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AREAS TO WATCH IN CONNECTED DRUG DELIVERY DEVICE DEVELOPMENT

In this article, Michael Earl, Director, Pharmaceutical Services, at Owen Mumford, identifies areas of development in the field of connected drug delivery devices, providing an insight into what can be expected in the coming years. He draws on Owen Mumford's own research, as well as discussions with industry experts and counterparts.

The market for parenteral drug device combination products has evolved rapidly over the last 15-20 years. In particular, there is a growing focus on connected devices that enable capture of a variety of data relating to drug administration. These devices are already enabling remote patient monitoring, producing many benefits for the healthcare ecosystem, such as promoting treatment adherence. However, there remains a whole host of potential benefits that are not yet available, but that are likely to emerge as the industry continues to innovate.

FLEXIBLE, MODULAR PLATFORMS

With connected drug delivery devices evolving rapidly, there are now multiple configurations to choose from. The debate tends to revolve around single-use versus reusable devices, and integrated versus add-on connectivity. Although reusable drug delivery products are more desirable in terms of cost and environmental impact, decisions between single-use and reusable autoinjectors, for example, depend on the therapy regimen, target market and specific patient needs.

Regarding connectivity features, opinions on the optimal choice are continually changing with enhancements in wireless technology and the performance of electronic components. Likewise, as regulations evolve, the commercial arguments and trade-offs for pharmaceutical companies may shift, meaning they need to keep their options open. Geographical differences on the route to market, regulatory approvals and environmental standards should be factored in, as commercialisation strategies suitable for one area may not work in another.

As a result, pharmaceutical companies are looking for flexible drug device platforms that can be adapted to different markets, therapies, drug formulations and/or patient groups. Platform devices that have the option of added connectivity allow relevant stakeholders to make a choice flexibly based on preference, cost and reimbursement considerations whilst maintaining the essential device functionality. Adding connectivity to existing combination products is another option, where possible, and can extend product lifecycle and potentially patent life.

THE ISSUE OF INTEROPERABILITY

Currently, healthcare systems are lacking adequate data integration and interoperability – the ability of different information systems, devices and applications to connect and share data

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in a co-ordinated manner.[1] Data captured from connected devices are often siloed and not combined with other data sources, such as electronic patient health records. This makes it difficult for healthcare stakeholders to make decisions based on available data and access it in real time. As the focus on remote patient monitoring grows, tackling interoperability challenges becomes increasingly important.

New standards are needed to streamline communication protocols. One challenge is that healthcare systems themselves, and the way in which they approach data integration, vary significantly across the globe. In Europe, for instance, data is highly fragmented, with different privacy laws at national and regional levels, creating challenges for pharmaceutical companies wanting to launch connected products into multiple markets.

Limited data access and interoperability is also hindering healthcare providers' aspirations to create new services and business models based on data generated from connected devices. One example is the US, where payers are placing increasing emphasis on adherence monitoring to deliver improved patient outcomes and strengthen population heath.

A NEW PLACE FOR CONSUMER DEVICES

Meanwhile, there is a wealth of new data being captured by smart consumer devices, which could have interesting implications for drug delivery – and healthcare as a whole. Smart devices that are able to monitor both physiological data, such as blood pressure and heart rate, and broader "lifestyle" data, such as sleep and exercise patterns, could be harnessed to tailor treatment to a patient and their environment (Figure 1). For example, asthma patients could be advised to increase their daily dose of inhaled corticosteroid when in areas of high air pollution. Smart use of these devices helps to create populations more aware of their health.

THE CHANGING ROLE OF APPS

Smartphone apps play a central role in the connected device ecosystem as they provide both a means for data upload and a user interface for patients to track and manage their therapy. In the future, it is likely that there will be more stand-alone digital health apps as new payer regulations allow healthcare professionals to prescribe apps. For example, in Germany digital apps have been eligible for prescription via the statutory health insurance system since 2020.

However, advancements in technology mean the role of apps is changing. With the emergence of 5G and edge computing, future devices will be able to send data directly to the cloud without the need for a secondary app or device. Apps may still play a role, with cloud data transmitted back to the app, but will become secondary in importance. This real-time data transfer will make tracking and monitoring device usage even easier for users as they won't need to install an app and pair their device. Real-time updates may also give pharma companies a commercial and competitive advantage.

Figure 1: Smart consumer devices are able to capture a wealth of health and lifestyle data.

"An optimised user experience is critical to driving continued product use, which in turn supports better treatment adherence."

ENHANCED USER EXPERIENCE

An optimised user experience is critical to driving continued product use, which in turn supports better treatment adherence. With connected devices, patients can manage their condition while receiving immediate feedback to guide them through each step of using the device. Rather than manually recording data themselves, they can effortlessly capture key information such as injection date and time, dose and injection site through automated features. In addition, notifications can help remind patients when their next dose is due, as well as alert them to missed doses.

However, to reassure patients worried about data privacy and security, and to prevent unauthorised use, manufacturers may consider adding medication and user authentication. There needs to be a balance though; multiple authentication steps can increase the difficulty of setting up devices and discourage adoption for those patients who are less familiar with the technology.

Patient feedback is another area where balance is required. While some feedback can be useful and reassuring for patients, it can also add complexity if the device is difficult to navigate ergonomically or cognitively. As it is, a significant proportion of the older, less tech-savvy population may struggle to embrace connected products. Direct-to-cloud solutions, as described above, can limit the amount of user interaction needed during the set-up stage and help to solve this issue.

IMPROVED TRAINING AND SUPPORT

The rise in self-administration means the delivery device itself has a greater role in supporting the patient through the injection process. To ensure patients properly understand how to use their products, manufacturers are increasingly deploying training devices. With options of added enhanced sensors and data capture, they can offer more specific guidance to patients who are using a new device or beginning a treatment for the first time.

Sensory feedback from devices can confirm that they are being handled and used correctly. For instance, visual feedback can help patients to rotate their injection sites, and audible clicks or beeps can indicate the beginning and end of a dose and guide patients on device hold times. These features are especially important as pharmaceutical companies continue to innovate with drug formulations.

Some newer drugs come in larger volumes, extending injection time but allowing a reduction in frequency. In some instances, treatment only needs to be administered biannually or quarterly. One example of this is Skyrizi (risankizumab-rzaa – Abbvie, IL, US),[2] which is used for the treatment of plaque psoriasis, psoriatic arthritis and Crohn's disease. Intuitive products facilitate administration even after long periods.

DATA TO IMPROVE DEVICES

Finally, data from connected devices can be used to enhance the performance of the device itself. Prior to product launch, data about how patients are holding a device and the amount of force or pressure applied during injection can be gathered during clinical trials. This data is invaluable for human factors studies and, with usability regulations becoming ever stricter, it can be used to prove devices are being used as intended during testing and that any user risks have been adequately addressed. Following product launch, new data can allow pharmaceutical companies to track complaints and concerns, and determine their root causes. They can then relay this information to the device manufacturers, enabling ongoing improvement of the product.

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A THOUGHTFUL APPROACH

The development of connected drug delivery devices holds great potential and new developments are constantly in the pipeline. However, introducing connectivity is a complex issue as digital tools need to be cost effective and user centric, as well as needing to provide real value. Some challenges, such as the need to streamline data capture and storage, may need the involvement of multiple players. Connectivity strategies therefore need to be approached thoughtfully and holistically. Many potential benefits are on offer. Intelligent digital solutions can provide a differentiating factor for pharma companies, improve the patient experience, assist clinicians in their daily work and help payers to reduce healthcare costs.

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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Michael Earl joined Owen Mumford as Director of Pharmaceutical Services in November 2020. He was previously the Commercial Vice-President at Bespak (now part of Recipharm), leading the commercial team there to drive growth in their substantial medical devices business. Prior to that, he worked for a number of pharma, biotech and device companies. In a career spanning more than 35 years, Mr Earl has been responsible for all aspects and stages of drug and device development and commercialisation. He has also completed a substantial number of commercial, licensing and mergers and acquisitions transactions.

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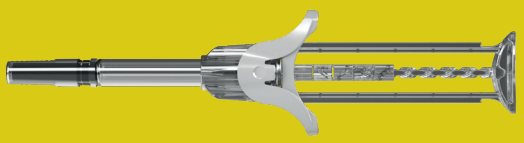

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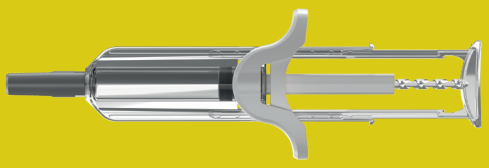

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