CONNECTED DRUG DELIVERY: ACHIEVING OPTIMAL BENEFITS THROUGH SMART COLLABORATION

In this article, George I'ons, Head of Product Strategy and Insights at Owen Mumford Pharmaceutical Services, discusses the challenges developing connected devices presents to key market stakeholders when it comes to successful rollout and implementation. Additionally, he considers the perspectives of these market players, as well as the patients themselves, with respect to how connected drug delivery devices can help them to better achieve their desired outcomes.

The covid-19 pandemic has driven the healthcare industry to make greater use of remote consultations and digital tools, but it is likely that this trend will continue even when cases abate. In fact, a recent poll found that the vast majority of general practice doctors in the UK intend to keep some or all of the new technology they have introduced after the pandemic (Figure 1).[1]

Accompanying this trend towards remote care is a growing market for digitally connected drug delivery devices. Analysis using both proprietary data and published market analyses (such as those from GrandView Research, Acumen Research and Future Market Insights) estimates that the global market for connected drug delivery devices (injection and inhalation) will grow at a compound annual growth rate (CAGR) of over 25%, reaching a total value of US$706 million (£529 million) by 2025.

"In a recent survey of pharmaceutical executives, gaining regulatory clearance was identified as a primary challenge in the development of smart drug delivery devices. The presence of electronic components in a device already makes it subject to additional regulatory requirements, such as compliance with the EU's WEEE."

THE COMPLEX DEVELOPMENT JOURNEY

In a recent survey of pharmaceutical executives, gaining regulatory clearance was identified as a primary challenge in the development of smart drug delivery devices.[2]

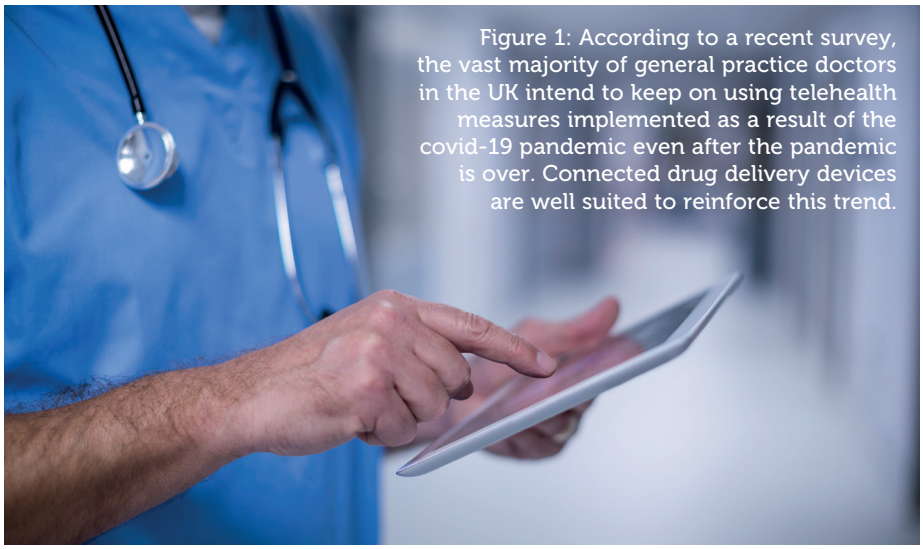


Figure 1: According to a recent survey, the vast majority of general practice doctors in the UK intend to keep on using telehealth measures implemented as a result of the covid-19 pandemic even after the pandemic is over. Connected drug delivery devices are well suited to reinforce this trend.

George I'ons
Head of Product Strategy and Insights
T: +44 1993 812021
E: pharmaservices@owenmumford.com

Owen Mumford
Brook Hill
Woodstock
Oxfordshire
OX20 1TU
United Kingdom

www.owenmumford.com

"For instance, the US FDA intends to apply its regulatory authority to software applications intended for use on mobile platforms (mobile applications or "mobile apps")."

The presence of electronic components in a device already makes it subject to additional regulatory requirements, such as compliance with the EU's WEEE (the Waste Electrical and Electronic Equipment Regulation). As the digital health industry continues to develop at a rapid pace, it is likely that regulators will increase their oversight accordingly to ensure that patient safety is not put at risk. For instance, the US FDA intends to apply its regulatory authority to software applications intended for use on mobile platforms (mobile applications or "mobile apps"). The organisation's recent guidance specifies that, if a mobile app meets the definition of a medical device, it may be referred to as a "mobile medical app" and therefore would be subject to FDA oversight.[3]

A further obstacle to gaining approval is that regulatory authorities need robust evidence of the value of the data that's gathered by connected devices, and the impact on healthcare outcomes; however, a strong body of hard evidence can only be sourced by testing devices in the field on a wide scale. Recognising the need for a more updated approach, the FDA launched the Digital Health Center of Excellence (DHCE) in September 2020. The DHCE is focused on "helping both internal and external stakeholders achieve their goals of getting high quality digital health technologies to patients by providing technological advice, co-ordinating and supporting work being done across the FDA, advancing best practices, and reimagining digital health device oversight".[4] Given that the regulatory processes for digital health are both complex and still evolving, investing in specialist knowledge and support – whether to write a regulatory submission, pre-emptively identify concerns or carry out human factors testing – may prove invaluable in getting a new connected device to market.

Regulators will also be closely scrutinising data protection measures, since connected devices raise a host of concerns around patient confidentiality. Medical device manufacturers with products on the US market must note that they "are responsible for remaining vigilant about identifying risks and hazards associated with their medical devices, including risks related to cybersecurity". The FDA further states that healthcare delivery organisations (HDOs) should evaluate their network security and protect their hospital systems.[5] For their part, pharmaceutical companies must clarify how data will be stored and who is responsible for it, as well as who owns the data generated by connected devices in their portfolio. They will also need to work with other stakeholders, including medical device manufacturers, governments and healthcare providers, to standardise data transfer protocols; implementing the use of connected devices will be doubly difficult without interoperability across standard clinical systems. It is important that a range of devices can be used seamlessly by different healthcare providers to realise their maximum potential.

Addressing these factors across the varied array of disposable drug delivery devices already comes at a significant cost, so may not be financially viable for single-use products. Moreover, such a solution would be detrimental to the environment. Though the cost of embedded electronics is decreasing over time, they use rare-earth metals, of which as little as 1% are recycled.[6] One solution is to take a hybrid approach to designing devices that tend to be single use. This means designing the device with two components:

- A reusable, connected "shell" device that includes the embedded electronics
- A traditional autoinjector or prefilled syringe that sits within the shell and can be disposed of and replaced.

Looking at the overall environmental impact of patient care and therapy, connected devices can reduce this impact if implemented effectively. Improved patient adherence may reduce the need for visits to healthcare centres or on-site procedures, and therefore also reduce the use of energy, pharmaceutical products and equipment required for treatment. In fact, one study found that overall greenhouse gas (GHG) emissions were reduced by around 50% when a patient with poorly managed paediatric asthma improved their adherence by using a smart inhaler.[7] The most significant environmental effects of switching to a smart inhaler were reduced reliever use and reduced hospital admissions.

"Though the cost of embedded electronics is decreasing over time, they use rare-earth metals, of which as little as 1% are recycled."

STAKEHOLDER PERSPECTIVES AND OBJECTIVES

The aforementioned factors make it clear that the actors involved in developing and implementing connected devices cannot work in silos, which makes it difficult to overcome challenges and find solutions. It is in the interests of each stakeholder to take the initiative, as improved patient adherence can help each to achieve their respective aims. This article focuses specifically on the attitudes to digitisation of payers, clinicians, pharmaceutical companies and patients.

Payers are increasingly focusing on reducing overall costs by helping to create healthier societies and reduce the consumption of healthcare services. Allowing for greater patient involvement in treatment and enabling teleconsultations leads to wider benefits for the healthcare system as a whole. For example, in the US, the Centers for Medicare & Medicaid Services (CMS) found that their telehealth chronic care management programme improved patient satisfaction and adherence to recommended therapies, improved clinician efficiency and decreased hospitalisations and emergency department visits.[8] These cost-saving benefits can be further enhanced by using connected device technologies.

Connected devices equip clinicians and healthcare professionals with data they would not otherwise have in a timely manner, meaning that they can provide more informed advice, take quicker action when needed and adjust treatments to specific patient needs. Currently, embedded electronics and sensors within connected devices allow clinicians to see when a patient has administered medication, the volume of the dose and the site of administration. In future, it is likely that monitoring and reporting capabilities will become more

Figure 2: Connected drug delivery devices provide clinicians with readily accessible, timely patient data. If used as part of patient support, this can increase effective drug efficacy and lead to significantly improved treatment outcomes.

sophisticated. One example is a closed-loop system for blood glucose monitoring, which not only monitors blood sugar levels but also regulates insulin delivery accordingly to maintain target levels. In the more distant future, it may be possible for clinicians to interact with connected devices, remotely adjusting dosage according to incoming patient data.

Therefore, combined with support from clinicians, treatment data can strengthen drug efficacy (Figure 2). For pharmaceutical companies, this data can help to build a concrete case regarding the benefits of their products, which is becoming increasingly necessary as healthcare providers and payers are more stringently assessing drug performance. Additionally, as pharmaceutical and medical device companies increasingly provide additional support services, such as patient training and education programmes, adherence information generated by connected devices would help to make such services more effective. Greater insight and engagement would allow companies to actively contribute to improving adherence, and thereby reduce waste of costly medications.

Patients themselves may not be particularly concerned with any connected capabilities in their drug delivery device. The factors most important to patients, according to an injection-focused qualitative human factors study with a 120-strong focus group, are comfort and ease of use. If these elements are not thoroughly considered throughout the design process, it will be a challenge to encourage adoption of the final connected device. Since patients may already struggle to remember to administer medication, or with the administration procedure itself, new products should ideally avoid introducing new challenges or complexities. Similarly, if a device is perceived to be complicated to use, it may lead to resistance from clinicians or carers.

Digital features, such as downloading and using mobile apps, can be confusing for some patient groups, so this will need to be considered during testing. The novel access to patient treatment data may also be overwhelming or distressing for some, especially if they receive frequent notifications. Training and support programmes may help to address some of these concerns and demonstrate the benefits of introducing digitisation in drug delivery.

CONCLUSION

There is still much room for development and innovation in the area of connected drug delivery devices, and there are significant gains to be made. Empowering patients to take a more informed and active role in their own treatment can improve outcomes for both patients themselves and the wider healthcare system. As remote healthcare becomes more prominent, smart devices will play a pivotal role in optimising treatment, sharing data and providing communication. Intelligent partnerships are critical to the future of the connected drug delivery market, whether to strengthen data protection measures, assess environmental impact or facilitate device use.

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.

REFERENCES

1. *Haynes L, "Should remote consultations be the default after covid-19?". GPOnline, Aug 2020.*
2. *"Injectable Combination Products: Industry Insights on The Challenges of Meeting a Growing Global Need". Pharma Intelligence, Aug 2020.*
3. *"Guidance for Industry and Food and Drug Administration Staff: Policy for Device Software Functions and Mobile Medical Applications". US FDA, Sept 2019.*
4. *"FDA Launches the Digital Health Center of Excellence". Press Release, US FDA, Sept 2020.*
5. *"Cybersecurity". Web Page, US FDA, Dec 2020.*
6. *Norman G, "Smart devices score poor marks on recycling". Deutsche Welle, Nov 2019.*
7. *"Digital Adherence Monitoring in Poorly Controlled Paediatric Asthma: Care Pathway Case Study". Sustainable Healthcare Coalition, 2017.*
8. *Schurrer J et al, "Evaluation of the Diffusion and Impact of the Chronic Care Management (CCM) Services: Final Report". Mathematica, 2017.*

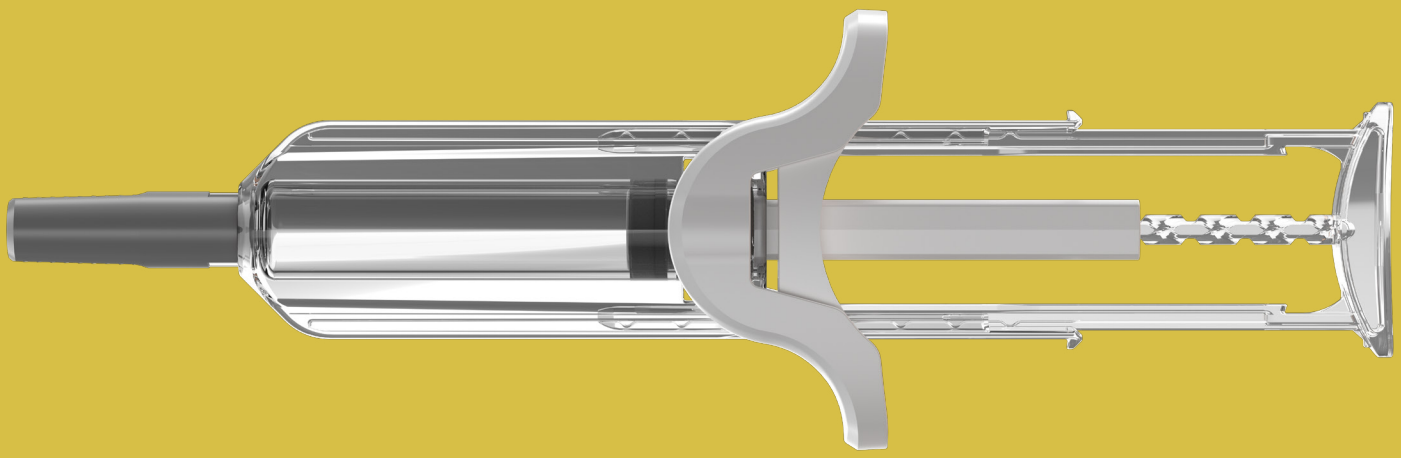
ABOUT THE AUTHOR

George I'ons is currently Head of Product Strategy and Insights at Owen Mumford, having worked for the former Original Equipment Manufacturer and now Pharmaceutical Services division of the organisation since 2006. His current focus is on deciphering the rapidly changing pharmaceutical and biotech sectors in relation to their needs for combination products. In his previous roles in business development, he worked closely alongside R&D to develop devices for a variety of global pharmaceutical and diagnostic clients. Prior to Owen Mumford, Mr I'ons worked for Abbott (Berkshire, UK) in Europe, the Middle East and Africa marketing roles in Germany, focusing on its diabetes business.

UniSafe® 2.25

Spring-free Simplicity

for higher volume formulations



Now a reality.

A springless, passive safety device for 2.25mL pre-filled syringes, designed for simple assembly and use.

Available now

Also available in 1mL

Scan the QR code to find out more or visit **ompharmaservices.com/unisafe-2-25/**

Owen Mumford
Pharmaceutical Services

OMPS/od/ad/ob/1120/7