THE DEVELOPMENT OF THE MOLLY® PLATFORM

SHL Group explores the growth of the Molly® family of drug delivery devices as an example of how the auto injector market has changed over the last five years, and looks to the future – with the growing interest in adding connectivity to the devices to improve the way data can be captured, stored and analysed for the benefit of patients.

The trends in drug delivery are set by the pipelines, technologies and innovations from the pharmaceutical, biotech and healthcare industries. However, when it comes to catching up on the latest technological, societal and regulatory changes, drug delivery companies are often ahead of their customers.

> "...both device manufacturers and pharma companies have to stay well informed of the most important and innovative device features on the market and co-operate in order to bring the best value to the patient."

Recent years have witnessed significant global market growth for injectable drug delivery devices. This trend is expected to continue well into the future. One research study suggests that it will grow from 68.6 million annual units in 2016 to 142 million annual units in 2026.[1] Self-injection devices are expected to grow at a compound annual growth rate (CAGR) of 16.1%, continuously increasing the market share.[2]

What explains this growth? What puts self-injection devices, such as auto injectors and pen injectors, in such a high demand among patients, payers and pharma companies?

There are several explanations behind this trend:

- Growing life expectancy means that people require longer and better care than before. Living longer, we are also suffering more from chronic diseases. According to the WHO estimate, the prevalence of chronic disease will increase by 57% by the year 2020.[3] As chronic disease management is a life-long process, many treatments are moving from hospital to home to increase patients' comfort and to reduce the healthcare spending burden as well as the workload of healthcare professionals.
- Yet another change associated with chronic disease management is the rise of biological drugs. These were already providing 22% of big pharma sales in 2013 and are expected to account for 32% by 2023.[4]
- A steady rise is evident in biosimilars of many top-selling biologics as patents for the original drugs are expiring. Pharmaceutical companies developing both biologics and biosimilars use auto injectors not just as a convenient and user-friendly delivery method, but also for drug lifecycle management and product differentiation.

DEVICE TRENDS

These industry trends mean that delivery devices are becoming an integral part of the healthcare industry. Therefore, both device manufacturers and pharma companies have to stay well informed of the most important and innovative device

SHL Group
#136, Kuo Sheng 2nd Street
Taoyuan
Taiwan
T: +886 3 217 0303
E: info@shl-group.com

www.shl-group.com

Copyright © 2016 Frederick Furness Publishing Ltd

features on the market and co-operate in order to bring the best value to the patient. Some of the current focal points for self-injection devices are:

- **Patient-centricity:** powered by human factors engineering and usability studies, today, both device and drug companies consider satisfying end-user needs to be one of the most important requirements for their products.
- **Seamless commercialisation:** with growing competition in the market of biologics and biosimilars, product differentiation and speed-to-market offers are as important in drug-device product development as technical specifications.
- **The biotech challenge:** the next generation of large molecule biological drugs often requires devices to accommodate larger dose volumes or higher viscosities.
- **Quality and regulatory control:** to ensure safety of patients and avoid financial losses by pharma companies, it is important for device companies to maintain highest quality standards and support their customers throughout the regulatory approval process.
- **Digital health:** the advance of the Internet of Things and availability of connected technologies mean that delivery devices are also entering the digital era.

THE MOLLY FAMILY

Some of these trends are very recent; some have been in the making for quite some time. SHL has always been a pioneer in drug delivery solutions and is very familiar with all the latest tendencies. To follow the development of the market in the last five years, you don't have to look further than the history of one of our most successful projects – the Molly® family. As a family of devices based on the same platform, but responding to different needs and requirements, Molly devices are the perfect reflection of the auto injector market history and direction.

THE NEW PLATFORM

The inspiration behind the first Molly device – Molly® 1.0 – came from both pharmaceutical industry and end-user needs. On the one hand, there was a clear supply vacuum for pharma and biotech companies who wanted to launch the device quickly and with minimum investment. From the patient perspective, the device had to be as safe and convenient as possible. Therefore, we needed a device that offered faster development timeline without sacrificing any essential design features. Also, we needed to minimise the complexity for the patient experience, to make the device intuitive and really simple to use.

> "As Molly® 1.0 has now been approved, our customers can use this device with secure knowledge that it is readily "approvable" from a regulatory perspective. This is a major advantage compared with new devices where there is always some risk of issues being highlighted during regulatory review."

The solution, as the problem itself, was twofold. The two-step operation was a revolutionary solution that simplified the injection process to two simple steps – uncap and inject – without compromising injection experience or patient acceptance. The device is easily activated by pressing down on the needle cover, with activation force optimised precisely for the ultimate user control.

From the engineering point of view, every detail of the mechanical design was thought through to guarantee that all injection requirements could be met. We developed a range of spring options adapted for various drug characteristics and took into consideration potential glass breakage issues by designing Molly® to hold the prefilled syringe by the neck instead of at the flange. Most importantly, SHL's engineers designed a unique power pack that offered the same functionality with significantly reduced number of components. Owing to this innovative solution, Molly® measures only 13 cm – not bigger than a regular prefilled syringe.

BENEFITS

What real value and benefits were created by applying this creative design and engineering? Fredrik Stromvall, Project Leader at the time for the Molly® project, emphasises: "Every feature of this product has been thought out and developed for the benefit of either the drug company or the end-user."

The ultra-compact design makes the device appealing, less frightening for patients and also extremely portable. It makes Molly® more acceptable as a disposable product, reducing the environmental impact during development, manufacturing, transportation and disposal. It even makes the storage easier for the patient, since most biologics need to be stored in the limited space of a fridge.

The simple two-step injection process is extremely easy to learn, requiring less explanation and training (Figure 1). To ensure safety for the patient, the protective needle shield locks as soon as the device is removed from the injection site. Not only does this mean that the risk of

Figure 1: Molly® 1.0 – easy two step injection process.

Copyright © 2016 Frederick Furness Publishing Ltd

Figure 2: Molly® becomes a branded platform – Molly® RNS..

needle injuries is reduced, but also that the patient never has to see the needle exposed, eliminating needle phobia concerns. Jochen Ratjen, Director of Industrial Design at SHL, concludes: "We have observed very high acceptance for the Molly® device in several user studies. Human factors experts also have pointed out that that Molly® is a positive example for good usability."

For pharmaceutical companies the benefits are also numerous. To minimise upfront investment, the platform device business model allows for significant savings on additional tooling, assembly and testing equipment. Molly® consists of a minimal number of components, making the manufacturing process less expensive and more efficient.

As a pre-configured device, Molly® requires significantly reduced timeline for development compared with a completely new bespoke device. At the same time, it still offers customisation of the spring and colour to answer the drug specifications and product differentiation requirements.

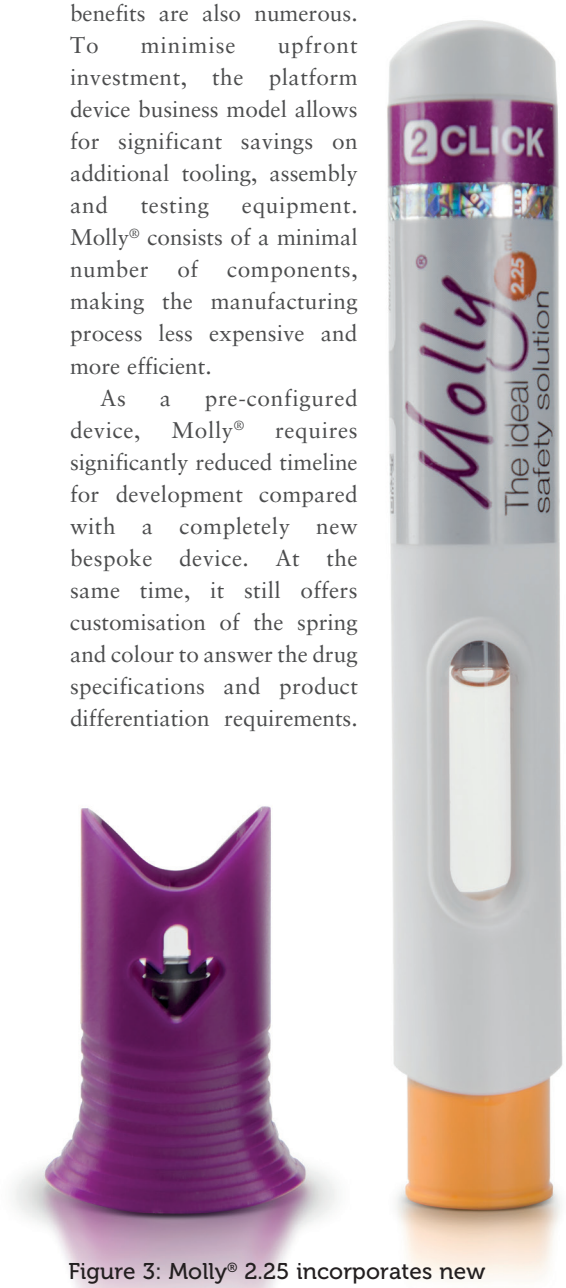

Figure 3: Molly® 2.25 incorporates new design features.

Moreover, as Nicholas Heaton, Executive Director for Business Development Europe, points out: "As Molly® 1.0 has now been approved, our customers can use this device with secure knowledge that it is readily "approvable" from a regulatory perspective. This is a major advantage compared with new devices where there is always some risk of issues being highlighted during regulatory review."

To ensure smooth market launch, SHL also offers robust final assembly, packaging and labelling services to keep all these important stages in-house, thus guaranteeing faster communications, tighter quality control and continuous support of the project management team for our biopharmaceutical partners.

MEETING NEW CHALLENGES

The success of Molly® as a technological solution led to the creation of the whole new branded platform. First, Molly® 1.0 became available with a rigid needle shield – Molly® RNS (Figure 2). However, industry needs kept evolving, and so did the Molly® platform. Mats Persson, Executive Vice-President of SHL, elaborates: "The 1 mL Molly® device has attracted a lot of success and interest since being launched, but increasingly we are seeing new biologics being unable to be formulated into a single 1 mL dose. To meet this need for simple delivery of large doses, SHL has developed a larger version of Molly® to accommodate a 2.25 mL prefilled syringe, enabling delivery of larger volumes with the same simple, easy and proven two-step operation."

To enhance the device's usability and user-friendliness, several design changes were made. Molly® 2.25 has a new rear end and a double-curved cap (Figure 3). They give the auto injector a more natural and ergonomic feel, at the same time ensuring anti-roll features. The new pull- or twist-off design of the cap, enlarged with two flanges, makes it easier to grasp and take the cap off for patients with diminished physical ability.

The result of combining the successful Molly® platform with a larger volume syringe and new design features is a robust and reliable drug delivery solution for larger volume formulations. Due to the success of previous Molly® devices, our partners can be sure that this branded auto injector will be just as safe, easy-to-use and quick to market as Molly® 1.0.

ADDING CONNECTIVITY

The latest big topic in the healthcare industry is digital health and the connected solutions associated with it. Even though the pharmaceutical industry, being quite conservative in its nature, is only taking slow steps in this direction, it is forecasted to be one of the next significant trends in the near future.[5] Connectivity works by providing means to capture, save and share data from an injection device.

Rasmus Renstad, the Vice-President of Innovation at SHL, explains how it could help all stakeholders: "One of the biggest hurdles is low adherence to medication. It contributes to unnecessary suffering for patients and their families. It also results in growing avoidable healthcare expenses and losses for pharma industry. A connected drug delivery device can support all stakeholders by providing real data to analyse. It can be used to enhance patient experience and support and will lead to healthier outcomes and benefits for all parties."

When developing an innovative concept, such as a connected auto injector, it is best to base innovation on a solid foundation of experience. Molly® platform was the perfect choice for the development team to start working with, due to its proven efficiency, usability and reliability.

To connect (C) the device, Molly® has been adjusted with a proprietary interface at the rear end. This interface connects to a reusable recording unit (RU) equipped with Bluetooth technology to transmit the injection data to the user's mobile device.

Copyright © 2016 Frederick Furness Publishing Ltd

The injection data saved can be further shared through the Cloud with as many parties as necessary and used to personalise and enhance patient support programmes.

The Molly® C and RU concept (Figure 4) combines the trusted branded platform device with the breakthrough technology. In addition to all the benefits of the auto injector platform, such as safety, ease-of-use and reliability, this concept also offers benefits of connectivity for multiple stakeholders in the age of digital health.

Figure 4: Molly® C and RU concept combines the trusted branded platform device with breakthrough technology.

THE FUTURE

The Molly® platform has been evolving together with the market – incorporating the most important and necessary design features, finding creative technical solutions, devising new business models to expedite commercialisation and integrating cutting-edge innovation. As we believe that continuous improvement is possible even when the device is already a success, there are already plans to develop the platform in the future. The design of Molly® is going to be further improved for better manufacturability, high speed assembly and next-generation connectivity solutions.

The story of the Molly® family is the story of the self-injection devices market. However, none of this would be possible without SHL's comprehensive in-house capabilities and services and, most importantly, the knowledge and experience of our team.

Drug delivery devices will keep developing hand in hand with biopharmaceutical industry. To keep up with the advance of the next generation healthcare, we will continue to develop solutions for today on the path to tomorrow.

REFERENCES

1. *Global Autoinjectors Market, 2016-2026, Roots Analysis, 2016.*
2. *Injectable Drug Delivery Market: By Devices, Therapeutics & Formulations 2015-2020, Research and Markets, 2015.*
3. *http://www.who.int/nutrition/topics/2_background/en/, World Health Organization.*
4. *Going Large, The Economist, 2015, http://www.economist.com/news/business/21637387-wave-new-medicines-known-biologics-will-be-good-drugmakers-may-not-be-so-good.*
5. *Global Health Care Outlook, Deloitte, 2016.*

Copyright © 2016 Frederick Furness Publishing Ltd

SHL GROUP

How do we meet industry challenges with our drug delivery solutions?

Find out more at 2016 PDA Universe of Pre-filled Syringes & Injection Devices

October 17-18, Huntington Beach, California

Please visit us at BOOTH #411 and TABLE TOP #1

Solutions for Today on the Path to Tomorrow