Impactful product strategies for injection devices

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04 March 2019

In recent years, injection delivery devices became the state-of-the-art for homecare self-injection therapies. In fact, many injectable drugs are now dispensed directly to the patient for self-injection at home with the help of a device supporting the drug delivery. Consequently, the competition for pharma companies became tougher in this product segment as well. In fact, pharma companies and device manufacturers are struggling for their position in the market and both industries are dealing with global competition in increasingly competitive markets.

Diverse differentiation strategies have been put in place to effectively compete, such as for example a plethora of innovations or low-cost products. Many pharmaceutical companies are defending their ethical or "originator" products' market position with the most innovative devices on the market. In response, biosimilar developers are trying to develop similarly innovative combination products while at the same time attacking the originator and biosimilar competition on price.

Innovation as a differentiation factor

The first driver for innovation is **patient needs**. An example is the reduction of the injection frequency with once-weekly or once-monthly therapies that will be much preferred by patients and HCPs in an effort to reduce the burden of the therapy, the pain associated with the injection, and the cost for the therapy. As a caveat, many of these new formulations are sensitive to shear forces, are delivered in larger volumes or in higher concentrations.

➔ These new pharmaceutical products will obviously require different and more sophisticated injection devices. Often the injectable volume will increase and/or the drug may be more concentrated and consequently more viscous. The devices will need to accommodate larger drug containers and higher forces to inject the drug, which on the other hand may be sensitive to shear forces. Responding to these needs, the device manufacturers developed solutions for such applications in the form of larger autoinjectors (e.g. 2.25 ml) tolerating higher injection forces, or more recently patch bolus injectors.

A second and equally important driver for innovation is **product lifecycle extension**. In fact, as originator products come closer to the end of patent protection, the lifecycle of the pharmaceutical product may be extended with a new indication, reformulation (such as liquid stable vs. an initial lyophilized formulation), or a change to the route of administration (from intravenous to subcutaneous or intramuscular). A poster child example for effective product lifecycle management is pegfilgrastim. Originally, the active substance filgrastim (Amgen's Neupogen®) has been administered once-daily from vials or prefilled syringes and then subsequently has been reformulated as a long-acting form with the INN pegfilgrastim (Amgen's Neulasta®) offered in prefilled syringes with needle safety device. More recently, this product is now being offered as a wearable on-body device kit. The next step that can be anticipated will be the delivery from a prefilled version of the wearable on-body injector in an effort to keeping one step ahead of biosimilar competition, even if there is little tangible benefit for the patient. Each step up on the lifecycle management escalation ladder comes with significant new complexities associated with such devices, and embedding of new features like hardware, software and automated functions.

➔ When devices are becoming more and more complex, the devil is in the details of requirements engineering. Traceability of all requirements has to be ensured all the way through design output, risk management, design verification and design validation. As a consequence, there is a new need for pharmaceutical companies developing biosimilars using complex delivery devices to have a strong quality management system (QMS) in place, as well as solid requirement engineering processes in order to succeed in such complex and demanding projects. The same applies for device manufacturers developing and supplying such devices.

Several new drug products are being developed with **different doses setting** depending on the patient's body weight in order to improve the drug efficiency, ensuring tolerable side effects and delivering a tailored dose instead of a one-size-fits-all dosing. This can be considered a first step towards more personalized medicine.

➔ This again creates additional challenges in the development of appropriate injection devices. In this situation, a suitable device cannot be sourced off-the-shelf but rather has to be developed and tested properly. It is therefore also important to develop the right test protocol. Moreover, usability engineering as well as appropriate and understandable product labelling is becoming increasingly challenging in order to guarantee that the patient receives the correct dose.

In addition to such device innovations derived from the drug's properties there are also new features becoming available as part of the device in an effort to enhance the patient's experience and to strengthen the market position of the combination product.

An additional hot topic at the moment is **device connectivity**. Arguably, the primary objective is less clinical effectiveness but rather the goal to make the therapy more pleasant for the patient in the form of helpful reminders and attractive history graphs. However, there is also an intended clinical benefit especially in the form of better adherence or for data logging in clinical studies. When engaging in this field you need to be prepared to compete with sophisticated technological companies and non-traditional pharmaceutical firms! Indeed, several IT companies are now developing data analytics and applications related to device connectivity.

➔ The compliance with regulations for such features can be a very significant challenge. For instance, the new Medical Device Regulation (EU 2017/745 MDR) requires significantly more clinical evidence to demonstrate the efficacy and safety of a medical device. This has to be taken into account during product development, when planning for data handling, integrity and analytics. Nevertheless, it can be expected that in the future data about patient usage will deliver a strong argument for payers turning to outcome-based payment models.

Finally, the **usability** of the device always becomes much more important, obviously for regulatory compliance, but also for marketing purposes. The patient-centric approach of most pharma companies requires more user-friendly devices and more ergonomic shapes tailored for the specific indicated use of the device.

- ➔ It is important to note, that human factors engineering has to be considered from the early phases of development throughout all development phases all the way through design validation, not limited to the device itself, but including the complete packaging and labelling.

- ➔ From a marketing standpoint this will be a trade-off between having a device from a standard platform at lower cost, quicker development and lower risk versus investing in longer dedicated device development with a unique design of the final product. Device manufacturers will have to build flexibility into their production process in order to offering customization options to their customers. On the other hand, the project manager or the project sponsor has to on-board the marketing representative early enough on the project.

Pricing challenges in different markets

Coming back to alternative product strategies, the other main differentiation strategy used by pharmaceutical companies is differentiated pricing. Obviously, it applies to both the originator and biosimilar products once biosimilar competition has been admitted to the market, however also to emerging markets. Finally, it also applies to originator products due to payers' policies and pressure (for example in tender markets or in order to get onto a formulary in the important US market).

This price competition is also a powerful innovation trigger for the injection device industry. Most of the biosimilar developers are sourcing devices from existing platforms and therefore apply significant cost pressure on the device manufacturers. As a consequence, it is a must nowadays, not only to be able to offer low-cost devices, but also to have more efficient processes in order to successfully bring competitive products onto fully developed and rapidly maturing markets.

- ➔ It is mandatory for pharmaceutical companies to think about manufacturing processes early on when developing a new product under cost pressure. The alliance management with the device supplier and the CMO is a key success factor when it comes to tackling all the potential issues.

- ➔ The device manufacturers and the CMO can only compete on such low-cost markets with a platform approach where they can deliver compliant products to different customers for different clinical indications from the same device platform with minimal changes. The processes, the documentation structure and the design verification have to be adapted to work for this business model.

Finally, the new European regulation for medical devices, the MDR will also impact the different device strategies and can be expected to rather slow down development of more complex devices. This may convince pharmaceutical companies to stick to known injection solutions for a longer period of time. In fact, the uncertainties related to the new regulation are increasing the risk for project sponsors who may become more reluctant to adopt and use new technologies.

anteris helvetia can support you

The injection device market is moving quickly and operating in this market is exciting. All the challenges of device and combination product development and registration turn into opportunities if you are well prepared and supported!

Thanks to the broad and deep experience of the associates of anteris helvetia AG and its independent sister company anteris medical GmbH in Germany, we will help you tackling all the issues related to your injection device development, registration and launch.

We will help you identify the most suitable injection system, support the technical documentation of requirements, risk management, design verification, and design validation, and last but not least, we have experienced regulatory experts for the registration of your product in most major markets.