SUSTAINABILITY AND DRUG DELIVERY DEVICES

In this article, Rob Veasey, Senior Sector Manager, Medical and Scientific, at DCA Design International, explores the environmental challenges facing the drug delivery device industry – and the opportunities they bring.

We are witnessing a global boom in the use of drug delivery systems. Valued at approximately US$500 billion (£382 billion) in 2016, this market is forecast to reach nearly $900 billion by 2025.[1] An increase in demand for self-administration and home healthcare devices has helped fuel this expansion, meaning that today's drug delivery devices are not only much more widespread, they have become easier to use, safer and more effective. They form an essential part of our healthcare infrastructure, enabling the delivery of countless therapies that save lives and improve patient outcomes on a vast scale.

As they have been targeted at wider audiences, more drug delivery systems have been designed to be disposable. This market trend has been driven primarily by the desire to improve safety and usability. Disposable devices typically require fewer operating steps than reusable ones and, because they have a finite life, they are less susceptible to wear and contamination. A good example is the evolution of dry powder inhalers (DPIs). These began in the 1970s and 1980s as relatively simple reusable devices, such as the Spinhaler® and Diskhaler® (GlaxoSmithKline, UK), in which users fitted replaceable capsules or blister packs containing the drug product. They are now predominantly disposable products, in which the primary pack is sealed for life.

Drug delivery devices have also evolved to become more mechanically sophisticated. For DPIs, the requirement to automatically manage drug primary packaging and the addition of safety features such as dose counters has driven this trend. A similar story is found with injection devices, where one of the latest generation of spring-powered disposable insulin pen injectors has 17 components. In contrast, when first developed in the late '80s and early '90s, disposable pen injectors typically had fewer than 10 parts.

Alongside the increase in device complexity, designers are now also able to select from an ever-growing pallet of polymers. This has enabled improvements in performance and reliability, but the mix of materials now found in many devices adds to the already significant challenges for recyclability.

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THE NEED FOR CHANGE

As scientific evidence of the environmental challenges we face becomes clearer, the necessity to reduce the environmental impact of products we use daily has become more pressing. We all share this responsibility, but governmental bodies have taken measures to drive adoption of more sustainable practices. Under the 2015 Paris Agreement, the United Nations (UN) is aiming to keep the global temperature rise to below 2°C above pre-industrial levels. Nationally determined contributions will lay out how each country aims to reduce emissions and adapt to the impacts of climate change.

The UK's current target is a reduction in greenhouse gas emissions of at least 80% by 2050, relative to 1990 levels.[2] As countries develop and publish their individual strategies, the impact of their commitments will become evident. It can be expected that changes will be needed to the way that most products are manufactured, distributed, used and recycled.

The contribution of our industry to environmental damage is also beginning to receive greater attention. Within the last couple of years, reports have emerged describing the global warming effects of pressurised metered dose inhalers (pMDIs). For example, it has been estimated that the propellants used within these devices contribute a staggering 4% of the total carbon footprint of the NHS in the UK.[3]

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Figure 1: Single-use plastics play a vital role in healthcare.

"Greener" alternatives are being developed, with at least two major players – AstraZeneca and Chiesi – recently announcing a commitment to develop pMDIs with near-zero global warming potential. This is one example of the steps our industry is taking, but further substantial actions will be needed and we must all start to plan for and develop more sustainable drug delivery systems.

A further concern that has recently received publicity is the dramatic increase in plastic waste entering and damaging marine environments. In response, the European Union (EU) has taken action to ban an array of single-use items, put in place new targets to encourage recycling of plastic products and mandated the use of more recycled polymers.[4]

Due to the vital role that single-use plastics perform in healthcare (Figure 1) and the difficulties in reusing many types of medical devices, this EU legislation does not apply to the medical industry. The performance and inherent safety of polymers, coupled with their cost effectiveness, makes them ideal for medical applications. This is unlikely to change in the short term but, in the context of increased legislation and efforts within other sectors, it seems almost certain that our reliance on single-use plastics in healthcare will start to come under greater scrutiny.

THE CIRCULAR ECONOMY

The environmental challenges we face are complex and multifaceted, meaning there is unlikely to be a simple "one-size-fits-all" solution. So what factors should we be thinking about and what opportunities might these bring?

At the heart of sustainable thinking is the concept of the circular economy (Figure 2). This idea involves the gradual decoupling of economic activity from consumption of finite resources and seeks to remove waste from systems. The aim is to build long-term resilience, generate new economic opportunities and provide environmental and societal benefits.

One important aspect of this model is the distinction drawn between biological and technical cycles. The ultimate aim is that consumption happens only within biological cycles, where biologically derived materials can be returned to the system through processes like composting. In contrast, technical cycles should aim to recover and restore products, components, materials and chemicals through strategies like reuse, repair or recycling.

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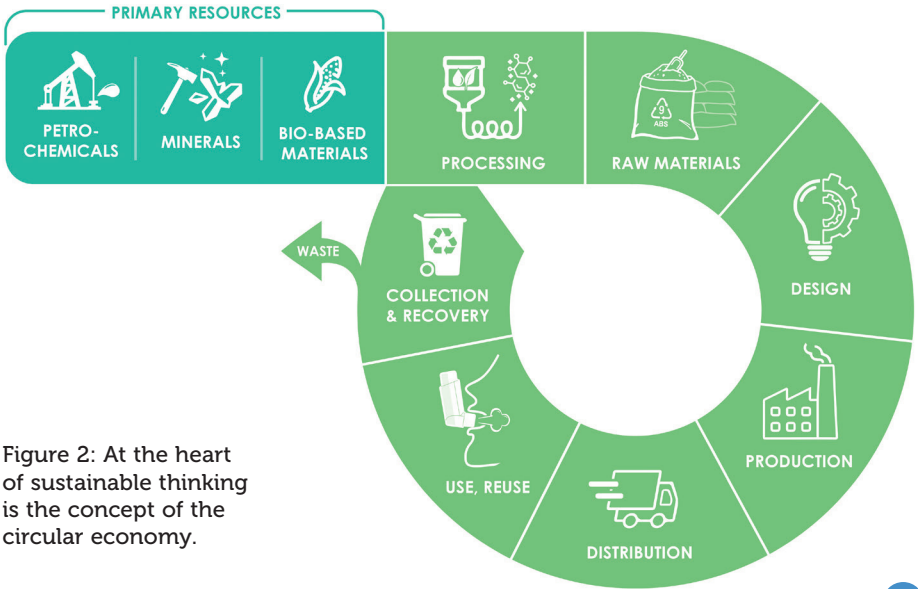

Figure 2: At the heart of sustainable thinking is the concept of the circular economy.

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MEASURING SUSTAINABILITY

When you set out to improve a system, it is essential to define the metrics by which the improvement will be assessed. Without doing so, it is impossible to know if or when progress has been made. The first step in defining sustainability targets is therefore to decide what to measure and how to compare performance. In the context of the circular model, three key parameters are important:

- The energy consumed in the manufacture, distribution and use of a product
- The amount of material that is derived from renewable or recycled content
- The amount of material that can be recovered for reuse at end of life.

In some instances, factors influencing the choices made in relation to these parameters may be conflicting, or they may conflict with other design requirements. It is therefore essential that we develop objective ways in which conflicts can be understood and resolved to achieve the best environmental profile for a product. This understanding is typically gained through lifecycle analysis (LCA), following methods defined within the ISO 14000 standards.

Owing to the huge array of factors involved in manufacture and distribution of products, LCAs are complex and time

consuming to compile. This makes them an impractical tool to inform design decisions in real time and, as a result, they are often used to analyse designs and production systems retrospectively.

To achieve the maximum value from an LCA, a detailed analysis of existing product solutions is best suited to inform the development of new ones. This identifies where the biggest opportunities for improvement exist, enabling effort to be directed where it will be most effective. This can sometimes be in unexpected places – for example, in the case of a device that requires cold-chain distribution, significantly more energy may be consumed in transporting and storing the product than manufacturing it. In this instance, improving the secondary packaging to increase packing density may be the most effective way to improve its environmental profile.

Whilst LCA remains the "gold standard" means for assessing the environmental impact of a product, the design industry needs other tools to help assess and inform design decisions rapidly during development. Such tools do not need to be fully comprehensive but they should allow engineers to make informed decisions about options that might have an impact on the environment.

Some promising early options, such as Eco-Indicator 99[5], have been developed, but to remain relevant and useful it is essential that these continue to be maintained and improved. Given the increasing focus on sustainable development, it seems inevitable that new tools will become available in the coming years.

DEVELOPING MORE SUSTAINABLE DEVICES

If we restrict our analysis to mechanical drug delivery devices, two issues that are commonly encountered in relation to sustainable development are materials selection and product lifetime. Neither of these issues are straightforward, since environmental design decisions are never taken in a vacuum. Instead, these factors must be weighed alongside many other requirements that safety-critical products such as drug delivery devices must achieve.

SUSTAINABLE MATERIALS

Most drug delivery devices are made predominantly from plastics, so careful selection of these materials is important when targeting more sustainable solutions. Following the principles of the circular economy, we can break this down into three aspects for consideration:

Renewable And Recycled Polymers

Devices are typically manufactured from "medical grade" polymers. These can be traced back to their raw material batches and come with guarantees that the formulation will not change. Recycled polymers are not currently available with medical grade certification and so the most sustainable alternatives in the medium term are likely to be biopolymers.

Derived from biological rather than petrochemical sources, a small range of biopolymers is starting to emerge. Unfortunately, in the short term, device developers are likely to be faced with a lack of choice for medical grade biopolymers. They also carry a price premium compared with conventional polymers, and some grades need to be separated from standard recycling streams.

Because of the relatively small size of the medical sector in comparison with the wider polymer market, it is unlikely that our industry will drive the development of new sustainable materials. Instead, we should seek to be fast followers of other industries, such as food packaging, that use greater quantities of polymer and for whom both regulators and customers are demanding rapid adoption of greener solutions.

End-of-Life Solutions That Enable Better Recovery And Recycling

Recycling the polymer materials contained in drug delivery devices is challenging, leading to problems in establishing the infrastructure to do so safely and effectively. Firstly, they usually contain some residual drug product (and may also be contaminated with biological materials). Secondly, because each component is optimised for its particular function, they typically contain a mix of polymer types as well as materials such as glass, aluminium and rubber. Thirdly, they are often designed to be inherently difficult to disassemble in order to deter tampering or counterfeiting.

As a result, it is difficult and expensive to reprocess devices by any means other than incineration for energy recovery. Chemical recycling, in which polymers are broken down into more basic chemicals that can be reprocessed to create new high-performance polymers, may be one option in the future, but is not yet a widely established technology. To improve the recyclability of drug delivery devices, many of these issues will need to be addressed at a design level, so must become a requirement at the outset of new development programmes.

Lower Embodied Energy

Not all polymers are created equal, having subtly different environmental profiles. Generally, more complex polymers require higher energy usage during their manufacture. For this reason, simple polyolefins, such as high-density polyethylene (HDPE) and polypropylene (PP), are usually considered more sustainable than alternatives such as acrylonitrile butadiene styrene (ABS), polycarbonate (PC) or polyoxymethylene (POM). Clever design and materials selection can optimise part count and the use of polymers, ensuring that more complex and highly refined materials are only used where they are absolutely necessary.

EXTENDING DEVICE LIFE

Given the challenges in sourcing more sustainable materials, extending product life may be the most effective path to improving the environmental profile of drug delivery devices in the near term (Figure 3). The longer a device can be used, the lower the environmental impact is likely to be in terms of material usage, waste and energy expenditure when assessed over a fixed period of therapy.

In this context, it is evident that reusable drug delivery devices are likely to have better environmental profiles than disposable ones. At the beginning of this article, I outlined that recent trends have been in the opposite direction, so what can be done to reverse this?

Reusable Devices That Are Easier, Safer And More Convenient To Use

A primary concern with reusable drug delivery devices has often been usability. Patient groups regularly contain large numbers of individuals with reduced manual dexterity or vision impairments. These patients can struggle to correctly replace a primary pack or reset the operating mechanism. To address this, we should continue to make reusable devices easier to use, for example ensuring that the mechanism resets automatically when the old primary pack is removed or when a new one is fitted.

Figure 3: Extending product life may be the most effective path to improving the environmental profile of drug delivery devices in the near term.

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Reusable Devices That Are More Appealing

In the past, there have often been no real advantages to selecting a reusable device over a disposable one. Indeed, as described above, there have been some legitimate concerns in relation to usability; yet this should not be the case. With reusable devices, cost is typically offset against a usable life of years rather than days or weeks, so there is an opportunity to specify better materials to achieve improved performance and to include more automated features.

One interesting development that may help to tip the balance in favour of reusable devices is the advent of connected drug delivery systems. For many applications, the cost of electronic monitoring and control functionality is currently seen as a barrier to embedding this technology within disposable devices – making reusable solutions much more attractive. Connected systems may also help to balance some of the usability downsides of reusable devices – for example, by providing warnings of potential use errors.

For some applications, it may remain impractical to offer fully reusable drug delivery devices. In these circumstances, an alternative solution may be to develop disposable products that have greater dose capacity, so that their use life is prolonged. This approach may, of course, bring challenges with drug stability and device affordability but it is a trend that is already well established in some consumer markets and we are likely to see further developments of this sort within drug delivery in the future.

CLOSING THOUGHTS

The environmental challenges we face are complex, but they also bring opportunities. By good design, there is no reason why more sustainable drug delivery devices cannot also be more cost effective and better for patients. But given the relatively long development cycles required for drug delivery devices, new environmental legislation may emerge that imposes targets that some businesses find difficult to achieve in the time frame demanded. We are currently witnessing this in the automotive industry, where companies that have proactively developed sustainable product ranges are now in a much stronger position than those that left it late.

In many ways, our industry is well equipped to deal with environmental challenges. We are systematic in our approach, data driven and highly analytical in our methods. Drug delivery devices are not subject to the whims of fashion; a device's performance and effectiveness must be comprehensively demonstrated before it enters the market, meaning that we tend not to embrace short-term thinking.

To effect change, we will all need to adopt a more sustainable mindset, in which we question the environmental impact of our decisions in the same way that we currently think about patient safety and therapeutic efficacy.

ABOUT THE COMPANY

Founded in 1960, DCA is one of the world's leading product design and development consultancies. Its multidisciplinary service offering includes systems engineering, mechanical engineering, industrial design, insight and strategy, UX/UI, human factors, electronics, software and prototyping.

With a range of global pharmaceutical, biotech and device companies amongst its long-standing clients, DCA has deep experience in the field of drug delivery devices. Work undertaken in this area includes design, development, analysis and industrialisation support for injection devices, inhalers, wearables, intra-nasal devices and applicators, including smart and connected devices. DCA has won many major industry awards and contributed to over 1,000 granted patents in the last 10 years. The company's development service is certified to ISO9001 and ISO13485.

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ABOUT THE AUTHOR

Rob Veasey leads projects within DCA's medical device sector. He has 30 years' experience in engineering, design and management roles with leading manufacturing and consultancy businesses and has worked exclusively on the development of drug delivery devices for over 20 years. His experience encompasses both mechanical and electromechanical devices, including work in the fields of injection, body-worn devices, metered dose and dry powder inhalers, intra-nasal sprays and topical applicators. A particular area of expertise is the development of pen injectors, in which Mr Veasey led DCA's team for the SoloStar®, Lyxumia®, AllStar® and AllStar® Pro device programmes with Sanofi.

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