Product Differentiation: The Prize for the Winning Drug–Device Combination

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The abbreviated approval pathway for follow-on biologics gives innovators and follow-on companies alike an incentive to distinguish their products from those of their competitors. One way for an injectable biologic to stand out is to be sold with a novel device that is comfortable for patients and improves compliance. Antares Pharma (Ewing, NJ) developed a needle-free delivery device to deliver Teva Pharmaceutical Industries's (Petach Tikva, Israel) Tev-Tropin, a human growth hormone originally administered with a needle and syringe. To find out about the regulatory, formulation, and manufacturing considerations involved in the transition, *Equipment and Processing Report* talked to Paul Wotton, CEO of Antares Pharma.

EPR: What technical considerations must be examined before moving from a drug-delivery method such as a syringe to an autoinjector or needle-free injection device?

Wotton: You have to show that the injection you're giving with the new delivery device gives you the same clinical performance as the needle-and-syringe version of the drug. You also have to show that the patient can use your device. A company that wants to launch a generic version of a drug marketed in a device must also prove to the US Food and Drug Administration that the patient will use the new device the same way he or she uses the original device.

EPR: Does the product's formulation need to be reevaluated when a company moves to a new device?

Wotton: The formulation that's used in needle-free Tev-Tropin is exactly the same as that delivered by the needle and syringe. You might need to change the formulation of a very viscous product, for example. But I would not recommend changing the formulation to fit into a device. You're better off trying to reengineer the device to accommodate the formulation.

EPR: Is that because of the clinical studies required for reformulated biologics?

Wotton: You'd have to do studies to show that the new formulation is the same as the old one, as well as show that the change in delivery method hasn't affected the performance of the drug. On top of that, if you change the formulation, you'd have to go back through some of the pharmaceutical development work and stability studies to show that the new formulation behaves the same on storage as the old formulation in every sense.

EPR: Do a biological's properties affect the kind of device that a company can choose?

Wotton: Highly viscous products such as antibodies cannot be delivered with certain devices. The main consideration is engineering the device to deliver the drug through the needle's small orifice. Sometimes you need a device that delivers the drug with the right amount of force at the right time. Our Vibex autoinjector is capable of giving biological products subcutaneously, even if they're highly viscous. A strong force has to be maintained over the correct interval of time to deliver the drug from the device.

EPR: Is it more challenging to develop a drug for delivery through a needle-free device than it is for delivery through a syringe?

Wotton: The challenges can be different for a needle-free injector. You can deliver viscous products through a needle-free injector, but you have to treat it on a case-by-case basis. You probably would find it more difficult to deliver a viscous drug with a pen injector such as those used with [Eli Lilly's (Indianapolis, IN)] Byetta. It would be hard for a patient because a pen injector is not necessarily mechanically assisted like an autoinjector is.

EPR: What other drug properties might influence a company's choice of device?

Wotton: Another consideration is the volume you need to deliver, in the case of a subcutaneous injection. You could use either a needle-free injector or an autoinjector to deliver a drug that's given in a volume of less than 1 mL. But if you were looking at a volume of more than 2 mL, then that would rule out most needle-free approaches and force you to use an autoinjector.

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The force you need to deliver 2 mL from a needle-free injector is quite high. This approach puts a lot of volume into the skin using needle-free delivery technology, which is difficult to do. An autoinjector, which has a needle and goes through the skin, is a more precise way of delivering [the drug] subcutaneously.

EPR: Do you foresee more manufacturers pursuing new devices to deliver their biologics?

Wotton: The injectable market is growing. Everyone's focused on the biosimilar market because it's a large market opportunity, but many small molecules could be delivered better using autoinjectors, for example. Devices provide an intelligent way to differentiate a product in the biosimilars segment, as our experience with Tev-Tropin has shown clearly. We also believe that some small molecules are not being delivered adequately today. We think that there's a huge opportunity for developing drug–device combinations that make it easier for patients.

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