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PRACTICAL PATHWAYS TO SUSTAINABILITY

In this article, Alex Fong, Head of Insight, and Olivia Houselander, Business Development Manager, both at Owen Mumford, discuss the importance of sustainability in the healthcare sector and the challenges that must be overcome to achieve it in a meaningful and lasting way.

There is wide consensus around the importance of transitioning to a more sustainable future – both in the healthcare industry at large and in the pharmaceutical sector that serves it.[1] This extends, naturally, to examining the environmental impact of single-use devices for delivering drugs to the patient.

However, the journey towards a greener, more sustainable future must be structured by each healthcare institution in a way that does not reduce the efficacy of treatments for patients and does not heap unaffordable costs on healthcare organisations, which are already under enormous financial pressure.

THERE'S PLASTIC AND THEN THERE'S PLASTIC

When it comes to reducing the use of plastics, context and prioritisation are helpful starting points. The first step for most healthcare institutions is to classify medical plastics into a series of categories according to their ability to be substituted without loss of utility, sterility or safety. A glance at most studies on the issue of replacing medical plastics with more environmentally friendly alternatives shows that the greatest opportunities lie in packaging, disposable masks, gloves and coverings, wound care and so on.

One study found that most medical plastic waste (70%) is made up of commodity plastics, used to make tubing, films, packaging, connectors, labware, intravenous bags, catheters, face masks, housings, luers, membranes, sutures, etc.[2] Syringes, in contrast, form just one part of the remaining 30%. Therefore, it would seem logical to first address commodity plastic alternatives to achieve near-term environmental goals, rather than prioritise parenteral drug delivery where drug stability, anti-contamination and infection control are paramount. As the standard UK NHS advice on infection control notes, "Needles and syringes are single-use devices, they should never be used more than once or reused to draw up additional medication."[3]

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Of course, the idea of a general substitute material for the petroleum-derived plastics used in most drug delivery devices is very attractive, and significant effort is being put into research and development in this area. Materials are coming down the line and, in time, production in the industry will substitute with either recycled materials or bio-based plastics. However, at this precise moment, healthcare systems around the world need a stock of delivery devices and prefilled syringes to manage clinical demand. Practical management of this situation requires a transition plan that recognises the reality – it will take the industry quite some years to move to sustainable alternatives and deliver them at scale. Suppliers and buyers will be best served by establishing a collaborative approach that manages this transition to produce the best clinical and patient-welfare outcomes.

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The sector has also carefully considered biodegradable options. This subject is considered to have an inherent flaw, in that biodegradability is sometimes in contrast with stability issues around drug integrity when considering prefillable pharmaceutical products. Therefore, current thinking is now focusing more on *reusable* drug delivery products that are also easily *remanufactured* and where their disposable element can be easily *recycled*.

In the meantime, healthcare organisations must face the challenge of planning a path to greater sustainability while also maintaining focus on the paramount interests of patients. Inevitably, this will mean purchasing plastic, single-use drug delivery products for the immediate future. However, these can be examined to minimise the carbon footprint of the products being bought, and collaborative forward planning with the supply-side can set achievable milestones for sustainability across a period of years.

SUSTAINABILITY BY DESIGN

The Owen Mumford Pharmaceutical Services team has designed Aidaptus, a true platform autoinjector with a wide design envelope, to be compatible with a range of formulations, fill volumes, needle sizes and primary containers, thereby providing pharma companies with flexibility. As there are often changes to formulation and dosage during the development of injectable drug products, as well as throughout their lifecycle, this flexibility is invaluable (Figure 1).

Specifically, it reduces the work and risk associated with changes in formulation, such as additional verification testing, human factors studies and regulatory documentation. It also contributes to sustainability by offering a single platform for multiple applications, reducing environmental impact at the manufacturing level.

It is possible to introduce environmental improvements through "sustainability by design" approach. In so doing, a number of specific sustainability considerations can be built into product design and engineering. For example:

- Ease of disassembly can have a major impact on recycling costs and methods
- Device size optimisation, device simplification and packaging reduction can reduce waste and transport impact
- Harmonising raw materials and production methods between different products can save on cost and waste, while also opening the possibility of greater agility for production tasks between production lines.

For disposable products, a reduction in the amount of single-use plastic associated with each treatment (while maintaining safe and effective usability) can be achieved with careful consideration at the design stage. Similarly, removing metal components has a major impact as the processing and shipping of metals has a far higher carbon impact than those of polymers.

Many of the key principles of sustainable product design begin with understanding and developing a product lifecycle, not just a product – considering concept development, material selection, design and engineering, manufacturing, packaging, transportation, sales, use and end-of-life disposal – right from the start. This approach is already deployed for manufacturing efficiency, time to market, risk reduction, safety and regulatory compliance, and packaging and transportation costs. It is simply a case of extending existing disciplines to also

Figure 1: Owen Mumford Pharmaceutical Services designed Aidaptus, with a wide design envelope, to be compatible with a range of formulations, fill volumes, needle sizes and primary containers.

evaluate energy efficiency, environmental impact, material usage and recycling. In some aspects, existing US FDA and EMA quality system requirements touch on these environmental considerations – particularly around tracking, materials safety, efficacy and disposal. Similarly, lean manufacturing methodologies seek to reduce inefficiency in several key related areas, such as overproduction, waiting time, transportation, processing, inventory, motion and scrap.

THE CHALLENGES OF REUSABILITY AND INTERCHANGEABILITY

The current reality is that most devices – especially parenteral or other invasive products – will have to retain a disposable element to meet regulatory safety and hygiene requirements. When it comes to autoinjectors, currently, the most compelling solution is to design a minimum disposable unit within a reliably reusable "shell".

In some therapies, such as diabetes, devices have become more digitally connected, delivering remarkable therapeutic and cost benefits for remote patient management and safe self-administration. However, from a sustainability point of view, the costs of disposable electronics would simply not be viable, and – as previously noted – would not be acceptable in the light of electronics disposal regulations. All the design science must then be focused on creating a simple, repeatable interface between the two component sections, ensuring that functionality and efficacy are not impaired.

Nevertheless, such reusable devices may hit another hurdle in the drive to more sustainable drug delivery – namely, biosimilar interchangeability.

Cost is not the only consideration when switching from biologics to biosimilars; the patient experience may also be affected by any change in drug formulation or the drug delivery device provided. As one study notes, "There is scarce information on the patient's attitude toward such switching, especially studies comparing the injection devices."[4] To safely identify the most suitable device for their biosimilar product, pharmaceutical companies should have access to data from human factors testing and other sources that attests to a device's ease of use. This data would then also support regulatory applications for interchangeability status.

However, if the interchangeability path is to be considered, it may be more straightforward to opt for disposable devices; introducing a substantially different reusable or remanufacturable device is less likely to ease the switch. This may then have the effect of perpetuating the existence of less sustainable devices. The alternative is to introduce delivery devices that prioritise sustainability but that may be less acceptable to the patient from a usability point of view. The choice between sustainability and competitiveness (for pharma companies) or adoption likelihood (for regulators and clinicians) is a dilemma indeed.

When it comes to the device component, the FDA stipulates that any regulatory application should provide evidence that the impact of switching between delivery devices has been assessed, stating, "Data and information supporting the appropriate use and performance testing of the delivery device constituent part of the proposed interchangeable product should be submitted."[5]

CONCLUSION

In conclusion, there is no question that the general momentum in the industry is towards more sustainable drug delivery products. However, healthcare organisations must deliver the best possible patient services today, with the tools currently that they have available and under current regulatory regimes. Similarly, pharma companies must remain competitive in fierce markets. While patient wellbeing remains paramount, current regulatory and market forces may govern the actual pace of change to more sustainable materials and products being deployed.

Therefore, practical judgements have to be made about the drug delivery devices deployed in the near term, with a more strategic "journey" towards adopting more sustainable alternatives as they arrive on the market and gain regulatory approval. As is so often the case, collaboration between buyer and supplier is likely to achieve the best and most practically effective pathways to a more sustainable future.

ABOUT THE COMPANY

Owen Mumford is a major healthcare company and device manufacturer that commercialises pioneering medical products in its own brand and custom device solutions for the world's major pharmaceutical and diagnostic companies. Owen Mumford's goal is to enhance access to diagnostics, encourage adherence to treatment and reduce healthcare costs, making a world of difference to a world of people.

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ABOUT THE AUTHORS

Alex Fong, MBA, Head of Insight at Owen Mumford, is an experienced senior manager in the insight, analytics and strategy fields. He has applied these skills in a broad range of Industries including the FMCG/CPG, retail, telecoms and management consulting sectors.

Olivia Houselander, Business Development Manager at Owen Mumford Pharmaceutical Services, joined Owen Mumford as a Product Manager in 2008 and currently serves as an accomplished Business Development Manager in the Pharmaceutical Services division. In this role, she applies her extensive experience in medical devices, marketing strategy, and product launch and development to support continued business growth and create innovative product launches, making her an asset in the dynamic healthcare landscape.

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