INNOVATIVE ADVANCED DRUG DELIVERY PRODUCTS AND SERVICES THAT SATISFY FUNDAMENTAL NEEDS

Here, SHL Group first explores the importance of fundamental design principles in injector design, as exemplified by the Molly® auto injector, and then goes on to introduce connectivity and describe how SHL is incorporating connectivity into its devices, via dedicated connectivity innovation program called Alubena™, and the significant benefits this brings.

Pharmaceutical companies and product manufacturers must be acutely aware of trending needs of existing and potential patients, prescribers, payers, and patient-care providers, to be able to provide products that resonate well with these different groups of customers. The relationship between pharma and product makers should also be successful, in terms of launching a successful product that is well received by these customer groups. Thus, it is crucial for manufacturers to produce innovative products and services that help pharma companies differentiate their products and services.

To achieve this, device manufacturers must understand what "innovation" means and how it is measured. In terms of devices, if we look at auto injectors and pen injectors, what makes a good injector? What is needed and what is currently missing in our existing product that has unmet user needs? What is the next step? What can make this product more useful and convenient for the user? Further, how do we stay a step ahead of our customers and predict their needs and preferences? These questions and more should be addressed purposefully as the process is a critical step towards meeting healthcare needs. Often, the best way to approach these questions is to go back to the basics, rediscover the fundamentals, and start over from there.

THE FUNDAMENTALS OF A WELL-DESIGNED AUTO INJECTOR

In the competitive auto injector market, a design and manufacturing company that is able to stand out with a long-lasting product in terms of its presence in the market will be an invaluable partner for a pharmaceutical company.

A successful and sustainable device manufacturer should follow the celebrated ten principles for good design of German industrial designer Dieter Rams. First and foremost, a good design is innovative, which is a principle device manufacturers must adhere to. A good design must be innovative in terms of function, use, and appearance. This is clearly the case for the Molly® auto injector,

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with its revolutionary two-step injection process, making it easy for patients and caregivers to administer a shot comfortably in their own homes. Apart from its essential functions, it is also aesthetically pleasing and extremely portable. According to Dieter Rams, "Only well-executed objects can be beautiful. The aesthetic quality of a product is integral to its usefulness because products used every day have an effect on people and their well-being." This is especially true in the medical and healthcare industry as the products will indeed affect patients' everyday lives.

A good design is also self-explanatory. Much like the Molly® 1.0, the Molly® 2.25 (Figure 1) is designed to be intuitive and self-instructing. Intuitive design is essentially human factors engineering or ergonomics, and clarifies the product's structure. Care and accuracy in the design process involve various case studies to understand user preferences and previously unmet needs. User-oriented design adds both intellectual and material value to a product and in turn increases satisfaction and the life situation of its user. Ergonomically designed products are generally self-explanatory and will be extremely simple to use, which should be the case for patients who use auto injectors or pen injectors on a daily basis. Following the "less but better" concept, SHL eliminates any unnecessary design without sacrificing safety and aesthetics. A good design is always the simplest possible working solution, unburdened with non-essentials and rid of unnecessary waste during the manufacturing process.

LARGE-VOLUME AUTO INJECTORS

Aside from the steadily increasing demands of auto injectors, the market for single-use technology and auto injectors for higher volume and more viscous drugs is increasing. The Molly® 2.25 has a larger capacity than its predecessor, with the same two-step simple operation. The cap is an ergonomic pull- or twist-off design with improved features to prevent unwanted rolling for safety. The ready-made platform Molly® 1.0 was given a new form to become the Molly® 2.25, which is able to effectively deliver more viscous drugs at a higher volume.

Mats Persson, Executive Vice-President of SHL, explains, "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 larger 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."

Figure 1: The Molly® 2.25 auto injector, with its revolutionary two-step injection process, makes it easy to administer a shot comfortably at home. It is also aesthetically pleasing and extremely portable.

As a pre-configured device, the development timelines, business model, and cost will be similarly attractive for the 1 mL Molly® to drug companies looking for the right device for their product.

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As previously stated, the Molly® 2.25 is designed to be as intuitive and self-instructing as its predecessor. However, unlike the Molly® 1.0, the larger version has a new back end, which is covered by a double curved cap; this gives the device a more natural and ergonomic feel and look. The needle shield remover cap is attached to the outer body to improve assembly. Furthermore the cap, which can be pulled or twisted off, is enlarged with two flanges intended for firm grasp (particularly for rheumatoid arthritis patients) and prevention of unwanted rolling of the product. The cap also comes with arrow-shaped cut-outs to further clarify handling directions (Figure 2). The result is a robust device that is easy to handle and improves user experience. Even if the original model is a success, that does not mean it can never be improved. A product can be reinvented again and again, equipped with new or improved forms and uses.

Figure 2: Molly® 2.25 has a much better grip with improved cap design.

CONNECTIVITY FOR ADVANCED DRUG DELIVERY SYSTEMS

Anything innovative these days may involve connectivity. Connectivity is obviously a widespread trend, one we see not only in healthcare, but with the Internet of Things assuming a greater role in our everyday lives, in lighting and home security as well, and so much more. Connectivity has now become a viable means to satisfy a need to communicate, as well as to store and transfer information, for example, through wearable sensors. For a healthcare industry facing many challenges, this can bring value from several different perspectives.

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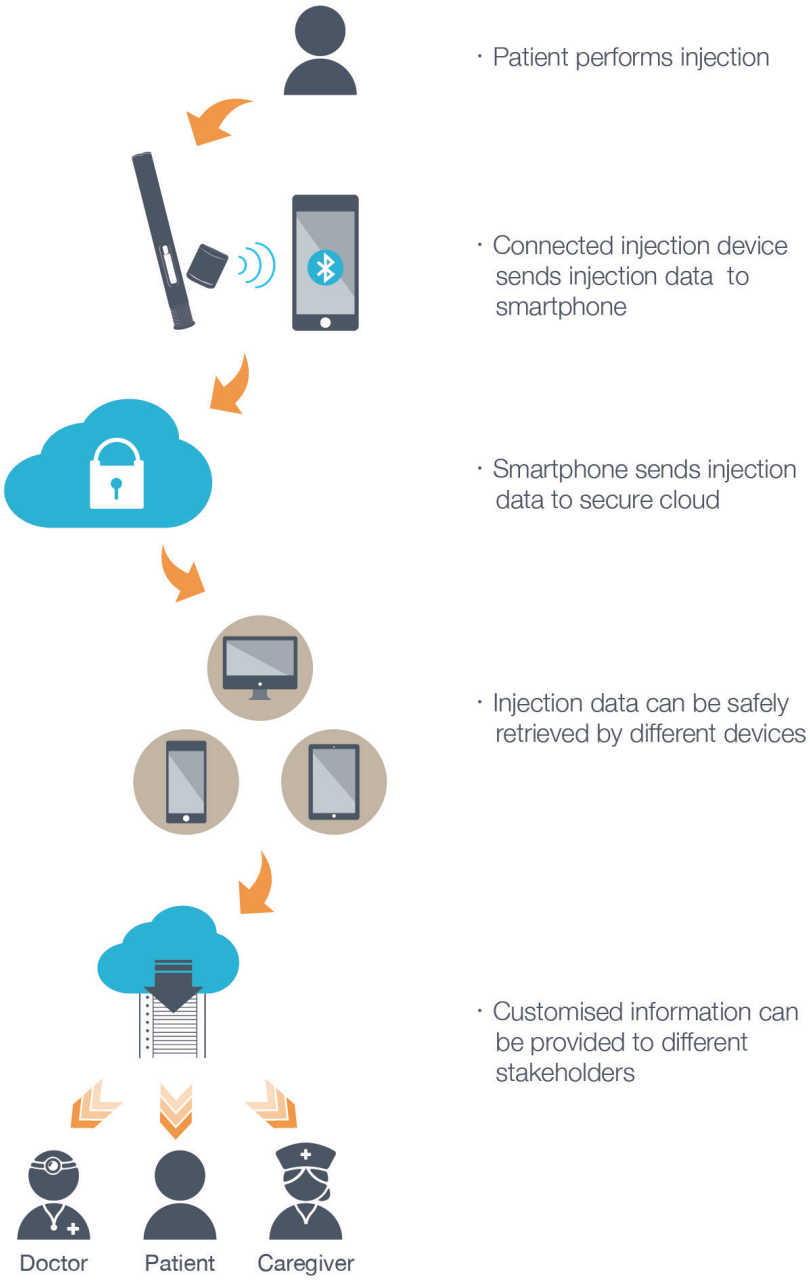

Figure 3: Summary of connectivity concept which enables a connected drug delivery device to enhance patient support programs by providing real usage data.

One of the biggest challenges in the healthcare industry is poor patient compliance. Low adherence to medication is important in many respects. First of all, it contributes to unnecessary suffering for both patients and their families, and also results in large but avoidable healthcare expenses, as well as significant financial loss for the pharmaceutical industry. A connected drug delivery device enables patient support programs by providing real usage data to analyse and personalise the patient's support and experience (Figure 3). The intention is to increase adherence to the prescribed therapy and increase patients' quality of life. Increased adherence will contribute to a healthy outcome, which will benefit all parties involved.

The pioneering devices on the market are stepping away from the traditional mechanical auto injector. With improving technical sophistication, and with decreasing costs, there is more flexibility to develop injection devices further in terms of functionality, usability, and aesthetics. There would be no fundamental changes to the core function, but only in whether the drug is delivered efficiently and effectively. Additional functions should and would only be added to target different patient groups with specific needs.

SHL has developed a connected auto injector concept, the disposable Molly® C auto injector with a reusable recording unit, which enables data recording and transmission to a smartphone via Bluetooth (Figure 4). This is the first initiative by Alubena™, SHL's connectivity innovation program for drug delivery systems.

However, connectivity inevitably raises issues such as protection of patient information, which has long been a focus for healthcare and its relative, regulatory affairs. With technology infiltrating deeper and deeper into our everyday lives, there is no doubt that connectivity will improve patient (and healthcare provider) compliance, but whether the data and information can be handled in a secure and robust system will be the next challenge.

As a current leader in design, development, and manufacturing of auto injectors and other delivery devices, SHL will have an advantage in developing connectivity capabilities, as it has extensive experience developing injection devices and possesses the core knowledge for tailor-made, user-friendly, and safe devices. SHL also has more leverage when it comes to in-house

manufacturing capabilities, exploration of new technologies, and keen market awareness. However, it is still imperative that the manufacturer approach the subject carefully and focus on providing unmet needs, rather than getting carried away with the numerous possibilities for connectivity, some of which the market is not yet ready for. First and foremost, the product must bring real value to both customers and users. Therefore, technology development is significant to a company's growth, but equally important is the ability and capability to develop solutions at different stages throughout the entire product chain.

Today's healthcare organisations need partners who can help design and introduce solutions that deliver care effectively and efficiently amidst evolving reimbursement structures. SHL has worked with many types of organisations, including worldwide international pharma companies as well as smaller organisations with less experience in developing a product from scratch. It is paramount for a device manufacturer such as SHL to learn and progress along with the industry, and develop innovative and good products that ultimately meet the fundamental needs of both customers and patients.

Figure 4: The connected, disposable Molly® C auto injector (a) with re-usable data recording and transmission device (b) which enables transmission to a smartphone via Bluetooth (c).