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PUTTING PATIENTS FIRST: INNOVATING DRUG CONTAINMENT AND DELIVERY

Wearable drug delivery technology offers patients an easy-to-use, reliable and integrated system for managing self-injection. However, to be safe and effective, manufacturers need to consider the interface between the drug, the device and the patient. Chris Henshall, Senior Director, Strategic Marketing – Biologics, West Pharmaceutical Services discusses how one such device – the SmartDose platform – can meet these requirements.

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For patients with chronic conditions, the use of injectable biologic therapies is on the rise, making it increasingly important for patients to be fully engaged and invested in their treatment regimens. While providing considerable therapeutic benefit, biologics can also present several challenges for both drug manufacturers and patients.

In particular, many biologics are highly viscous and others require large doses to be injected slowly over time. Additionally, ongoing management of chronic conditions is increasingly shifting from doctors' offices and hospitals into the patient's home in an effort to provide patients with more independence and control over their treatment while helping to stem growing healthcare costs.

For patients tasked with self-injection, this can be difficult to do consistently and effectively every time, potentially impacting medication adherence. This is especially true for patients with chronic conditions such as diabetes, haemophilia, rheumatoid arthritis and multiple sclerosis, which often require repeated injections for effective, long-term care.

One of the most promising options to help patients managing chronic conditions is wearable drug delivery technology. For most patients, an easy-to-use, integrated delivery and administration system can be key to creating the reliability that can help to bring about compliance with treatment plans. A truly successful wearable delivery system must also consider the needs of the end-user during the different stages of a patient's journey.

> "The next generation of prefilled products will include a preloaded option, with the objective of reducing patient handling steps."

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One such example is West Pharmaceutical Services' SmartDose® platform, which is designed to integrate easily into a patient's lifestyle. The SmartDose platform is a single-use, electronic wearable injector that adheres to the patient's body, usually on the abdomen. Discreet, intuitive and designed to minimise discomfort, the SmartDose platform currently incorporates a polymer-based drug container (made from Daikyo Crystal Zenith® cyclic olefin polymer) with a drug delivery device that can be pre-programmed to deliver high volumes of viscous or sensitive drug products over time, making it easier for patients to self-administer medication outside of the clinical setting (Figure 1).

SAFE, EFFECTIVE DELIVERY

Safety and effectiveness are the top priority when designing a wearable drug delivery system. To accomplish this, it is critical for biopharmaceutical companies to have a thorough knowledge of the potential interactions between a drug and its packaging.

In order to design a drug delivery system that helps to address the needs of both the drug and the patient, pharmaceutical manufacturers must consider the interface between the drug, container, delivery device and, of course, the patient. As such, it is critical to consider the ultimate method, location and person involved in the preparation and administration of the medicine.

For the development of any delivery system – and certainly in the development of the SmartDose platform – the following considerations are key:

- **Primary container format:** The selection of a drug's primary container is an important consideration for drug efficacy and stability. Vials may be necessary for initial use, but a syringe or cartridge system may provide a desirable solution for the patient when the system reaches the market. Custom systems may also help to differentiate the product and should be considered early in the development process.
- **Drug/container compatibility:** The container material must be safely and effectively paired with the drug product when selecting the type of primary container. While glass is suitable for many pharmaceutical products, high pH drugs or otherwise sensitive products may require vials or syringes made from alternative materials such as cyclic olefin polymers.
- **Container/delivery system interface:** Once the primary container has been selected, efforts must be made to ensure that it works with the delivery system. Dimensional tolerances and functionality should be tested to ensure proper activation and glide force. If the interface between the primary container and the delivery system is not effectively understood, the performance of the combined system may suffer.
- **Patient interaction:** Perhaps the most essential consideration is how the patient will use the drug delivery system. Even the most innovative drug can only provide the appropriate therapeutic benefit if it can be delivered effectively and the patient adheres to a prescribed treatment regimen. It starts from a thorough understanding of patient needs, including the fact that these needs may change during the journey from diagnosis through ongoing treatment. These same inputs also ensure that risks from user-based errors are identified early in the development process and provide critical user information for risk mitigation measures.

Figure 1: The SmartDose platform.

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TAKING A PATIENT-CENTRIC APPROACH

While developing the SmartDose platform, it became clear that when patients deem a system inconvenient, there can be a negative effect on the emotional attitude and motivation to sustain adherent behaviour. As a result, the SmartDose platform was developed with extensive human factors testing to address potential obstacles to compliance:

- **Improved patient comfort:** The SmartDose platform was designed to maximise comfort throughout the drug delivery process thanks to the hidden 29 gauge needle featured in the automatic needle protection design that prevents accidental needle injuries. Upon safely completing the injection, the SmartDose platform can be easily removed.
- **Keeping it discreet:** Many patients prefer a delivery mechanism that is not visible to others. Special consideration was taken with the SmartDose platform to ensure that it is easily concealed to avoid calling undue attention to the system, creating distractions to others or creating feelings of stigmatisation.
- **Ease of use:** Because injectable medications are administered completely by the patient with the SmartDose platform, the process needed to be so intuitive that only minimal instruction is required. To this end, the SmartDose platform currently allows for the patient to load the cartridge containing the drug. A user-friendly activation button on the front of the device and LED indicator lets the patient know that the dose delivery is in progress.
- **Dose notification:** A critical aspect of the SmartDose platform is its patient-focused design elements that address the possibility a user did not receive the full dose, or did not receive their medication at all. To account for this possibility, the device is equipped with a microprocessor that is designed to offer immediate feedback via a dose confirmation window and visual and audible cues indicating whether the prescribed medication was delivered.

USING TECHNOLOGY FOR GOOD

One way to increase a patient's affinity for their self-injection system – and ultimately increase the likelihood for adhering to a prescribed treatment regimen – is to connect it to another device that they already use: their smartphone. Smartphones and other 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, West understood the vast potential of smartphone apps for helping to improve the patient experience and medication adherence. To that end, West collaborated with HealthPrize Technologies (Norwalk, CT, US) to incorporate its dynamic software-as-a-service platform that engages and educates patients into the SmartDose platform. Through this collaboration, an electronically connected drug delivery system can track when patients take their medication, educate and engage patients to help increase adherence and medical literacy, and reward them for compliance with their prescribed regimen.

THE POWER OF COLLABORATION

Partnering with a company like West that can provide expertise in the field of drug packaging and delivery systems should be an important part of the launch plan for any biologic to be delivered in a wearable system. By developing a thorough understanding of the drug's intended use and the patient's needs, packaging manufacturers can lend their expertise to drug manufacturers to develop a delivery system that differentiates the drug in the market and helps to ensure that the patient's needs are met.

West assists pharmaceutical and biopharmaceutical customers every day in the development of innovative delivery solutions, and there are multiple active programmes at various stages of pre-commercial development utilising the SmartDose platform. Additionally, West is currently in the process of expanding the SmartDose platform to ensure continued leadership and innovation in this area. The next generation of prefilled products will include a preloaded option, with the objective of reducing patient handling steps.

CONCLUSION

Looking ahead, it's imperative that the pharmaceutical industry remains focused on better understanding the interaction between a medication, the drug delivery system and the patients using it, as this relationship may have a substantial impact on patient experience and outcomes. Through close collaboration between the pharmaceutical industry and their manufacturing partners, there is an opportunity to truly innovate the care and experience for patients managing chronic conditions.

SmartDose® is a registered trademark of Medimop Medical Projects Ltd, a subsidiary of West Pharmaceutical Services, Inc. West seeks partners for its SmartDose drug delivery 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.

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 African where he received his undergraduate degree. He is now permanently in the US, where he also received his MBA.

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Wearable Injector

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- Able to link with adherence solutions
- Onboarding and training solutions available

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- Maximize patient comfort through pre-programmable delivery times

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