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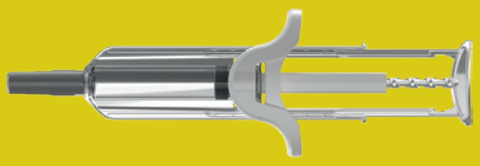

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DRUG DELIVERY & ENVIRONMENTAL SUSTAINABILITY

This edition is one in the ONdrugDelivery series of publications. Each issue focuses on a specific topic within the field of drug delivery, and is supported by industry leaders in that field.

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DESIGNING SUSTAINABILITY INTO PHARMACEUTICAL DEVICES

In this article, Will Davies, Design Consultant at Shore, discusses how to address the challenges of designing sustainability into pharmaceutical devices.

We are all aware of the climate crisis. With governments recently battling over national responsibilities at COP27, we all need to look at our own behaviours, habits and practices – and this extends from an individual level all the way through to global industrial complexes. As a whole, the healthcare industry's climate footprint, at 2.2 gigatonnes carbon dioxide equivalent (CO_2e), is equivalent to 4.4% of net global emissions – if it were a country, it would be the fifth largest in the world.[1]

Given that emissions and healthcare outcomes are closely linked, this creates a deep irony for the industry. Traditionally (and justifiably), so much emphasis has been given to safety, hygiene and quality that virgin materials, single-use devices and cautious packaging have been prioritised over any fledgling sustainability concerns. The standard pharmaceutical model has been "formulate – fill – distribute – deliver – repeat"; a single-use pathway that is typically material and emission heavy. Now, with tangible effects of global warming being felt around the world, and major healthcare bodies such as the NHS in the UK declaring that it will no longer purchase from suppliers that do not meet its commitment to net zero by the end of the decade,[2] the pressure is on the healthcare industry to reform its practices and standard models in order to significantly reduce its footprint, all the way down to net zero.

The NHS's landmark report, "Designing a net zero roadmap for healthcare" (intended to be globally influential), identifies that more than six megatonnes CO_2e can be saved from the NHS England footprint through the reduction of single-use plastics, device reuse, process and product innovation, and pharmaceutical suppliers meeting the NHS's net-zero commitments. These are all factors that the medical and pharmaceutical supply chain has a direct influence on. This equates to 37% of the total NHS footprint of 16.5 Mt CO_2e; if that same 37% reduction can be applied globally, that's an emissions reduction of 814 Mt CO_2e – an enormous figure.

> "It is self-evidently in the interests of all industry stakeholders to maintain a viable and responsible industry."

On top of customer specification for reduced footprint comes increased legislation, not least in the form of extended producer responsibility.[3] Originating in the EU but steadily rolling out across US states and elsewhere, this places a responsibility for post-consumer waste back onto the original manufacturer. Although not yet extended to the pharmaceutical industry, it is increasingly embracing consumer electronics, which includes the wellness and digital health industries, and it is not hard to imagine it moving further into the medical sector in the future.

ADDRESSING THE CHALLENGE

So how do we do it? How do we modify/reinvent/disrupt the well-established standard models of the behemoth pharmaceutical industry to slash these emissions? It is self-evidently in the interests of all industry stakeholders to maintain a viable and responsible industry. Those involved in the design and development of drug delivery devices and system designers are ideally placed to address those key areas identified by the NHS: single-use plastics, reusable devices, and process and product innovation.

We see the word "sustainable" used extensively these days, particularly in corporate literature and advertising as manufacturers aim to demonstrate their corporate social responsibility credentials when describing new product ranges in comparison with older versions, and frequently used alongside the phrase "minimising our carbon footprint". But is it really sustainable – and are they really minimising their footprint?

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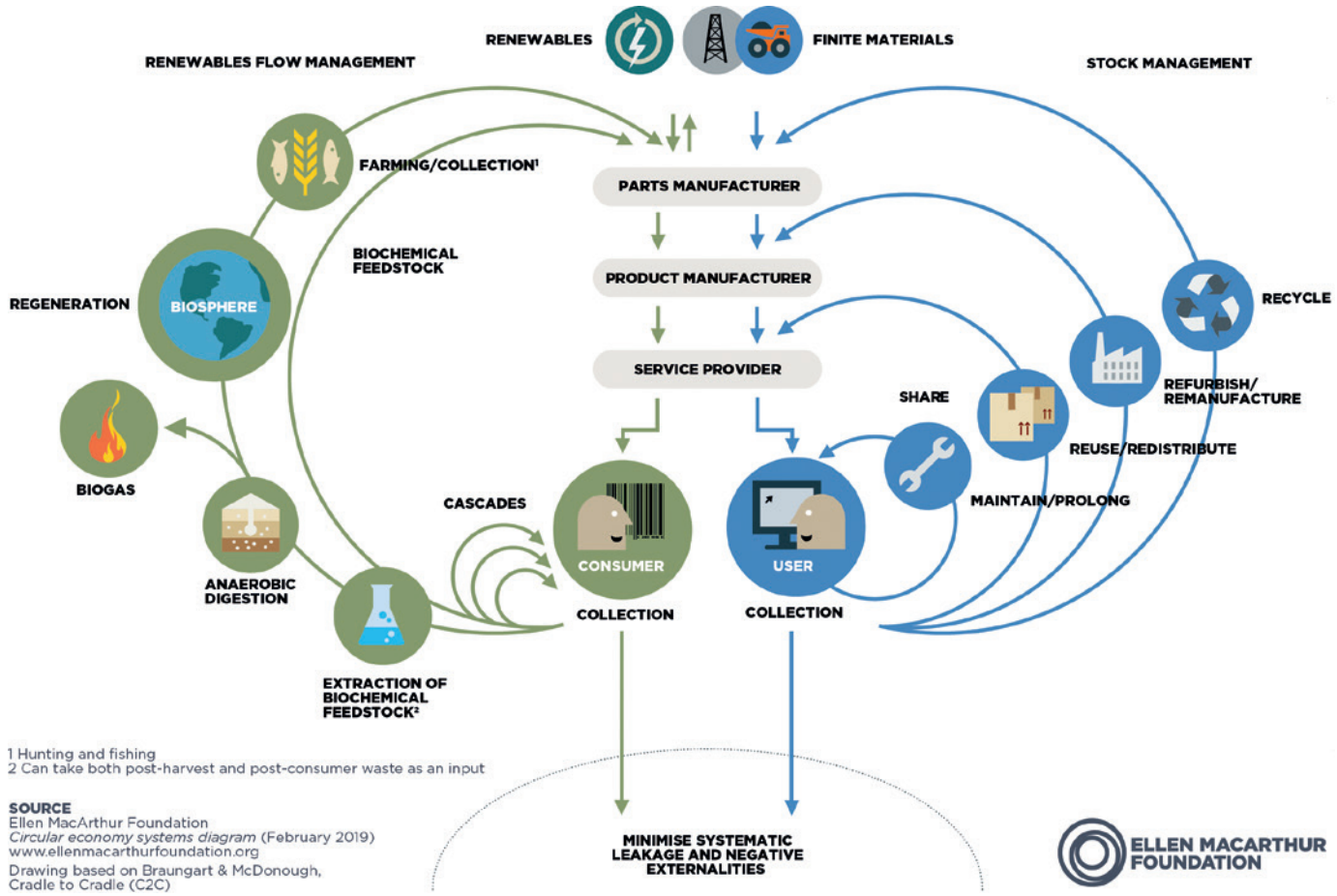

Figure 1: Circular economy butterfly diagram.

Take, for example, a new hypothetical range of packaging – single material, 100% recyclable, 50% lighter and smaller than the previous range, etc. Great effort, and a significant reduction in emissions related to manufacture and transport. But, to be truly sustainable, it must be 100% recycled at end of life, otherwise it is just a continued – albeit reduced – consumption of a finite resource, which by definition is not sustainable. There are various definitions of sustainability, but it is broadly agreed to refer to the ability of maintaining something at a certain rate or level. Therefore, if a practice is depleting a resource at any rate, it is not sustainable. To guarantee 100% recycling rates and true sustainability, the manufacturer must take responsibility for the end-of-life materials and return them to the supply chain within a closed loop; otherwise they are relying on existing recycling streams, which are full of holes (not least the consumer – less than 50% of plastic packaging is recycled globally on average).[4] Therefore, the claim that they are minimising their footprint is only true within the confines of the existing business model – to minimise it absolutely would be to change that model to one that closes the loop.

CLOSING THE LOOP

It is widely recognised that the primary – perhaps only – route to true sustainability is to adopt a circular economy model. Popularised by Braungart and McDonough in *Cradle to Cradle* (2002), a leading contemporary exponent of this – and possibly provider of the clearest and most compelling information – is the Ellen MacArthur Foundation. In summary, this is a model that takes the principles of the three Rs (reduce, reuse, recycle) to its logical extreme. It differentiates between renewable and finite material streams and establishes loops to return these materials either to nature or into new products indefinitely, minimising waste and negative external effects (Figure 1). This, therefore, is the ultimate method by which those key NHS-derived criteria are satisfied: elimination of single-use plastics by returning and recycling such materials; the development of reusable devices through their return and remanufacture; and ongoing process and product innovation resulting in the minimising of resource use in the first place.

> "One of the key changes required is to transition to a product-as-a-service model."

All very well in theory. But how does that translate into practice? One of the key changes required is to transition to a product-as-a-service model, whereby the function of the device (drug delivery, diagnosis, monitoring, etc) is the commodity, and the device itself is merely a vehicle for that commodity and remains the property and responsibility of the supplier. Philips is one of the pioneers of this approach; initially with large items, such as MRI and CT scanners, which it would take back for reconditioning, and now increasingly with smaller items of equipment, such as monitors and ventilators.

One key advantage of this system is that it also allows the equipment to be upgraded as it is reconditioned, perhaps with just software changes or limited component changes, but either way without the virgin material demands and associated emissions of a completely new product; even though the reconditioned item appears new (or as good as) to the next user, at lower cost. At inception of this strategy in 2012, the then Philips Chief Executive Officer

Frans van Houten was so confident that it would increase competitiveness, deliver cost savings and form stronger customer relationships that he implemented some key performance indicators specifically focused on circularity and sustainability, with a commitment to 25% of revenue from circularity by 2025.[5]

Very laudable and compelling. But CT scanners and hospital monitors are a very different proposition from autoinjectors, wearable devices and blood glucose monitors, which are patient-orientated. These kinds of devices present several challenges to circularity, the main one being user behaviour. Whereas a device such as a ventilator sits within a controlled environment (a hospital) and is managed by trained users under strict policies, making it easy to track and recover, instead we have a very large number of small devices that are taken into uncontrolled environments (the home), with no monitoring and no incentive or mechanism to return the device at the end of its life. At present, such devices tend to be built with a focus on low cost, rapid assembly and robustness; all of which make disassembly difficult. What's more, a used device may well present significant biohazards, especially those with needles.

ENTER DESIGN

The User Challenge

The first challenge is to address consumer behaviour and encourage (or compel) the user to return the device. Novo Nordisk is trialling an autoinjector return programme[6] in Denmark, whereby the user takes their old injectors to the pharmacy, from where they are shipped to a reprocessing facility. As it happens, they are not currently turned into new autoinjectors, but instead downcycled into other products, so the loop is not fully closed – still, much better than landfill. GSK ran a similar scheme in the UK, called "Complete the Cycle", to collect used inhalers but – after a reported return rate of just 0.4% (which is still two million inhalers) over 10 years – discontinued it in 2020.[7]

There is a key barrier here: asking the user to take their devices to a collection point, such as a pharmacy. This requires the user to be sufficiently motivated and organised, and also to travel. The travel element itself is particularly problematic, as this feeds into the "last-mile" factor of product-related emissions, especially if a private internal combustion engine[8] vehicle is used, by increasing the emissions associated with the device's lifecycle. Similarly, travelling to a pharmacy to collect a new device in the first place is also a contributory factor to the product's emissions.

So, can good design promote increased user engagement and facilitate a worthwhile return rate? Financial deposit schemes – akin to bottle return deposits – are not reliable and run counter to the ethos of health services such as the NHS where "free at point of use" is sacrosanct. User education alone is optimistic, relying on goodwill and motivation. The key is to keep the user engaged whilst removing any burden or sense of chore.

Let us use autoinjectors in a hypothetical example of how it might work. A patient gets a new or repeat prescription of a course of injections from their healthcare professional (HCP). Rather than the standard model of the patient collecting the prescription from the pharmacy, they instead receive a package direct to their door via a trackable courier service from the manufacturer – this would be arranged by the HCP or pharmacist via a secure online portal system. The package containing the autoinjectors could be a letterbox-friendly chocolate box format – a slim rectangular cardboard box, fully recyclable and attractively printed, containing a recyclable pulp tray in which is nestled the course of autoinjectors. A bespoke label for the prescription is adhered to the tray, identifying the application date for each injector (Figure 2).

Once the injection is complete, the user simply puts the injector back in its original position in the tray. When all injectors have been replaced, the user reseals the box and it is ready for collection for return and reprocessing by the same courier service – automatically scheduled according to the prescription and dosage rate. Should the course need to continue beyond the number of injectors in one box, then subsequent deliveries would also be pre-scheduled.

The entire process is managed automatically, reducing margin for error, and no extra effort is required on the part of the patient – injection reminders, delivery information and so on could even be sent to the patient's phone. The use of a courier, dedicated to delivering and collecting multiple prescriptions and devices (such delivery services are already commonplace) vastly reduces those last-mile emissions whilst using specialists in handling medication and maintaining any necessary environmental conditions. The box would provide a large amount of space for print and graphics – keeping the user informed and engaged with the process.

Thus, medication is provided as a service rather than a product, with the device itself only temporarily relinquished, and the burden of effort on the user greatly diminished. A huge additional benefit of this system would likely be a significant increase in adherence and compliance – one of the healthcare industry's other major challenges – due to the use of automatic scheduling and dose reminders.

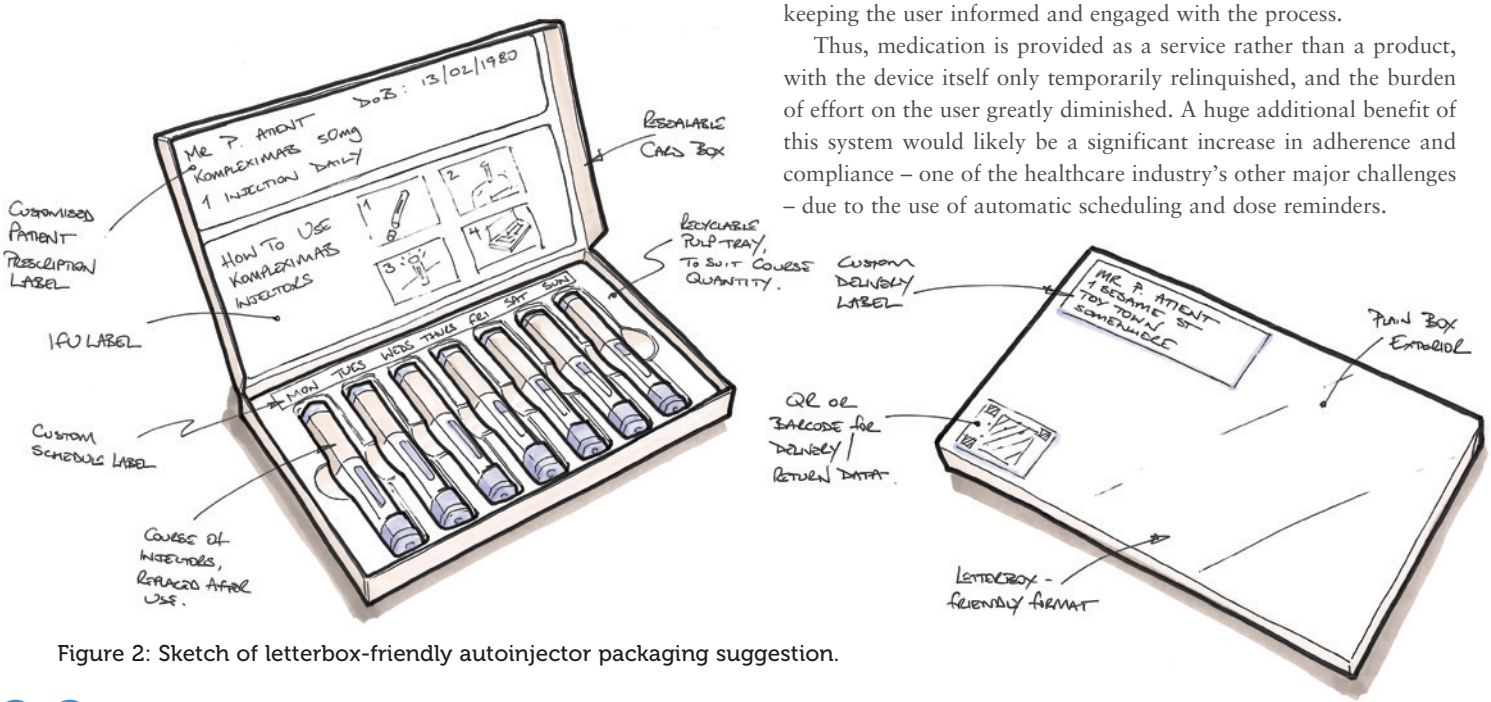

Figure 2: Sketch of letterbox-friendly autoinjector packaging suggestion.

The Return Challenge

So, our box of used devices has been picked up and is making its way back to close the loop. But back to where? The devices may be comprised of a mix of high-specification plastics, glass, metals and electronics, now with some biohazard thrown in. Do they go to the original manufacturing plant perhaps, which has a disassembly and remanufacturing facility? This could work efficiently if well set up, although it might present logistical problems as it is likely to be a single plant, which is drip-fed devices from global sales regions. Perhaps better could be regional disassembly hubs – probably operated by third parties dealing with other products as well – that receive the devices and separate them into various controlled streams. These streams would likely be:

a. Reusable components or modules, subsequently returned to the assembly plant for integration into remanufactured devices.
b. Damaged, soiled or contaminated components to be cleaned and ground into recyclate and returned to the original component supplier for reprocessing.
c. Organic materials, such as card packaging or pulp trays, recycled into new paper/card stock or anaerobically digested to create biogas for power generation (for example).

As these three streams seem likely to head off to different destinations, this favours the regional disassembly hub model. Each stream would be shipped in bulk when sufficient volumes are reached, minimising emissions.

Stream A

How do we know if a component or module in stream A is fit for reuse without laborious and expensive manual inspection? Some manual intervention will, of course, always be required, although there are sophisticated machine vision systems[10] available now that would take some of the burden out of this task, for instance recognising and rejecting damaged components. Parts or modules could be tested for function at a stage on the reassembly line prior to integration. However, there are now a number of companies developing component labelling systems that will enable rapid identification and lifecycle tracking, facilitating automatic rejection of components that are nearing their lifetime number of actuations. An example of a company currently focusing on packaging is Polytag (Deeside, Wales).

Stream B

Can material recycling for stream B satisfy the quality demands for medical devices? With current recycling processes, this is unlikely – but current processes are focused on the mass recycling of packaging and similar consumer waste in just a few broad streams, resulting in contamination and ultimately material downcycling. However, with an increased focus on circularity and enhanced collaboration between the manufacturing and recycling industries – particularly with advanced component identification – it is entirely foreseeable that segregation and recycling processes could be refined to cope with and preserve a range of engineering polymers and metal alloys, for reintegration into the original manufacturing process. Designers and engineers would initially have to be careful to select materials that can be recycled indefinitely without degradation (such as polypropene (PP)) to facilitate this, just as raw-material suppliers will need to increase the development of fully recyclable (zero-degradation) polymers to meet engineering demand.

"It is unlikely that devices currently on the market and designed for today's single-use model can be efficiently incorporated into a circular economy model."

The Device Design Challenge

It is unlikely that devices currently on the market and designed for today's single-use model can be efficiently incorporated into a circular economy model – some elements may be recovered and reused effectively but a device that has not been designed for disassembly will probably throw up multiple barriers. One-way fastening features (snap fits), adhesives and overmoulds could all be such examples. Therefore, to fully embrace circularity, devices will need to be redesigned accordingly. This redesign work could address the following areas:

a. **Labels**: useful not only for displaying instructions, graphics and logos, labels can also be used on a device to hide features such as screws and snaps. Typically, product labels are made from polyethylene terephthalate (PET), PP or similar and are difficult to remove, often leaving behind a contaminating adhesive residue. However, there are now solutions, such as dissolvable label products, that would overcome this – the device or component simply needs to be placed in a bath for a short while. An example of a company developing dissolvable labels is SmartSolve (OH, US). For devices where exposure to water is not an option, labels could be readily peelable with a dedicated releasable adhesive (perhaps with a controlled method of accessing a peel start point).
b. **Reuse or Recycle**: some components or sub-assemblies of a product will remain fully functional and in as-new condition post use, for instance sprung drive systems or printed circuit board (PCB) assemblies. These could be designed as single recoverable units, perhaps requiring a reset procedure but otherwise ready to slot straight into a new assembly. Some may require a decontamination procedure, which could be achieved in – for example – a chlorine solution (perhaps in combination with dissolving a label), an ultrasonic bath or with ultraviolet light. Conversely, some components will be soiled, damaged or worn to the extent that they cannot be reused and should be recycled instead. This would likely include product casings and interaction points such as handles or buttons – and, of course, needles and vials. These should ideally be comprised of materials that can readily be recycled back into the original components without degradation, but otherwise could be downcycled into alternative products.
c. **Design for Disassembly**: this must be embedded into the design process to the same degree that design for assembly and design for manufacture are. Quality standard BS-EN/ISO 8887-1:2006 (currently being updated) provides guidance in this area; however, there are some fundamental concepts that can be pursued to facilitate efficient disassembly. Firstly, just as jigs and fixtures for assembly are often designed in parallel with the device design, so too should disassembly jigs and fixtures. These could be used to release snap features, neutralise springs or safely remove and isolate sharps and

contaminated components. In developing such jigs, the designer inherently considers and embeds disassembly into the product. Secondly, some basic rules should be followed:

i. Avoid adhesives between components of different materials, unless creating a reusable module (and, even then, ideally not).
ii. Avoid overmoulds, if possible – fine for a few cycles of reuse, but ultimately these prevent recycling at end of life due to the mix of inseparable materials.
iii. Use a minimal variety of materials to reduce recycling complexity.
iv. Device robustness and durability should be maximised, even if cost is increased as a result (offset by reduced production volumes), to extend product/component lifetimes.
v. Furthermore, research is ongoing into technologies generally termed "active disassembly". This proposes the use of elastomeric materials in fasteners that collapse under increased atmospheric pressure[9] or shape memory alloys/smart polymers to neutralise a fastener under increased temperatures[10] – both enabling rapid disassembly of a product. As the demand for circularity increases, these technologies are likely to mature rapidly.

d. **Design for Reassembly**: the main consideration here is that components may be assembled several times over their lifetimes. This may mean ensuring that snaps do not come close to their elastic limit or that screws and screw bosses are carefully selected and designed for multiple insertions without stripping. A device reassembly line would probably need to be integrated into the original assembly plant for the transfer of components, fixtures and operator skills to ensure consistency of quality.
e. **Design for Sterility**: ensuring the sterility of a device (or certain aspects of a device) from manufacture to patient is critical for many medical products. Is it possible to maintain this with a remanufactured device? As identified above, it should be possible to sterilise components and modules that are being reintegrated into new devices, with clean room procedures followed just as for new device manufacture. But what about packaging?

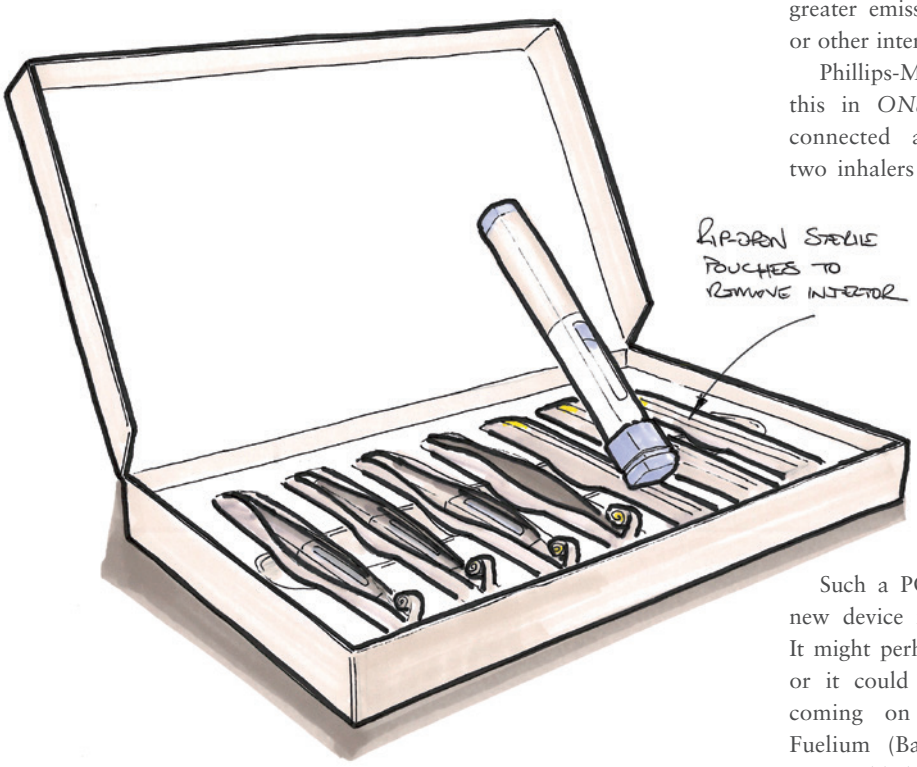

Figure 3: Sketch of sterile autoinjector packaging suggestion.

We are all familiar with sterile barrier pouches used to protect items such as lines, syringes, catheters and so on. These can now be made from highly recyclable single materials, such as PET or high-density polyethylene – for example, the 100% PET blister pack developed by RotorPrint (Olost, Spain) – and kept in a closed loop. But that relies on the end user returning the material to the system (alongside the device), when the more likely outcome will be that it is put in the waste and sent to landfill. One option to avoid this is to integrate the sterile barrier into the delivery/return box concept – this would add complexity to the design of the packaging but remove the separate material issue. Imagine a sterile pouch mechanically trapped within the card delivery box; the pouch could have a pull tag to rip it open along a weakness line, similar to an Amazon delivery envelope. Thus, the device is removed from its sterile barrier but the barrier itself is retained, returned, separated and recycled along with the box. Another option – not possible in all cases, admittedly, and complex in others – is to design out the packaging by integrating the sterile barrier into the product itself. For instance, a cap or cover on the product that maintains a hermetic seal around the sensitive components but is itself reusable upon return and sterilisation (Figure 3).

A WORD ON ELECTRONICS

By mass, the emissions footprint of a PCB assembly and associated components is 10–20 times that of a plastic component;[11] therefore the integration of electronics into traditionally "dumb" or purely mechanical devices has immediate implications for that product's footprint. However, this should not necessarily be looked at in isolation, especially as the development of connected health picks up speed. If the inclusion of electronics into a medical device prompts the patient to medicate correctly, or otherwise aids disease control and treatment development through data provision to the healthcare provider, this can lead to the avoidance of far greater emissions downstream associated with hospital admission or other interventions.

Phillips-Medisize provided an excellent example analysis of this in *ONdrugDelivery*, Issue 139 (Nov 2022),[12] looking at connected asthma inhalers. For the treatment of asthma, two inhalers are typically prescribed – a preventer and a reliever. The former is to be taken regularly and aims to keep the disease under control. The latter is to be taken upon the onset of symptoms. However, it is quite common for people to disregard the preventer and rely solely on the reliever; thus the disease is not managed correctly, resulting in unnecessary hospital admissions. The resultant emissions associated with patient travel, hospital power, waste, water, etc outweigh those of a small PCB integrated into a preventer inhaler that would prompt the patient (directly, or via connectivity with their HCP) to manage their condition correctly.

Such a PCB could be recovered, reset and reintegrated into a new device in a circular process, further reducing its footprint. It might perhaps have a lithium-ion battery that needs recharging, or it could use one of the more sustainable battery solutions coming on stream if a non-rechargeable cell is required. Fuelium (Barcelona, Spain) is one such company pioneering sustainable battery solutions.

REFRAMING THE PROBLEM

Rather than trying to make existing designs and approaches fit the circular economy, there might be opportunities to reduce emissions in other ways. Sticking with inhalers: the propellant gas used in metered dose inhalers (MDIs) – those typically used by asthma patients – is a hydrofluorocarbon, which typically has a global warming potential tens or even thousands of times that of CO_2.[13] As such, MDIs contribute a massive 3% to the entire emissions footprint of the NHS.[3] Because the propellant is expelled into the atmosphere with the medication, this cannot be returned and reused within a circular model.

The obvious approach, therefore, is to transition to low-carbon inhalers, of which there are several types already available, generally in dry powder form, but they only occupy a very small portion of the market. So, if an inhaler manufacturer wanted to pursue a wet inhaler but without the propellant emissions, it would have two choices:

a. Develop an emissions-free propellant gas to maintain existing technology
b. Design out the propellant.

The first route involves chemistry, experimentation and long clinical trials to ensure that the new propellant is not harmful when inhaled. The second is a design challenge that could yield further benefits, such as faster time to market and integration into the circular economy.

How do you design the propellant out of a system that relies on a propellant? The key here is the circular economy itself. Current inhalers are comprised of two simple plastic mouldings and a sealed, pressurised cartridge incorporating a metering valve – mass producible for minimal cost on an enormous scale but destined for landfill. By moving to a circular product-as-a-service system, complexity and cost of the device can increase as production volumes decrease. This paves the way for, by way of a hypothetical example, a pumped-air system: in such a device, the user might apply a few depressions to a large button (in lieu of the top of the cartridge) to pressurise a chamber. A visual indicator displays when sufficient pressure has been reached, and a one-way valve prevents over-pressurisation. A trigger then releases the air from the chamber, into which a metered dose of medication is injected (driven by the same air pressurisation, the mechanical action of button depression or the Venturi effect) through an aerosolising nozzle in the mouthpiece to the patient as per the current devices. The pressure indicator could act as an interlock for the trigger, preventing low-pressure activation. Complex? Yes, compared with current inhalers. Unforeseen issues? Probably – that is the nature of research and development. Impossible? No – there is no groundbreaking new science or technology here. Component count might be high and accuracy important but, with many of these components directly reusable, this should not be a barrier.

CONCLUSIONS

The challenges to making medical and pharmaceutical products truly sustainable are not insignificant – but not insurmountable either. Transitioning to the circular economy is essential, and there are some significant business and logistical steps to be taken by the industry – and manufacturers in particular – to establish successful systems of reclaim and remanufacture.

Collaboration between all facets of the industry, including new providers not traditionally involved, will be necessary. But many of the inherent challenges are readily solvable through good design, by influencing user behaviour, designing for disassembly and reuse or entirely changing the established nature of a device. Once a product-as-a-service model has been implemented and embedded as a standard business model within a company, then solutions will always be found as an imperative to make the system as efficient and cost effective as possible – that is just the nature of business. The future is circular – and good design will get us there.

ABOUT THE COMPANY

Shore is a leading medical product design consultancy with a proven track record of delivering end-to-end solutions that optimise usability and performance. Longstanding partnerships with some of the world's largest pharmaceutical and medical device companies is testament to its expertise in medical and drug delivery device development. A flexible approach ensures that the specific needs of each customer are met, from early-stage feasibility all the way through to clinical manufacture and supply.

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Will Davies, Design Consultant at Shore, has extensive experience in all stages of product development. This spans from concept ideation and mechanism design through to design for manufacture, and project and production management. He has a deep understanding and appreciation of the underlying and subconscious values of design to consumers, end users, society and the environment, and how to use this successfully through design strategy for business. His expertise, coupled with his passion for design, allows him to deliver exceptional award-winning results for Shore's clients.

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SUSTAINABILITY IN DRUG DELIVERY: HOW DO WE GET THERE?

In this article, Tim Wooller, Principal – Industrial Design, Sector Lead Healthcare at PDD, discusses the urgent need to transition away from disposable models of drug delivery device design and move towards reusables, providing insights into the reasons why and the methods by which this can be achieved.

Sustainability has become an increasingly hot topic for pharmaceutical companies and medical device manufacturers in recent years, with many setting themselves ambitious goals to dramatically reduce their carbon footprints. Pfizer, for example, has pledged to become carbon neutral and reduce the company and its value chain's emissions by 90% by 2040,[1] while Johnson & Johnson aims to obtain 100% of its electricity from renewable sources by 2025.[2]

There are multiple reasons why companies in this sector are making such pledges. First, there is the acknowledgement of the huge impact the healthcare sector has on the environment – believed to be 4.4% of worldwide greenhouse gas (GHG) net emissions and five million tonnes of waste per year.[3] Healthcare companies have been galvanised to respond to this challenge because of the direct link between poor health and climate change. Put simply, to better serve their patients, healthcare companies have a responsibility to address their own environmental footprints.

Secondly, it can be directly observed in user studies that patient opinion is rapidly changing to include a demand that this topic be addressed. For those who self-administer their therapies at home, the constant filling and disposal of sharps bins acts as a tangible reminder of the issue at hand.

Finally, the scientific consensus and resultant government regulation are only headed in one direction, so it is important for many businesses within healthcare to be proactive rather than reactive to the situation. For an industry renowned for its cautious pace and pragmatism, the future is fast approaching, and the sense of urgency is increasing with it. Most recently, a UN climate change report urged that "inaction and delays are not listed as options".[4]

While it would be naive to say that achieving sustainability in the healthcare sector will be easy, particularly given the industry's reliance on disposable materials, it is in no way an impossible feat. Instead of tackling the healthcare industry as a whole, which can be daunting, looking at each area individually makes it appear a much more achievable and realistic goal. It's also encouraging to see that most doctors and nurses want to help hospitals reach net zero, with only 12% of respondents saying they did not have the time or resources to be involved.[5]

Looking to drug delivery in particular, the use of disposable autoinjectors and pens has increased rapidly in recent years. While disposable devices are of great benefit to patients, pharmaceutical companies and healthcare systems, there are very good reasons why steps need to be taken right now to phase out disposables in favour of reusables for many therapies.

In order to fully understand where to go and what to do to get there, it's also important to understand the progress made to date. This article will explore all of these elements with a focus on injectable drug delivery, providing tangible guidance for pharmaceutical companies and manufacturers on the best way forward.

"While disposable devices are of great benefit to patients, pharmaceutical companies and healthcare systems, there are very good reasons why steps need to be taken right now to phase out disposables in favour of reusables for many therapies."

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WHAT PROGRESS HAS BEEN MADE TO DATE?

Autoinjectors and pens that support the subcutaneous self-administration of a range of biologic drug therapies have become a popular choice for patients who struggle to use prefilled syringes. They are most commonly used at home to treat chronic conditions, which often impact mobility, giving patients greater independence and confidence to adhere to their treatments. Naturally, greater adherence benefits pharmaceutical companies, but autoinjectors and pens also provide an important means of differentiation for off-patent drugs to defend against biosimilars, or for biosimilars to compete with established brands when coupled with a compelling device design.

Healthcare systems also benefit by reducing the number of hospital visits patients need to make.

Because of this, the use of autoinjectors and pens has increased exponentially, with the most popular type being prefilled, single-use disposables. This has happened for a variety of reasons; for example, the initial financial outlay for each unit is relatively low compared with some of the more complex reusable devices on the market. They are also simple and convenient to use and, because they require a minimal number of user steps, they can often be perceived as lower risk.

In terms of sustainability progress made within the industry, there have been some interesting developments. The "Alliance to Zero" is a collective of eight founding companies that aims to transition the pharmaceutical supply chain to meet the net zero targets set out by the Paris agreement. Ypsomed's (Burgdorf, Switzerland) Ypsomate Zero disposable autoinjector claims to be the first carbon-emission-free prefilled autoinjector,[6] which it achieves through a combination of using alternative polymers, value-chain optimisation and carbon offsetting. These developments have provided a crucial foundation for the industry to build upon. However, it's evident that progress in this area needs to be accelerated to effect greater tangible change.

"Before embarking on any significant sustainability initiative, it is critical to take a step back and understand the broader system, starting with the patient and therapy journey."

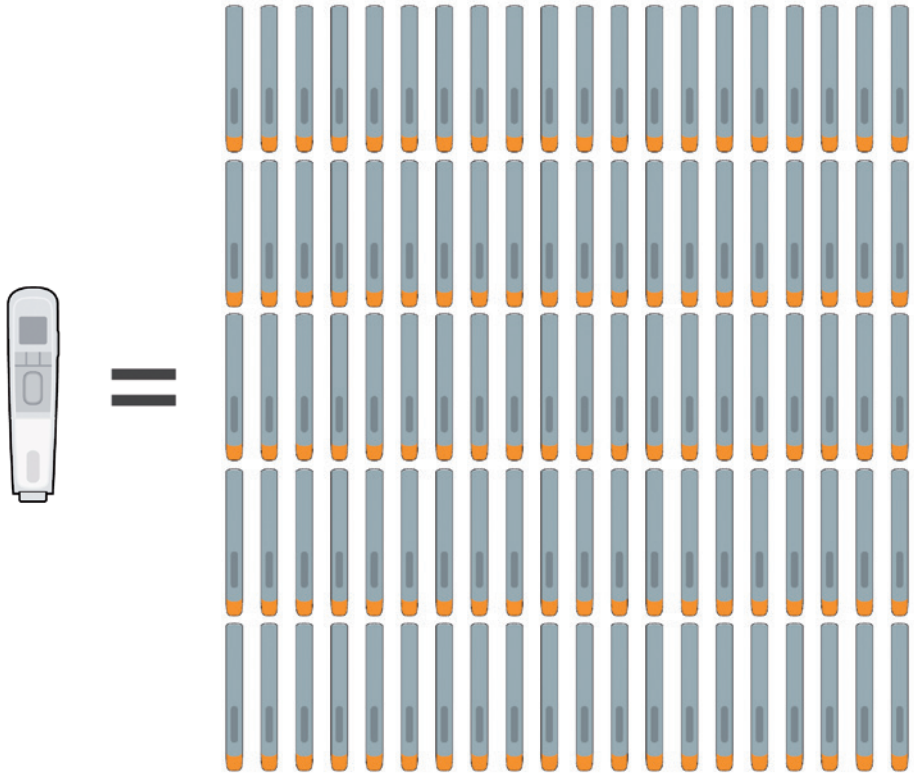

Figure 1: A therapy requiring weekly injections over the course of two years would need either 100 disposable single-use autoinjectors or a single reusable one.

CONSIDERING THE USER AND THERAPY JOURNEY

Before embarking on any significant sustainability initiative, it is critical to take a step back and understand the broader system, starting with the patient and therapy journey. Using a range of human-centred-design (HCD) methods, such as stakeholder and user journey mapping, contextual enquiry and creative workshop techniques, it is possible to frame the problem in the correct way by asking some fundamental questions, such as:

- How will the drug-device combination be used?
- What steps are required throughout the process of prescription, supply, preparation and use?
- Will the drug require regular or infrequent injections?
- What effect does the patient's condition have on their ability to use a device?

The answers to these questions will define the right approach and application, saving unnecessary time and material in the process. For example, therapies that only require infrequent injections may be best administered by a healthcare professional without the aid of any device beyond a syringe.

HCD methods can also be used all the way through the development of a device to ensure that intended uses are optimised and adhered to and that unintended uses, which may have an impact on sustainability, are avoided.

RETHINKING THE BUSINESS MODEL – THE PATH TO REUSABLES

Consider a drug therapy that requires weekly injections, spread across just two years – this would require 100 disposable devices or a single reusable autoinjector (Figure 1). Excluding the disposable elements common to both these types of injectors, such as glass drug cartridges, needles and secondary packaging, there is a considerable amount of material, such as plastic enclosures and mechanisms, that find their way to incinerators or landfills with each injection using the disposable model. Removing this material in a value chain right from the outset has significant positive environmental impact. Similar to other industries seeking to remove single-use plastics, healthcare systems must take these important steps.

"Once the decision has been made to move towards reusable devices, there is great potential to add many patient-centred features and functions that simply aren't practical if the device is disposed of every time."

Once the decision has been made to move towards reusable devices, there is great potential to add many patient-centred features and functions that simply aren't practical if the device is disposed of every time, including:

Comfort features: reusables don't need to be quite as slimline and basic as disposables. Their forms can have more overt and optimised features to aid usability, which would be deemed wasteful in disposables.

Automation: one way to mitigate the fact that disposables are pre-primed is for reusables to use motor systems. As well as expelling the drug, motor systems can aid comfort by offering adjustable settings, such as injection depth, injection speed and dwell time, to overcome some of the issues patients face when injecting. A great example of a product already in the market with these features is easypod® by Merck (Darmstadt, Germany).

Electronics: reusable devices, especially if motor driven and already containing batteries, can include sophisticated electronics encompassing sensors, graphical user interfaces and connectivity, opening up a world of additional benefits to the patient.

Combining these features can result in a better product with better patient engagement which can aid adherence. This in turn can encourage brand loyalty of great benefit to pharmaceutical companies in the longer term.

CONSIDERING THE ENTIRE VALUE CHAIN AND PRODUCT LIFECYCLE

In addition to the efficiencies and benefits achieved by reusable devices, it is important to consider the value chain and product lifecycle (Figure 2). R&D can employ methods to make an efficient product, but is the greater business run with environmental considerations in mind? Clinical trials generate a lot of medical waste – how can this be reduced? Has the manufacture of both the drug and device been optimised to be as efficient as possible? What about distribution and storage – what efficiencies can be achieved here? Finally, do suppliers to the pharmaceutical company or medical device manufacturer share the same environmental goals? There is a range of methods and guiding principles which can help answer these questions, including lifecycle assessments (LCAs), design for optimisation, design for efficient distribution and design for optimised end of life and disassembly.

Lifecycle Assessments

LCAs enable companies to assess their entire value chain by entering data and getting back actionable results. Sometimes the results are surprising once all aspects of the lifecycle are considered. One very good example is when drug therapies require refrigeration – this has major impacts all the way through the value chain, from manufacture, storage and distribution to end use. Storing a disposable injector and its packaging in a patient's refrigerator has a far greater impact than just a drug vial; it takes up more space and a greater proportion of the refrigerator's energy budget. It is important, therefore, for cold-chain logistics to consider everyday use as well as distribution and storage.

LCAs don't just find efficiencies for existing products and systems; they are also an essential tool to help develop new products. They do, however, have their drawbacks. The richer the data that is inputted, the better the result. The opposite is equally true – there can be major shortcomings in comparing the value chain of design concepts with existing products if a range of inputs is unknown at the conceptual stage. It is difficult to establish how concepts might be manufactured, distributed and stored until these factors are far more resolved downstream. A better approach is to "compare apples with apples" and use LCAs as a tool when considering multiple early concepts against each other using a range of educated assumptions.

Design for Optimisation

Recent progress in artificial-intelligence-driven generative tools has allowed developers to design, analyse and simulate designs that require less material and energy to manufacture with increasing speed, accuracy and confidence. Selecting materials with a lower environmental impact is another consideration. There are now many US FDA-approved biodegradable polymers to choose from for medical applications, so the options open to developers to optimise their products are greatly increased.

Design for Efficient Distribution

Once manufactured, how might the product be most efficiently transported? The most impactful upstream consideration is to locate manufacture as close as possible to where the product is marketed. The next best solution, if the first isn't commercially viable, is to consider package, carton and crate proportions, and to design devices and secondary packaging to nest in the most efficient way possible to eliminate empty air during transport.

Design for Optimised End of Life and Disassembly

Designing the end of life for a product is increasingly important to ensure circularity or "cradle-to-cradle" compatibility. First, limiting the number of different materials used in a product greatly aids sorting and recycling efforts at its end of life. Second, providing a clear path

Figure 2: The value chain of an autoinjector.

> "This is not the time to tinker at the edges and seek marginal gains – the reliance on single-use devices has to be significantly reduced."

to disassembly is critical. With various levels of "right to repair" legislation now implemented in the US, EU and UK for consumer goods, it makes sense for healthcare to follow that lead. Given that medical devices are generally not user-serviceable, this would have to take the form of an end-of-life return process set up by the manufacturer.

THE WAY FORWARD

As the urgency regarding the climate and the environment gathers pace, the tools and methods discussed, such as considering the user and therapy journey, value chain and lifecycle, provide a way forward for pharmaceutical companies to take more effective steps to reduce waste and emissions.

This is not the time to tinker at the edges and seek marginal gains – the reliance on single-use devices has to be significantly reduced. When it comes to single-use materials, the issue of hazardous waste will hamper sustainability efforts in hospitals, there is less of a barrier for patients using autoinjectors for at-home self-injection. Pharmaceutical companies and medical device manufacturers have much to gain by balancing patient, planet and purpose, and by aspiring to develop more durable and engaging products that promote adherence in the process.

The author would like to thank Luke Robbins, Senior Consultant – Industrial Design, for his contribution to this article. Mr Robbins leads sustainability initiatives at PDD.

ABOUT THE COMPANY

PDD is a leading innovation consultancy that creates products and experiences that enhance businesses and improve people's lives. With a unique multidisciplinary approach that is rooted in human-centred design, PDD helps customers in the healthcare and consumer industries achieve commercial and creative success. The company's clients include some of the world's leading healthcare and consumer companies, such as BD, Novartis, Samsung and Nestlé, as well as influential start-ups in Europe, Asia and the US.

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ABOUT THE AUTHOR

Tim Wooller has over 20 years of experience designing compelling and effective products for global healthcare and consumer brands, picking up numerous awards and patents along the way. He passionately believes in the role of design to keep user insight and experience at the heart of every innovation project, balancing those needs against functional and commercial aspects through close multidisciplinary collaboration. Mr Wooller leads PDD's Healthcare sector, defining and driving new business development strategies and relationships. He holds a BA(Hons) degree in Product Design from Ravensbourne University (London, UK).

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WHY SUSTAINABLE PACKAGING MATTERS IN PHARMA'S CIRCULAR APPROACH – *APTAR PHARMA'S FUTURITY PLATFORM LEADS THE WAY*

In this exclusive interview, Julien Storz, Director Business Development, Consumer Healthcare, at Aptar Pharma, discusses the importance of sustainable packaging in the pharma industry and introduces the company's Futurity platform and its role in product circularity.

JULIEN STORZ, APTAR PHARMA

Julien Storz is Director of Business Development within Aptar Pharma's Consumer Healthcare (CHC) division. He holds a bachelor's degree in Business Administration and has over 19 years of medical industry experience. Mr Storz joined Aptar Pharma and the CHC Global Market Development team in 2019 and is responsible for supporting business development efforts across numerous application fields in addition to driving CHC sustainability efforts.

Q Where do you see the biggest opportunities for the pharmaceutical industry to advance sustainability objectives?

A Good question! Industry estimates seem to agree that about 4%–5% of global greenhouse gases (GHGs) come from the healthcare sector,[1] with up to one-third of those emissions related to pharmaceutical products.[2] To understand where those emissions are coming from, one can look at data provided by the European Federation of Pharmaceutical Industries and Associations. Their members have classified and broken down GHG emissions, where approximately 20% are classified as Scope 1 and Scope 2 and the other 80% are classified as Scope 3 emissions. That means that 80% of the pharmaceutical industry's GHG emissions are generated in their upstream and downstream value chains.[3]

Pharma value chains are quite complex and therefore Scope 3 emissions must be approached at many different levels to achieve a sustainable reduction of the emissions. However, the industry is highly motivated and actively developing new innovative ways to lower its emissions. This has recently been underlined by a number of major pharma companies that have made a clear commitment to deliver net zero health systems collectively, applied across their supply chains, patient care networks and clinical trials.[4]

> "Changes to enhance the sustainability of the packaging systems cannot result in reduced safety or product efficacy."

Another initiative gaining traction is the development of the iGAL calculator, which illustrates how green chemistry and engineering innovation can reduce waste during API manufacturing.

From our perspective, a very important approach to lowering Scope 3 emissions is through primary packaging and devices. Primary packaging really matters to patients and consumers as it is the most visible "problem". They hold the packaging or device in their hands every time they use their medication, and when it's fully consumed, it is the same patients or consumers that ultimately control how they dispose of it. We strive to make that easy for them by making more recyclable packaging systems.

As primary packaging systems are highly regulated and complex, it will be essential for the industry to pursue common objectives collaboratively to advance sustainability objectives fast enough.

Q What challenges does the pharmaceutical packaging industry face in reducing its CO_2 footprint and achieving more sustainable solutions?

A One of the things that is significantly different for the pharmaceutical packaging industry is, again, the level of regulation. It's a very high bar. The regulations impose some limits on what we can do, especially for primary packaging, as this has direct contact with the drug formulation. Changes to enhance the sustainability of the packaging systems cannot result in reduced product safety or efficacy. Right now, many of the packaging and waste regulations are still being defined and implemented, so there is still some uncertainty around the details. For example, the deadline for implementing new EU regulations for recyclable packaging in the pharmaceutical industry is still over 10 years away. The pharma industry needs this time to create and innovate new compliant packaging solutions that will lead to a more circular approach. New product packaging regulations for

Figure 1: In the end, the patient or consumer decides on how or if a device is recycled.

recyclability for consumer products will become effective in only two years, by 2025, so they have very little time to solve these challenges. These tight timelines and high expectations for the consumer business mean we have to move in a more sustainable direction immediately. We are focused on innovations in primary packaging and drug dispensing that support the circular approach while simultaneously meeting drug-safety requirements. We believe this dual approach will help us to meet the tight timelines and create value for both the consumer and the planet.

Q Can you explain what some of the main limitations or challenges are with pharmaceutical primary packaging meeting sustainability objectives?

A Drug delivery systems are often complicated and made of many individual components, composed of different materials, all designed to work perfectly together to deliver drug products to patients with precision and accuracy. These are systems like nasal sprays, inhalation devices and semi-solid dispensers. The pharmaceutical regulations for these types of primary packaging systems are both strict and comprehensive, posing challenges to quickly adapting them to meet sustainability targets. In the past, material composition was defined by safety and use requirements, which were clearly documented for regulatory filings. Changing or replacing materials with more sustainable materials isn't just a simple switch. The implications are more significant for pharmaceutical packaging.

> "Having common goals with the customer allows us to work co-operatively with them to achieve the specified, targeted sustainability goal, while making sure safety and regulatory requirements are covered."

Changes may require new assessments if safety requirements are fulfilled, such as extractables or leachables testing, and associated regulatory documentation may need to be updated. Our experience and capabilities allow us at Aptar Pharma to support customers with required testing and documentation. Having common goals with the customer allows us to work co-operatively with them to achieve the specified, targeted sustainability goal, while making sure safety and regulatory requirements are covered. This support will be critical for the industry to be able to deliver sustainable next-generation drug delivery systems on time.

Q How do consumers feel about the importance of recycling or sustainability with respect to pharmaceutical packaging?

A Consumers hold the packaging in their hands every time they use the product. They see and touch the packaging materials and will ultimately decide if the packaging system will be recycled or not (Figure 1). As they are directly involved in the decision process, their views on the importance of sustainable packaging systems is critical for us. Our surveys clearly show us that consumers have a strong preference for products that come in packaging that can be recycled.

Consumers are increasingly paying more attention to how they produce waste and recycle packaging. Most consumers are willing to take an active role in recycling, but they still need some additional education to make it more effective. For example, most consumers perceive that a device made of both glass and plastic parts is more recyclable than a full-plastic mono-material unit. But this is incorrect. Even in locations with high consumer awareness of longstanding recycling practices, current recycling processes can fail when the consumer is unaware of the best way to dispose of or recycle the complex packaging components of the emptied unit.

Therefore, we've really reinforced the importance of making our products easy to recycle. With our sustainable product solutions, consumers can put the entire emptied device in an existing recycling stream without any disassembly or separation effort. This guarantees that most components find their way to the right recycling path and stay in the circular process as long as possible. We also find that having a device that is clearly labelled or certified regarding its recyclability makes a measurable difference in the frequency of it being recycled effectively by the consumer.

Q What is circularity and how is Aptar committed to applying the circular economy model?

A Circularity considers the overall expected lifecycle of a product and incorporates sustainability optimisations at the design stage. In a circular economy, when the consumer is finished with a product, it is returned to the supply chain to be recycled, reused or repurposed and not put into landfill (Figure 2). As material resources are finite in nature, we must consider a product's entire lifecycle to enhance its circularity in practice. We all need to understand that we will need to use what was once considered "waste" as a valuable resource moving forward in order to achieve circularity.

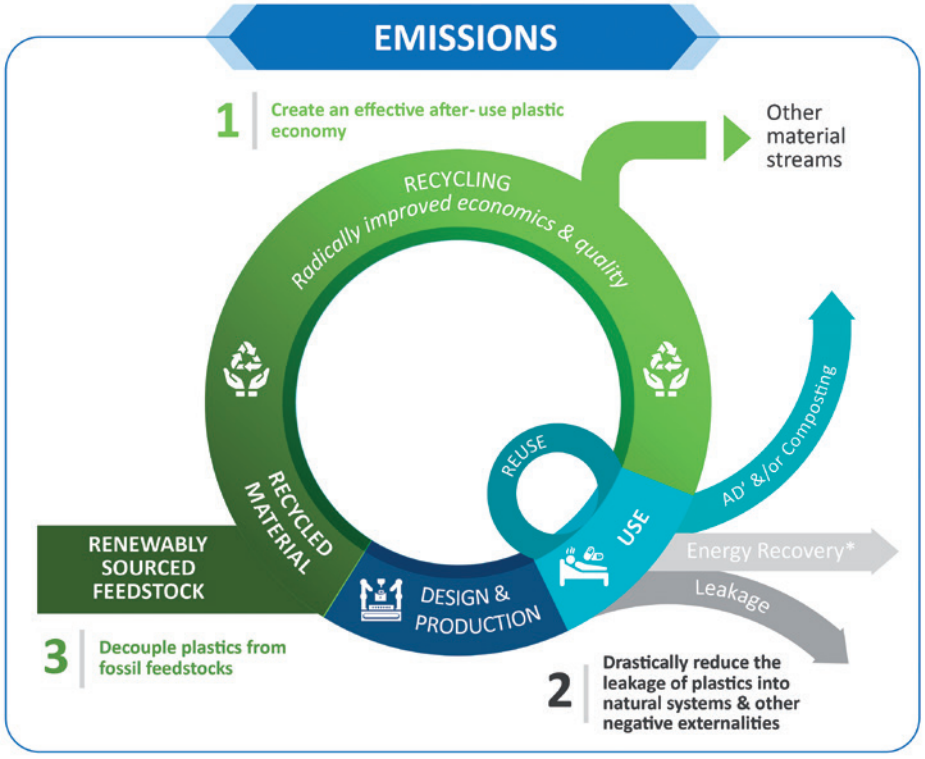

Figure 2: Aptar Pharma is aligned with the Ellen MacArthur model for circular economy in the plastic packaging industry, which includes reduction of plastic leakage, as well as minimising the use of fossil feedstock. Based on this model, reduction of emissions through recycling, reuse, replacement of materials and sustainable product design is evaluated.

Beyond efficient handling of our resources, circularity is important to keep the environment cleaner. Successful circularity will see improved quality of materials, including recyclates, and reuse of materials. To date, using post-consumer resins (PCRs) gained by mechanical recycling is still rarely an option for primary packaging components in pharma, at least when the components are in direct contact with drug formulation. However, using innovative processes, such as chemical recycling to generate clean PCR recycled materials, needs to be further developed and scaled up.

Another approach to generating high quality recyclates from recycling streams is PureCycle Technologies' (FL, US) patented recycling process. Aptar entered a strategic partnership with PureCycle in 2019 to bring forward the use of ultra-pure recycled polypropylenes into Aptar's dispensing solutions for food-grade applications. Such processes could also prepare the future for the use of recycled materials in primary packaging for pharma, and we need to look together with regulatory authorities into furthering such solutions.

We need to be better at reusing and recycling materials, as well as improving

"Aptar entered a strategic partnership with PureCycle in 2019 to bring forward the use of ultra-pure recycled polypropylenes into Aptar's dispensing solutions for food-grade applications."

the way we are designing products and packaging systems right from the beginning. It will be crucial to develop systems using fewer materials, eliminating recycling disruptors and minimising the number of different materials used in a device.

Q How does Aptar Pharma effectively design sustainability into its products?

A Aptar Pharma takes an integrated approach to incorporating sustainability into every new device or technology system. We have already implemented the use of our proprietary EcoDesign tool, which incorporates lifecycle assessment (LCA) functionalities into the process. This allows us to assess how our packaging systems will impact the environment before we ever make them, and we can also use it to assess our existing products. Aptar has committed itself to using EcoDesign tool assessments on every new packaging system we develop moving forward, and to design sustainability into the product development process from the very beginning. We did this in the absence of a standardised EcoDesign tool that was suitable for our industry, so Aptar invested in developing its own EcoDesign

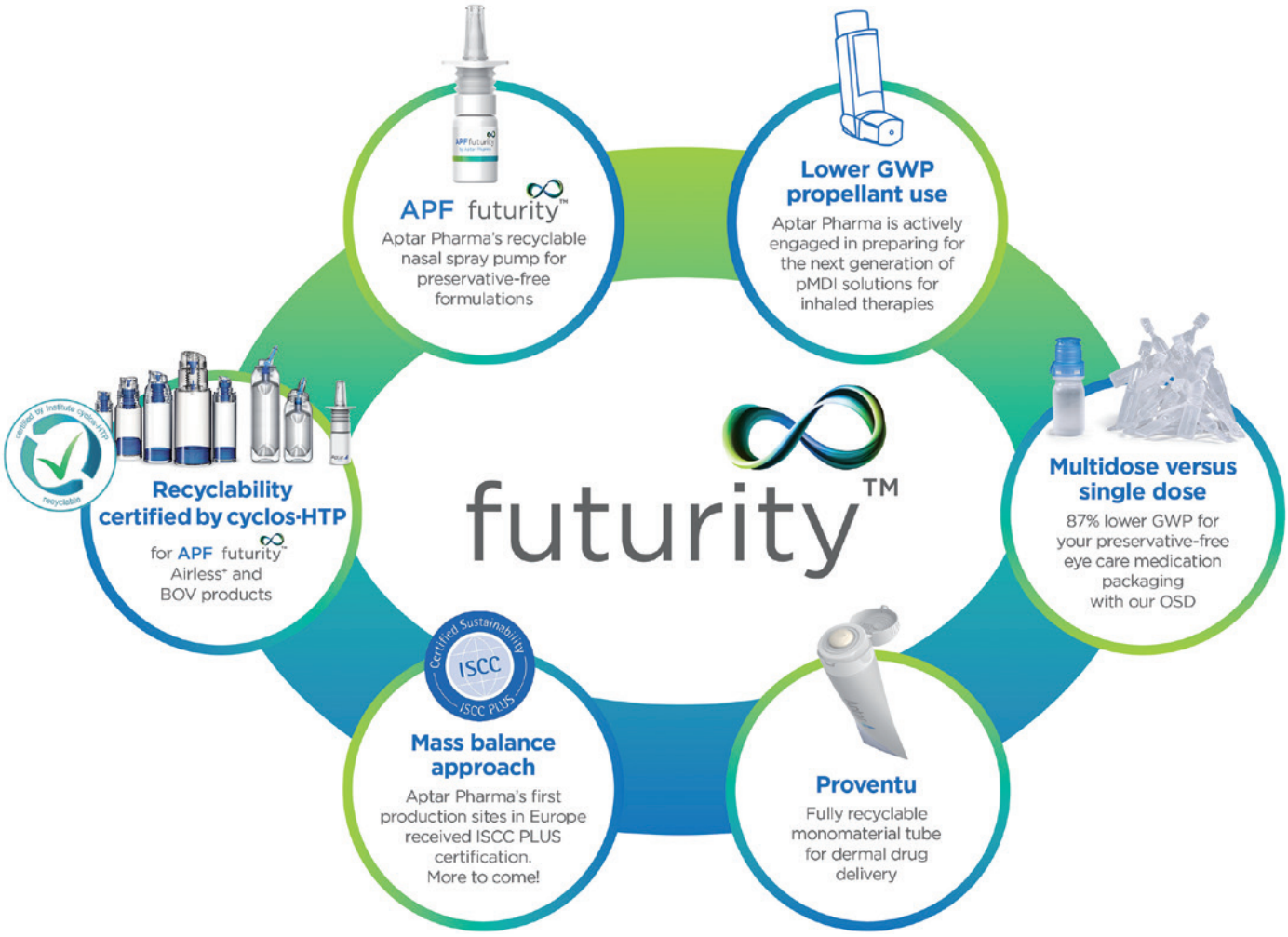

Figure 3: Aptar Pharma's growing platform for more sustainable solutions, Futurity™, comprises drug-delivery solutions and services that enable reduction of emissions through increased recyclability, use of circular materials, reduction of packaging materials, reduced waste or other means.

tool in co-operation with established LCA authorities that incorporated available standards, considered best practices and ISO standards. Our tool provides relevant, measurable results and enables us to design products that add to a circular approach.

With numerous EcoDesign tools out there, it is difficult for the industry to arrive at a consistent and comparable approach to EcoDesign and LCAs. This inherently poses a challenge for the industry as there is no common way to validate these assessments. We believe that the way forward will be to harmonise the best practices from these various assessment tools into a common approach.

> "Because sustainability has become an important company-wide objective at Aptar Pharma, we decided to use the term Futurity to represent our sustainable solutions platform."

Q What is Futurity™ and why is it important to Aptar?

A Because sustainability has become an important company-wide objective at Aptar Pharma, we decided to use the term Futurity to represent our sustainable solutions platform (Figure 3). This new branding will help our customers and consumers easily identify products and technologies from Aptar Pharma that are designed with enhanced sustainability and circularity in mind. This can include devices designed with enhanced recyclability features, those using lower global warming potential (GWP) propellants, mono-material construction or other impactful design features.

These are not simple solutions. For example, changing from a traditional HFA propellant in a pressurised metered dose inhaler (pMDI) to a newer one with lower GWP is a complex affair. This can involve modifications to the pMDI container closure system, including the metering valve itself, but beyond that, the new propellant must be assessed for safety and toxicology, and the final formulation may need to be optimised or redeveloped to ensure appropriate formulation stability.

The propellants currently used in pMDI devices for asthma or chronic obstructive pulmonary disease applications may be a significant contributor to the CO_2 footprint of these products for pharmaceutical companies. Therefore, changing them can result in major reductions in CO_2 output and is worth the effort. We work very closely with our customers to support this critical conversion process, both in the lab and with our regulatory teams, to make the switch easier and faster for them.

We also work on drug delivery solutions that incorporate circularity, such as replacing conventional materials with circular resins, waste reduction, packaging reduction and improved recyclability, to which we apply LCAs and external validation of recyclability claims.

Q What is APF Futurity™ and what makes it a more sustainable packaging technology?

A The Advanced Preservative Free (APF) Futurity is our latest multidose nasal spray system (Figure 4). With the support of our EcoDesign tool, we were able to create a highly recyclable nasal spray system that maintains all the reliable functionality and precise dosing of our traditional APF system. APF Futurity is metal-free, using a polyolefin-only material mix. Nasal sprays usually contain metal springs or even stainless steel balls in their pump and dosing mechanisms. Without metal components, a straightforward recycling of the pump is possible, ensuring higher quality recyclates.

One of my favourite features is the new oval finger flange because it increases the likelihood that the product gets into the right recycling stream. Round components often roll away after the infrared (IR) scanner detects them on the recycling belt. This can lead to items being sorted incorrectly, which has an impact on the quality of recyclates. The new oval flange feature stops the device from rolling and therefore results in it being correctly sorted as the IR sensors trigger air streams that are able to hit the nasal spray more accurately.

In a nutshell, the APF Futurity was designed for easy recycling. Consumers do not need to disassemble or separate it into parts – they can place the emptied device as is into the regular local recycling stream.

Q Can you provide an outlook on Aptar Pharma´s way of moving forward in terms of sustainability?

A Our focus on sustainability is always driven by customer needs and our own objectives. Whether they are looking for a reduced CO_2 footprint, increased recyclability or reusable/refillable solutions, our sustainability efforts tend to align with their common objectives. Obviously, our customers help to direct our sustainability objectives. We also pay close attention to what consumers are telling us they want with respect to primary product packaging and sustainability, and we ask them directly through surveys and primary research. Every day consumers are becoming more aware of the importance of sustainability in their lives and are demanding that the products they buy reflect that. All of this is done under the overarching considerations of the regulatory bodies to ensure continued compliance with changing requirements.

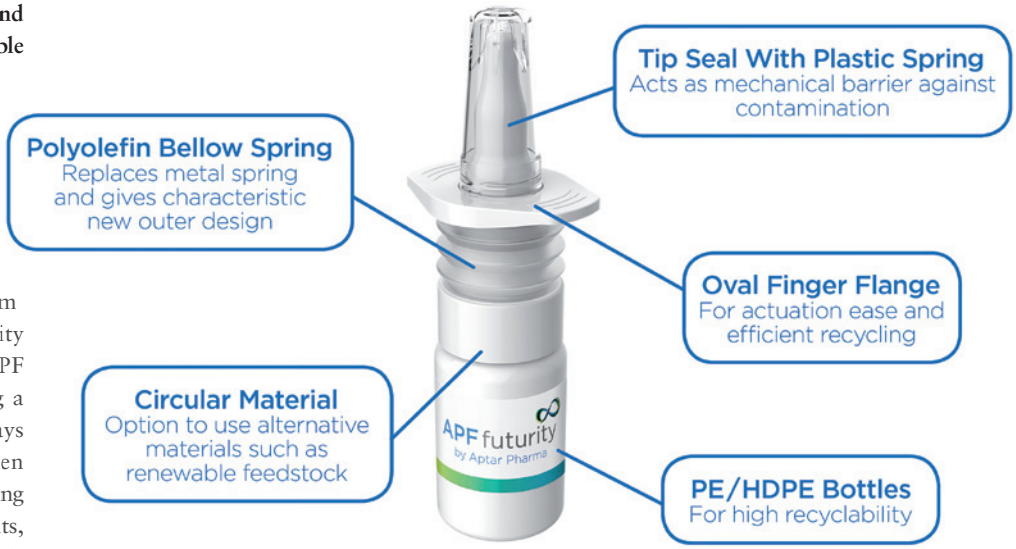

Figure 4: APF Futurity, metal-free nasal spray pump is designed for easy recycling by the user, and is certified highly recyclable by cyclos-HTP.

So how will Aptar Pharma achieve this in practice? We will continue to use our EcoDesign and LCA tools to design enhanced sustainability into all our new packaging systems and optimise our existing products wherever possible. This allows us to consider the critical sustainability aspects of the design from the earliest stages of development, ensuring that we maximise positive impact throughout the entire product lifecycle. I'd like to add that we are using state-of-the-art materials and methods that will move us closer to achieving our larger sustainability goals and ultimately move our products fully into the circular economy. Stay tuned, there is more to come.

ABOUT THE COMPANY

For pharma customers worldwide, Aptar Pharma is the go-to drug delivery expert, from formulation to patient, providing innovative drug delivery systems, components and active material solutions across the widest range of delivery routes, including nasal, pulmonary, ophthalmic, dermal and injectable. Aptar Pharma Services provides early-stage to commercialisation support to accelerate and de-risk the development journey. With a strong focus on innovation, Aptar Digital Health is leading the way in developing digital health solutions to help improve the patient treatment experience. With a global manufacturing footprint of 14 manufacturing sites, Aptar Pharma provides security of supply and local support to customers. Aptar Pharma is part of AptarGroup, Inc.

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*Aptar Pharma consumer survey, 2022

Nemera
we put patients first

COMMITTED TO SUSTAINABILITY!

In this article, Sandrine Coutarel, Global EHS Director at Nemera, looks at the company's sustainability road map and the steps being taken to achieve its aims.

Since its creation, Nemera has been resolutely focused on the wellbeing of patients, true to the motto, "*We put patients first*", as well as the health and safety of its employees. When Nemera developed its sustainable development roadmap, it became obvious that, to better serve these two missions, Nemera needed to think beyond them and consider its impact on the environment and society. As such, Nemera has articulated its sustainable development strategy around four pillars: labour and human rights, environmental protection, societal impact, and value chain. Through its roadmap and the concrete actions that follow, Nemera aims to create a strong dynamic on these four pillars within its sphere of influence. This cannot be done alone – it is only by creating solid partnerships with its customers and suppliers that Nemera will be able to achieve its sustainability goals.

> "Through its roadmap and the concrete actions that follow, Nemera aims to create a strong dynamic on these four pillars within its sphere of influence."

CONTRIBUTING TO THE WELLBEING OF EMPLOYEES AND ENSURING THEIR PROFESSIONAL DEVELOPMENT

Of course, these are not new themes. Ensuring good working conditions that allow employees to flourish is an integral part of Nemera's culture, prioritising the balance between the professional and personal lives of its employees. The company also aims to achieve zero injuries in its manufacturing facilities, and it is getting closer to this goal every year thanks to the strong commitment of its employees (Figure 1).

Training is another important part of Nemera's people strategy. Investing in developing the skills of its employees

Figure 1: Buffalo Grove (Chicago, IL) manufacturing facility.

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"Since 2023, 100% of Nemera's factories have been using green or decarbonised energy."

contributes to their professional fulfilment and allows the company to constantly adapt to new challenges. Developing internal skills goes hand in hand with attracting new talent. This balance is constantly sought in order to address new challenges such, as the digitalisation of work methods.

The balance of a successful company also lies in the diversity of its employees. Nemera's ambition is to increase the representation of women in management positions in order to have the full range of skills and qualities that both men and women can bring. It is through diversity of gender and culture that the best working conditions can be achieved. Additionally, the company conducts business in an ethical manner, implementing policies and processes to establish a framework of trust for reporting possible unethical or corrupt practices. Each report is analysed at the highest level to ensure that swift action is taken.

REDUCING ITS ENVIRONMENTAL IMPACT – A KEY CRITERIA IN BUSINESS CHOICES

Nemera's main environmental impact centres on its electricity consumption. In 2019, the company chose to find new partners to supply green or decarbonised electricity. Since 2023, 100% of Nemera's factories have been using green or decarbonised energy. This has resulted in a reduction of more than 80% of its CO_2 emissions from Scopes 1 and 2.

In parallel with the work on energy supply contracts, each of Nemera's manufacturing plants is developing an energy-saving plan. Work on installing LED lighting and the reuse of heat produced by the machines to heat the premises has been underway for several years. Today, Nemera is making major investments in more efficient heating and cooling equipment, as well as in production machines that consume less energy. The company already has two ISO 50001 (Energy Management System) certified sites and a third will be certified by the end of 2023.

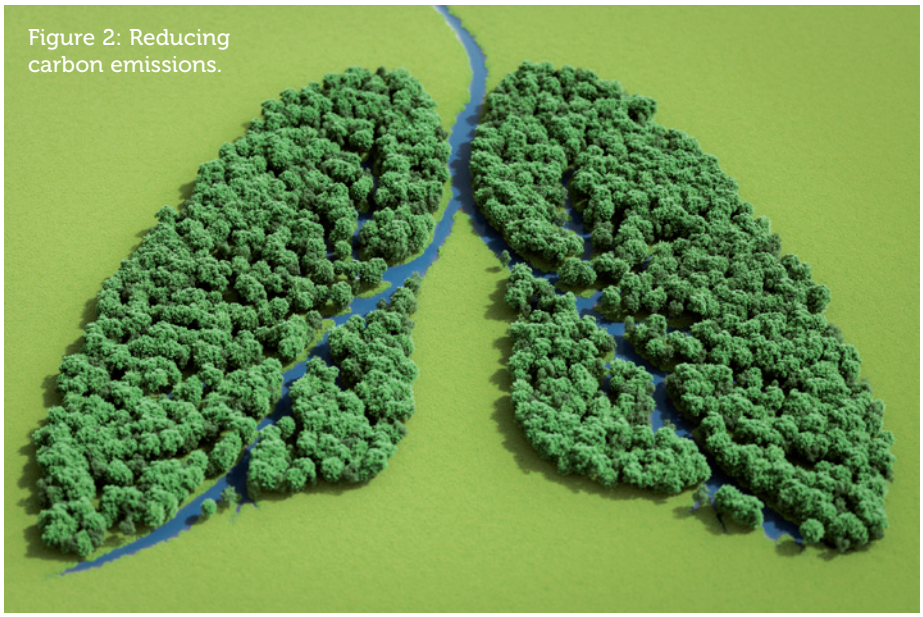

Figure 2: Reducing carbon emissions.

"Nemera favours long-term initiatives to create solid partnerships that will evolve with society."

In 2021, to go even further down the road to decarbonisation, Nemera made a commitment to the Science-Based Targets Initiative (SBTi) to set its CO_2 reduction targets and to contribute, on its own scale, to limiting global warming to 1.5°C in 2030 compared with the pre-industrial era. This is a very strong commitment because the company must reduce its CO_2 emissions from Scopes 1 and 2 by 90% and CO_2 emissions from its indirect activities (Scope 3) by 55% (tCO_2/added value). Nemera is designing and developing action plans for 2023, targeting the various categories of emissions that will enable it to achieve these objectives. This is a multi-disciplinary effort that is, once again, being developed in conjunction with the company's supplier and customer partners (Figure 2).

Another major area of development for Nemera is the eco-design of its products. Led by Insight, Nemera's R&D team, this year, the company is going to carry out its first lifecycle analysis on one of its own products: Novelia®. The aim of this process is to quantify the environmental impact of this product and to identify the best levers for action to make it more sustainable and more easily recyclable. Given the development cycles for pharmaceutical equipment, which can take 10 years, this is a long-term task, but it is essential to complete the 2030 decarbonisation plan for Nemera's activities.

While Nemera is free to choose how to take action with regard to its own products, it is also engaging in discussions with its CMO partners. Indeed, its development and production teams are ready to work on low-carbon resins or the reuse of production scraps on the shop floor. The company is looking forward to bringing its skills on these innovative projects for the pharmaceutical sector.

MAKING SURE NEMERA HAS A POSITIVE IMPACT ON SOCIETY

Having a positive impact on society means contributing to local development and community life. This requires looking beyond the company's walls, engaging with local public or private stakeholders and choosing initiatives that correspond to Nemera's values and that are meaningful for the company and its employees.

Nemera favours long-term initiatives to create solid partnerships that will evolve with society. This approach enables the company to measure its impact over several years and build strong bonds of trust with local actors.

For example, following the move of its headquarters to Lyon (France) in September 2022, Nemera signed the "Charte des 1000" in January 2023, initiated by "Le Grand Lyon" and the "Metropolitan Integration Center for Employment". This is a strong

commitment to promote the integration and employment of the most vulnerable people in Lyon (Figure 3).

For several years, Nemera has been contributing to the "Sport dans la Ville" association. This Lyon-based association operates in neighbourhoods where employment is a significant challenge. In these areas, one in three young people has a level of education lower than the Brevet d'études professionnelles and Certificat d'aptitude professionnelle. Unequal access to diplomas and training, combined with other difficulties, such as poor social mobility and housing, excludes a growing number of young people.

Sport dans la Ville encourages the social and professional integration of these young people through sport. Nemera participates in sports events with the young people it sponsors. In February 2023, the company also welcomed 25 young people to its headquarters for a one-day seminar with several of Nemera's managers, presenting the company's businesses and challenges.

Figure 3: Commitment to local employment.

ENGAGING WITH VARIOUS STAKEHOLDERS TO INCREASE NEMERA'S IMPACT

Nemera's sustainable development dynamic is not limited to its own activities. The beneficial effects of its strategy will be amplified if the company can convince its suppliers, customers and financial partners to participate in its initiatives at their own level. However, this is not an easy task, as Nemera's strategy must be explained to its stakeholders, who must also be convinced to take part in these initiatives.

For example, with greenhouse gas emissions, Scope 1 and 2 emissions are directly linked to Nemera's activities, and the company has a direct influence on them. By implementing actions at each of its production units and acting quickly and efficiently, Nemera is on track to reach its reduction targets for these emissions by the end of 2023.

> "The beneficial effects of its strategy will be amplified if the company can convince its suppliers, customers and financial partners to participate in its initiatives at their own level."

As such, Nemera's indirect emissions from its value chain, also known as Scope 3 emissions, will account for more than 70% of its carbon footprint by 2023. The real challenge lies here. Nemera needs to work on the carbon footprint of the products it purchases, as well as the transportation of raw materials and finished products. This requires building strong relationships with its suppliers and customers so that they accept the changes proposed by Nemera. A virtuous circle is then established, in which Nemera's suppliers will also have to bring their own suppliers on board. This is the effect that Nemera aims to achieve.

LEVERAGING INTERNATIONAL AND SCIENTIFIC INITIATIVES TO PROVIDE TRANSPARENCY

In 2019, EcoVadis assessed Nemera's sustainability roadmap for the first time. This allows the company to be evaluated annually by an independent third party, with its efforts translated into a score that is completely transparent. Since then, Nemera has undertaken numerous sustainability projects, resulting in a continually improving score. In 2021 and 2022, the company received a Silver rating, placing it in the top 15% of companies in the industry. With the projects undertaken this year, the company is expected to soon achieve a Gold rating and be in the top 5% of companies in the industry.

In 2021, Nemera made a commitment to the SBTi to validate its greenhouse gas emission reduction targets. This guarantees that Nemera's aims align with the global challenge of limiting global warming to 1.5°C by 2030, compared with the pre-industrial era.

Finally, at the beginning of 2023, the company signed up to the UN Global Compact to contribute to the 17 sustainable development goals defined by the UN. The company's next step is to analyse its strategy in relation to these 17 objectives, identify any gaps and define a higher ambition (Figure 4).

The regulations relating to sustainable development are evolving very quickly. Nemera is actively preparing for the upcoming new guidelines on non-financial reporting by companies by putting robust and repeatable corporate social responsibility indicators and data collection processes in place. The whole company will be involved, which is what makes the business so attractive.

Nemera published its first sustainability report in 2023, which is an important step for the company because it brings together all its initiatives, along with testimonials from its teams, in a single document. This report will evolve into an improved version in 2024, as the company will also be able to realise its double materiality matrix. The results will determine the architecture of the next report and the indicators will be published annually.

Figure 4: Commitment to UN Global Compact.

Nemera is at the beginning of its journey, but the involvement of its employees and management team is already clear. The company is actively working to engage its stakeholders and maximise its positive impact on the environment and society. Nemera is confident that it is on the right track in its contribution to build a better world for future generations.

ABOUT THE COMPANY

As a world-leading drug delivery device solutions provider, Nemera's purpose of putting patients first enables it to design and manufacture devices that maximise treatment efficacy. Nemera is a holistic partner and helps its customers succeed in the sprint to market with their combination products. From early device strategy to state-of-the-art manufacturing, Nemera is committed to the highest quality standards. Agile and open-minded, Nemera works with their customers as colleagues. Together, they go the extra mile to fulfil its mission.

ABOUT THE AUTHOR

Sandrine Coutarel graduated from the University of Lyon with a degree in Environmental Sciences and Occupational Health and Safety. She has worked for over 20 years as EHS Manager in various international industrial environments. Ms Coutarel appreciates the transversality of projects, diversity of cultures and the people she works with. At Nemera, she is developing, implementing and overseeing the company's sustainability strategy; a challenge that resonates with her personal convictions.

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Discover Nemera's first sustainability report!

Visit: https://www.nemera.net/who-we-are/sustainability-our-esg-approach/

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RETHINKING PLASTIC: HOW ECO-FRIENDLY DESIGN IS DRIVING SUSTAINABLE CHANGE

In this article, Giorgio Sardo, Senior Design Systems Engineer at Flex, discusses sustainable material selection and the results of tests comparing the performance of sustainable bio-based plastic resins with their fossil-based equivalents.

In 2015, the United Nations unveiled its Sustainable Development Goals (SDG) – a blueprint for a more sustainable future. These goals have informed the sustainability strategies of public and private organisations of all sizes around the world, including medical equipment manufacturers.

One of the goals specifically aspires to ensure sustainable consumption and production patterns and serves as a guiding principle for manufacturers keen to reduce demand on natural resources.

A ROLE FOR PRODUCT DESIGNERS

Product designers rely on the disciplines of design for assembly or design for manufacturing to improve aspects of a product. But reducing the environmental impact over the entire product lifecycle requires a focus on design for environment (DFE). These guidelines offer product designers numerous options to improve the sustainability of their product, including increased durability, better energy efficiency, and easier disassembly and reassembly to enable maintenance, repair, refurbishment or recycling.

DFE guidelines can also support the selection of raw materials with lower greenhouse gas emissions as measured in CO_2 equivalent (CO_2e). This metric can be used to standardise the measurement of climate effects of various greenhouse gases.

REDEFINING PLASTIC

Plastic is the chameleon of modern materials. Its versatility, resiliency and durability have made it an indispensable material for an incredible range of applications, from automotive and agriculture to construction, containers, textiles and toys. It is also widely used in healthcare, for both disposable and durable products.

> "Not all plastics are the same, nor do they generate the same CO_2e emissions."

Plastic has an important role to play in ensuring sustainable production. However, not all plastics are the same, nor do they generate the same CO_2e emissions. For example, acrylonitrile butadiene styrene (ABS) plastic creates about half the CO_2e emissions of polycarbonate (PC).

ABS has a similar tensile modulus and a smaller tensile strength but high impact, heat, chemical and abrasion resistance. ABS also has a higher natural ultraviolet (UV) resistance and rigidity compared with polycarbonate. This means there are cases where PC can be replaced by a PC/ABS blend – or even pure ABS – to give a significant reduction in resin emissions.

Table 1 lists some commonly used resins with their respective CO_2e emissions, and the energy and water consumption needed to produce 1 kg of raw material.

MAKING A MATERIAL DIFFERENCE

When it comes to material selection, there are several design guidelines that can influence the CO_2e number. The most straightforward of these is to reduce the amount of material used. To illustrate the point, it is now common for beverages to be packaged in plastic bottles with thinner walls and less material.

When it comes to choosing lower-emission materials, manufacturers have a choice of, but are not limited to:

- A traditional (fossil-based) resin but with lower emissions, as described in the ABS/PC example

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"Using recycled, rather than virgin, materials raises the bar and offers an immediate CO_2 saving."

- A fully or partially recycled material
- A material made from bio/vegetal feedstock and based on a mass balance approach.

FULLY OR PARTIALLY RECYCLED MATERIALS

Using recycled, rather than virgin, materials raises the bar and offers an immediate CO_2 saving, as between 30% and 70% of the total material weight can be replaced with post-consumer or post-industrial recycled waste. This has a double benefit of both diverting waste from landfill and producing fewer emissions – i.e. less energy is required to process (recover, sort and clean) the waste material and turn it into a new resource than would be needed to create it.

Polystyrene used in food packaging is a good example. Once the waste material is collected, an infrared detector is used to identify and separate resins. The polystyrene is then shredded and cleaned to remove foreign materials like food, labels and metallic parts. It is then ready for a new production cycle, but with 50% less CO_2 emissions. Its overall characteristics and material purity make recycled polystyrene acceptable for food contact. However, for a medical product, where biocompatibility standards are more sophisticated, we must raise the bar once more.

"Bio-based material offers an opportunity to create a sustainable material suitable for use in a healthcare environment that is substantially identical to its fossil-based equivalent."

Material	Description	CO_2e (kg)	Energy (MJ)	Water (M^3)
ABS	Acrylonitrile-butadiene-styrene	4.7	120.7	0.014
PC/ABS	70/30 PC ABS	6.9	129.2	0.018
PET	Polyethylene terephthalate	4.0	102.6	0.021
PMMA	Polymethyl methacrylate	7.6	154.0	0.014
Polycarbonate	Polycarbonate	7.9	132.9	0.019
Polypropylene	Polypropylene	7.9	132.9	0.019
Polyurethane	Polyurethane	2.0	81.7	0.006
POM	Polyoxymethylene (acetal)	3.1	63.8	0.011

Table 1: Sourced from Ecoinvent v3.9. data.

BIO-BASED MATERIAL

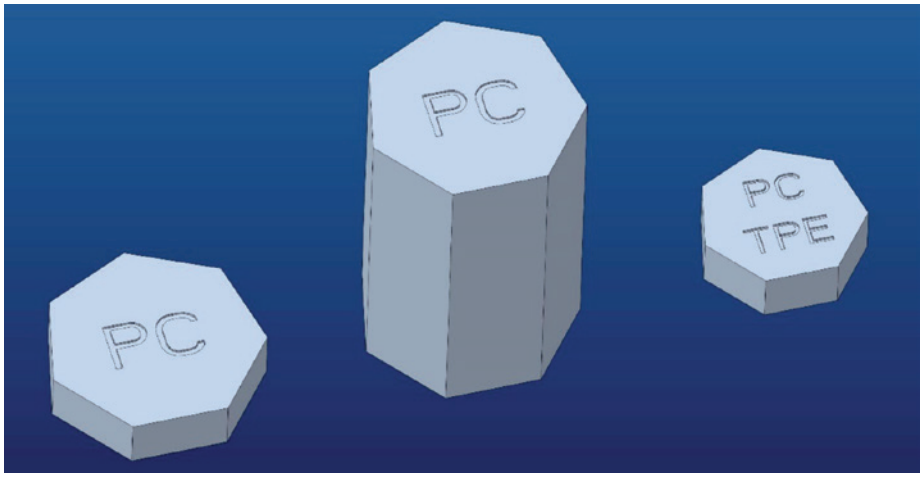
Bio-based material offers an opportunity to create a sustainable material suitable for use in a healthcare environment that is substantially identical to its fossil-based equivalent but made from a biological source and following the mass balance approach.

When we consider the CO_2e emissions based on a cradle-to-gate lifecycle assessment, which calculates emissions from resource extraction (cradle) to the factory gate, we can validate CO_2e reductions that in some cases – such as a bio-based polycarbonate – lead to a climate neutral material. Additionally, traditional fossil-based material can be directly substituted with biomaterials without changing the parts production process and thus without the need for revalidation activity.

TESTING THEORY

To prove that biomaterials can offer a drop-in solution, directly replacing existing materials, the Flex team at the Milan Design Center (Italy) performed a comparative evaluation between standard resin (PC) commonly used in durable devices and a climate-neutral biocompatible grade of this material that we'll call the "green" version.

The test was carried out on a subassembly comprising three components designed in transparent PC: two of them made from standalone PC, while the third was two-shot injection moulded (2 k shot) PC plus thermoplastic elastomer (TPE). The three parts had the shape of heptagonal prisms, whose dimensions are shown in Figure 1. Two groups of tests were carried out to examine the equivalence of the injection moulding process and the mechanical resistance.



Part 1	Part 2	Part 3
⌀42 mm, height 10 mm	⌀42 mm, height 10 mm	⌀35 mm, height 10 mm

Figure 1: Material and dimensions of the parts under test.

MOULDING TEST

To evaluate the mouldability characteristics, 100 kits in the standard material and 100 kits in the "green" material were produced in the same day, according to the following rules:

- Both materials were handled and prepared under the same conditions
- Both materials were moulded with the same process parameters and the same equipment
- For each material, the outputs reported into the process parameters sheet were recorded.

The tooling team used three criteria to evaluate the mouldability properties of the two materials:

- The injection parameters
- The dimensional report
- The aesthetic appearance of the parts.

The result of the comparison is summarised in Table 2.

No appreciable difference was found between the two materials – even aesthetic defects, such as the weld lines shown in Figure 2, were identical.

Evaluated Item	Standard Resin verses "Green' Resin
	Test Results
Injection parameters	Negligible pressure difference at injection peak and switchover
Measurement report (FAI)	No relevant change or minor differences (less than 0.05 mm)
Visual inspection	No relevant difference. In one of the three parts the same weld lines are visible (see figure 2)
Conclusion	**The two material grades analysed can be considered equivalent based on the three tested parts**

Table 2: Summary table of the mouldability evaluation.

> "No appreciable difference was found between the two materials – even aesthetic defects, such as the weld lines, were identical."

MECHANICAL RESISTANCE TEST

The mechanical resistance evaluation was carried out using three tests, listed below, and taken from IEC 60601-1-11:2015 + AMD1:2020 (requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment):

- Drop (clause 15.3.4.1)
- Push (clause 15.3.2)
- Impact (clause 15.3.3).

This evaluation was used to perform a thorough mechanical test campaign of the subassembly comprising the three parts produced with the two PC versions. These tests are applicable to wearable devices.

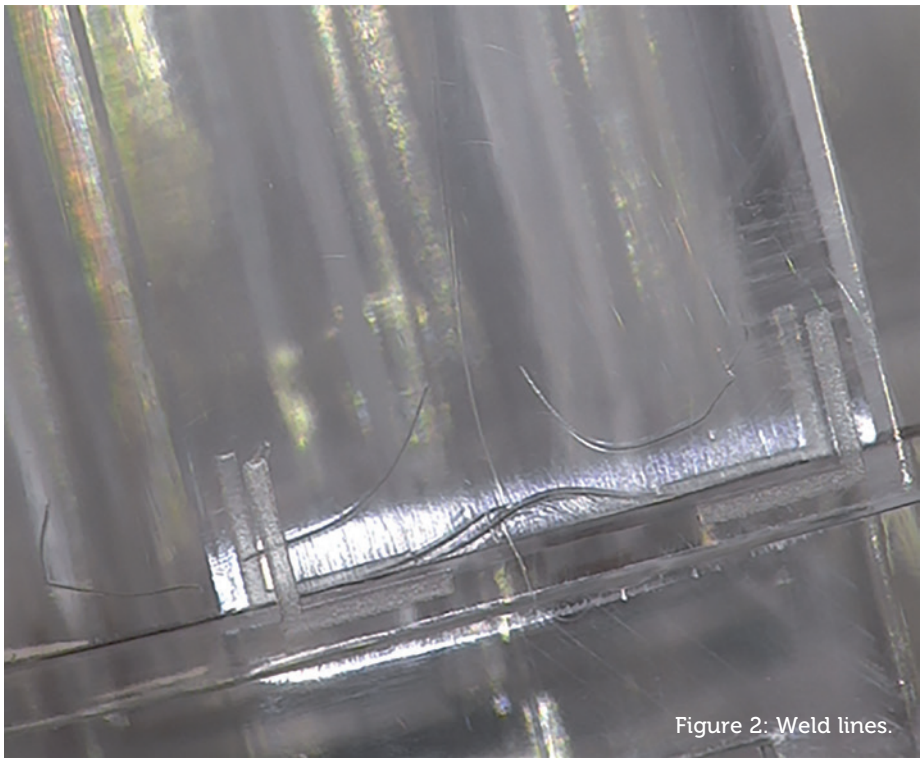


Figure 2: Weld lines.

DROP TEST

In the drop test, the samples were allowed to fall freely once from three different starting positions onto a 50 mm thick hardwood board lying on a rigid concrete base. The drop height was progressively increased from 1 m until failure, to identify the material equivalence. The test was carried out in Flex laboratories using the drop machine shown in Figure 3.

Table 3 shows the test results summary. Each column represents a drop, beginning from 1 m in height and going up to 2.1 m. The yellow cells identify "test observations" – e.g. a partial part detachment – while red cells identify a part breakage. Looking at the colour distribution, the two groups behave in an equivalent way. Using a statistical T test to compare the cumulative means of the drop height further confirmed the equivalence.

PUSH TEST

In the push test, the devices were subjected to a steady force for five seconds that was applied using a flat tool, as shown in Figure 4. The tested subassembly is depicted as a blue cylinder.

The subassemblies were stressed by applying and increasing the load along the

Figure 3: Drop machine.

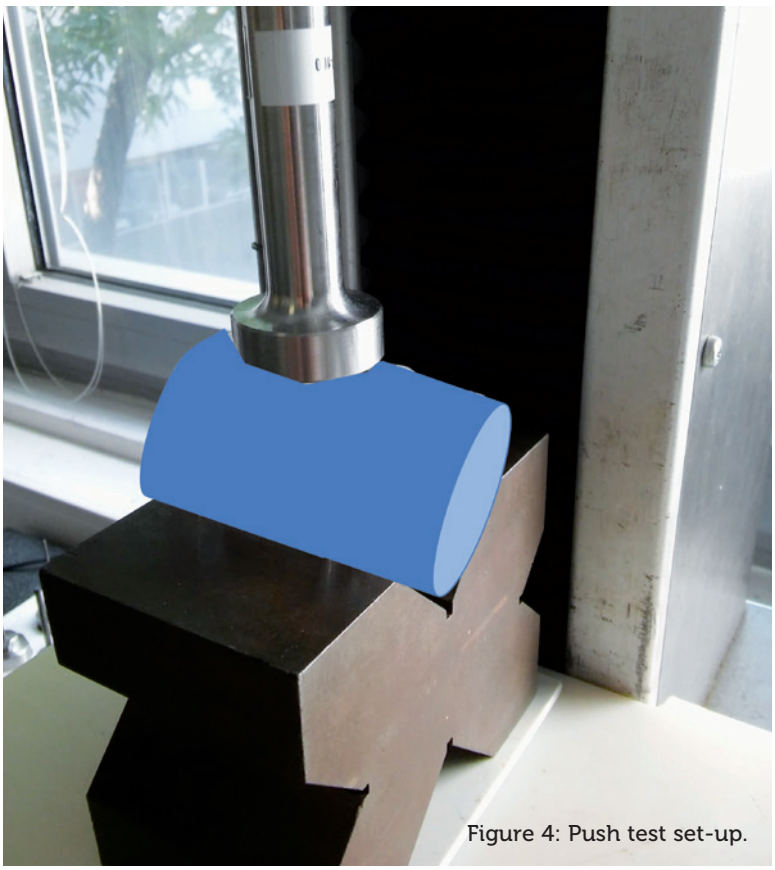


Figure 4: Push test set-up.

orientations shown in Figure 5, up to and including the point of failure. The tests were performed in a Flex laboratory using a tensile tester.

The equivalence of the two materials is visible in Figure 6 (next page), which shows the tensile tester output (load [N] versus displacement [mm]). The brown line represents the standard material, while the green line corresponds to the "green" material. The two curves almost overlap, thus the elastoplastic behaviour of each assembly, using two different materials, is practically identical.

"When it comes to plastic resins, Flex's tests have shown that bio-based options are a valid substitute for the fossil equivalent. This green material can be used with the same tools and moulding parameters as the fossil-based version."

	Drop height [m]	1	1.1			1.2			1.3			1.4			1.5			1.6			1.7			1.8			1.9			2			2.1		
	RUN	1 to 5	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3
Standard	MA001	P	O	P	P	P	P	P	O	P	P	O	P	P	O	P	P																		
	MA002	P	P	P	P	P	P	P	P	P	O	P	P	O	P	P	O																		
	MA003	P	O	O	O	O	P	O	O	O	O	F																							
	MA004	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P																		
	MA005	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P																		
	MA006	P	P	P	P	O	P	P	O	P	P	O	P	P	O	P	O																		
	MA007	P	P	P	F																														
	MA008	P	O	P	O	O	O	O	O	P	O	O	F																						
	MA009	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P																		
	MA010	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P																		
	MA011											P	P	P	O	P	P	P	P	P	P	P	P	O	P	P	O	P	P	O	P	P	O	P	P
	MA012											P	O	O	P	P	O	P	P	P	P	P	F												
	MA013											O	P	O	O	F																			
	MA014											P	P	P	P	P	P	P	P	P	P	O	P	P	P	P	P	P	P	P	P	P	P	P	P
	MA015											P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	O	P	P	P	P	P	O	P
Green	RE001	P	P	P	P	P	P	P	O	P	P	O	P	P	O	P	O																		
	RE002	P	P	O	P	P	P	P	P	P	O	P	P	O	P	P	P																		
	RE003	P	O	P	P	O	P	O	P	O	O	O	P	F																					
	RE004	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P																		
	RE005	P	P	O	P	P	P	P	P	P	P	P	P	P	P	P	P																		
	RE006	P	P	P	P	O	P	P	P	P	P	O	P	P	O	P	P																		
	RE007	P	P	P	O	P	P	P	P	P	P	P	P	O	P	P	O																		
	RE008	P	P	P	P	P	P	P	O	O	O	F																							
	RE009	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P																		
	RE010	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P																		
	RE011											O	P	P	P	P	P	O	P	P	P	P	P	O	P	P	F								
	RE012											P	P	O	P	P	O	P	P	P	P	P	P	P	P	F									
	RE013											O	P	P	O	P	O	F																	
	RE014											P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	RE015											P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

Table 3: Drop test summary table.

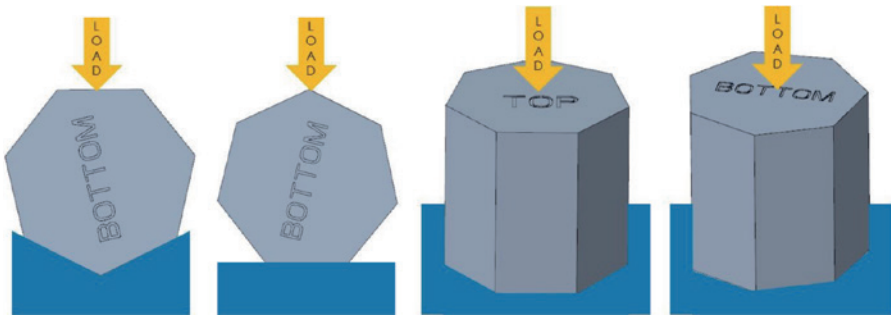


Figure 5: Push test – load orientations.

IMPACT TEST

The impact test was carried out in a Flex laboratory using a 250 g metal bullet falling freely from an increasing height, up to and including the point of failure. The same point used for the push test shown in Figure 6 was used in the impact test. The test results are summarised in Figure 7, where each coloured bar represents one impact, with its length proportional to the energy. The red bars correspond to failures (cracks) and show comparable results for both materials at the same energy level, confirming equivalence in this test.

CONCLUSION

Sustainability-focused companies are incorporating a lower CO_2 footprint into the materials used in their medical product designs.

When it comes to plastic resins, Flex's tests have shown that bio-based options are a valid substitute for the fossil equivalent. This green material can be used with the same tools and moulding parameters as the fossil-based version, so no additional tooling, validation expenses or effort are needed.

CO_2e emissions reduction can be evaluated in a comparative lifecycle assessment performed for both new and existing products.

ABOUT THE COMPANY

Flex is the manufacturing partner of choice that helps a diverse customer base design and build products that improve the world. Through the collective strength of a global workforce across 30 countries and responsible, sustainable operations, Flex delivers technology innovation, and supply chain and manufacturing solutions, to diverse industries and end markets including pharmaceutical and medtech companies. Its approach is supported by US FDA-registered and ISO 13485 compliant and ISO 11608-1 accredited facilities, with a world-class single quality system across sites.

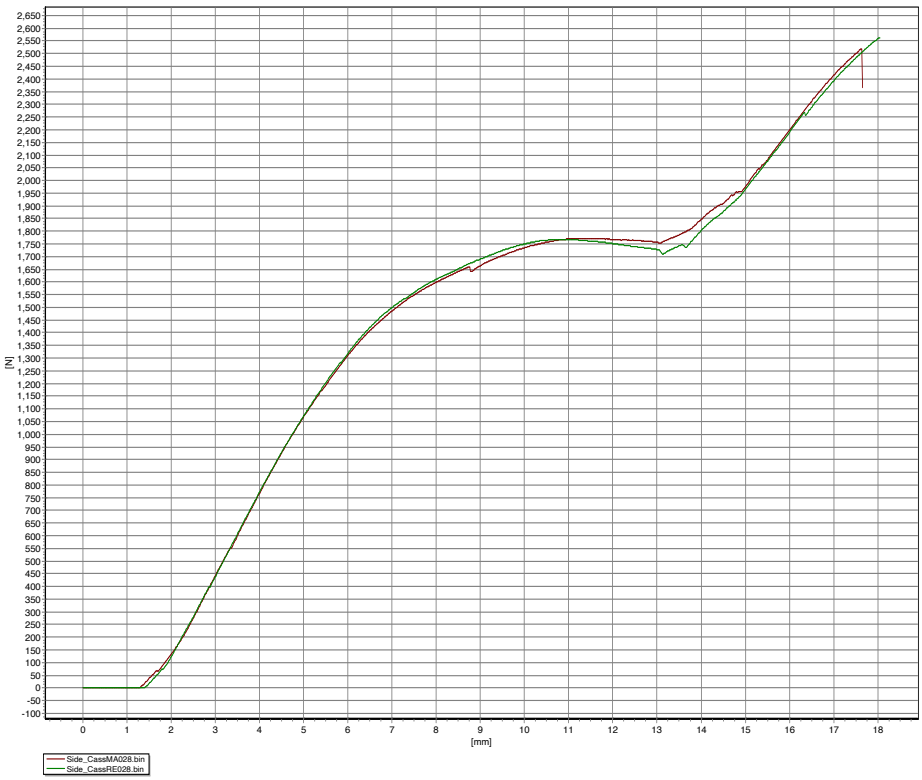


Figure 6: Push test – tensile tester graph (N versus mm).

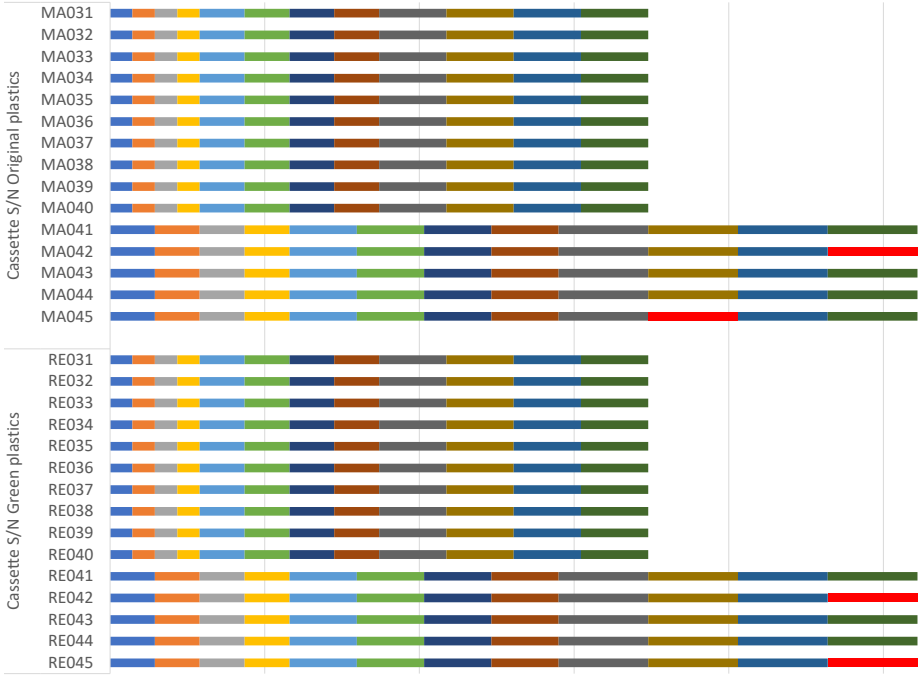


Figure 7: Impact test results summary.

ABOUT THE AUTHOR

Giorgio Sardo is a design systems senior staff engineer based at the Flex Design Center in Milan, Italy. He joined the Systems Engineering Team last year, having spent 14 years with the Mechanical Engineering Department at Flex. Mr Sardo has deep experience in the design, prototyping and industrialisation of various types of medical devices, such as autoinjectors, pen injectors, glucose meters, hand-held drug delivery devices and a dental tomograph. Prior to Flex, Giorgio worked in the space industry after graduating in Aerospace Engineering at the Polytechnic University of Milan.

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IMPROVING RECYCLABILITY IN DRUG DELIVERY

In this article Julien Tremblin, General Manager at TerraCycle Europe, looks at the recyclability challenges facing the drug delivery market and considers how companies can enhance the recyclability of their packaging and devices.

The drug delivery industry is uniquely beholden to stringent regulations that make it challenging to incorporate recycled materials into packaging and devices, as well as to recycle these items at their end of life. The good news is that the industry is not too far behind others, such as the consumer packaged goods (CPGs) industry; the bad news is, nor is it better. Recycling rates are low across all industries, and the drug delivery industry has some of the lowest rates of all.

> "In a world where awareness of the waste crisis is at an all-time high, consumers are looking for products and manufacturers that embrace sustainability and recyclability."

The drug delivery industry is frequently granted exemptions and extended timelines for meeting the changes and targets that are required of other sectors. The European Commission's Draft Packaging Regulation from November 2022, for example, specifies that medical packaging is exempt from the 2030 recyclability targets until 2034.[1] However, in a world where awareness of the waste crisis is at an all-time high, consumers are looking for products and manufacturers that embrace sustainability and recyclability. According to research from 2022, some 72% of consumers consider sustainability in their purchasing decisions.[2] In other words, although the drug delivery industry has looser deadlines to hit recyclability targets, customers will favour those manufacturers and brands that offer solutions right now (Figure 1).

Figure 1: TerraCycle's Metered Dose Inhalers Zero Waste Box. For more information about the Zero Waste Box solutions visit zerowasteboxes.terracycle.co.uk

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WHAT ARE THE RECYCLABILITY CHALLENGES FACING DRUG DELIVERY?

Obstacles to improving recyclability include:

- The plastics commonly used in the industry are often complex, and easily recyclable alternatives are few and far between
- Products may contain elements and chemicals that are considered hazardous and have to be disposed of in certain ways, such as incineration
- A conservative attitude towards the disposal of pharmaceutical waste, meaning recyclable packaging can sometimes be sent for incineration for fear of breaking medical waste disposal laws.

It is also important to understand what is meant by the term "recyclability". While almost everything is technically recyclable, councils and municipalities only recycle items when the recycled end-product is worth more than the cost of recycling process. Drug delivery products tend to be composed of multiple materials that enable them to serve their medical function. This makes the recycling process more complex and therefore more costly. For example, inhalers are made up of a casing that typically includes one or more types of plastic, as well as a metal canister that needs to be separated and sorted to be properly recycled. This is why so many medical devices and packaging are considered "unrecyclable".

WHAT CAN BE DONE TO IMPROVE RECYCLABILITY?

It is unlikely that most devices and primary packaging for drug delivery will have municipal recycling solutions available in the near future. However, there are alternative solutions readily available that can improve recyclability today.

A lot of the drug delivery devices and packaging currently sent to landfills or incineration are done so out of fear of breaching regulations around hazardous waste, when, in fact, the WHO has estimated that only 15% of all healthcare waste is actually considered hazardous.[3] Improving the recycling rates of the remaining 85% of the industry's waste should be a priority, and there are various ways to achieve this. It is possible to find solutions for almost all waste streams that are not considered hazardous. By partnering with drug delivery manufacturers, industry-first recycling programmes have been developed for a wide range of items, including medicine blister packs, syringe filters and inhalers, which cannot be recycled municipally but are not classified as hazardous waste.

However, the key to achieving wide-scale recyclability is by factoring it into each product at the design stage. Even considering industry-specific requirements, certain elements of drug delivery products, including anything that does not come into contact with the drug or patient, can and should be made out of recycled or recyclable materials wherever possible. Packaging should be kept to mono-materials, such as aluminium, glass and widely recyclable plastics like polyethylene terephthalate (PET), and the same is true for the devices themselves, wherever possible.

In the case of drug delivery products and packaging where using multiple materials is unavoidable, recyclability should still be a priority. Taking medicine blister packs as an example, the need to be able to open the pack easily and safely means that the use of two different materials is necessary – usually plastic and aluminium – and they are therefore excluded from municipal recycling. However, by making the main polymer as recyclable as possible – think PET and not polyvinyl chloride (PVC), for example – it makes existing solutions more efficient in terms of costs and processing, but also plans for a time when the infrastructure may exist to separate and process these materials at a municipal level.

> "Favouring light and easy-to-separate materials will not only reduce the amount of packaging waste generated per product but also limit complexities and costs at the processing stage."

Environmental impact is measured in reduction as well as recyclability rates. Favouring light and easy-to-separate materials will not only reduce the amount of packaging waste generated per product but also limit complexities and costs at the processing stage. Similarly, the industry should strive for consistency instead of offering similar products in a range of materials. The current model sees a vast range of blister packs coming to market, some made from PVC, some PET, some polychlorotrifluoroethylene (PCTFE) and so on, with little thought towards streamlining materials.

WHAT DOES THE FUTURE LOOK LIKE?

The drug delivery sector has benefited from exemptions and lengthier timelines to deliver on sustainability regulation, but this is expected to change over the next five to ten years as the focus shifts away from waste in the CPG industry and moves to more

specialist industries. An upsurge can already be seen in the number of pharmaceutical and drug delivery companies looking for sustainability solutions to offer consumers, looking to get ahead of future regulation and growing consumer expectations. By taking measures now, such as recycling primary packaging and integrating recycled materials into their supply chain, moving to mono-materials and pushing regulators to declassify medical waste that is wrongly seen as hazardous so that it can be recycled, companies can demonstrate to stakeholders and consumers that they have the future of the planet firmly in mind.

ABOUT THE COMPANY

TerraCycle is an international leader in innovative sustainability solutions, creating and operating first-of-their-kind platforms in recycling, recycled materials and reuse. Across 21 countries, TerraCycle is on a mission to rethink waste and develop practical solutions for today's complex waste challenges including industry-first recycling solutions for medicine blister packs, syringe filters and inhalers. The company engages an expansive multi stakeholder community across a wide range of accessible programmes, from Fortune 500 companies to schools and individuals.

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ABOUT THE AUTHOR

Julien Tremblin is the General Manager of TerraCycle Europe, a global leader in the collection and repurposing of otherwise non-recyclable post-consumer and post-industrial waste. Through TerraCycle, Mr Tremblin is pioneering a new waste management process across TerraCycle's 12 European markets (UK, Republic of Ireland, France, Spain, Germany, Austria, Switzerland, the Netherlands, Belgium, Norway, Sweden and Denmark) in a period of real innovation and exciting growth for the business. This process involves manufacturers, retailers, governments and consumers creating circular solutions for materials such as pharmaceutical waste, laboratory waste, PPE waste, food packaging and even beach plastics that otherwise have no other path to be recycled.

ON drugDELIVERY

2023/24 EDITORIAL CALENDAR

Publication Month	Issue Topic	Materials Deadline
May	Delivering Injectables: Devices & Formulations	Deadline passed
May/Jun	Oral Drug Delivery	Deadline passed
June	Connecting Drug Delivery	May 25, 2023
Jun/Jul	Industrialising Drug Delivery	Jun 1, 2023
September	Wearable Injectors	Aug 3, 2023
October	Prefilled Syringes & Injection Devices	Sep 7, 2023
Oct/Nov	Drug Delivery & Environmental Sustainability	Sep 21, 2023
November	Pulmonary & Nasal Drug Delivery	Oct 5, 2023
December	Connecting Drug Delivery	Nov 2, 2023
January 2024	Prefilled Syringes & Injection Devices	Dec 7, 2023
February	Skin Drug Delivery: Dermal, Transdermal & Microneedles	Jan 4, 2024
March	Ophthalmic Drug Delivery	Feb 1, 2024
April	Pulmonary & Nasal Drug Delivery	Mar 7, 2024
Apr/May	Drug Delivery & Environmental Sustainability	Mar 21, 2024
May	Delivering Injectables: Devices & Formulations	Apr 4, 2024
May/Jun	Oral Drug Delivery	Apr 18, 2024

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