EASING PATIENT EXPERIENCE WITH INNOVATIVE LARGE-VOLUME WEARABLES

In this article, Victoria Morgan, Director, Segment Marketing, Global Biologics, West Pharmaceutical Services, discusses the growing sector of wearable injectors, with a specific focus on West's own SmartDose® injector and the value of fill-finish services.

With an estimated 50% or more of the global population living with at least one chronic health condition – such as autoimmune disorders, cancer, cardiovascular disease, diabetes or neurological disorders – patients have an increasing need and desire for easy-to-use and reliable self-administered medications.

Pharmaceutical and medical device manufacturers are answering this call by rapidly developing new solutions designed to benefit the whole person holistically, rather than just their health condition. Modern healthcare seeks to provide patients with more individualised, flexible treatment options. In fact, in the context of the covid-19 pandemic, where many patients are wary about visiting doctors' offices and hospitals, some of these innovative solutions can help patients manage their conditions safely at home.

A GROWING HIGHER-VOLUME TREND

Higher-volume wearables are transforming the patient experience in an especially positive way. Large volume medicines have traditionally been infused or administered intravenously, due to the challenges of getting the required volume of drug into a patient's bloodstream. Historically, self-administration by a user has been unsuccessful for several reasons, including the inherent difficulty of holding a device in place for the required amount of time, the high viscosity of the drug(s) to be administered and the inability of subcutaneous tissues to absorb large drug volumes. Therefore, patients frequently had to travel to clinics and hospitals for treatment.

For patients, this state of affairs causes inconvenience and disruption to daily life, incurs transportation costs and acts as a constant reminder of their disease state, all of which results from the lack of a functional self-administered treatment. Thus, pharmaceutical and device manufacturers are driven to focus on designing cost-effective drug administration processes that prioritise a better patient experience.

The invention of wearable devices and technologies, for example, which degrade the hyaluronan in the subcutaneous space,

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are upstream changes that have met with the downstream desire of patients to have more influence over their disease management.

BENEFITS OF BIOLOGICS

Advancements in technology have allowed for larger volumes to be administered subcutaneously, over a longer period, in a non-clinical setting by ensuring user requirements are at the heart of the patient experience. Pressures on drug formulation and packaging have been particularly relevant in the field of biologic drug administration, which utilises high volume, high viscosity formulations. The new biologics pipeline continues to grow, with a focus on lifecycle management and total cost reduction. The total number of drugs in the pipeline has grown 42% from 2016 to 2019, as has the number of injectables.[1]

Pipeline biologics molecules are often focused on narrowly targeted therapies and small patient populations with reduced side-effects and reduced dosing. Current trends see a consistent growth in approval of combination products with a compound annual growth rate of 13% from 2015 to 2019, according to IQVIA audited data.

With changes in delivery methods for patients targeted towards increasing ease-of-use and compliance, the shift from intravenous therapies to subcutaneous injections is rapidly expanding beyond the diabetes and auto-immune therapy spheres, into blood diseases, cardiology, oncology and other chronic conditions (Figure 1).

Along with new molecular entities, drug development companies are looking to reformulate existing commercial molecules into volumes suitable for a wearable. As shown in Figure 2, these companies are becoming more comfortable with bringing combination products to market. This increase in combination products means more opportunities for device innovation, benefitting pharmaceutical companies, patients and payers as follows:

- For the pharmaceutical company, drug delivery methods can be used to protect market share from biosimilar competition, such as with Neulasta® (pegfilgrastim) Onpro® (Amgen, Thousand Oaks, CA, US).
- For the patient, high-volume subcutaneous injections for chronic indications offer advantages such as less frequent injections, improved adherence and a home setting for a better patient experience.

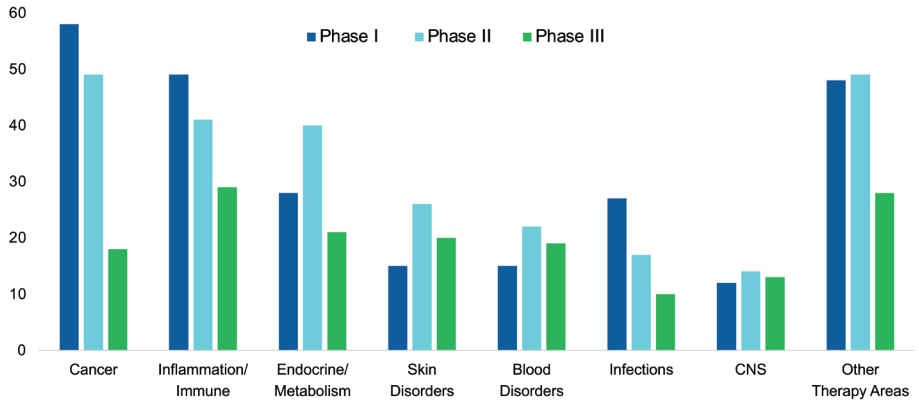

Figure 1: Number of new molecular entity subcutaneous biologics programmes in the clinic, sourced from PharmaCircle.

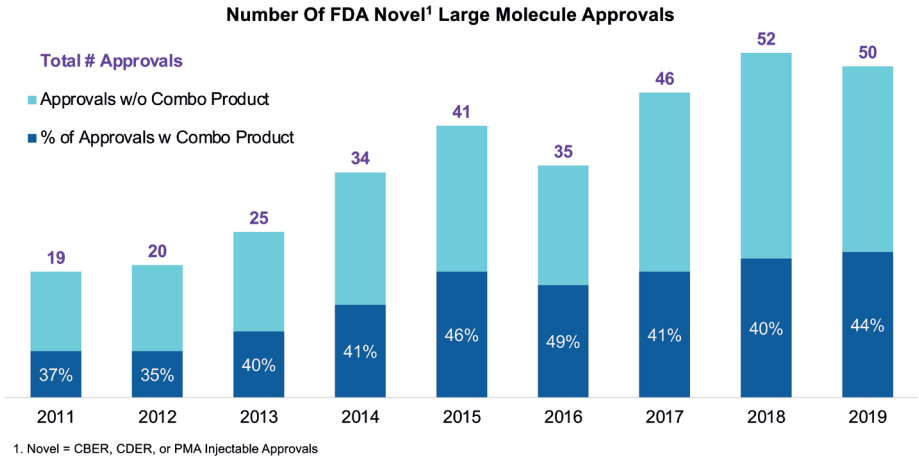

Figure 2: The increase in combination products means more opportunities for device innovation.

- For the clinic/payer, a move from intravenous to subcutaneous drug delivery offers savings including:
  - faster drug prep-time improves pharmacy efficiency[2]
  - fixed dosing reduces drug waste and medication error[3]
  - less set up reduces nurse's time.[2]

WEST'S SMARTDOSE® INJECTOR

West Pharmaceutical Services recognised these trends over a decade ago, and has been investing in wearable technologies since 2010. West's first offering was the wearable and programmable SmartDose® injector, which is a technology used by Amgen today in their Pushtronex® device (Figure 3). Amgen's Repatha® (evolocumab) was approved by the US FDA In 2016 for hyperlipidaemia in the Pushtronex® device. This became the first FDA-approved large-volume wearable for commercial use. Human factors testing showed the design, functionality, size and comfort were all favourable to the patient, whilst simultaneously allowing Amgen to differentiate their offering to the market.

Figure 3: West's SmartDose® 3.5 injector used by Amgen for their Pushtronex® system.

Figure 4: SmartDose® 10 injector.

"West's SmartDose® 3.5 injector revealed a patient need for higher volume, subcutaneous delivery with programmable features to suit the dosing regimen of the therapy. As a result, West expanded its development to a platform of devices, demonstrating the company's commitment to wearable technologies."

West's SmartDose® 3.5 injector revealed a patient need for higher volume, subcutaneous delivery with programmable features to suit the dosing regimen of the therapy. As a result, West expanded its development to a platform of devices, demonstrating the company's commitment to wearable technologies. scPharmaceuticals (Burlington, MA, US) announced its intent to go to market with West's 10mL SmartDose® 10 injector (Figure 4) for FUROSCIX®, a proprietary, subcutaneously delivered furosemide solution, for the treatment of worsening heart failure due to congestion.[4] West's SmartDose® wearable injector provides an outpatient alternative for the treatment. The FDA accepted scPharmaceutical's NDA resubmission of FUROSCIX® in July 2020.

Alexion (Boston, MA, US) has also announced its adoption of the SmartDose® injector for two blood disorder products. ULTOMRIS® (ravulizumab-cwvz) utilises the SmartDose® 3.5 injector to help facilitate at home self-administration for ease of use.[5] The SmartDose® platform helps to provide patients with confidence in their therapy and reduce and prevent the need for frequent visits to infusion centres.

With considerable market traction around the SmartDose® platform, it's clear to see the results from West's early recognition of the trend for larger volume delivery. The SmartDose® 10 injector leverages the success of the SmartDose® 3.5 injector with proven engineering and industrialisation on a larger scale. New features include:

- Up to 10 mL delivery
- Preprogramable delivery times from minutes to hours
- Formulation viscosities up to 100 cP
- Continuous or pulsatile delivery modes
- Training system (Figure 5)
- Filling pathway.

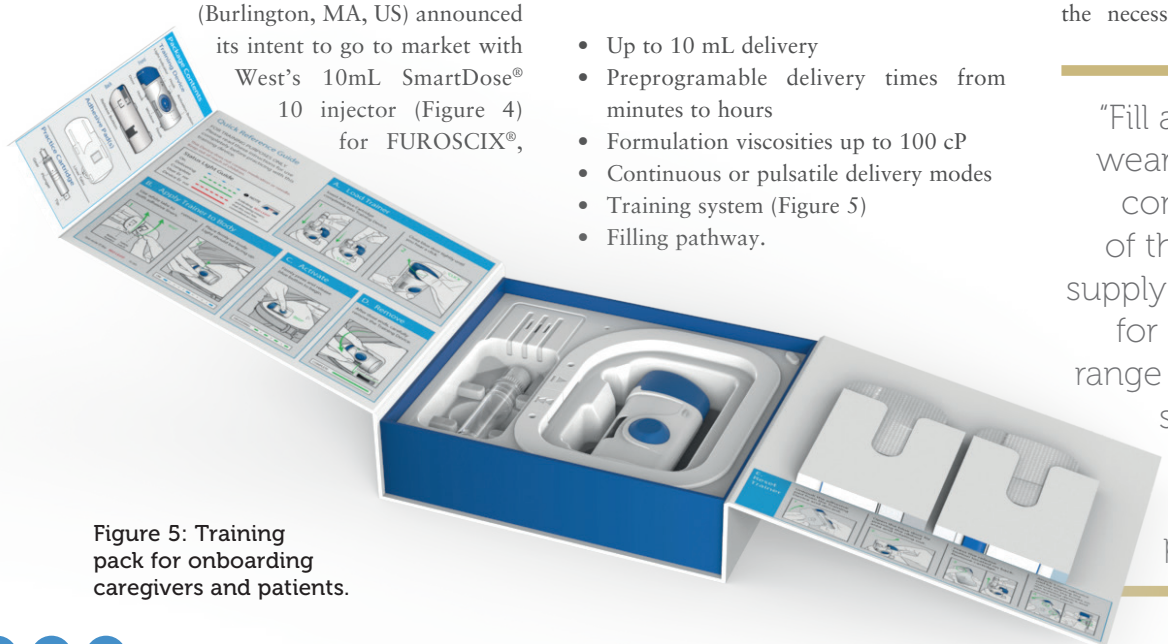

Figure 5: Training pack for onboarding caregivers and patients.

Extensive human factors testing has helped examine these usability and feature enhancements. The comprehensive design incorporated body mass index, age, health status and experience, and was arranged to test design usability, acceptability, comfort, whether the device addressed the patient needs and what was the monthly preference for administration. Study users selected the SmartDose® 10 injector as an acceptable treatment and rated it higher than all of the alternatives, including autoinjectors, visiting a clinic for intravenous injection or infusion, and even multiple doses with the lower volume SmartDose® 3.5 injector (Figure 6).

FILL-FINISH CONNECTS DEVELOPMENT AND DELIVERY

Fill and finish services for wearable containers are a complex yet critical part of the drug development supply chain. Requirements for fill and finish services range from small-scale fills, suitable to take to the clinic, through to commercial scale production volumes. Finding a partner who can support a drug developer's requirements in the right way, at the right time and without risk to the overall development timelines can be time consuming.

Recognising the need to strengthen the device offering and take a more collaborative, integrated approach to supporting a customer has been a key driver for West. When it's time to move an injectable drug product to clinical testing or commercialisation, drug developers need a partner who can provide an integrated solution that will streamline drug product development and provide the necessary expertise and partnerships

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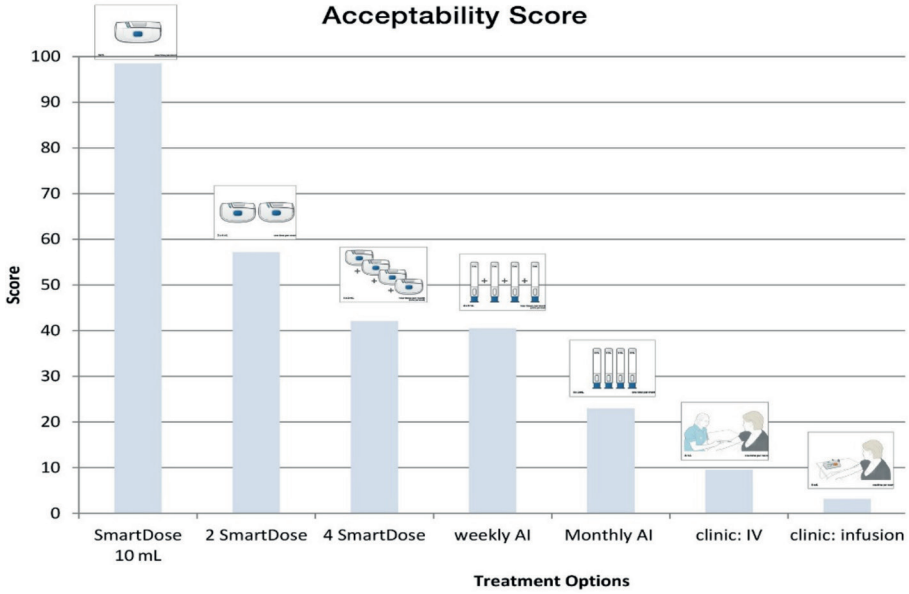

Figure 6: Human factors study results showing SmartDose® 10 injector is the preferred administration route.

to accelerate drug products to market. West is now able to offer in-house small-scale laboratory filling services to help customers with sample preparation for product testing through to product and process characterisation. West can support a drug development company with good manufacturing practice filling at established contract manufacturing organisations, or enable a customer's new fill-line or retrofits in-house.

To further strengthen the offering to customers, West partners with Swissfillon (Visp, Switzerland), a provider of aseptic fill and finish services to pharmaceutical and biotechnology companies. Swissfillon specialises in flexibility, quality and speed, and with expertise in complex biologic fill-finish services, from clinical through small-scale commercial opportunities. Swissfillon enables fill-finish for West's SmartDose® platform of wearable injectors, including the 10 mL cartridge.

Through this collaboration, it is anticipated that West will be able to deliver an integrated solution with filled Crystal Zenith® cartridges for the SmartDose® platform, which is expected to accelerate clinical development and enable customers to bring their innovative injectable drugs to market quickly. This collaboration is expected to offer customers a robust fill-finish manufacturing service.

West has seen many changes over the past decade whilst developing its device platform, enabling fill and finish capabilities and leveraging a wealth of expertise in componentry, devices, regulations and testing as an integrated solution to customers. The appetite for wearables is considerable and West will continue to grow and evolve to predict and respond to the trends to help ensure its customers are providing up-to-date and innovative options for patients.

ABOUT THE COMPANY

West Pharmaceutical Services is a manufacturer of packaging components and delivery systems for injectable drugs and healthcare products. Working by the side of the world's leading pharmaceutical, biotechnology, generic drug and medical device producers from concept to patient, West creates products that promote the efficiency, reliability and safety of the global pharmaceutical drug supply. Additionally, West provides a comprehensive Integrated Solutions programme that combines high-quality packaging and delivery systems with analytical testing, device manufacturing and assembly, and regulatory services to support customers throughout the drug development lifecycle.

West is headquartered in Exton, PA, US, and supports its customers from locations in North and South America, Europe, Asia and Australia. West's 2019 net sales of US$1.8 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.

SmartDose® is a registered trademark of West Pharma. Services IL, Ltd, a subsidiary of West Pharmaceutical Services, Inc. Crystal Zenith® is a registered trademark of Daikyo Seiko, Ltd. Crystal Zenith® technology is licensed from Daikyo Seiko, Ltd.

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ABOUT THE AUTHOR

Victoria Morgan, Director, Segment Marketing, Global Biologics, at West, has been in the pharmaceutical industry for more than 25 years. She has extensive experience across primary and secondary care and the area of injectable drug delivery products, including primary packaging and combination products for vial, prefilled syringe systems, cartridges and devices.

Throughout her tenure at West, Ms Morgan has served in various functions across sales and marketing. Ms Morgan has spent more than 17 years in global sales roles, followed by three years as Director of Segment Marketing, Biologics, at West, where she has responsibility for global biologics strategy development and implementation.

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