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SELFCARE SOLUTIONS

PAVING THE WAY TO ZERO CARBON EMISSION COMBINATION PRODUCTS: INSIGHTS FROM THE YPSOMATE ZERO CASE STUDY

In this article, Sebastian Gerner, Innovation & Business Development Manager, and Andreas Schneider, PhD, Innovation & Business Development Director, both of Ypsomed, discuss how the adoption of prefilled self-injection systems has put the drug delivery device industry at the forefront of the the global plastics challenge. The authors introduce YpsoMate Zero as a case study, Ypsomed's net-zero carbon emission prefilled autoinjector, covering how the use of alternative materials, supply chain optimisations and offsetting the remaining carbon footprint result in an eco-friendly device without compromising on usability or patient safety.

SELF-MEDICATION AND SUSTAINABILITY: TURNING THE VICIOUS CYCLE INTO A VIRTUOUS ONE

When Susanna, who has been living with arthritis for about five years, started taking her newly prescribed biologics in a prefilled autoinjector, she realised that it really did reduce pain, swelling and joint stiffness. This prompted her rheumatologist to propose the new treatment option for the coming years to stop further joint erosion. However, she soon discovered that her injection routine would lead to a considerable amount of waste.

In fact, more than 16 billion injections are administered worldwide every year. A significant portion of these injection devices heads straight for the landfill – shockingly, less than 10% of diabetes patients used specific containers for the disposal of their needles, syringes and pens. For patients living with chronic diseases, injection devices are an indispensable part of their disease management routine. Instead of burdening the environment – and unnecessarily forcing patients to adopt non-eco-friendly habits – self-care should help to preserve natural resources and contribute to minimising waste and pollution. Self-care should have minimal impact on our environment.

> "Self-care should help to preserve natural resources and contribute to minimising waste and pollution."

Easy-to-use self-injection systems contribute to shifting the point of care from the hospital to the home, and are demonstrating success in doing so. At-home treatment of chronic diseases not only improves access to healthcare and lowers overall costs, it also helps to minimise the overall environmental impact by, for example, reducing the need for travel or to use hospital infrastructure and resources. The increasing adoption of single-use and prefilled self-injection devices, however, has put the pharmaceutical industry in general, and the drug delivery device manufacturers in particular, in the public spotlight with respect to some of the most pressing issues of our time: the use of plastics and its effect on the environment.

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"The vision is clear: Ypsomed is committed to achieving net-zero carbon emissions by 2030."

There is little debate about the responsibility of the pharmaceutical supply chain to help minimise the impact of healthcare on the environment and contribute to a more sustainable future. Additionally, there is considerable scope for systemic improvements where we see healthcare-related environmental impacts. However, the environmental costs of medical devices, healthcare facilities and care concepts are often overlooked. As Simon Michel, CEO at Ypsomed states, "Every year we manufacture millions of self-injection devices. As this number continues to increase, it puts us at the forefront of plastic waste – one of the world's biggest environmental challenges. We need to act now, and send a clear signal that we are taking our responsibility seriously."

Ypsomed has adopted a corporate sustainability programme that embraces environment-friendly and resource-saving actions. The vision is clear: Ypsomed is committed to achieving net-zero carbon emissions by 2030. Step-by-step, the company is reorienting its manufacturing processes, supply chain and self-injection device designs towards a less resource-intensive, more circular mindset. Ypsomed is shifting from a linear take-make-waste economy to a circular way of thinking, embracing, wherever applicable, the three core principles proposed by the Ellen MacArthur Foundation (Cowes, UK) and others to build a positive future economy:

1. Design out waste and pollution – consider waste as a design flaw and use new materials and technologies.
2. Keep products and materials in use – enable product and component reuse, repair and re-manufacturing. Allow materials to be recovered so that they do not end up in landfill.
3. Regenerate natural systems – restore valuable nutrients to the soil and other ecosystems to enhance our natural resources.

Despite all the challenges of achieving net-zero carbon emissions by 2030,

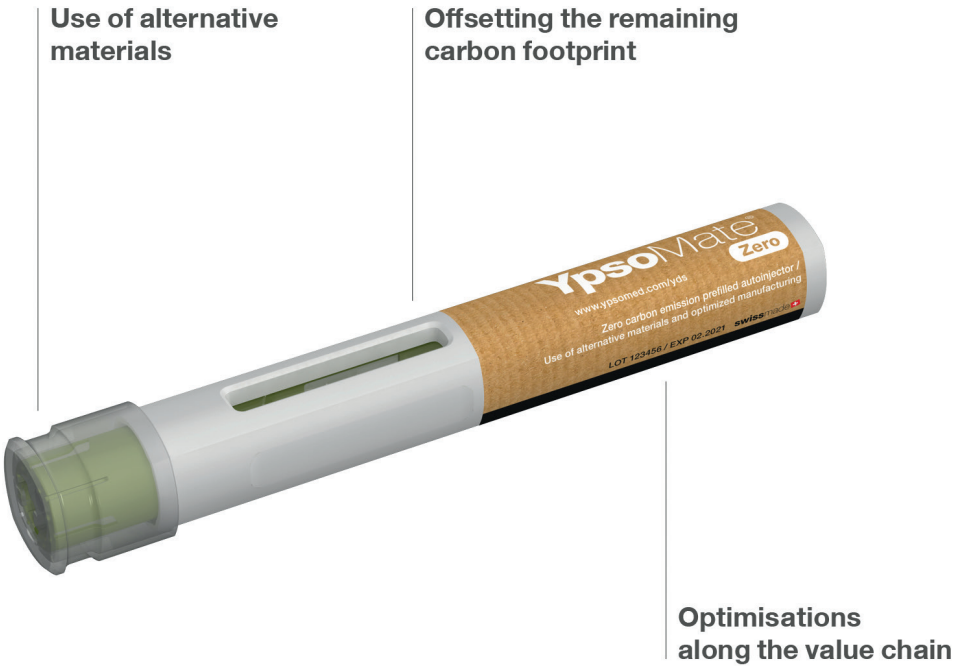

Figure 1: The YpsoMate Zero autoinjector with zero carbon footprint. The use of alternative materials, optimisations along the value chain and offsetting of the remaining carbon footprint result in a carbon emission free prefilled autoinjector without compromising on usability and patient safety.

Ypsomed has already set out on the journey to zero. This article introduces the case study of YpsoMate Zero, a prefilled autoinjector with net-zero carbon emissions and a first step towards achieving Ypsomed's net-zero carbon emissions by the 2030 goal. The case study illustrates how the use of alternative materials, optimisations along the supply chain and offsetting the remaining carbon foot print lead to an environment-friendly device offering without compromising on usability and patient safety.

"Before optimising the YpsoMate device design to minimise its carbon footprint, it was essential to gain detailed insight into the environmental impacts associated with the device as it stood."

INTRODUCING YPSOMATE ZERO – THE CARBON NEUTRAL PREFILLED AUTOINJECTOR

There are two main reasons that the YpsoMate autoinjector for use with prefilled 1.0 mL syringes was selected to have its environmental impact minimised (Figure 1). First, YpsoMate is a state-of-the-art prefilled autoinjector that provides patients with a simple and convenient automatic two-step injection procedure. YpsoMate prioritises patient safety and the ability to use the device effectively. However, its single-use nature has put the prefilled autoinjector at the forefront of the global plastic challenge, urging Ypsomed to take action. Second, YpsoMate 1.0 mL is used across chronic disease areas where patients regularly self-inject over a long period of time. Patients pull off the cap to remove the needle shield from the prefilled syringe, press the autoinjector onto the skin to trigger the injection and then dispose of the autoinjector after use. Continued YpsoMate-based self-injection leads to a considerable accumulation of waste during therapy. YpsoMate 1.0 mL, therefore, is a key priority when it comes to reducing the environmental costs of self-injection systems.

Before optimising the YpsoMate device design to minimise its carbon footprint, it was essential to gain detailed insight into the environmental impacts associated with the device as it stood. A lifecycle assessment was conducted to obtain a quantitative and systematic perspective

on the environmental costs of the two-step autoinjector over its entire lifecycle, including raw materials, manufacturing and final disposal. Figure 2 shows the YpsoMate autoinjector value chain and highlights those areas included in the case study.

Not only did the lifecycle analysis assess those process steps controlled by Ypsomed, but also included the end of life of the final assembled drug product to better understand the environmental impact associated with its disposal. A breakdown of the total carbon emission of the YpsoMate autoinjector is shown in Figure 3. The lifecycle analysis highlighted the environmental hotspots and enabled evidence-based and data-driven design optimisations.

The analysis provided two key insights that guided the subsequent optimisation efforts to minimise the environmental effects of the device. First, the materials used for the device components had the greatest impact on the device total carbon emissions. In fact, the polymer components, such as the device housing, the syringe holding unit and the components used to remove the needle guard, accounted for about 60% of the total carbon emissions of the device. Second, the analysis confirmed that the packaging materials used to ship the device components either in-house or to the final assembly sites also constituted a significant environmental impact, and were therefore a key priority. The weight of the materials used to securely package the autoinjectors is more than half of the overall device weight, and contributed to about 20% of the total carbon emissions. Interestingly, the lifecycle analysis showed that the transportation of raw materials was less critical for the environmental impact of the device.

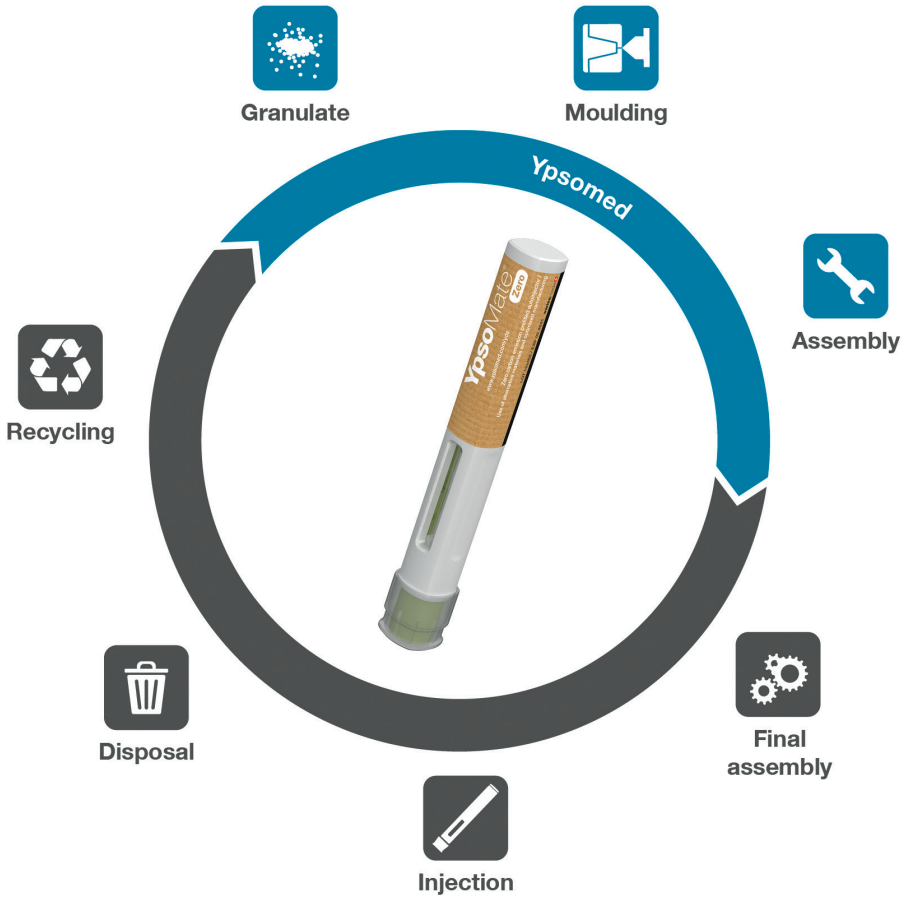

Figure 2: From vicious to virtuous circle. An introduction to the YpsoMate autoinjector value chain. The areas included in the YpsoMate Zero case study are highlighted in blue.

The lifecycle analysis thereby provided the basis for reducing the YpsoMate carbon emissions, directing the engineering efforts towards the most pressing environmental hotspots:

1. Use of alternative polymers for selected device components and packaging (e.g. device housing and packaging tray)
2. Close the loop for the packaging of device components and device sub-assemblies (e.g. trays, pallets)
3. Implement design for recycling into the development process.

The iterative implementation of the aforementioned measures was key to eliminating waste, fostering a sustainable use of natural resources, engendering resource efficiency and, most importantly, avoiding carbon emissions. As illustrated in Figure 4, several optimisation loops have resulted in a substantial reduction of the total carbon emissions.

However, a state-of-the-art injection device cannot be designed in such a way that the carbon footprint is zero. With the aim of creating a fully carbon neutral prefilled autoinjector, a separate programme is needed to offset the remaining carbon footprint. Ypsomed invests in its own programme to substitute carbon emissions. The Ahueni reforestation programme in Kenya enables the generation of carbon emission certificates while committing to the highest industry standards. Since its launch three years ago, the programme has planted 350,000 indigenous tree species to bind carbon in the long run, create new habitats for plants and animals and proactively include local communities in the project to regenerate their ecosystem.

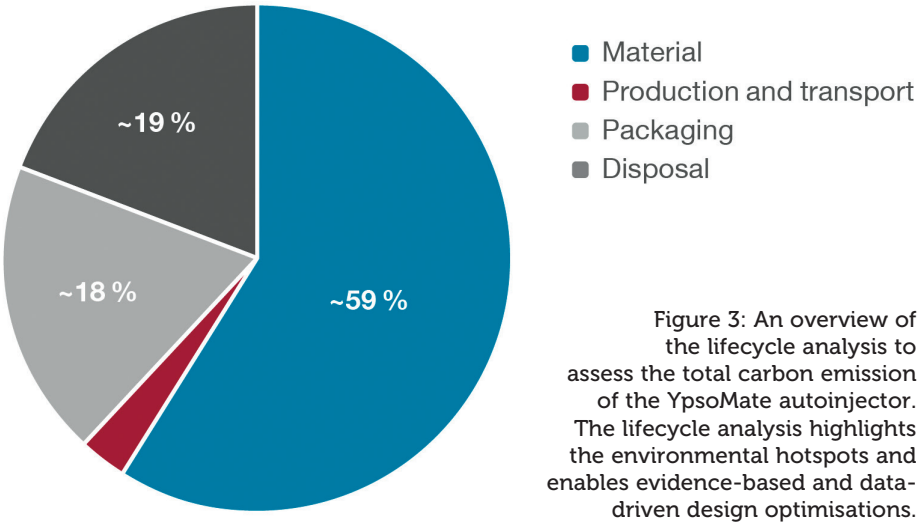

Figure 3: An overview of the lifecycle analysis to assess the total carbon emission of the YpsoMate autoinjector. The lifecycle analysis highlights the environmental hotspots and enables evidence-based and data-driven design optimisations.

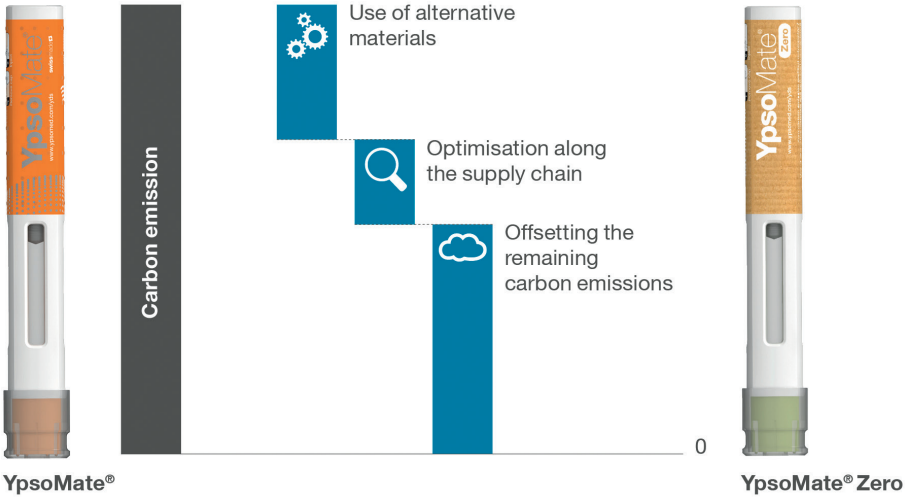

Figure 4: Transforming the proven autoinjector into a zero carbon emission device platform. The use of alternative materials and optimisation along the value chain have resulted in a substantial reduction of the total carbon emission. The Ahueni reforestation programme in Kenya, committing to the highest industry standards, is used to offset the remaining carbon footprint.

COLLABORATION TO ENABLE ZERO CARBON EMISSION COMBINATION PRODUCTS

The world's first net-zero carbon emission autoinjector paves the way towards carbon neutral combination products. On the one hand, the insights gained from YpsoMate Zero inform the overall transition to zero carbon emission self-injection device platforms at Ypsomed. On the other hand, the YpsoMate Zero also reiterates the need to bring together the commitments of partners to achieve a net-zero carbon emission combination product.

Enabling the launch of a zero carbon footprint combination product requires the involvement and co-ordination of multiple actors along the value chain in order to adopt the principles of the circular economy and remove its barriers to adoption. The journey to zero goes beyond Ypsomed's own operations, products and services. To this end, the company is fostering collaborative problem solving, shaping regulatory frameworks and promoting the circular mindset with a science-based approach. Collaboration along the value chain will help Ypsomed to enable zero carbon footprint combination products.

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ABOUT THE COMPANY

Ypsomed's comprehensive drug delivery device platforms include autoinjectors for prefilled syringes in 1 mL and 2.25 mL formats, disposable pens for 3 mL and 1.5 mL cartridges, re-usable pen injectors, ready-to-use prefilled wearable patch injectors and connected devices and digital services. Unique click-on needles and infusion sets complement the broad product portfolio of self-injection systems. With over 30 years of experience and pioneering spirit in the development and manufacturing of innovative injection systems, Ypsomed is well equipped to tackle one of the most pressing challenges of our time: the reduction of carbon emissions. Ypsomed anticipates the future needs of patients, pharmaceutical customers, payers and healthcare professionals, striving with its product solutions to change patients' lives and minimise environmental impact.

Ypsomed is ISO 13485 certified and all processes comply with design control and cGMP guidelines with operational QA/QC experts on site at each location. Ypsomed's US FDA-registered manufacturing facilities are regularly inspected by both pharma customers and regulatory agencies to supply devices for global markets including the US, Europe, Japan, China and India.

Get in touch with us to join our journey to zero: zero@ypsomed.com

ABOUT THE AUTHORS

Sebastian Gerner is Innovation & Business Development Manager with Ypsomed Delivery Systems. He is driving the transition of Ypsomed from a linear take-make-waste economy towards a circular economy. He is a mechanical engineer with more than 10 years of medical device experience in various medical and pharmaceutical companies.

Andreas Schneider is Innovation & Business Development Director with Ypsomed Delivery Systems. He leads a team that drives the definition and development of new drug delivery device platforms, such as next-generation autoinjectors, wearable bolus injectors, connected systems and digital solutions. Dr Schneider has published various articles and given presentations in the areas of innovation management and drug delivery. He holds a PhD in innovation management from ETH Zurich, Switzerland.

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