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CONNECTING PATIENTS AND HEALTHCARE PROVIDERS IN THE AGE OF SELF-ADMINISTERED INJECTABLE DRUGS

In this article, Gemma Wood, Innovation Manager at Bespak by Recipharm, explores connected device development trends, the patient-centric benefits the technology has to offer and how, with the help of experienced manufacturing partners connected to key enabling technology partners, they can develop products that deliver improved patient outcomes.

Global growth in the use of parenteral biopharmaceuticals to treat chronic and age-related disease is expanding rapidly. In particular, the administration of biopharmaceuticals by global healthcare providers (HCPs) to treat chronic conditions, such as arthritis, diabetes and other autoimmune diseases, continues to drive global growth and development of injectable drugs. For this category of pharmaceuticals alone, the market is projected to reach US$856 billion (£683 billion) by 2030.[1]

This growth is supported by decades of combined drug and device innovation to support the safe self-administration of parenteral drugs. In the wake of the pandemic, the trend towards remote self-care to treat chronic diseases of all kinds is driving a similar demand for better, smarter and more effective ways for patients to self-administer their medications. Rapid innovation is occurring within the pharma industry to help care providers deliver better modes of self-care.

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To deliver better care overall and overcome the challenges related to remote parenteral drug delivery, drug developers are looking to integrate new ways to connect the patient, the combination device and the healthcare provider (HCP) via the cloud. However, integrating connectivity to device development adds complexity into product development strategy.

REMOTE PATIENT SELF-CARE TREATMENT MODELS TRENDING

To reduce the overall cost of healthcare and provide a better life balance for patients, especially for those with chronic conditions, HCPs have steadily moved patient care models away from administering drugs in clinical settings towards remote self-care models that put the patient in control of delivering their therapy themselves.

More recent events, such as the covid-19 pandemic, have accelerated this trend. During the pandemic, travel to clinics became more challenging. In addition, there was a desire to reduce the possibility of vulnerable patients becoming infected during visits to clinics.

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The pandemic highlighted the potential for a deterioration in outcomes when patients are unable to have face-to-face contact with care providers. As a result, pharmaceutical developers, device developers and digital health experts are continually seeking more effective ways of improving therapeutic outcomes.

There are few signs that healthcare's adoption of remote self-care will slow anytime soon. Key factors driving the uptake of self-administered drugs (such as topicals, inhalable compounds and injectables) include the rise in demand for combined, prefilled medical devices, developments in the biologics segment and rising technological innovation in delivery and automated dose control. Furthermore, the rise in the number of outpatient services and the growing prevalence of government-funded insurance is expected to further influence growth.[2]

DOSE COMPLIANCE CRITICAL TO BETTER PATIENT AND PAYER OUTCOMES

The therapeutic efficacy of a drug depends on its pharmacology, bioavailability and patient compliance. The negative effects of non-compliance, especially for chronic conditions, is well studied and remains one of the biggest impediments to delivering affordable, sustainable pharmaceutical-based healthcare successfully. In a recent brief, McKinsey noted that failure to adhere to prescribed-medication regimens is one of the principal reasons that patients do not achieve expected outcomes. Studies reveal 50% or more of patients with chronic illnesses miss doses, take the wrong dose or drop off treatment in the first year. A McKinsey study cited an estimated 125,000 lives are lost each year in the US alone, which drives additional healthcare expenditures of $290 billion as a result of non-adherence.[3]

Reasons for poor dose adherence and compliance are often associated with symptomatic aspects of the disease, negative side effects of the drug, dose frequency and usability of the drug delivery device.

For millions of patients who inject themselves frequently, there is a growing preference for "smarter" and "friendlier" ways to self-administer their medications. Connecting patients and providers with the drug delivery device via the internet has been hailed as a potential part of the solution to this challenge.

By allowing dose compliance data to be transmitted from an injectable device to a patient's own smartphone and/or an HCP's database, it is possible for both the patient and their HCP to monitor dose compliance remotely in real time. As such, data connectivity via the cloud is becoming a smarter way to identify any potential gaps in the quality of care that might arise through remote care and that could adversely affect treatment outcomes.

THE CHALLENGE OF DRUG CONNECTIVITY

Consequently, designing drugs and devices that ease administration and support patient compliance and adherence to drug treatments has become a major driver for improving chronic disease control and optimising the use of healthcare resources and costs. However, truly harnessing the benefits of connectivity for the patient and HCP entails more than simply integrating smart technology into the device. Questions need to be answered, such as reimbursement, data privacy and security, what kind of data to collect, how it should be stored and which stakeholders should be included.

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Questions around the nature of the device and the usability of the smart component of the device also need to be answered to ensure true patient-centricity; a device that can share data but becomes more complex for the patient to use is unlikely to offer the overarching benefits sought by including the connectivity in the first place. In addition, it is important to consider the value proposition – whether the benefits of connectivity for all stakeholders outweigh the cost of development and implementation into a device. This can be a particular challenge when considering single-use devices.

KEY CONSIDERATIONS FOR SUCCESSFUL CONNECTED DRUG DEVELOPMENT

Development of connected devices to meet HCP and patient needs is set to grow dramatically in the near term. Mordor Intelligence's recent report notes that, during 2022–2027, the market for connected devices is expected to register a compound annual growth rate (CAGR) of 40.2% during the forecast period.[4]

Behind this projected growth is the fact that so much of the world is connected by the internet. According to Mordor Intelligence, as of September 2020, Internet World Stats reported there were approximately 4.92 billion people, about 60% of the world's population, actively using the internet.[4]

Figure 1: Syrina® AS autoinjector device.

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Therefore, there are several key considerations to bear in mind for any drug developer when embarking on a connected, injectable drug development project:

- Usability and patient-centricity (design and function)
- Desired patient outcomes and efficacy goals
- Information architecture and data-set requirements
- Reimbursement
- Device compatibility
- Data security requirements
- Software/platform management
- Cost/risk/benefit analysis
- Data security and risk.

OVERCOMING CONNECTED DRUG DEVELOPMENT CHALLENGES

The additional elements associated with developing and manufacturing connected delivery devices requires a network of technology partners with deep expertise in digital health.

Recognising this need, in 2020, Recipharm collaborated with Team Consulting (Cambridge, UK) to jointly develop a connected proof-of-concept for the Syrina® AS autoinjector device (Figure 1). This included a Bluetooth-enabled connectivity module within the device that can sense various functionalities. An application was developed to inform users that the device had been used successfully and when dose delivery was complete. The software also included reminders about subsequent prescribed dosing and is readily adaptable to include additional functionality where required.

Working with an experienced device developer and its network of digital health specialists provides the following benefits:

- Guidance on achieving therapeutic value and patient goals
- Design and delivering turnkey cloud-based system architecture
- Levering existing data infrastructures
- Clear, efficient commercialisation
- Market-oriented products
- Desired patient and payer outcomes.

It is important that adding electronic modules does not impact the design of the base device. This helps minimise design risks or duplicating manufacturing equipment and supports continuing development and production of the base device design when the connected requirements are not fully understood or in their infancy. With this in mind, it is important for drug developers to consider both the potential value and the risks of connectivity when embarking on new projects.

Experienced device developers and digital health partners can support pharma companies in their deliberations, helping them decide whether connectivity is right for their project, and assist them in developing a product that will truly transform healthcare for the patient.

CONNECTING PATIENT AND CARE FOR BETTER OUTCOMES

What does the future hold for connected drug products? Although the category is set to grow to unprecedented levels, not all injectable drugs, self-administered or not, will be or need to be connected. However, connectivity will continue to play an important role in maximising the quality of healthcare for patients, especially those with chronic conditions. For the treatment of these and other vulnerable patient groups, connectivity certainly may offer a better path to a healthier remote-care relationship with patients.

ABOUT THE COMPANY

Recipharm delivers drug/device combinations targeting inhalation and injectables. By providing expertise in the development of combined drug/device products together with commercial manufacturing, Recipharm minimises hurdles and accelerates time to market. Through its business unit, the company has implemented technology platforms to provide drug formulation development expertise and comprehensive analytical support, as well as manufacturing capabilities for a wide range of devices. Recipharm offers highly innovative design, development and manufacturing capabilities for injectable drug delivery devices to the global pharmaceutical market, offering a range of autoinjectors with its proprietary VapourSoft technology. Keeping the end user in mind, Recipharm produces autoinjectors designed to facilitate patient-friendly administration and overcome formulation challenges, particularly for high-viscosity formulations. Its customers include several of the world's largest pharmaceutical companies.

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ABOUT THE AUTHORS

Gemma Wood, Innovation Manager, currently leads the Bespak by Recipharm Innovation team in Cambridge (UK), and has over 22 years' experience in the management of injectable device developments. The Innovation team focuses on the identification and development of novel drug delivery technologies that address unmet market needs and create new opportunities for the Recipharm Group.