THE EVOLUTION OF WEARABLES – REPRESENTING THE VOICE OF THE ENTIRE ECOSYSTEM

In this article, Lauren Orme, Director, Regulatory Policy and Intelligence, Victoria Morgan, Director, Segment Marketing, Global Biologics, and Shari Krusniak, Director, Strategic Marketing, Contract Manufacturing and Integrated Solutions, all of West Pharmaceutical Services consider the current landscape for on-body delivery systems and discuss how West is responding to the demands of various stakeholders.

As with so many aspects of drug delivery post-pandemic, there have been tangible improvements in the evolution of on-body delivery systems (OBDSs). Today, OBDS platforms can deliver higher volumes of medicines subcutaneously that have traditionally required an infusion to be administered intravenously at a clinic under the supervision of a healthcare professional (HCP).

Shifting the focus of treatment away from clinical settings means that patients can benefit from greater choice and control over the management of their disease, but also has wider implications for payers and HCPs in terms of adherence, symptom management and, of course, cost. However, as the evolution of OBDSs continues, regulators have begun to weigh in on the agenda – the updates to the ISO 11608 series of standards, as well as ongoing developments in the guidance issued by regulatory authorities, mean there is a great deal for pharma companies to consider in their OBDS development paths.

> "It is hardly surprising that there is growing interest in this novel and ever-evolving delivery route across the pharmaceutical ecosystem, from pharma companies to payers to patients."

A MARKET RICH WITH OPPORTUNITIES AND SOME CHALLENGES

The global wearable injectors market is projected to reach US$11.6 billion (£9.6 billion) by 2026 at a compound annual growth rate (CAGR) of 9.9%.[1] As such, it is hardly surprising that there is growing interest in this novel and ever-evolving delivery route across the pharmaceutical ecosystem, from pharma companies to payers to patients.

This projected growth can be attributed to several factors, not least of which is the sustained effort to shift treatment from clinical to at-home settings, a factor that was accelerated by the practical difficulties triggered by the pandemic. Indeed, the global home healthcare market is expected to expand at a CAGR of 7.9% from 2022 to 2030 as patient behaviours that pivoted during the pandemic become habitual.[2] Other drivers include the rising prevalence of chronic diseases and advancements in technology that have enabled OBDSs to deliver larger volumes of drugs subcutaneously over longer time periods and in non-clinical settings.

Lauren Orme
Director, Regulatory Policy & Intelligence
T: +1 610 594 3195
E: lauren.orme@westpharma.com

Victoria Morgan
Director, Segment Marketing, Global Biologics
T: +44 1743 341619
E: victoria.morgan@westpharma.com

Shari Krusniak
Director, Strategic Marketing, Contract Manufacturing & Integrated Solutions
T: +1 480 570 9860
E: shari.krusniak@westpharma.com

West Pharmaceutical Services
530 Herman O West Drive
Exton
PA 19341
United States

www.westpharma.com

Non-communicable diseases (NCDs) are the leading cause of mortality and ill health globally and account for seven out of ten deaths worldwide,[3] with a sustainable development goal (SDG) target to reduce premature mortality from NCDs by a third by 2030, relative to 2015 levels. West believes that the market readiness of OBDS platforms that can deliver higher volumes of more viscous biologics is a key step forward in achieving this SDG target.

ADDRESSING KEY PATIENT NEEDS

Established in 2012, patient-focused drug development (PFDD) is a systematic approach to help ensure that patients' experiences, perspectives, needs and priorities are captured and meaningfully incorporated into drug development and evaluation. As experts in what it is like to live with their condition, patients are uniquely positioned to inform the understanding of the therapeutic context during the development of a drug product.[4]

For example, insights from the series of reports into lung and breast cancer from PFDD entitled "The Voice of Patient" highlighted the real challenges patients with these conditions face.[5,6] Cancer and its treatments impact all aspects of patients' lives, with participants in both studies describing limitations in physical activity due to fatigue or pain, as well as the burden of frequent doctor or hospital visits. Indeed, fatigue or lack of energy was highlighted as a key pressure point throughout these patients' treatment regimens, with one participant describing not being able to walk without feeling "like I was lifting up weights".

> "There is a great deal of evidence to suggest that supporting disease self-management offers several benefits to patients, including an increase in overall wellbeing, improved mental health, better clinical outcomes and smarter, more cost-effective use of health services."

There is a great deal of evidence to suggest that supporting disease self-management offers several benefits to patients, including an increase in overall wellbeing, improved mental health, better clinical outcomes and smarter, more cost-effective use of health services.[7] In this context, it is clear that OBDS platforms can play a critical role in delivering a successful self-management approach.

ADDRESSING KEY PHARMA NEEDS

This evolving patient preference landscape inevitably drives how pharma needs to deliver medicines. While patient safety and regimen efficacy are prerequisites for any therapy, adherence and the patient experience have always been high on the list of pharma priorities – ones that OBDS platforms can certainly play a key role in delivering.

From an experiential perspective, all the objections raised about travelling to a clinic or hospital are nullified, along with many of the other common reasons for non-adherence. Advances in therapeutic proteins are also enabling better treatment regimens for patients with cancer, cardiovascular or other chronic conditions, such as Crohn's disease or rheumatory arthritis – in particular by decreasing the required dosing frequency, which contributes to improved patient adherence. This means that the scope for OBDS platforms is also growing as the historic challenges of delivering higher volume, more viscous drugs is increasingly overcome.

ADDRESSING KEY PAYER NEEDS

For payers, OBDS platforms represent a significant potential for change. Currently, these stakeholders are facing several challenges, whether in the form of increasing healthcare costs or the growing level of complexity in personalised healthcare provisions. As payers have already acknowledged, increased patient engagement results in better outcomes, with the net effect often being a lower overall cost of care.

Greater patient engagement, in many cases, comes from patient-driven care in a home environment. OBDS platforms could therefore provide part of the game-changing, disruptive influence payers need as the need for treatment for chronic diseases grows, relieving the strain on healthcare centres by reducing their need for staffing, patient capacity and expensive equipment. Add to that the fact that transitioning from infusion therapies in hospitals,

	Injector	Pump
Dose Delivery Profile	Delivery is comprised of administration of a fixed dose of drug product from a prefilled container in a predetermined time	Delivery is comprised of administration of a fixed dose of drug product from a prefilled container in a predetermined time
Determination of Time and Rate of Delivery	Rate and time of delivery is based on patient tolerability and/or convenience	Rate and time of delivery is based on clinical relevance (e.g. medication efficacy)
FDA-Recognised Consensus Standards	ISO 11608 Series (Part 1–6)*	ISO-26825, Second Edition 2020-10 ISO-7886-2, Second Edition 2020-04 AAMI TIR38:2019 ISO 9626, Second Edition 2016-08-01 ISO 23908, First Edition 2011-06-11
Applicable Regulations	21 CFR 880.5860 – Piston Syringe	21 CFR 880.5725 – Infusion Pump

**Note: Current consensus standards are not defined for product code QLF. The ISO 11608 series is expected to be the approved by the FDA for product code QLF.*

Table 1: Key differences between injectors and pumps.

clinics or infusion centres to at-home care could result in a cost saving of up to 70% for both patients and healthcare payers,[1] and there are many compelling reasons for payers to welcome OBDSs as an important part of the modern healthcare delivery mix.

ADDRESSING KEY REGULATORY NEEDS

Of course, any gains for patients or payers must be realised within the changing regulatory framework. The original ISO 11608-1:2014 has recently been updated for the first time since 2014 and is now in its fourth iteration, providing several new technical updates and a new chapter dedicated to requirements for OBDSs. The ISO 11608 series includes requirements for design verification of the needle-based injection system's conformance with its design specification to a highconfidence level.

Because OBDSs can now deliver larger volumes of a drug product, a key consideration is whether the dose-delivery profile classifies the device as an injector or a pump. Answering this question is key to applying the correct product classification and standards during development, meaning that determining whether a device is a pump or injector should be decided as early as possible in the development process.

Using available information from the US FDA and ISO,[8,9] the key consideration to determine if an OBDS qualifies as an injector or a pump is whether the dose-delivery profile is tied directly to the clinical efficacy of the product. If the drug sponsor confirms that the delivery rate has a significant impact on the clinical efficacy via its clinical study, the OBDS will be classified as an infusion pump, otherwise, it will be classified as an injector. The key differences between injectors and pumps are summarised in Table 1.

THE WEST RESPONSE

As therapies become more complex and self-administration increasingly becomes the new norm, pharma companies are responding by demanding devices that are both more intuitive and capable of delivering more complicated medicines. This all comes against a backdrop of an evolving regulatory landscape.

OBDS platforms offer a range of tangible benefits throughout the ecosystem.

> "With increased market opportunity comes greater oversight, and the evolving regulatory landscape requires pharma and biotech companies to partner with an expert device developer that can help them navigate the development path successfully."

For patients, disruption to daily life is limited, with a growing body of evidence that clinical outcomes are improved via the patient-driven care route.[7] For payers, there is the potential of a very real cost saving. For HCPs, there are reduced treatment times and workloads. And for pharma companies, there is now an opportunity to develop more complex therapies, with higher-volume capacities than previously possible.

Figure 1: The SmartDose 10 OBDS is an adaptive technology for large-dose volumes.

With increased market opportunity comes greater oversight, and the evolving regulatory landscape requires pharma and biotech companies to partner with an expert device developer that can help them navigate the development path successfully. West combines its full-service portfolio of expertise, including device development, containment systems, regulatory support, analytical testing, combination product manufacturing and fill-finish solutions, to enable partners to develop OBDSs faster, more safely and with less risk, all while ensuring that the end product is reliable and usable (Figure 1).

West leverages over 90 years' experience in developing, testing, manufacturing and commercialising containment systems and devices to support development teams in navigating the challenges and mitigate the risks encountered on the path to commercialisation. From preclinical support to post-market launch, West's full-service portfolio, complemented by a range of drug delivery devices, enables pharma and biotech partners to maximise the benefits only an integrated provider can deliver.

ABOUT THE COMPANY

West Pharmaceutical Services is a leading provider of innovative, high-quality injectable solutions and services. As a trusted partner to established and emerging drug developers, West helps ensure the safe, effective containment and delivery of life-saving and life-enhancing medicines for patients. With approximately 10,000 team members across 50 sites worldwide, West helps support its customers by delivering over 45 billion components and devices each year.

REFERENCES

1. *"Wearable Injectors Market by Product Type (On-Body and Off-Body), Therapy (Immuno-oncology, Diabetes, Cardiovascular diseases), Technology (Spring-based, Motor Driven, Rotary Pump, Expanding Battery), Care Setting (Hospitals) - Global Forecast to 2026". Markets and Markets market report, 2021.*
2. *"Home Healthcare Market Size, Share & Trends Analysis Report By Equipment (Therapeutic, Diagnostic), By Services (Skilled Home Healthcare Services, Unskilled Home Healthcare Services), By Region, And Segment Forecasts, 2022 – 2030". Grand View Research market report, 2021.*
3. *"NCD Countdown 2030: pathways to achieving Sustainable Development Goal target 3.4". The Lancet, 2020, Vol 396 (10255), pp 918–934.*
4. *"CDER Patient-Focused Drug Development". US FDA webpage, accessed August 2022.*
5. *"The Voice of the Patient – Breast Cancer". US FDA report, Sep 2015.*
6. *"The Voice of the Patient – Lung Cancer". US FDA report, Jun 2013.*
7. *De Silva D, "Helping people help themselves". Health Foundation, May 2011.*
8. *"ISO 11608-6:2022 – Needle-based injection systems for medical use – Requirements and test methods – Part 6: On-body delivery systems". ISO, Apr 2022.*
9. *"ISO 11608-6:2022 – Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems". ISO, Apr 2022.*

ABOUT THE AUTHORS

Lauren Orme is Director of Regulatory Policy and Intelligence at West Pharmaceutical Services. Ms Orme has over 15 years of experience in the pharmaceutical packaging, medical device and analytical testing services industries. Currently, Ms Orme leads a regulatory team that oversees the monitoring of global regulatory requirements, changes in the regulatory landscape and the implementation of related strategies.

Victoria Morgan is Director of Segment Marketing, Global Biologics, at West Pharmaceutical Services. Ms Morgan has over 25 years of sales and marketing experience in both large pharma companies and in pharmaceutical supply. Currently, she has responsibility for West's global biologics strategy development and implementation.

Shari Krusniak is Director of Strategic Marketing, Contract Manufacturing and Integrated Solutions at West Pharmaceutical Services. Ms Krusniak has over 20 years of experience in medical device manufacturing, sales and marketing. Currently, she has responsibility for West's global services strategic development and implementation.

A Logical Choice for Biologics

Biologics and biosimilars hold tremendous promise to address unmet medical need, but manufacturing these products is fraught with complexity and risk. Having trusted partners with expertise in containment and delivery systems is essential for any company working to bring advanced therapies to the market.

West Is a Trusted Manufacturing Partner

For more than 100 years, West has provided packaging, transportation, storage and manufacturing solutions to pharmaceutical and biopharmaceutical partners all over the world. The success of these partnerships has resulted in the use of more than 112 million West components and/or devices each day, including wearable devices and self-administered injectables. In fact, eight out of 10 biggest-selling biologics rely on West packaging.

West®

You can rely on us, too. Visit our website to learn more or start a conversation.

WestPharma.com

West's SmartDose® drug delivery platform is not independently cleared or approved by any Regulatory Body for general healthcare professional or patient use, nor is it available for general commercial purchase. Its distribution and use are subject to applicable regulatory requirements for clinical investigation, and for marketing authorization, as used in combination with a specific drug or biological product. Each component of a combination product is subject to the requirements established by the Regulatory Body for that component (drug, biologic or device). The regulatory process can be more complicated for combination products including an evaluation of the product characteristics, delivery system and its functionality, as well as the potential for undesirable interactions between the drug or biologic and the delivery system. As a result, we note that the SmartDose® drug delivery platform's compatibility with any particular drug or biologic must be confirmed, and its ability to achieve the desired patient benefits must also be confirmed, on a case-by-case basis in a manner sufficient to meet Regulatory Body requirements.