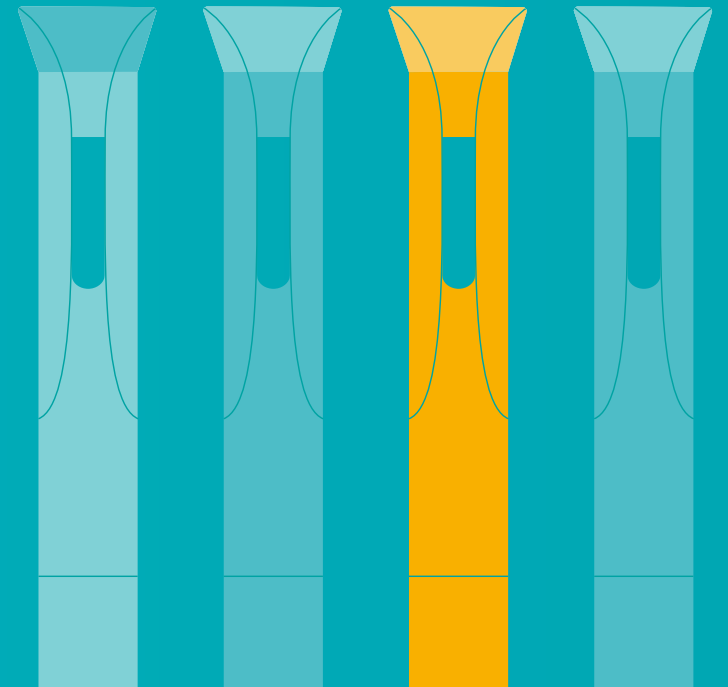# Self-administered injectable drugs: choosing the right delivery device for your product

BESPAK
by Recipharm

# Introduction

Patient experience is a major factor in the success of any drug delivery device. For injectable drug products designed for the patient to self-administer, it's particularly important for patient compliance that the devices are easy to use and cause minimal discomfort.

If a self-administered injector device doesn't offer a positive experience for the patient, they may be discouraged from continuing treatment, undermining its effectiveness, and negatively impacting their health.

It is no surprise that a growing number of pharma companies are opting for auto-injectors and pre-filled syringe devices that can be easily administered by patients themselves, outside of the clinical environment.

However, choosing the right device for self-administered drugs is not without its challenges. Identifying the most appropriate device and optimising it for the unique needs of a drug formulation is the best way to develop products that patients will prefer to use.

In this eBook, we will explore how drug developers can best identify and develop the right drug delivery device for their self-administered injectable products. We will also highlight the potential disadvantages of poorly designed devices.

We will provide practical, straightforward advice around choosing the right device for the needs of self-injected products, and the considerations that need to be made to ensure optimum performance and long-term patient acceptance as well as highlight the added value of engaging device experts early in the design and development process.

## Content

▶ Improving patient experience with self-injectable drug devices

▶ The challenges

▶ Overcoming obstacles

▶ The benefits of expert collaboration

▶ How Bespak by Recipharm can help

▶ Summary

# Improving patient experience with self-injectable drug devices

In their daily lives, patients are used to consumer devices that are easy and enjoyable to use. Medical devices designed for self-administration, especially injectables, need to be similarly convenient to encourage patients to persist with their treatment. In particular, the patient needs to experience minimal pain and discomfort. They also need to be able to administer their treatment at home, without disrupting their daily routine.

Today, patients are increasingly familiar and comfortable with smart innovations, such as connectivity between devices with the Internet of Things (IoT). Medical devices that connect to a smartphone or other computer can improve patient satisfaction by allowing their clinician to view information about how patients take their drugs and use the information to potentially adjust their dosage, which in turn can reduce side effects, and increase drug effectiveness. The IoT can also be used for patient reimbursement, especially for insurance-based healthcare systems, such as in the USA.

Self-injectable drugs are also becoming more common because of the growth of biologics, dominating the best selling drug product lists due to their effectiveness for a number of autoimmune diseases such as Rheumatoid Arthritis and Psoriasis, where patients administer the drugs themselves. Given the growing pressure on the limited capacity in the clinic and hospital environment for healthcare professionals (HCPs) to administer drugs to patients, there's been a shift towards products that can be self-administered in the home.

The self-administration market is growing for injectable drug delivery and as a result, there's been an evolution in delivery devices. Pre-filled syringes have grown in popularity due to their convenience, and are now being replaced by auto-injectors, which are more acceptable to patients with needle phobias. There's also been a growth in connectivity to help patients track their doses.

All these developments are spurring more and more drug companies to develop new drugs for self-administration.

In 2019, according to Pharma's Almanac[1], the global market for all non-oral drugs was estimated to be expanding at a 6% compound growth rate (CAGR) and is expected to reach a value of $802 billion by the end of 2029. Bringing these innovations to market presents unique challenges that drug developers must overcome.

1. https://www.pharmasalmanac.com/articles/trends-shaping-the-dynamic-market-for-parenterals

# The challenges

There are several obstacles that can impact the successful delivery of self-administered drugs.

## Delivery device selection

It is crucial to identify the most appropriate device for delivering the drug while maximising patient experience. This process can include ensuring the formulation is compatible with the physical characteristics of the device, requiring time and resource to ensure both work together for optimum delivery performance.

For example, it's important to mitigate the self-administration challenges posed by high-viscosity formulations. These are becoming increasingly common in the pharmaceutical industry due to the rise of biopharma treatments. The biologics market is expected to grow from $244.1 billion in 2019 to $546.6 billion by 2027, at a CAGR of 10.6% during the forecast period from 2020-2027[2].

Biopharma formulations tend to be more viscous than those for small-molecule active pharmaceutical ingredients (APIs), due to their larger molecules. The entanglement of these long-chain molecules causes the higher viscosity.

Higher viscosities can also be the result of the aim to reduce frequency of injections, which often leads to higher doses and subsequently higher concentration and viscosity to maintain the injection volume low enough for an auto-injector.

Viscous formulations are difficult to deliver using the fine needles traditionally incorporated into self-administered injection devices. They require additional pressure, which can be difficult for patients to apply and can put stress on the device that can raise the risk of the device breaking. Using a thicker needle can reduce the pressure needed, but is not a desirable option as they can generate undue pain and discomfort for the patient during administration.

## Supply chain complexity

As commonly experienced when adopting any new formulation or delivery mechanism, the supply chain for new drug delivery devices can be complicated to manage. Managing multiple supply partners is a serious challenge that needs to be addressed. Mitigating against unforeseen issues, such as disruptions to the supply of raw materials for devices is also something that needs to be considered.

## Intellectual property

When developing business cases for injectable products, companies must pay close attention to intellectual property. For example, developers must navigate the intellectual property landscape to ensure freedom to operate (FTO) and may consider the exclusive use of patent-protected technologies to maximise market share.

Failure to address these issues could delay the product reaching the market, or result in a poor business case with low financial return.



2. https://reportcrux.com/summary/2868/Biopharma-Market#:~:text=The%20Biopharma%20Market%20is%20estimated%20to%20grow%20from,disease%20burden%20and%20 increasing%20tendency%20toward%20targeted%20therapy

# Overcoming obstacles

When considering the delivery device for a new self-administered medication, drug developers need to ask themselves several critical questions.

### Useability
First, does the device truly enhance useability, convenience, and comfort for the user? For example: Needle phobia is a common condition among patients, making them reluctant to take injectable treatments if they consider the needle is too large. This can be overcome by selecting an auto-injector with a hidden needle and push-on-skin operation, which can remove the needle from view, helping to allay patient fears prior to administration. Such a feature can also help reduce the risk of needle-stick injuries for both patients and caregivers.

### Cost-effectiveness
Evaluating cost effectiveness of the device can be more complex than first thought. For example: Can the device drive user preference and thus market share? Does the device facilitate access to broader patient groups? How does the device fit with the broader drug portfolio – are you looking the most cost-effective device for a particular drug product or are you evaluating across your portfolio and seeking a device platform available for multiple drug products where branding value is important?

### Compatability
Drug developers also need to consider whether the physical characteristics of the device are compatible with the drug formulation. This can be because of its potential for chemical reactions or the risk of stability problems, due to storage issues and a shortened shelf life. As one example: Our Syrina® AS auto-injector can be used with both 1ml and 2.25ml pre-filled glass or COC/COP syringes, providing flexibility and choice for customers to select the optimal primary packaging material for their drug product and its stability requirements.

### Adaptability
The device also needs to be easy to adapt and customise to the unique needs of the drug formulation and the patient population that will be using it. For example: Is the power source for the auto-injector easily adjusted to deliver formulation through a wide range of needle sizes, fill volumes and drug delivery times?

### Patient friendly
Patient experience is crucial to choosing a delivery device. For example: Does the device clearly indicate – perhaps using an audible 'click' – that the patient has finished injecting the dose. Is the device fully automated once the patient has pressed it onto their skin?

### Viscosity
If the formulation has a high-viscosity, the device technology also needs to be capable of administering high-viscosity injections. Using auto-injectors designed specifically for that purpose can help to optimise the delivery experience, increasing convenience for patients which ultimately help increasing adherence with the regimen.

### Manufacturing and distribution
Finally, the drug developer needs to consider the manufacturing and distribution process. Can the device be easily manufactured at the required speeds and volumes to meet the development and final manufacturing needs of the finished drug product?

# The benefits of expert collaboration

Working with the right development and manufacturing partner, with expertise in injectable drug delivery device development, can help pharma companies streamline the device development process.

An injectable device specialist can provide guidance on developing and customising devices to fit the drug formulation and meet the needs of patients. Especially companies with broad experience in developing proprietary devices can help navigate issues around intellectual property, evaluate FTO and can develop unique, patent-protected delivery devices designed to optimise patient experience.

For example, we have a patent portfolio that includes auto-injectors that can be customised to the needs of our clients. Our VapourSoft® Technology is extremely flexible in its function, meaning that its performance can be tailored according to drug viscosity, needle size, fill volume and drug delivery time.

Moreover, by working with an experienced manufacturing partner with established, proven technologies and devices, drug developers can rapidly ramp up production of drug delivery devices to meet patient needs during clinical trials or for commercialisation.

## Key benefits

▶ Managing complex supply chains

▶ Mitigating risks

▶ Regulatory expertise

▶ IP/patents

# How Bespak by Recipharm can help

Bespak by Recipharm is an ideal example of a specialist in the development of high-performance self-injected devices. We offer a range of self-injection devices, including *Syrina® auto-injectors* with our patented *VapourSoft® technology*.

Our Syrina® auto-injectors come in multiple specifications, including the Syrina® AS auto-injector and Syrina® Viscala auto-injector for ultra-high viscosity formulations. Our innovation portfolio also includes our proprietary spring-powered auto-injectors with ASI® technology used in multiple launched auto-injectors, available for customer specific programs for aqueous to medium-viscosity solutions. Each of these products can be further customised to meet our clients' needs.

We offer a custom design process for clients who need an innovative and bespoke solution to medical devices for self-injection. We also provide bespoke solutions for large-scale manufacturing for clients who have a device design that needs scaling up from pilot study to clinical trial or taking to market.

**Bespak by Recipharm** is part of the service offering of Recipharm, a large and leading contract manufacturing and development organisation (CDMO). As a market-leading manufacturer of innovative drug delivery devices, we support companies looking to create patient-friendly self-injected therapies.

We offer collaborative and tailored solutions to self-administered drug design and development. These start with a concept and feasibility stage and move through multiple development and validation stages to product launch. Each stage is led by a dedicated risk manager and is designed to comply with regulatory requirements.

We also offer a range of innovative and unique self-injection technologies and devices. These can be customised to customer requirements and scaled up from pilot level to commercial scale. For each project, our customers benefit from Recipharm's expertise as a leading CDMO with expertise throughout the drug design and development process: from formulation to analytical development and commercial manufacture.

We are part of a wider Recipharm service offering, our customers can access specialists with a broad range of skills, helping them streamline supply chains and reduce their time-to-market. As a global CDMO with headquarters in Sweden, and local sites spread across Europe, the US, India and Israel, Recipharm is a reliable and trusted partner for pharmaceutical companies at all stages of development.

## VapourSoft® technology

VapourSoft® technology uses a miniature canister containing liquefied gas to power a range of devices, including Syrina® auto-injectors and Micro Assisted Syringe. The gentle release of a pressurised vapour is capable of delivering high-viscosity drugs with low user effort and minimal discomfort. As a flexible energy source, VapourSoft® can be tailored to a variety of syringe sizes, drug viscosities, needles, fill volumes and drug delivery times.

## Syrina® auto-injectors

Syrina® auto-injectors are market-leading products that use VapourSoft® technology for quiet discreet operation and a compact design. The Syrina® auto-injectors can deliver high volumes of highly viscous drugs in a short delivery time. By doing so, the Syrina® AS and Viscala address many of the issues seen with traditional auto-injectors, such as patient discomfort.

## Spring-powered auto-injectors

We also offers spring-powered auto-injectors with proven ASI® technology for customer specific programs. These auto-injectors are designed to deliver aqueous to medium-viscosity therapies while keeping needles hidden from view.
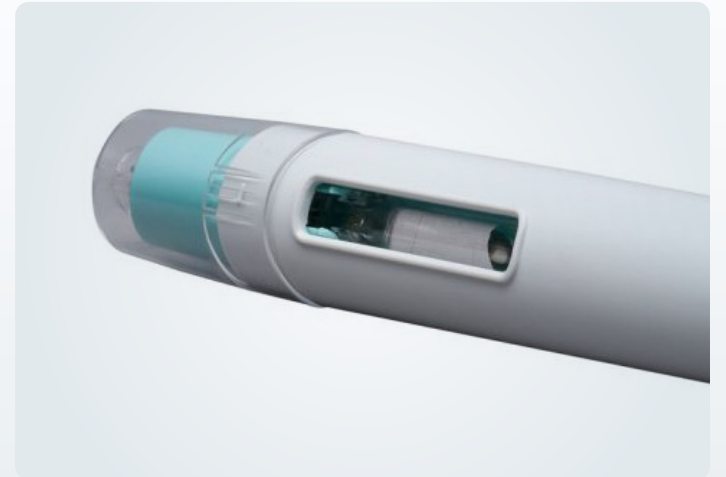
# Summary

Self-administered injections are a popular and growing area of drug delivery due, in part, to the rise of biological therapies. Choosing the right delivery device can improve patient experience and ensure long-term compliance to a therapy, which increases the drug's market share, improves clinician buy-in and enhances patient health.

There are a wide range of factors to consider when selecting a delivery device, including drug viscosity and stability. Each of these can potentially affect patient comfort and convenience when delivered through a sub-optimal delivery mechanism, such as slow release of a high-viscosity drug through a thin needle.

We offer a wide range of drug delivery devices for self-administration, all of which can be tailored to customer requirements. These form part of a wider Recipharm offering of services, ranging from drug design to commercial manufacture, which – together – can reduce time-to-market and simplify supply chains.

By working with specialists like Bespak by Recipharm, drug developers can be confident they can overcome drug delivery device obstacles, ensuring they deliver an effective self-injection product that transforms patients' lives for the better.

To find out how we can support your self-injected product, contact us today:

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