OWEN MUMFORD
Pharmaceutical Services

SUSTAINABILITY IN DRUG DELIVERY – THE STATE OF PLAY IN 2023

Here, Isobel Filipova, Design Engineer – Sustainability Lead Product Development at Owen Mumford, explains where the healthcare industry stands on current environmental objectives, identifies obstacles to achieving sustainability in drug delivery and looks at how the sector can make progress to meet its objectives.

Once a relatively niche concern, sustainability and environmental protection is now a mainstream requirement in society – and in the medical device market. Traditionally, drug delivery devices have relied heavily on single-use plastics to ensure safe, effective administration to the user. However, given increasing pressure from regulators and consumers alike, medical device manufacturers are making environmental concerns a greater priority. There is an industry consensus that sustainability must be addressed – and urgently – to reach the ambitious objectives set by international standards, such as net zero by 2050 (Figure 1).

WHERE DO WE STAND TODAY?

It is widely accepted that the healthcare industry is a major polluter. According to a 2019 report, which remains the most recent study available, health systems produce 4%–5% of national greenhouse gas (GHG) emissions – meaning that if the healthcare industry was a country, it would be the fifth largest emitter of greenhouse gases in the world.[1] Although current literature on GHG emissions in the pharmaceutical industry is limited, studies published to date indicate a significant contribution to climate change.[2]

Figure 1: There is an industry consensus that sustainability must be addressed – and urgently – to reach the ambitious objectives set by international standards such as net zero by 2050.

Isobel Filipova
Design Engineer – Sustainability Lead Product Development
T: +44 0 1993 812021
E: pharmaservices@owenmumford.com

Owen Mumford
Brook Hill
Woodstock
Oxfordshire
OX20 1TU
United Kingdom

www.ompharmaservices.com

"The purchasing power of healthcare systems is being used to encourage suppliers to consider environmental impacts more carefully."

Until now, the healthcare industry has been somewhat sheltered from scrutiny surrounding its sustainability practices, with current European legislation on sustainable manufacturing practices, end-of-life management and packaging often containing exemptions for medical devices, and strict regulatory requirements demanding single use for many invasive medical devices. However, several directives, including the Waste Electrical and Electronic Equipment (WEEE) and Restriction on Hazardous Substances (RoHS) directives, are in the process of being reviewed and could be applicable in future. One area in which progress is essential is packaging; under the revised Packaging and Packaging Waste Directive, all packaging placed on the EU market will need to be "reusable or recyclable in an economically feasible way" by 2030, with minimal exceptions for the healthcare industry.[3]

With the increasingly strict regulatory requirements surrounding environmental reporting, and the regular inclusion of environmental credentials in medical device tenders, companies who do not act now risk losing access to markets around the world.[4] There is already evidence that the purchasing power of healthcare systems is being used to encourage suppliers to consider environmental impacts more carefully. For example, in the US, group purchasing organisations are appointing Senior Directors of Environmentally Preferred Sourcing and, in the UK, the NHS's "*Delivering a 'Net Zero' National Health Service*" report sets out sustainability targets and the interventions required to achieve them, including steps to decarbonise the supply chain by no longer working with suppliers who do not meet its net zero commitments by the end of the decade.[5]

While international treaties, legislation and corporate social responsibilities to investors and wider society have led companies in all sectors to set sustainability targets, measure climate change impacts and report GHG emissions, a high level of fragmentation remains in how this is done in the medical device and pharmaceutical industry. Multiple methodologies, impact measures and data sets are used, and national regulations for both practices and reporting vary. Additionally, even where companies apply the same methodologies, there are inconsistencies in reporting, particularly regarding Scope 3 reporting,[2] resulting in a lack of comparable data across the industry.

WHAT SHOULD WE BE MEASURING AND HOW?

To appreciate the full environmental impact of drug delivery devices, it is vital that sustainability is not reduced to product manufacturing or disposal alone. The corporate footprint as a whole, including Scopes 1, 2 and 3, must be taken into account.

When examining the products themselves, lifecycle assessment offers a holistic methodology for fully understanding environmental impact at every stage and allowing immediate changes to be made to products already on the market, rather than starting from scratch and creating entirely new products. While ISO standards 14040[6] and 14044[7] provide a framework and guidelines for lifecycle assessment, they do not specify the methodologies or impact measures to be used, contributing to the fragmentation and differences in reporting across the industry. This, in turn, limits the ability to effectively compare products in terms of their environmental impact.

Consequently, it is vital that industry-wide standards and best practices are established if ambitious targets are to be met. This will require medical device manufacturers to collaborate and pool knowledge and resources if true progress is to be made.

WHAT IS HOLDING US BACK?

Safety Concerns

While sustainability in the healthcare system is an important objective that must not be neglected, the safety of patients and users remains the critical priority. The risks associated with hazardous medical waste and biological contamination, in addition to cost considerations associated with sterilisation and reprocessing, have meant that manufacturers have been hesitant to move away from their usual practices. In addition, the reprocessing and reuse of single-use devices is discouraged in both Europe and the UK[8] – unlike in the US, where reprocessing has been more widely accepted since the 1970s[9] – and the US FDA is currently working to advance the science of reprocessing.[10] Moving forward, it is likely that invasive devices will continue to require some disposable components to meet regulatory requirements surrounding safety and hygiene.

Packaging is another area where safety concerns can obstruct sustainability efforts. Medical device packaging must play several roles – protecting the contents of the packaging, protecting people (including children) and preventing counterfeiting. This often requires a combination of materials, complicating waste management.

Legislative Barriers

Strict regulatory requirements, driven by legitimate safety concerns surrounding medical waste, limit the reprocessing and reuse of medical devices to limit healthcare-associated infections. Under the European Medical Device Regulation, recycled devices are subject to the same level of scrutiny as new devices, with full responsibility for the device being placed on the reprocessor.[11] The complexity of compliance with these rules may discourage manufacturers from taking this approach.

Differing national legislation on separating hospital waste, and even differing definitions of hospital waste itself, further contribute to the complexity of the issue. The use of disposable personal protective equipment during the covid-19 crisis highlighted issues with healthcare waste management, with data from 2019 (the latest available) indicating that 30% of healthcare facilities are unequipped to handle the amount of waste they produce, even outside of the pandemic.[12] As a result, most hospital waste ends up in mixed waste due to lack of user training and risk aversion, and thus loses its value.[13] Even where materials are properly sorted and recycled, the inclusion of recycled materials in medical and pharmaceutical packaging is particularly difficult, as packaging legislation currently does not take into account advanced recycling techniques.

Although current legislation presents a range of obstacles to implementing greener solutions, widespread acceptance of the need to prioritise sustainability means shifts are likely in the near future, particularly as we move towards the deadlines set out in the European Green Deal.[14]

Commercial Viability

Affordability and cost are major concerns for manufacturers, particularly in today's financial climate. Given the high proportion of many manufacturers' revenues that come from disposable, single-use devices, which are responsible for 1.4% of supply chain emissions in the NHS alone,[15] it is essential that any steps towards sustainability are commercially viable. The cost of certain processes, such as sterilisation, is a factor that may be discouraging their wider adoption.

Commercial concerns, in particular the competitive mindset, also foster a secretive climate where many manufacturers are hesitant to collaborate with competitors and share their solutions. This contributes to the multiplication of approaches and measures, reduces efficiency and impedes far-reaching industry-wide change.

WHERE CAN WE MAKE IMPROVEMENTS?

Sustainability by Design

Device design already takes into account a number of factors around the whole lifecycle of a product, from development and material selection to scalability and end-of-life disposal. However, the current focus on user-centricity and profitability must be extended to include environmental and social impacts at an early stage.

Device design considerations are essential. Many small steps are already being taken at every stage of the product lifecycle to streamline the use of resources, optimise manufacturing processes and reduce waste. Even where products must retain a disposable element for safety and hygiene reasons, there are myriad opportunities for improvement, including assessing the impact of raw products to select the most environmentally friendly materials, optimising device size and decreasing packaging volume. Producing a minimum disposable unit within a reliably reusable "shell" is also a realistic ambition.

Manufacturing processes also present opportunities for reducing environmental impact. From optimising logistics to reducing water use and increasing energy efficiency, greener initiatives not only offer a sustainability benefit but also reduce operating costs. Additionally, new technologies play a role in reducing waste, through streamlined manufacturing processes.

Behavioural Change

To meet ambitious sustainability targets, both within and beyond the industry, systemic change is necessary, which must consider not only how the product is manufactured, but also the whole system. New business models must focus on circularity instead of the current linear approach, for example, reducing the number of materials used per product to facilitate recycling, thus enabling waste management companies to provide a high-quality supply of recycled products for use in subsequent manufacturing.

User information is crucial to prevent undermining efforts to produce more reusable or recyclable materials. Healthcare facilities alone generate an estimated one million tonnes of clean, non-infectious healthcare plastic waste per year.[16] Providing healthcare professionals with training on how to properly sort and dispose of this waste would considerably increase the amount available for reprocessing and reuse. UK legislation requiring hospitals to become more sustainable may encourage NHS trusts to provide such training.

Finally, cross-industry collaboration must be encouraged to drive standardisation and allow the whole industry to benefit from procedural and technological advances. It is vital that manufacturers work with regulatory bodies to review and revise current legislation, creating an environment in which the necessary changes can be made, allowing for greater sustainability while maintaining the highest standards of safety and hygiene.

"User information is crucial to prevent undermining efforts to produce more reusable or recyclable materials."

CONCLUSION

Despite the challenges that adopting sustainable practices will present for the device industry, many stakeholders have begun to realise that greener practices contribute to revenue growth and improved customer relationships,[17] providing a strong business case for environmental progress.

This recognition means that innovation will play an important role in the endeavour to meet ambitious sustainability targets, but a holistic approach to product design – based on industry-defined lifecycle assessment methodologies and cross-industry collaboration – will be the essential components in achieving far-reaching progress.

ABOUT THE COMPANY

Owen Mumford is a medical device manufacturer with a global presence across the UK, Europe, the US and Asia, pioneering the advancement of medical technology for 70 years. The company manufactures its own brand of medical products and is a trusted partner to many of the world's largest pharmaceutical and diagnostic companies. Its leading medication administration, blood-sampling and testing solutions are designed and manufactured for the comfort, safety and dignity of patients, healthcare professionals and caregivers as a priority. Driven by its purpose to do business in the right way, Owen Mumford is one of the first medical device companies in the world to achieve B Corp certification and has set science-based targets to achieve net zero by 2045, as part of its long-established and continually evolving sustainability agenda.

REFERENCES

1. *"Healthcare's Climate Footprint". ARUP, Sep 2019.*
2. *Booth A et al, "Pharmaceutical Company Targets and Strategies to Address Climate Change: Content Analysis of Public Reports from 20 Pharmaceutical Companies". Int J Environ Res Public Health, 2023, Vol 20(4), p 3206.*
3. *"Revision of the Packaging and Packaging Waste Directive". ThinkTank, European Parliament, Mar 2023.*
4. *"Sustaining the Pace". Company Web Page, Owen Mumford, accessed Sep 2023.*
5. *"Delivering a 'Net Zero' National Health Service". UK NHS, Oct 2022.*
6. *"ISO 14040:2006 Environmental management – Life cycle assessment – Principles and framework". International Organization for Standardization, 2022.*

7. *"ISO 14044:2006 Environmental management – Life cycle assessment – Requirements and guidelines." International Organization for Standardization, 2022.*
8. *Guidance for Industry "Single-use medical devices: implications and consequences of re-use". Medicine and Healthcare Products Regulatory Agency, Jan 2021.*
9. *"Reuse of Single-Use Medical Devices". Centers for Disease Control and Prevention, Sep 18, 2016.*
10. *"Working Together to Improve Reusable Medical Device Reprocessing". US FDA, Apr 5, 2022.*
11. *"Industry Criticizes EC's Specifications for Reprocessing Single-use Devices under EU MDR". Regulatory Affairs Professionals Society (RAPS), Aug 21, 2019.*
12. *"Global analysis of health care waste in the context of COVID-19". World Health Organization, Feb 1, 2022.*
13. *Singh N, Ogunseitan O, Yuanyuan T, "Medical waste: Current challenges and future opportunities for sustainable management". Crit Rev Environ Sci Technol, 2021, Vol 52(1).*
14. *"A European Green Deal". European Commission, accessed Sep 2023.*
15. *"Delivering a 'Net Zero' National Health Service". UK NHS, Oct 1, 2020.*
16. *"Why Recyclers Should Consider Healthcare Plastics as a Valuable Feedstock". HPRC, Jan 23, 2019.*
17. *"Rethink: why sustainable product design is the need of the hour." Capgemini Research Institute, accessed Sep 2023.*

ABOUT THE AUTHOR

Isobel Filipova holds the role of Design Engineer – Sustainability Lead Product Development at Owen Mumford, bringing expansive knowledge on corporate social responsibility and on implementing sustainable practices for businesses. Ms Filipova is responsible for establishing and maintaining the sustainability strategy across Owen Mumford's research and development division. Since joining the company in early 2021, Ms Filipova has accelerated Owen Mumford's sustainable product design approach by using a holistic approach incorporating systemic research, rationalised concept development and a clear understanding of user experience and needs to present innovations that meet customer needs and enable a circular economy. Ms Filipova believes in a holistic approach to sustainability that reviews the entire ecosystem to identify opportunities for positive change, reduced environmental impact and truly innovative solutions.

Aidaptus®

2-step single-use auto-injector platform

Versatile design
intuitive delivery

reddot winner 2023

Your fill volume may change, with Aidaptus® **auto-adjust plunger technology** your auto-injector doesn't need to

Now in production

Accommodates both 1mL and 2.25mL glass syringes in the same device

See our auto-adjust plunger technology in action

Find out more by scanning the QR code or visiting **ompharmaservices.com/odd-nov2023**

In collaboration with Stevanato Group

*In addition to an air bubble and overfill

OMPS/odd/ad/ob/1123/7

Owen Mumford
Pharmaceutical Services