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PUTTING PATIENTS FIRST: INNOVATING DRUG CONTAINMENT AND DELIVERY

Innovations in self-administered drug delivery systems are supporting care for a variety of medical conditions transitioning out of hospitals and clinical settings into the home. To ensure patient compliance with treatment is maintained, an easy-to-use self-administration system can be key. Chris Henshall, Senior Director, Strategic Marketing – Biologics, West Pharmaceutical Services, discusses the factors manufacturers should consider to ensure self-injected therapies meet patients' needs and therefore improve patient outcomes.

Increasingly, the biopharma industry is moving towards precision medicine, and a patient-centric approach to treatment along with a shift in healthcare costs being shared more evenly with the end user. Innovations in drug delivery are supporting care for a variety of medical conditions transitioning out of the hospital and clinical setting and into the home. This is good news for many patients with chronic conditions such as diabetes, multiple sclerosis, rheumatoid arthritis and haemophilia, who are now able to self-administer injections safely at home away from the traditional healthcare setting, and take a more active role in their treatment.

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While it is convenient for patients to self-administer medication, it can also be quite difficult to accomplish effectively. As a result, drug delivery systems that can support home use and aid in patient compliance, adherence and safety have rapidly evolved using new developments in technology such as wearable drug delivery injectors.

While wearable injectors offer a safe, reliable and effective method for at-home administration and improving potential patient outcomes, developing these new systems can pose a significant challenge for pharmaceutical manufacturers, i.e. how to design a wearable injector that patients not only can use, but also want to use.

To meet this challenge the makers of injectable medicines must fully understand and incorporate the needs of end users when bringing a self-injected therapy to market. This requires careful thought about how a medication will be administered by patients. As such, the design of an injectable medicine's delivery system is fast becoming an essential aspect of the manufacturer's go-to-market strategy. To be successful, however, it is important that pharmaceutical manufacturers consider several factors.

KEY FACTORS IN THE DESIGN OF SELF-INJECTION SYSTEMS

User Experience

The user experience is an extremely important element when designing a

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Figure 1: West's SmartDose® platform includes a Daikyo Crystal Zenith® cartridge with elastomer components using FluroTec® barrier film.

drug delivery system. With many chronic conditions on the rise, it is critical that the healthcare industry find ways to improve patients' ability and desire to maintain an appropriate self-care treatment regimen. The WHO reports that adherence rates for patients with chronic conditions are only approximately 50% in developed countries, and much lower in developing countries.[1]

While many products do provide systems that aid compliance reasonably well, a truly successful combination product must also consider the needs of the end user at a variety of stages during the patient journey. A diabetes patient, for instance, may transition through a variety of injection systems: from a syringe to an auto-injector and, ultimately, to a wearable pump.

Human Factors

When creating a delivery system, pharmaceutical companies and their drug delivery system partners must consider patient needs in conjunction with functionality along all stages of the patient journey. Drug makers stand a better chance of satisfying the needs of users if they bring the relationship between the delivery system design and the patient experience into the centre of the development process.

Human factors research, testing and analysis can provide a deeper view of the emotional needs and desires of users, and provide valuable perspective on features and visual cues. It can help manufacturers understand the nuances of where a delivery system is used and who is using it. This research can yield valuable insight into users' preferences and emotional requirements, which can then translate into feature sets and design elements of the drug delivery system before it goes on the market.

Additionally, while it is best to think about delivery systems during the initial development process, it is never too late to employ human factors analysis for drugs that have already cleared regulatory approval. Improved usability can be retrofitted into manual drug delivery systems that might not be faring as well on the market as they should – for example, adding ergonomic features for a self-injector to aid patients with dexterity issues – and help support product differentiation.

Figure 2: SmartDose® platform incorporates human factors and usability testing to deliver a truly patient-centric approach.

Figure 3: West's SmartDose® injector adheres to the patient's body, usually on the abdomen.

"The overall patient experience can be improved by careful consideration of patient-centric device design, human factors, the integration between a delivery system and its components, and effective education and onboarding."

Component Compatibility

The compatibility of a drug and its integrated delivery system is of utmost concern for all injectable drugs and particularly with biologics. Wearable drug delivery systems that effectively manage the interrelationship of a drug, its primary container and its administration system can help ensure the system functions accurately, effectively and reliably every time.

Many modern biologic formulations may be sensitive to silicone oil – used as a lubricant in glass syringes – or tungsten and, therefore, may require alternative packaging component materials such as cyclic olefin polymers. These can be attractive alternatives as they offer solutions to several drug delivery challenges, including break resistance, dimensional precision, consistent gliding forces, reduced extractables and leachables. They also minimise the risk of drug-container incompatibility due to the impact of silicone oil and tungsten on drug stability and protein aggregation. Additionally, polymer-based syringes can provide dimensional precision and strength, which can be significant factors when combining a syringe with a spring-based auto-injector.

Wearable Drug Delivery Systems

While prefilled syringes have been common drug delivery systems for many injectable medicines for years, some patients either don't want to inject themselves with medications in prefilled syringes, or their conditions make it difficult for them to do so. Additionally, for some injectable medicines with higher-volume doses, it can be hard to administer the drug consistently via a prefilled syringe. Furthermore, some drugs – including many new biologics – might require large volumes of viscous solutions, making a single-dose option either difficult or impossible.

Wearable auto-injectors are quickly becoming popular choices for delivering therapies for chronic conditions. They are convenient and easy to use, can eliminate the need for patients to measure dosages and can help prevent the risk of needlestick injuries. One example is West's SmartDose® platform (Figures 1 & 2) – a wearable, subcutaneous injector with an integrated drug delivery system that incorporates human factors and usability testing to deliver a truly patient-centric approach to self-administration.

The single-use SmartDose® injector adheres to the patient's body, usually on the abdomen (Figure 3), and is pre-programmed to deliver high volumes of viscous or sensitive drug products. The SmartDose® platform includes a Daikyo Crystal Zenith® cartridge with elastomer components using FluroTec® barrier film. It is ideal for silicone-sensitive biologic formulations. Additionally, it offers connectivity to a variety of software platforms.

Onboarding

Another critical consideration for self-administration is how the patient will learn to use the self-injection system. New patients with self-injectors often make errors in administration. One reason

> "Multisensory, comprehensive, human factors-based educational and training programmes for drug delivery systems can reduce patients' anxiety and the risk of administration errors."

for this is that many patients do not thoroughly read the steps outlined in the Instructions for Use document prior to beginning drug treatment. This can potentially lead to administration errors and may impact a patient's compliance with a prescribed therapy.

Pharmaceutical and drug delivery companies should therefore consider and plan for patient education and onboarding in the development phase. Multisensory, comprehensive, human factors-based educational and training programmes for drug delivery systems can reduce patients' anxiety and the risk of administration errors.

Encouraging Adherence

Even with proper education and onboarding it can be difficult for many patients to stay motivated to stick with their prescribed treatment regimen. To address this issue, West has collaborated with HealthPrize Technologies (Norwalk, CT, US) on a connected health offering that rewards medication adherence using unique gamification technologies.

HealthPrize's Software-as-a-Service (SaaS) medication adherence and patient engagement platform is integrated within West's injectable drug delivery systems, providing an end-to-end connected health solution for pharmaceutical companies and patients. The combined offering provides electronically-connected drug delivery systems that track when patients take their medication, educates and engages patients to increase their medical literacy and foster adherence, and rewards them for compliance with their prescribed regimen. By offering education and rewards-based self-injection systems, West and HealthPrize aim to motivate patients, boost medication adherence and help improve patient outcomes.

Partnering for Success

While there are numerous self-injection systems on the market, pharmaceutical companies need forward-thinking drug packaging and delivery system partners that anticipate and address the needs of end users and the requirements of new sophisticated therapies for chronic conditions and can help develop the right system for their injectable drug product.

It is important for drug makers and their partners to have conversations at all stages of the development process about how to impact patient outcomes positively.

CONCLUSION

The overall patient experience can be improved by careful consideration of patient-centric device design, human factors, the integration between a delivery system and its components, and effective education and onboarding. Advanced self-administration systems that incorporate these essential elements can help improve the overall value and effectiveness of a drug product, and may drive down healthcare costs by helping to keep patients on their medication plans and avoiding health problems associated with non-compliance.

ABOUT THE COMPANY

West Pharmaceutical Services, Inc, is a leading manufacturer of packaging components and delivery systems for injectable drugs and healthcare products.

Working by the side of its customers from concept to patient, West creates products that promote the efficiency, reliability and safety of the world's pharmaceutical drug supply.

West is headquartered in Exton, PA, US, and supports its customers from locations in North and South America, Europe, Asia and Australia. West's 2016 sales of US$1.5 billion reflect the daily use of approximately 112 million of its components and devices, which are designed to improve the delivery of healthcare to patients around the world.

REFERENCE

1. *World Health Organization, "Adherence to Long-Term Therapies: Evidence for Action", 2003. Retrieved from: http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf*

ABOUT THE AUTHOR

Chris Henshall leads the strategic marketing efforts in global biologics for West. In this role, he is responsible for the development and delivery of strategic and operational commercialisation plans across the biologics portfolio. Working in partnership with the sales and customer-facing teams and other functional leadership, Mr Henshall drives performance, ensuring the success of West biologics is optimised for both the short and long term, securing organisational alignment from strategy through execution.

Mr Henshall has a wealth of pharma and biotech experience across his 20 plus years in the industry. He has led and launched multiple brands in his career both domestically and globally. He is an entrepreneur at heart who brings a new dimension to the team with his diverse background and unique blend of professional experience.

Mr Henshall is a native of South Africa where he received his undergraduate degree. He now lives permanently in the US, where he also received his MBA.

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FDA Approved

- The first combination product that incorporates the SmartDose platform technology was recently approved by the US Food and Drug Administration (FDA)
- Thousands of doses have been administered using the SmartDose platform
- Proven engineering, manufacturing and regulatory expertise to support your needs

Wearable Injector

- Subcutaneous self-administration
- Ability to deliver high volume and high viscosity drug products

Patient-Centric

- User-centered design
- Connectivity to a variety of software platforms
- Able to link with adherence solutions
- Onboarding and training solutions available

Flexible Technology

- Address a variety of delivery times through adaptable, pre-programmable technology
- Maximize patient comfort through pre-programmable delivery times

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West seeks partners for its SmartDose platform. This platform is intended to be used as an integrated system with drug filling and final assembly completed by the pharmaceutical/biotechnology company.

For more information visit www.westpharma.com

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