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## CONNECTED HEALTH: THE FUTURE OF EFFECTIVE DRUG DELIVERY

The development of connected injection devices by West Pharmaceutical Services is already well advanced. In this article, Chris Evans, Vice-President, Innovation, and Nicolas Brandes, Director, Market Development EU/Asia-Pacific, both of West, set the company's movement into connected health in the context of trends in the pharmaceutical industry, such as the increased number of biologics coming through the pipeline and the need for patient-centric approaches, and describe the specific requirements those trends place on their injection device designs. They introduce their partnership with HealthPrize which brings in elements of gamification and reward programmes into therapy adherence software and, looking to the not so distant future, they describe in detail a number of specific benefits – to various stakeholders – that their connected delivery systems will bring.

Keeping up with new drugs in development and the technologies to support them requires a novel approach to drug delivery. One of the biggest challenges in the injectable drug market today is patient centricity. With more patients diagnosed with chronic conditions and tasked with self-care at home, it's becoming increasingly important for patients to be fully engaged and invested in their treatment regimens. Connected health – and its integration within drug delivery systems – is showing great promise for meeting the patient-centrality challenge head-on and thereby improving the user experience and helping drive adherence.

### PUTTING PATIENTS FIRST

With a steady pipeline of biologics and biosimilars poised to come onto the market for the treatment of chronic conditions, we are experiencing the very beginning of the potential that exists for a new wave of drug delivery. Patients who must regularly self-administer medication – not to mention the providers and health insurance payers that are invested in these treatments

"Our connected health collaboration incorporates the power of a smartphone app with the SmartDose integrated drug delivery system to improve and reward medication adherence."

– have eagerly awaited this shift to more user-friendly drug delivery systems that better align with how people live their everyday lives.

Patients are demanding more autonomy in managing their own self-care at home whenever possible. However, as the use of biologic therapies is on the rise, it can be challenging for patients tasked with injecting high-volume doses to do so consistently and effectively. This is especially true for patients with chronic conditions such as diabetes, haemophilia, rheumatoid



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Figure 1: West and HealthPrize Technologies are working to provide an end-to-end connected health solution for pharmaceutical companies and patients.

arthritis and multiple sclerosis, which often require repeated injections for effective, long-term care.

While there are numerous auto injector devices on the market, pharmaceutical companies need innovative and responsive packaging partners that can keep up with the requirements demanded by advanced biologics. Some glass-sensitive biologics must be housed in polymers because of the risk of incompatibility, breakage or protein aggregation with glass. Other requirements are more suited to injectors that can control the delivery of large doses over time when the drug is too much for a single injection.

experience of patients required to self-inject a larger volume biologic drug at home. This wearable injector adheres to the patient's body, usually the abdomen, and automatically injects a drug slowly over time via an electromechanical drive. By making it easy for patients to self-administer medication, the SmartDose system encourages patients to comply with their prescribed dosing regimen.

We recently partnered with HealthPrize Technologies, a leader in patient engagement and medication adherence solutions, to make the SmartDose injector even more patient centric. Our connected health collaboration

technologies. In doing so, we have created a patient-friendly injector that allows for system configurations that not long ago seemed part of the distant future.

Putting all three together – the right containment materials, delivery systems and apps that track compliance to prescribed treatment regimens and reward patients in order to reinforce medication adherence – creates a powerful next-generation digital health ecosystem that can help solve some of the more significant issues that evolving healthcare models pose.

#### ADDRESSING USABILITY

Before bringing a connected health offering to life, it is important to understand the fundamentals of patient-centric design. One of the most successful elements in fulfilling the need for patient-centric design is human factors analysis, which benefits the patient by making injection systems more comfortable and user-friendly. More patients are using auto-injection systems to take medications at home that previously were delivered in a clinical setting. Increasingly, patients are taking biologics that require less-frequent, high-volume doses. In some cases, doses

**"One way to increase patients' affinity for their self-injection system is to connect it to another device that they already use: their smartphone. Smartphones are powerful tools used by most of us every day."**

West's SmartDose® Electronic Wearable Injector, incorporating a Daikyo Crystal Zenith® cyclic olefin polymer (COP) cartridge, is designed to enhance the

incorporates the power of a smartphone app with the SmartDose integrated drug delivery system to improve and reward medication adherence with unique gamification

only need to be delivered once a month, making it easy to forget these processes from month to month.

By taking a systematic, data-driven human factors approach to addressing usability earlier in the development of injectable drug delivery systems, it is possible to troubleshoot and eliminate or minimise the risk of potential user errors and help build successful outcomes for the end-user patient. Incorporating patient feedback earlier into the design process also assists in creating delivery systems that address factors such as reducing fear and discomfort during the injection process.

What does patient-centered design mean in practical terms? For West, it includes listening to patients to address their personal priorities. Often this involves talking to users three to five times before even prototyping a self-injection system to understand their needs and how best to meet them. It also means understanding how patients feel about their diagnoses, and conceptualising how to make a drug delivery system that will improve their outlook, as well as finding out what features and design factors will improve medication adherence.

We also continually validate and improve our designs to ensure that data-driven research is driving our approach to designing patient-friendly injectors. Armed with this knowledge, we can create delivery systems that patients are more likely to use correctly the first time and every time.

## PUTTING QUALITY INTO DESIGN

In addition to considering human factors testing and analysis, the selection of components that go into a drug delivery system is patient-critical: packaging components must be of the highest quality in order to help the injector function safely and effectively. Incorporating scientific Quality by Design (QbD) principles into both the design and manufacture of packaging components can lead to greater understanding of the impact that material attributes and process parameters have on the critical quality attributes. It also enables greater control over sources of variability in manufacturing.

Regulatory agencies set high expectations for pharmaceutical and biotechnology manufacturers and hold them accountable for assuring all of the parts of integrated drug delivery systems are of the highest quality. The use of components within a

self-injection system based on a holistic QbD process assures a well-understood product that has been developed to protect patient safety and minimise risk for the pharmaceutical manufacturer. And, most importantly, it helps put parameters in place to ensure the injectable medication contained within a delivery system can be used safely and effectively.

West developed the components for prefilled systems with QbD in mind, addressing the needs for today's biologics. One example is the West NovaPure® brand of elastomeric components. NovaPure components, such as stoppers and plungers, were created through QbD processes that have been shown to optimise breakloose and extrusion performance, provide low part-to-part variability and particulate specification while ensuring high cosmetic quality. When combined with West FluroTec® barrier film, the components help improve auto-injector performance through dimensional consistency.

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"Connected health programmes such as HealthPrize and other systems that "gamify" treatment regimens – and allow doctors and nurses to monitor patient data and medication adherence – show promise in giving patients better reasons for caring for themselves."

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This data-driven component of container development helps ensure a biologic reaches the market in a delivery system that not only helps to protect the drug product's quality and efficacy, but will also help maintain reliable drug delivery throughout the drug product lifecycle.

## CONNECTED HEALTH

The quality of a delivery system is critically important for patients. However, a patient's top concern is often usability; it is important to have a drug delivery system that is easy to use. Auto injectors that are designed with this patient-first approach have the ability to help improve medication adherence.

When a self-injection system is comfortable, reliable and familiar, a patient is more likely to use it as prescribed, which can lead to improved outcomes, positively impacting patients, providers and pharmaceutical companies.

One way to increase patients' affinity for their self-injection system is to connect it to another device that they already use: their smartphone. Smartphones are powerful tools used by most of us every day. They help us remember the grocery list, who won last week's sporting event, who recorded a popular song or acted in a favourite film and keep us in touch with family and friends in ways we never could before. In much the same way, smartphones and intuitive apps can also be used to make information about medications and step-by-step instructions on how to administer them easily accessible in patients' daily lives.

When setting out to design the next generation of drug delivery systems, the West team understood the vast potential of smartphone apps for helping to improve medication adherence. But we also knew we needed to find a software partner to accelerate our plans for integrating a connected health app with our self-injection systems. We chose HealthPrize, which created a dynamic software-as-a-service platform that engages and educates patients and records when they take their medication. In the future, the platform may also potentially provide the ability to track more details about patient behaviour, as well as automate the reporting process through sensors in the injector.

Leveraging gamification, the HealthPrize platform rewards patients for medication adherence. As a concept, gamification has made inroads in online marketing by applying elements of game playing, such as scoring points, competing with others, setting a hierarchy of rules and, of course, reaping rewards for success. But it is showing promise in other sectors as well, including fitness and healthcare, and for helping patients find a new way to meet the daily challenges of chronic disease management.

Connected health programmes such as HealthPrize and other systems that "gamify" treatment regimens – and allow doctors and nurses to monitor patient data and medication adherence – show promise in giving patients better reasons for caring for themselves, in both incentive and accountability.

Such technology options are a value-add for pharmaceutical companies and payers as well. By pairing their injectable drugs with innovative and engaging patient-focused delivery systems that track when a dose is delivered, drug makers and payers alike can have greater confidence that treatments are being taken as prescribed.

Forward-thinking companies are now also looking at the potential for smartphone apps to improve patient education and experience around self-injection systems. By using an app to guide patients in training, they don't have to remember everything outlined to them at the doctor's visit, when they might have many other things on their mind. Additionally, having the opportunity to reward patients for documented training, as well as to provide prompts and reminders around additional resources, has great potential for the safe, effective use of self-injection systems.

## LOOKING TO THE FUTURE

With drug delivery systems, one size may not fit all patients, at all points, in different stages of different diseases. But learning how patient attitudes towards diagnosis evolve, how they view and use their drug delivery system, and how their needs change as they progress through various stages of the patient journey will lead to better understanding of how to keep them from going off their critical medications... and what reasons they have for doing so.

The pharma industry is conservative, but connected health's return on investment is beginning to show better outcomes,

spurring the movement to build a digital health ecosystem around injectable drug delivery. In the future, data around medication adherence will be effectively tracked in real-time, including what medication was administered, where, when and how much was delivered. This critical intelligence will be reported back to providers and pharma companies.

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There will be reminders and messaging when a patient misses a dose of a needed therapy and, when needed, an appointment will be initiated with a healthcare professional to reassess their treatment plan. That might sound like a great leap patients will have to take. But, in the end, we can all benefit from investing in better connected systems in the pursuit of healthier outcomes.

Additionally, by focusing on value-added offerings, along with the right primary packaging for injectable biotech drugs early in the drug development process, drug makers can better differentiate their products with unique packaging and

delivery systems that may help aid patient compliance, and ultimately, outcomes.

The greatest benefit, however, is to patients. Patients living with chronic conditions who must inject themselves daily want their routines simplified and straightforward. Having a sensor detect when a dose is taken, logging the details so the patient doesn't have to do it manually, and sending confirmation to a care provider is the kind of simplified process likely to be welcomed among people whose lives have already been complicated by living with a chronic disease. The lesson today's technology companies are learning, over and over, is very clear: provide clear benefits to the end-user. Give patients value that will enrich their health, comfort and care quality. This is the promise and opportunity of connected health.

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# Empower your patients

The SmartDose® electronic wearable injector combined with the HealthPrize adherence program makes for a powerful combination.

The SmartDose injector helps your patients leave the treatment center behind, making self-administration at home simple and easy. And while at home, HealthPrize helps your patients stay on track with their therapeutic routine, through rewards-based patient education and adherence tracking.



West seeks partners for its SmartDose electronic wearable injector technology platform. This platform is intended to be used as an integrated system with drug filling and final assembly completed by the pharmaceutical/biotechnology company. The SmartDose system, HealthPrize platform integration is for conceptual purposes only.

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