particularly positive results to date. GSK ran the Complete the Cycle scheme for 9 years from 2011 to 2020 and collected over 2 million inhalers from participating pharmacies across the UK in that time [23]. However, as over 60 million inhalers are prescribed each year, this value represents a recycling rate of <0.5%. Likewise, Chiesi's Take AIR scheme ran in Leicestershire for 12 months and involved providing patients with pre-paid envelopes to return used inhalers, rather than the drop-off service offered by GSK and Teva in the ongoing Terracycle scheme. Approximately 2% of inhalers within the scheme's scope were recycled. The Take AIR scheme was reported to have saved a minimum of 119.3 tonnes of carbon from entering the atmosphere, however this was calculated solely on the amount of propellant recovered [24].

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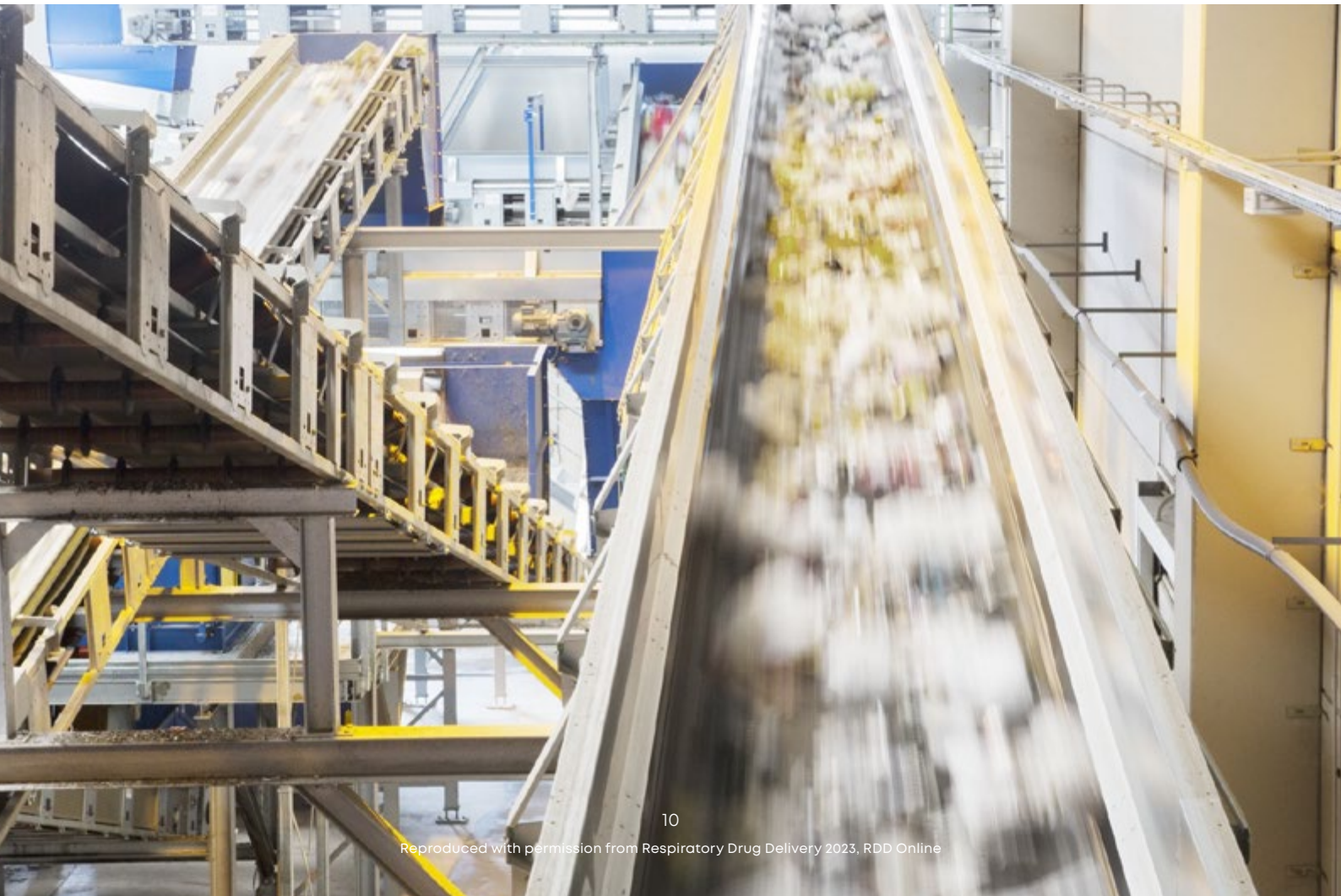
Other industries have seen much greater engagement. Nespresso achieved a global coffee pod recycling rate of 28% in 2021, with a further 27% incinerated for energy generation [25].

Recommendations for the design of any new inhaler recycling schemes include:

- Take the burden away from the user. The Nespresso scheme offers a near-frictionless collection that makes the process almost as easy as disposal. This contrasts to some of the inhaler initiatives which required devices to be returned to a pharmacy.
- The scheme must be well-advertised. Awareness is key to getting buy in from users, and successful schemes tend to have large marketing campaigns which inevitably come at a cost.
- Global support and a unified approach across different locations. This makes the system as uncomplicated and easy to understand as possible. An industry consortium should be formed to drive through these changes.

The burden of reverse logistics and processing material may make recycling an unattractive and uneconomical option for many medicine providers. To increase viability of this option, the following design principles should be followed to minimise the cost and time associated with processing material for recycling:

- Devices should be easy to disassemble into individual components of single materials.
- The mix of materials should be kept to a minimum to help to reduce the separation burden.
- Composite materials should be avoided; if possible, use materials that are easily recyclable.
- Colorants and additives should be reduced.
- Hazardous materials should be reduced to simplify the reverse logistics.



7 Biodegradable/compostable

Biodegradable polymers have gained traction in consumer products over the last few decades. From picnic cutlery made from corn starch to compostable tea bags and coffee pods, biodegradable products are being touted as having superior eco-friendly credentials. Despite perceptions of these materials having weak mechanical properties or insufficient sterility or biocompatibility, there may be some benefits for inhalers, over non-biodegradable polymers like polypropylene. While this solution is worthy of consideration alongside the routes mentioned above, there is debate as to whether biodegradability is a good enough fit for an effective circular economy [26].

Bioplastics (plastics from natural or renewable sources) can provide two key environmental benefits, the first being that bioderived sources are from renewable sources that can often have lower carbon footprint than their fossil-derived alternatives. These are already in use in some inhalation products. The second is that certain classes of bioplastics are biodegradable, allowing for disposal methods more favourable than landfill or incineration [27]. There are several promising biodegradable material developments such as cellulose acetate, polylactic acid (PLA) or polyhydroxyalkanoates (PHAs) [28]. PHAs are a recently emerging class of plastics that are both bioderived and biodegradable, produced through bacterial fermentation using bio-derived feedstocks, including waste substances. The chemical composition of PHAs can also be tuned, resulting in a wide range of thermal processing and mechanical properties that can be tailored to specific applications [29].

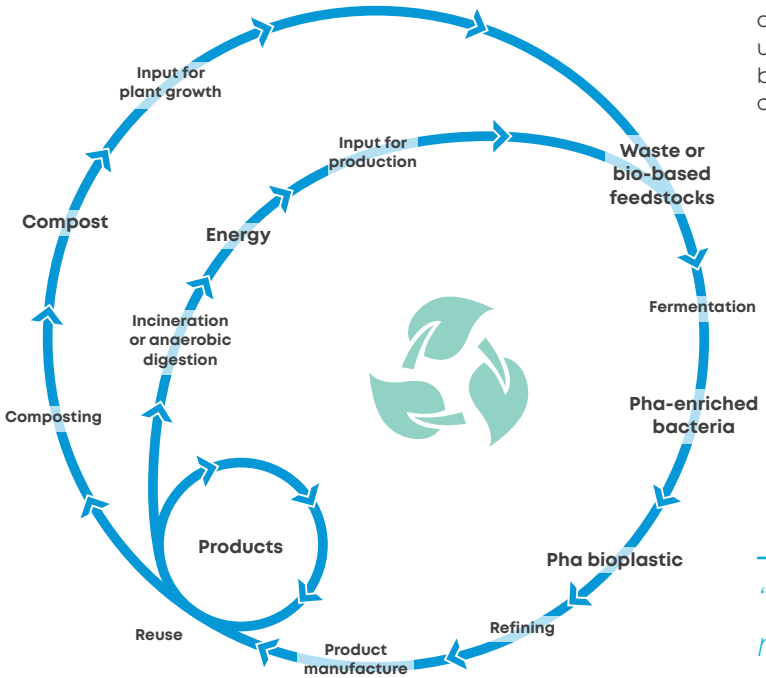


Figure 5: PHA lifecycle [29]

It is often argued that for a material life cycle to be circular the material should maintain several generations of usable life via reuse, reprocessing and so on. Biodegradable materials that degrade through composting, anaerobic digestion, or other means, turn organic matter into H_2O, CO_2, CH_4 and perhaps nutrients for plant growth, but are no longer 'usable' in any tangible capacity. CO_2 and CH_4 are both greenhouse gases, thus increasing the carbon footprint of this approach too. However, under certain carefully managed conditions, biodegradable materials like PHA can play a role in the circular economy. This is where energy can be recovered from the biodegradation, or nutrients can be used to feed plant growth for agricultural or non-food competing feedstock for biopolymers. Advancements in PHA formulation also allow for multiple uses, and potentially even mechanical recycling, though no recycling schemes for PHA are currently known to be commercially active [29].

Despite great advancements and numerous benefits of biodegradable materials, there remain some significant challenges. The possibility of leaching potentially ecotoxic substances (i.e., active pharmaceutical ingredients) or non-biodegradable materials into the environment presents a largely unknown risk. The lack of immediately available materials for medical applications is also an obstacle for fast implementation of this solution. Composting prevalence, at user's homes or in industry, is also inconsistent at a regional and international level [30].

To progress towards developing biodegradable solutions, further investment into the research and development of emerging material technologies, like PHAs, could alleviate the remaining challenges mentioned above. As uptake in home and municipal composting increases, biodegradability can become a more responsible long-term option, preventing waste material entering landfill.

"Despite great advancements and numerous benefits of biodegradable materials, there remain some significant challenges."

8 Conclusions

There are several feasible end-of-life options for inhalers beyond landfill and incineration. Circularity can be introduced into the product life cycle which, if implemented correctly, can greatly reduce their impact across a wide variety of categories.

Some initiatives are aimed at alternative end-of-life strategies for medical devices, but few have been truly effective yet. This is particularly evident in the slow uptake of recycling schemes. There are encouraging success stories from the consumer world where circularity has been implemented and is currently making a tangible difference. The medical sector can learn from this and improve its offering by streamlining the process for patients and making it as straightforward as possible.

It can be unclear which end-of-life route to apply to a given product, and often a combination may be appropriate to achieve the desired effect. Products must be assessed on a case-by-case basis to determine the potential benefit and cost across a variety of impact categories.

In strategizing product end-of-life, the following should be considered:

- Conduct LCAs as part of the early-stage design process so that informed decisions can be made about the best approach.
- The European Waste Directive gives a clear order of preference for end-of-life strategies. Prevention is the most impactful factor, followed by reuse then recycling. The options are also not mutually exclusive; it would be preferrable to have a highly reusable device that is remanufactured many times before finally being recycled.
- Moving to a more reusable product could be one of the simplest options to implement as there are no reverse logistics or challenging waste processing procedures. It is possible that an existing product such as a pMDI or capsule DPI could have its use life extended with little or no physical design changes, rather just revalidation with greater utilisation. When designing a new inhalation product, consideration should be given early in the design process to maximising the use life of durable elements and minimising the impact of consumable elements.
- Implementing a reprocessing, refurbishment or remanufacturing scheme requires investment in new facilities, reverse logistics and additional product validation, but offers a means to significantly reduce environmental burden. The process should be carefully designed up front to ensure it is of net benefit.
- Whilst recycling is often the go-to method for reducing impact and is the most publicly visible option, it is also third in the five-tiered hierarchy because energy is required to process material, and often the material recovered is of lower grade than the original. For this reason, recycling should be considered in conjunction with other end-of-life options.
- Biodegradability is likely to enhance the circular material economy in the future where the other options are not technically feasible or economically viable. However, there are no known options for biodegradable materials suitable for inhaler manufacture available in the short term.
- Patient engagement is critical, and schemes must be simple to use and well-advertised. Awareness and education are key to ensuring the necessary level of adherence.
- The appropriate end-of-life treatment will depend upon economic viability. Many of the options will require investment, the feasibility of which will depend upon the value of the output and the production volumes. Industry collaboration will greatly increase the chances of success by increasing volumes and sharing the cost of implementation.
- Responsible alternatives to landfill and incineration are needed. The economic value of the waste being generated should be considered to understand if value can be reclaimed. If not, biodegradability may be a lower impact option than landfill or incineration.

In summary, there are significant opportunities to reduce the environmental burden of currently marketed products through use life extension (reuse), switching to less impactful resins (reduce), or recovering materials at the end of life (recycling) rather than sending inhalers to landfill. Even greater improvements are possible by carefully designing the next generation of inhalers to maximise circularity and minimise waste. The environmental impact of making positive changes versus ignoring this challenge will be significant, and that work needs to start today.

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Lit-WHI-065 v0.3 '2023_Respiratory Drug Delivery_Whitepaper'