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NEW HOME-BASED CARE MODELS CREATE CHALLENGES FOR PATIENTS WITH CHRONIC CONDITIONS

In this piece, Graham Reynolds, Vice-President, Marketing and Innovation, West Pharmaceutical Services, first takes a look at therapeutic compliance and shows how truly patient-centric delivery devices can be of benefit. In the context of chronic conditions, he emphasises the importance of an awareness of the patient's journey, and how needs change at various stages from diagnosis and throughout the treatment period.

Patients with chronic conditions are finding new freedom and comfort through self-care at home with injectable drug delivery systems, and will soon be offered new therapies delivered by wearable injectors. But these new home-based care paths pose challenges in ensuring compliance with drug therapies that can require life-long commitments, and often may not offer a perceived short-term benefit.

In fact, the World Health Organization reports that adherence rates for chronic conditions, such as diabetes or autoimmune diseases, are roughly 50% in developed countries. Non-compliance with daily drug regimens can adversely impact the outcomes of patient therapy, and impose significant costs on healthcare providers that could be avoided. It also impacts pharmaceutical companies in numerous ways as well, including lost revenue.

What triggers patients diagnosed with chronic conditions such as diabetes, haemophilia, rheumatoid arthritis or multiple sclerosis to go off their medications? For one, emotions: anger, depression, denial, fear or anxiety triggered by their diagnosis or the realisation that they will be dependent on these medications for the rest of their lives. Another root cause can be con-

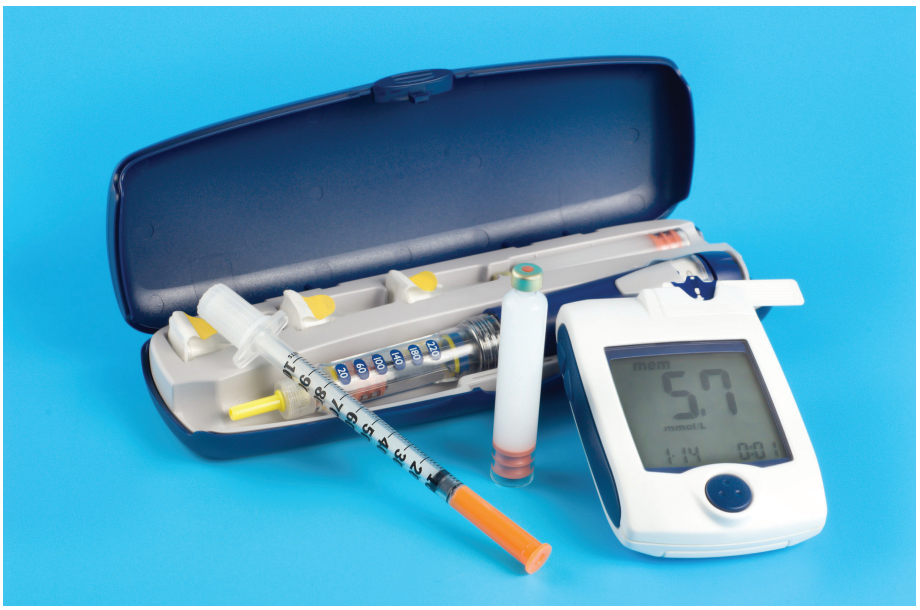

Figure 1: A variety of options exist for diabetes management and insulin delivery, including syringe systems, pen injectors and wearable insulin pumps.

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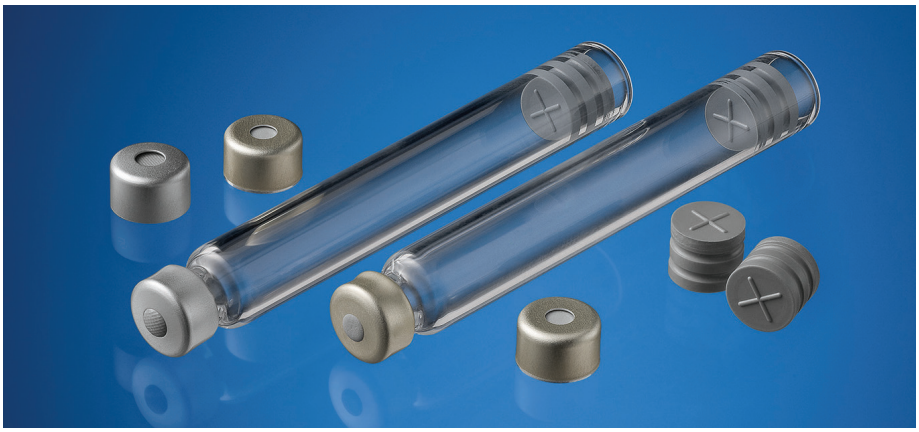

Figure 2: West's insulin pen cartridge components are used by the world's leading suppliers of diabetes therapies.

"When they apply best-practice user-research methodology, pharma manufacturers can gain insight into a user's preferences and emotional requirements; those findings can translate into feature sets and design elements of the drug delivery system"

nected with education: learning the skills associated with self-care can be daunting, especially when it can get more difficult as the condition becomes more acute. Later, as the patient ages or degrades, lapses in therapy may occur due to the physical and emotional burdens of the condition.

CUSTOM DRUG DELIVERY SYSTEMS ENHANCE COMPLIANCE

For most patients, an easy-to-use, integrated delivery and administration system can be key to creating the routines that bring about compliance with care plans. Integrated systems combine the drug, its primary containment system and its delivery system. While many products do this 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. As an example, for a diabetes patient they may transition through a variety of injection systems, from a syringe to a pen, and ultimately to a wearable pump. In addition, their diagnostic method may change from a finger-prick to a continuous glucose monitoring technology (see Figure 1).

When they apply best-practice user-research methodology, pharma manufacturers can gain insight into a user's preferences and emotional requirements; those findings can translate into feature sets and design elements of the drug delivery system. Focusing on the relationship between the delivery system design and the patient interface, pharma manufacturers stand a better chance of satisfying the emotional and physical needs of the intended user/patient throughout the course of treatment.

When drug delivery systems are intuitive and easy to use, they stand a better chance of encouraging adherence because the impact on daily routines becomes negligible. Conversely, delivery and administration systems deemed inconvenient or overly conspicuous can negatively affect a patient's emotional attitude and motivation to sustain adherent behaviour.

Patients also prefer a more discreet device that does not call undue attention to the delivery system and create distractions to others or feelings of stigmatisation. Such a shift from a product-centric focus to a patient-centric focus may help manufacturers design a product that encourages adherence – and brand loyalty – in crowded market segments.

Figure 3: 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 uses Daikyo Crystal Zenith® prefillable cartridges, is designed for the delivery of viscous biologic drugs.

QUALITY IS THE LINCHPIN OF BIOLOGIC DRUG CONTAINMENT

Many new biologics create significant challenges for containment systems, which can impact container and delivery system selection. Sensitivity to certain materials such as silicone oil, metal ions or extractables/leachables will drive the need for a container system that minimises adverse impact of containment materials over time (Figure 2).

Quality concerns regarding glass particles and delamination are driving increased interest in polymer-based systems. In addition, many newer biologics require higher concentrations, leading to higher viscosity and/or higher dosage volumes. In such cases the options include multiple doses of a smaller volume within 10 seconds with a syringe or auto-injector, or a prolonged injection of a higher volume through a wearable injector technology (Figure 3).

Figure 4: West's Mix2Vial® system is the ideal solution for one-piece preparation of powder drugs to be reconstituted by a diluent prefilled syringe.

Understanding all key elements of a drug delivery system provides the cornerstone that enables this system to achieve the goals of encouraging adherence in the home-care environment. The US FDA has provided recommendations for medical device design optimisation through human factors analysis, testing and validation.[1]

ANOTHER CRITICAL DESIGN COMPONENT: HUMAN FACTORS

Human factors experts can help define and prioritise the needs of the intended users and determine what else needs to be learned about user and delivery system interaction. Common methods include qualitative, quantitative and human factors/ergonomics analyses. Discovery research, usability testing, and directional and preference testing offer a strong framework for the development process.

It is also helpful for human factors experts to interview the user in the proper context or environment of use. Someone sitting in a conference room will have a different user experience than a stay-at-home mother who is also taking care of an aging parent.

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Drug manufacturers should seek a partner that can apply proprietary technologies, manufacturing excellence and patient understanding to their drug products and the products' packaging, delivery and administration systems. Such partnerships will help drug marketers offer successful, integrated solutions, benefitting manufacturers, clinicians and patients alike, while helping to ensure optimum adherence and improving patient outcomes (Figure 4).

To get the richest data, human factors experts must follow the patient on his or her journey – from diagnosis to end of therapy – and then translate the multitude of qualitative and quantitative data into features of a product that will not only provide a patient with an intuitive and easy to use delivery system, but also meet the emotions, needs and desires of the user at different stages of disease management.

SAFETY FEATURES: BUILD THEM INTO YOUR DELIVERY SYSTEM

Patient safety at home extends beyond the individual to the family and anyone involved in caregiving. When used, stored or disposed of incorrectly, delivery system containing a needle may cause a needlestick injury for caregivers and/or family members. The healthcare industry has seen advances in needlestick prevention thanks to legislation in both the US and Europe. However, such mandates are limited to the clinical environment.

For home-based care, needle-based systems that incorporate a safety mechanism – or those that are completely needle-free – can greatly reduce accidental needlesticks. Moreover, they reduce the spread of infectious disease, reduce costs associated with care, and help ensure the safety of those who come into contact with the system during disposal.

Patients start their journey with an initial diagnosis, but they travel a long road with a chronic condition. Pharmaceutical and delivery systems manufacturers must start the development journey with this in mind, and create systems and options that will not only help patients learn to care for their condition, but also comply with their prescribed treatment regimens throughout their course of care, with the goal of optimising patient outcomes.

REFERENCE

1. *US FDA, "Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design". June 22, 2011 (www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm259748.htm).*

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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.