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DRUG PACKAGING SYSTEMS FOR THE DIGITAL HEALTH ERA

In the context of the SmartDose high-volume injection device, in this article, Nicolas Brandes, PhD, Business Development Manager, Daikyo Crystal Zenith, West Pharmaceutical Services, describes how the company is bringing together primary containment materials, the delivery device and a smartphone app from HealthPrize, in order to achieve significant advantages, including optimal patient compliance to chronic therapeutics.

Keeping up with new drugs in development and new technologies to support them requires a novel approach for drug delivery. At West Pharmaceutical Services, we believe in the importance of connecting delivery systems with tools that can improve the user experience and drive adherence. Through our partnership with HealthPrize, a leader in patient engagement and medication adherence solutions, we are able to combine the strengths of the Daikyo Crystal Zenith® polymer cartridge available in the SmartDose® Electronic Wearable Injector with the power of a smartphone app. In doing so we have created a patient-friendly injector for pharmaceutical manufacturers – allowing for system configurations that not long ago seemed part of the distant future.

But this is just the beginning of the potential that exists for drug delivery, which patients – not to mention health insurance payers – have eagerly awaited. They are demanding more autonomy from the physician's office in managing their own self-care at home whenever possible. However, as the use of biologic therapies is on the rise, patients tasked with injecting large quantity doses are challenged with delivering a consistent dose every time. This is especially true for patients with chronic conditions such as diabetes, haemophilia, rheumatoid arthritis and multiple sclerosis.

By focusing on value-added offerings, along with the right primary packaging for injectable biotech drugs early in the drug development process, pharmaceutical companies can now set their product apart with unique packaging and delivery systems that may help aid patient compliance, and ultimately, outcomes.

Putting all three together – the right containment materials, delivery systems, and apps that record doses and reward patients in order to reinforce medication adherence – creates a powerful next-generation system that can help solve some of the more significant issues that new healthcare models pose.

CRYSTAL ZENITH: NEW BIOLOGICS MAY REQUIRE NEW PRIMARY PACKAGING POLYMERS

Some biologic drug products do not react well with glass, requiring drug manufacturers to look at other options for containment and delivery. For example, modern biologic formulations sensitive to silicone oil or tungsten may require alternative packaging. Silicone oil, used as a lubricant in glass containers to obtain plunger gliding functionality, has been strongly connected to protein aggregation as well as the presence of subvisible particles in the suspension.

Other undesirable effects in combination with glass primary packaging include potential breakage, delamination, or heavy metal release, low dimension control and lack of design flexibility.

Challenges with glass as well as a sharpened focus on safety – now that chronic disease patients are treating themselves more frequently at home – drives pharmaceutical companies' demand for increased quality from drug containment and delivery system manufacturers. While glass remains the standard for injectable drug containment for the prefilled syringe market, the material's higher dimensional variability in manufacturing could be a concern when evaluating

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Figure 1: The West SmartDose® electronic wearable injector, designed for patient convenience, incorporates a Daikyo Crystal Zenith® cartridge and can deliver a dose of up to 3.5mL, which may allow for viscous biologics that are sensitive to glass, metal ions and/or silicone oil to be administered over longer periods of time.

the functionality of the syringe or cartridge in conjunction with the delivery system.

These high-quality polymers maintain the quality of sensitive biologics through enhanced cleanliness and decreased interaction with the drug product. Primary containers made from materials such as the Daikyo Crystal Zenith polymer (Figure 1) can help contain higher dose volumes or provide delivery options for viscous drug products. Cartridges and syringes moulded from Daikyo Crystal Zenith polymer are free of silicone oil und tungsten, and exhibit break resistance as well as consistent and predictable gliding forces. The rubber components that are used in the CZ® systems are laminated with Flurotec®, which functions as an effective barrier against extractables and provides lubrication at the same time.

SMARTDOSE INJECTOR: DESIGNED HOME USE

Some patients either do not want to inject themselves with medications in prefilled syringes, or their conditions make it difficult. Furthermore, some drugs – including the aforementioned cutting-edge biologics – might require large volumes of viscous solutions, making a single-dose option either difficult or impossible.

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 these biologics create. Some glass-sensitive biologics must be housed in polymers because of potential breakage or protein aggregation with glass. Others 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. An example is West's SmartDose® electronic wearable injector system (Figure 2), incorporating a polymer-based drug container (made from Crystal Zenith resin) and designed to enhance the experience of patients required to self-inject a larger volume biologic drug at home.

Choosing the correct packaging and delivery system can not only make medication adherence easier on the patients, but it can also encourage brand preference among patients and practitioners. By making the right choices early on in the development process, packaging and pharmaceutical manufacturing can mitigate risk and deliver a high-quality product to patients.

HEALTHPRIZE APP: MEDICATION ADHERENCE SUPPORT IN YOUR POCKET

Digital health, mHealth and the wearables revolution are all current catchphrases that describe the movement to enhance traditional clinical care with patient-owned mobile devices. On the simplest level, apps associated with drug delivery systems can drive adherence by sending reminders to the patient and provide a means to log when and how much of a drug they administered.

On a more advanced level, a wearable injector paired with an app offers opportunities to educate the patient on the medication and its administration; automatically track when and where a dose was administered, and how much was used; and even offer feedback to the physician as well as data analytics over time.

Research indicates that a patient's medication adherence is directly linked to favourable treatment outcomes for a variety of chronic therapies, including multiple sclerosis and diabetes. Yet patient compliance with chronic medication therapies is remarkably low – the World Health Organization

Figure 2: West's SmartDose® electronic wearable injector provides a solution for the challenge of delivering a large-volume dose of a drug product. Easily tailored to specific pharmaceutical customer needs, West's SmartDose technology, which incorporates Daikyo Crystal Zenith® prefillable cartridges, is designed for the delivery of viscous biologic drugs.

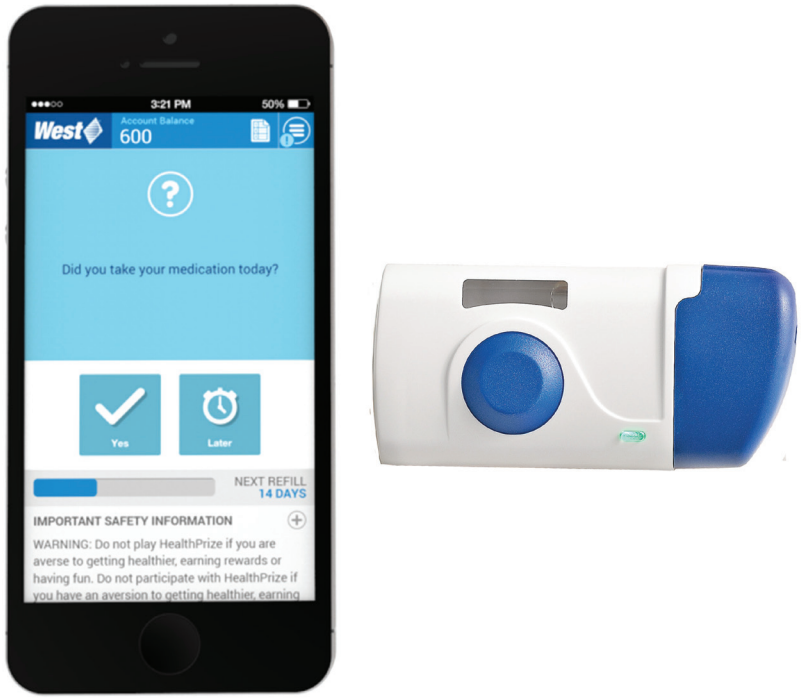

Figure 3: HealthPrize's medication adherence and patient engagement platform is intended to be integrated with West's injectable drug delivery systems, including the SmartDose® electronic wearable injector and injectors for drugs and various biologics.

estimates it at 50% internationally. Non-compliance leads to poor clinical outcomes, lost revenue for pharmaceutical companies worldwide and increased costs for many healthcare financial stakeholders, including the patients themselves.

New formulations such as some once-a-month biologic injections take some burden off of patients administering medications in self-care. But as the time between doses grows, it becomes easier to forget to take it. The problem to solve, then, becomes one of reminding – and even rewarding – patients for medication compliance. Technology offers a potential new solution to this ongoing problem, as smartphone and tablet app developers attempt to create software that helps chronic disease patients stick to their medication regimens.

As a company invested in next-generation care, West has joined forces with HealthPrize to develop apps in conjunction with self-injection drug delivery (Figure 3). It is our way of getting involved with the connected health movement for the sake of patient engagement: A way of adding value for patients living with disease and who sometimes need a little help improving their health, and to offer our pharmaceutical partners a range of choices. The heart of the HealthPrize system is motivation through rewards – giving the patient a gift card after achieving medication-adherence milestones set by the pharmaceutical company or healthcare provider.

Product development in the pharmaceutical industry takes time in order to ensure that we are adhering to the highest quality standards. That is neither good nor bad; it just is reality. By partnering with an established, connected-health company that has built a healthcare gamification app we hope to be able to help more patients by making it available to our pharmaceutical partners.

At first, patients will be able to scan barcodes manually or otherwise enter data about their medication compliance into the smartphone/tablet app or on an internet browser from a computer if they don't have a wireless device. It is imperative for us and our partners to make the app as intuitive as possible. This way the app itself doesn't become a barrier to medication compliance. In the future, pending applicable regulatory requirements, we would like to make app usage even more automated, streamlined and interactive. We would accomplish this by enabling our drug delivery system to signal the smartphone numerous data points about each dose administration.

For example, a self-injection patient's app might automatically, in real time, confirm that a particular dose was used, the syringe safety was released, all the medication was injected, and other details. The app is designed to offer the patient feedback and validation, ultimately reinforcing the efficacy of the treatment path.

CONCLUSION: PUTTING THE PIECES TOGETHER

Each element of these novel drug delivery models – the Daikyo Crystal Zenith polymers, the SmartDose electronic wearable injector system, and the HealthPrize app – are powerful next-generation tools by themselves.

Taken together, they put pharmaceutical companies in a position to create cutting-edge systems that not only benefit patients by helping avoiding the consequences of skipping their medications but help the drug manufacturer ensure that the products delivered to market are used to their full potential.

The combination of these three drug delivery components also can yield data points previously unavailable to drug companies for analysis. By performing data analytics on usage patterns, more can be learned about these medications and the way they are used by patients in their homes, with an eye toward ultimately help improving therapies and creating better, more comfortable lives for patients living with chronic diseases.

SmartDose® is a registered trademark of Medimop Medical Projects Ltd., a subsidiary of West Pharmaceutical Services, Inc. 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.

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ABOUT THE AUTHOR

Nicolas Brandes is responsible for business development and all project and product management activities related to Daikyo Crystal Zenith products in Europe, working hand-in-hand with West's strategic partner Daikyo Seiko in Japan. Dr Brandes received his PhD in Biology from the University of Wuerzburg, Germany in 2010, after performing his research studies at the University of Michigan, US.

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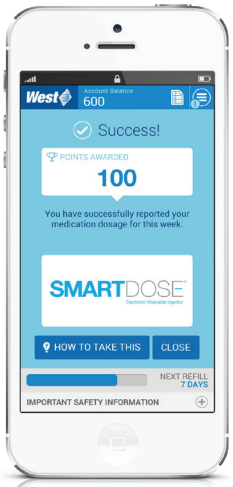
Empower your patients

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.



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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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