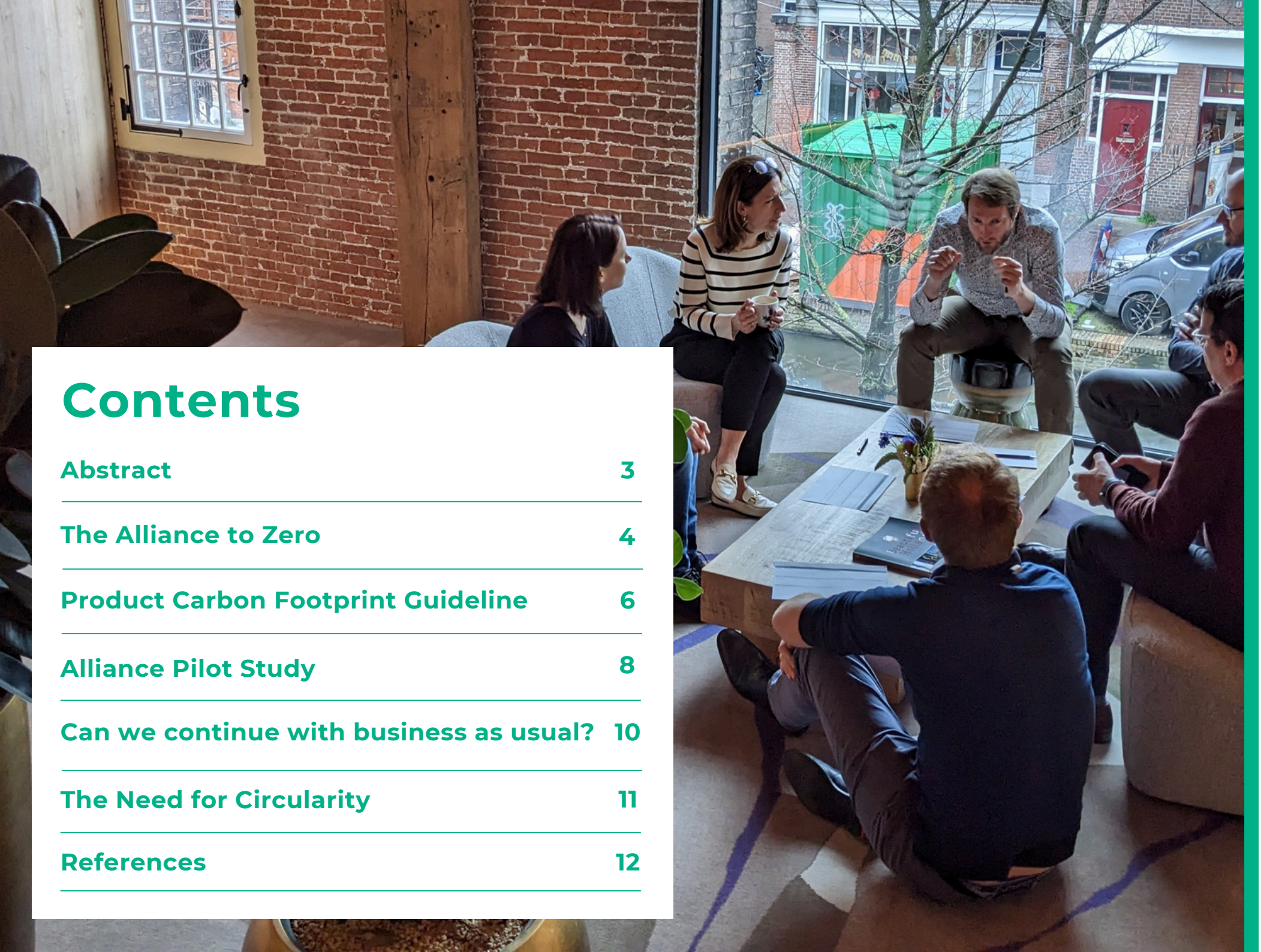
JULY 2024

Enabling Net Zero
Pharma Products

NET ZERO REQUIRES CIRCULARITY

ALLIANCE TO ZERO



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Abstract

This paper outlines the work of the Alliance to Zero in fostering collaboration between various players in the self-injection device supply chain in order to achieve a net zero product offering.

The discussion includes an overview of the current situation, an outline of the Alliance's shared Product Carbon Footprint Guideline, detail from the pilot study of the carbon footprint of a self-injection device conducted by the Alliance to Zero and evidence of the need for a transition to a circular economy.

The challenge of Net Zero in the pharmaceutical industry

The global climate crisis is demanding action from governments and industry alike, with many stakeholders setting themselves ambitious targets to reach net zero emissions by 2050 or sooner, acting in accordance with the goals of the 2015 Paris Climate Agreement.

The pharmaceutical industry is no exception to this. In fact, it is currently a major contributor to global emissions. According to current data, pharma has overtaken the automotive industry for emissions, producing 48.55 tons of carbon emissions for every $1 million it generates which compares to the automotive industry at 31.4 tons per $ million revenue.[1]

Given that the industry is currently undergoing a period of significant growth, this contribution is unlikely to decrease without significant intervention.
One of the primary growth sectors is the parenteral market – specifically injection devices for patient self-administration.

The key drivers for this growth include a major increase in the number of biologic and biosimilar medications reaching market, ageing populations in many countries around the globe and increasing demands on healthcare services leading to a movement of care from the clinic to the home wherever possible.

If pharma and biotech players are going to achieve their net zero targets without stalling their growth, there must be co-operation, shared ambition, and openness across the supply chain, from material suppliers to manufacturers to distributors.

Some suppliers have already recognised this and are beginning to prioritize working with each other where there is a shared mindset, one such example being the Alliance to Zero.

Figure 1: Parenteral Drug Product examples

> Transitioning from a linear to **a circular model** will be key to reducing emissions from both raw materials and end of life, which, when combined, account for **over 50%** of the emissions associated with disposable autoinjectors including secondary packaging.

The Alliance to Zero

The Alliance to Zero was established to facilitate the transition of the pharmaceutical industry to compliance with net zero emission targets. It has brought together like-minded and highly specialized companies from across the supply chain to create a framework under which all its members can work together to support their customers in achieving the goals of the 2015 Paris Climate Agreement.

Figure 2: Autoinjector example packed in monomaterial carton

The primary focus of the Alliance is the manufacture of injection devices, including secondary packaging for patient self-administration. The eight founding members – Ypsomed, SCHOTT Pharma, Dätwyler, Schreiner MediPharm, Sharp, Harro Höfliger, Körber and HealthBeacon – represent the key parts of this supply chain.

> To further promote co-operation between its members in pursuit of net zero, the Alliance has established **multiple working groups**. Some of these work in collaboration with subject matter experts to develop guidelines and facilitate more productive interactions.

Mission

To stimulate further co-operation between its members in pursuit of net zero, the Alliance has established multiple working groups. Some of these work in collaboration with subject matter experts, to develop guidelines and facilitate more productive interactions towards more sustainable outcomes.

For example, one of the Alliance's working groups has developed a guideline for communicating sustainability concepts. This allows compatibility and interoperability between Alliance members' operations when working together towards net zero goals.

> The complexity and standards involved in manufacturing a self-injection device, going all the way from raw materials to distribution to the end user mandates **co-operation** involving a variety of companies, each with their own expertise.

The Alliance has also established a methodology for its members to calculate the carbon footprint of their own companies and to reveal which emission sources are responsible for the largest footprint shares to set priorities for mitigation in the value chain of the auto-injector – across the industry. The lack of standardised practices for establishing the carbon footprint of products is a serious unmet need and risk to delivering on net zero commitments.

In combination, the common language and the carbon footprint calculation methodology form the basis of the Alliance's Product Carbon Footprint (PCF) Guideline.

The PCF Guideline is intended to facilitate standardised comparisons between assessed products and establish a baseline to work from when making advancements in reducing the CO_2 emissions associated with self-injection devices.

Ambition 2023

We will have raised awareness and created a strong network in the industry. Specific programs to reduce GHG emissions including waste reduction in injection devices have been established within our companies. The full supply chain of injection devices is represented by the Alliance.

Ambition 2026

Business models have been developed collaboratively based on GHG emissions reduction and Circular Economy principles. We have developed multiple supply chain solutions to significantly decarbonise injection devices that can be used across a wide variety of existing and future devices.

Ambition 2030

Our company operations covering the supply chain of the net zero product offering will be net zero or show significant GHG emissions reduction. Our solutions will have contributed to the launch of the first generation of net zero injection devices.

Product Carbon Footprint Guideline

The Alliance's PCF Guideline was developed in collaboration with Carnstone (now SLR Consulting) and South Pole consultancies who are both subject matter experts in developing practices and methodologies to help companies achieve their net zero goals. The PCF Guideline is based on existing carbon accounting standards and has been validated via peer review with pharmaceutical companies.

It is intended to function as a core pillar of the Alliance's work going forward, guiding its decision making and enabling its members to clearly communicate sustainability ideas and principles, facilitating closer co-operation across the supply chain towards a common goal.

The PCF Guideline sets out a standardized methodology for measuring and communicating the carbon footprint of a self-injection device. The guideline sets out a six-step process, which is defined in detail on the next page.

Product Carbon Footprint Guideline

1 Define Scope

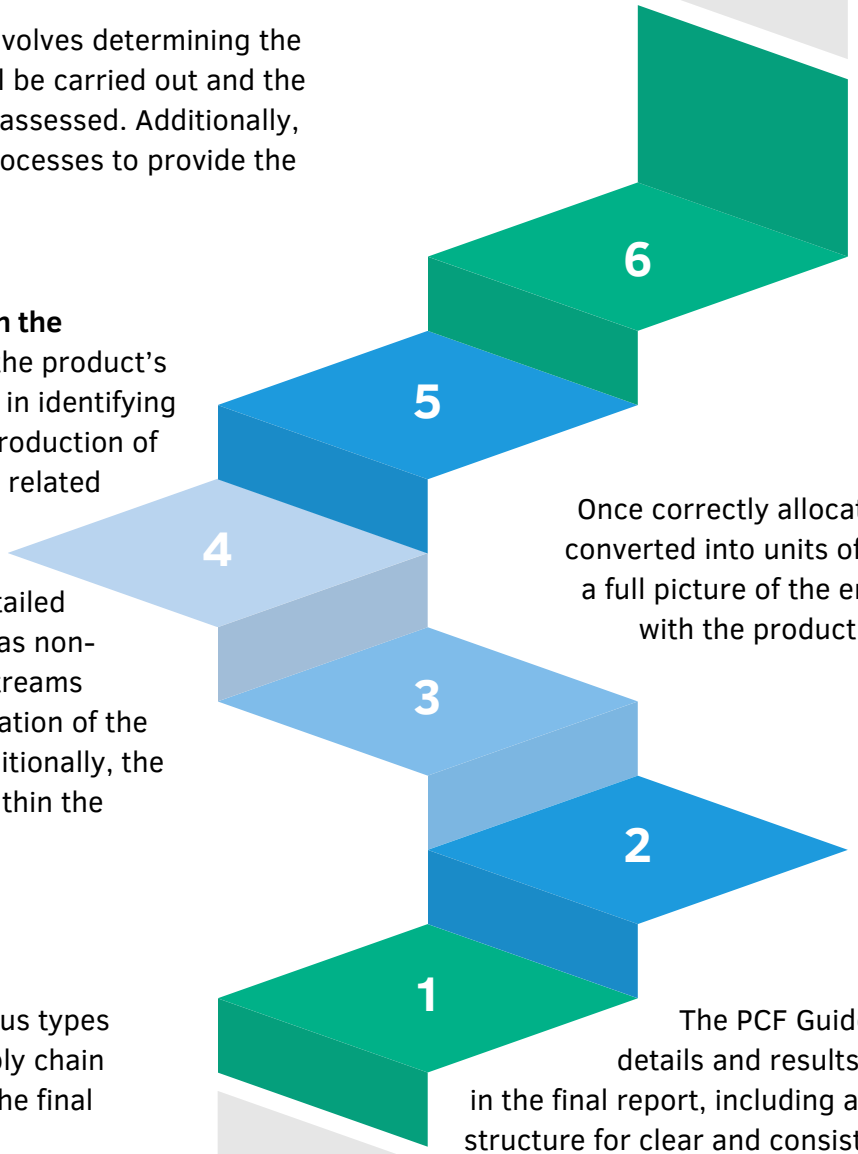
Focus in on a specific product. This step involves determining the level of detail to which the investigation will be carried out and the individual components and materials to be assessed. Additionally, this definition should include production processes to provide the most accurate picture possible.

2 Set Boundaries

Determine which CO_2 emission to include in the calculation. Map out the various stages of the product's cradle-to-grave lifecycle at this point to aid in identifying which emissions are directly linked to the production of the product under investigation. All directly related emissions should be included, as well as some additional indirectly linked emissions as detailed in the PCF Guideline. These are referred to as non-attributable processes and include waste streams generated during production and transportation of the raw material to the manufacturing site. Additionally, the Alliance decided to include capital goods within the scope of the PCF Guideline.

3 Collect Data

Follow the plan for the investigation. Various types of data should be collected across the supply chain to account for and mitigate uncertainty in the final data set. The PCF Guideline includes a Data Collection Sheet, which shows how the product lifecycle is broken down in alignment with the value chain for the device, to assist in structuring and streamlining data collection.



4 Allocate Data

Assign the collected data to functional units outlined in the scope of the investigation.

5 Calculate Results

Once correctly allocated, the data can be converted into units of CO_2 equivalent and a full picture of the emissions associated with the product can be determined.

6 Report

The PCF Guideline outlines which details and results should be included in the final report, including a standard reporting structure for clear and consistent communication of the results. This allows action to be taken as data is converted into units of CO_2 equivalent and a full picture of the emissions associated with the product is determined.

Alliance Pilot Study

The PCF Guideline, which is based on the 'Product Life Cycle Accounting and Reporting Standard' ('Product Standard') from the 'GHG Protocol', allows users to calculate the carbon footprint for a defined product. The Alliance has used the PCF Guideline to calculate the baseline of its pilot study, which investigated the CO_2 emissions associated with a disposable 1 milliliter autoinjector and its secondary packaging (as manufactured by the members of the Alliance). The scope of the investigation included solely the manufacture of the device itself and secondary packaging – the carbon footprint of the drug formulation was not included as part of the study.

The results of the pilot study showed the distribution of CO_2 emissions broken down by lifecycle stage and Alliance members. These results have allowed the Alliance to identify the key points in the production of a disposable autoinjector that contribute to the carbon footprint so that future efforts to reduce it can be appropriately targeted for maximum effect.

Results

By far the biggest single contributing factor to the carbon footprint of an autoinjector is the **raw materials used for production (40%)**, following which are its **packaging (20%)**, and **end of life (20%).** Other factors, which include processing, transport and waste, together account for the remaining 25% of emissions.

With the major contributing factor to an autoinjector's carbon footprint coming from the materials used to manufacture it, it is imperative that consideration be undertaken on how to reduce their contribution to the overall carbon footprint.

One option to reduce the raw material contribution is to apply circularity. This way, the demand to introduce new raw material gets reduced. At the same time, circularity is a mean to address the end-of-life contributions. As such, circularity is a mean to address both RM and EOL and hence >50% of the footprint (or even more when excluding Use). **This brings us to the conclusion: net zero requires circularity.**

The application of circular economy thinking will be key here – by adopting a make, use, collect, reuse and recycle mindset, a move can be made from using virgin materials to non-virgin alternatives.

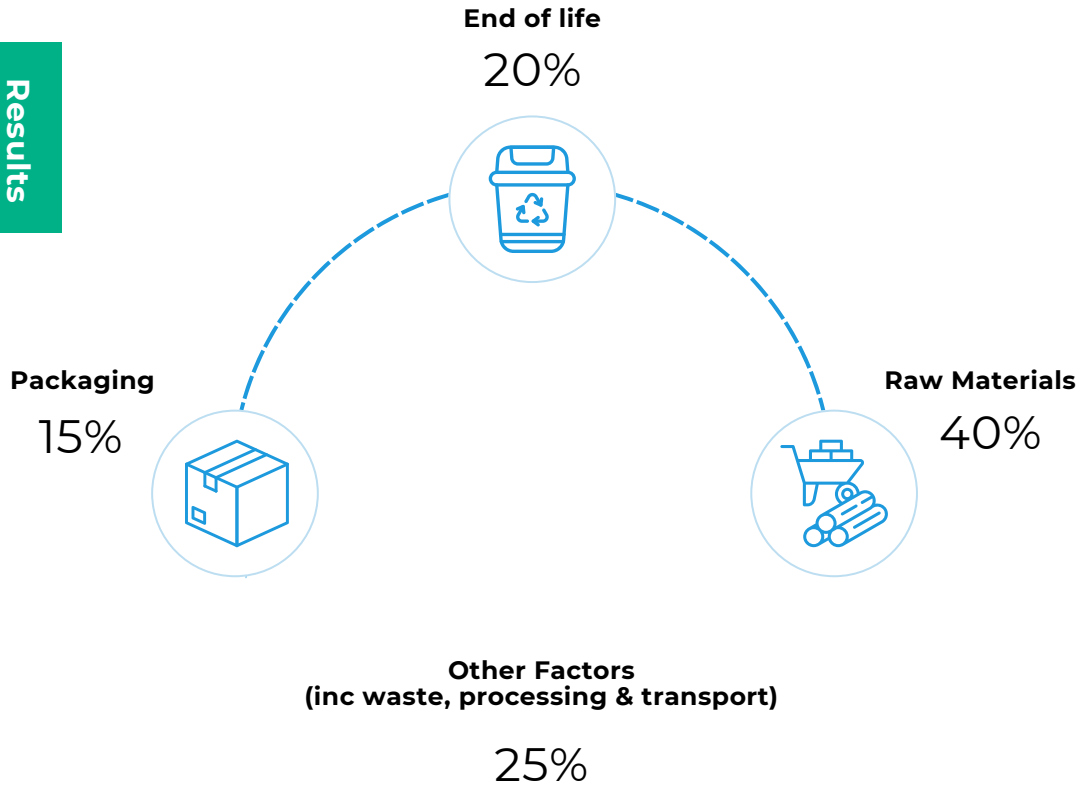


Figure 3: Contributing Factors to the Carbon Footprint of an Autoinjector, data as per Alliance 1ml AI case, Version 2 2023

Reusing and recycling poses a specific challenge to the pharmaceutical industry. Considering the exceptionally high demands on material control quality for its products, the first-and-foremost concern for patient safety and need to handle sharps and biohazard waste at end of life, the use of virgin materials and disposal in landfill or incineration plants has been the traditionally preferred approach for simplicity. However, if net zero goals are to be met, this paradigm must change.

Transitioning to the reuse of components and the use of recycled materials may be difficult, but some companies are already making headway in this area. The first challenge to overcome is the collection of used devices so that they may be refurbished or recycled. Two leading pharmaceutical companies, Johnson & Johnson[2] and Novo Nordisk[3], have implemented product take-back schemes that aim to encourage patients to secure the resources bound to the used self-injection devices.

One scheme operates by post and envelope, whereas two basic concepts are in several national pilots. With both approaches, the collected devices get sent back to the supplier free of charge. Expansion and widespread adoption of this sort of scheme will be critical for implementing a circular economy in the pharmaceutical industry.

Once the materials are collected, efficient methods for breaking down the device and recycling its constituent materials will be necessary to maximize the reduction to the carbon footprint of future devices. This will be simpler for secondary packaging components than for the primary packaging, which counts as medical waste and must be thoroughly sterilised before reprocessing.

However, undertaking the work to implement these processes will provide dividends in carbon footprint reduction and progress towards net zero goals.

Can we continue with business as usual?

Pressure continues to mount from the public, governments, and regulators to tackle the climate crisis across all industries. Many countries are mandating extended producer responsibility schemes, including for sharps, electronics and drug products, that are intended to result in an increased prevalence of take-back schemes and greater availability of recycled materials.

Furthermore, governments are reacting to social pressure by implementing green taxes and making investments to encourage industry to transition to sustainable practices and achieve net zero targets by 2050.

The pharmaceutical industry cannot afford to be left behind, despite the unique challenges it faces. The Alliance to Zero is championing the drive to net zero in the field of self-injection devices and their secondary packaging, representing players from across the supply chain with the shared ambition of reaching net zero product offerings. Collaboration across the supply chain will be essential to achieving these goals.

The linear economy is no longer suitable for our modern world – the trend towards circularity is both desirable and necessary. The pharmaceutical industry must turn its efforts towards synthesizing the priority on patient safety and high-quality products with circular thinking. This will involve both a transformation of internal operations to make use of emission-reducing circular technologies and an increased use of recycled rather than virgin materials.

Towards a circular future

Net zero requires circularity. We understand this from our own LCA data, just as other industries extrapolate this from theirs. The principle of a circular economy, is to reduce waste production and pollution by reusing, repairing, remanufacturing and recycling products at their end of life and, in the same way, reduce reliance on virgin materials.[4] The circular economy is opposed to a more traditional linear economic model, where raw materials are harvested from natural sources, processed, manufactured into products, distributed and, ultimately, disposed of.

There is already movement towards a circular economy in various areas of the pharmaceutical industry, including the product take-back schemes as mentioned previously. The need for a circular economy in the drug delivery industry is reflected in our own carbon footprinting exercise, however, achieving true circularity is not something any one player can hope to accomplish alone – it requires co-operation across the supply chain.

Our devices require complex assembly and a variety of materials, including polymers, metals and glass. They must also be manufactured to an exacting standard of quality, sterility, and functionality, as they often contain life-saving medications.

Through the Alliance to Zero we are aligning on concepts and solutions that move beyond company agendas; integrating with academic institutions to make visible our business-induced blind spots and develop ecosystem thinking.

The journey to net zero has begun and we are excited to see it through.

Demonstrator from concept study between Alliance to Zero und TU Delft

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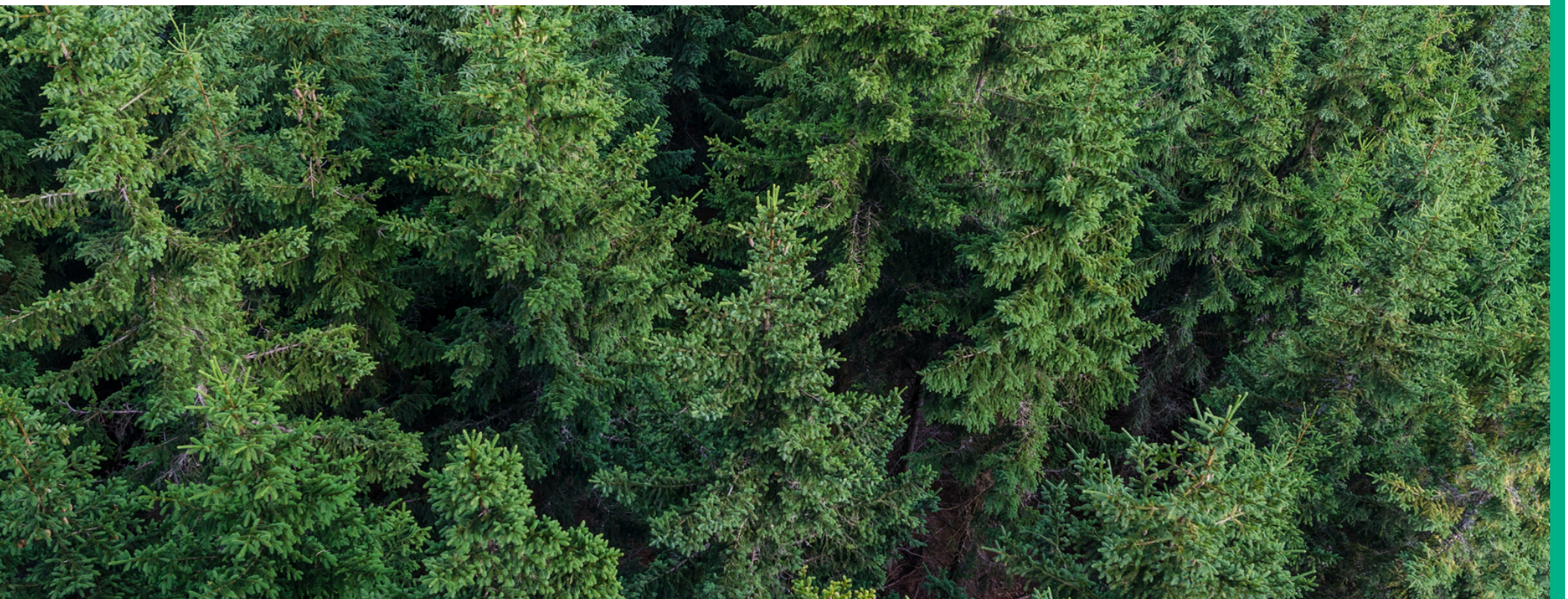

This document was produced by the members of the Alliance to Zero.

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