



DRUG-DEVICE CO-PACKING SOLUTIONS TO ENHANCE DIFFERENTIATION AND IMPROVE EXPERIENCE

In this article, Janice Adkins, Associate Director, Global Marketing, BD, discusses the benefits that co-packing, the practice of providing drug preparation and delivery systems along with a medication, can bring to pharmaceutical manufacturers, clinicians and patients.

A WELL-ESTABLISHED SOLUTION TO AID IN MEDICATION ADHERENCE

With medication nonadherence estimated at 50%,¹ packaging solutions have emerged as useful tools to help patients manage their therapies. Several studies have suggested an adherence benefit as a result of packaging interventions, such as calendarised blister packages.²⁻⁶ In addition to adherence packaging, some manufacturers have employed co-packing strategies to facilitate improved adherence to medications that are co-administered. Examples include:

- Kisqali® (ribociclib) and Femara® (letrozole) Co-Pack for breast cancer by Novartis (Basel, Switzerland)
- Viekira Pak-RBV® (ombitasvir/paritaprevir/ritonavir, dasabuvir and ribavirin) for hepatitis C from AbbVie (Chicago, IL, US)
- Orkambi® (lumacaftor/ivacaftor) for cystic fibrosis from Vertex (Boston, MA, US).

Not all of these packaging configurations are complex, with some involving a simple “box within a box” design.

Co-Packing Medications With Devices

The growing number of self-administered, parenteral medications entering the market with large volumes, high viscosities,

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complex dosing regimens and/or reconstitution requirements has spurred innovation in packaging solutions as well. However, rather than drug-drug co-packing, as is the case with co-administered oral medications, parenteral medications often require packaging solutions where drugs are provided alongside delivery devices or other supplies to enable their preparation or administration. This is most apparent in areas where patients or caregivers are required to manipulate drug components, for example reconstitute a lyophilised product. In some of these cases, simple supplies, such as vial adapters, blunt fill needles or intravenous infusion sets, are co-packed with medications, while others involve specifically-designed devices to

Janice Adkins

Associate Director, Global Marketing
T: +1 201 847 4176
E: janice_adkins@bd.com

BD Medical Delivery Solutions

1 Becton Drive
Franklin Lakes, NJ 07417
United States

www.bd.com

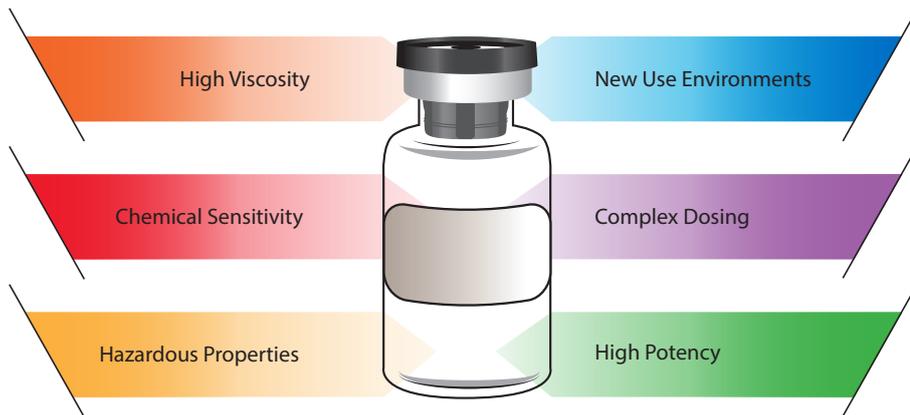


Figure 1: Complicating factors.

aid in performing particular use steps.⁷⁻¹⁵ Examples include:

- Genotropin Mixer® from Pfizer (New York, NY, US)
- saizenpro® from EMD Serono (Rockland, MA, US).

Increasing molecule complexity has also demanded a higher degree of rigour and consideration from drug manufacturers to ensure drug and clinical compatibility with their chosen drug delivery device (Figure 1). This is particularly true in areas where new devices are adopted and used in clinical practice without pharmaceutical manufacturers having a clear idea of exactly which devices are being used for what purpose. A recent study published in the PDA Journal of Pharmaceutical Science and Technology evaluated several chemotherapy vial spikes for their propensity to cause stopper push-in at the device-to-vial interface, and concluded that variability in device size, design and lubricity may contribute to primary container complications.¹⁶ Providing a vetted, co-packaged device alongside a drug product can put manufacturers at ease that their products are being used as intended and help prevent variability that may lead to product complaints.

BD PROVIDES DRUG DELIVERY SOLUTIONS FOR CO-PACKING

BD brings its long history of device excellence and diverse product portfolio to co-packing engagements. With a wide range of best-in-class syringes, needles, vial adapters, catheters and hazardous drug solutions, pharmaceutical manufacturers partnering with BD have the flexibility to select the optimal product for their specific

application. Moreover, BD's extensive experience in drug delivery and its global presence make it able to help customers understand market needs and make data-driven device decisions. BD has successfully partnered with manufacturers to accomplish this in several therapeutic areas, including rheumatoid arthritis, multiple sclerosis, haemophilia, short bowel syndrome, oncology and radiology.

Pharmaceutical manufacturers have integrated BD's drug delivery devices in their co-packing designs in various forms.

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One approach is a fully-integrated solution where the pharmaceutical manufacturer provides the appropriate device(s) within the same unitary package, directly alongside the drug product (Figure 2). This configuration ensures that patients uniformly have every component they need when they receive the drug product, and minimises complexity for other healthcare providers and prescribers. In a second configuration, pharmaceutical manufacturers supply the desired devices separately from the drug product as a

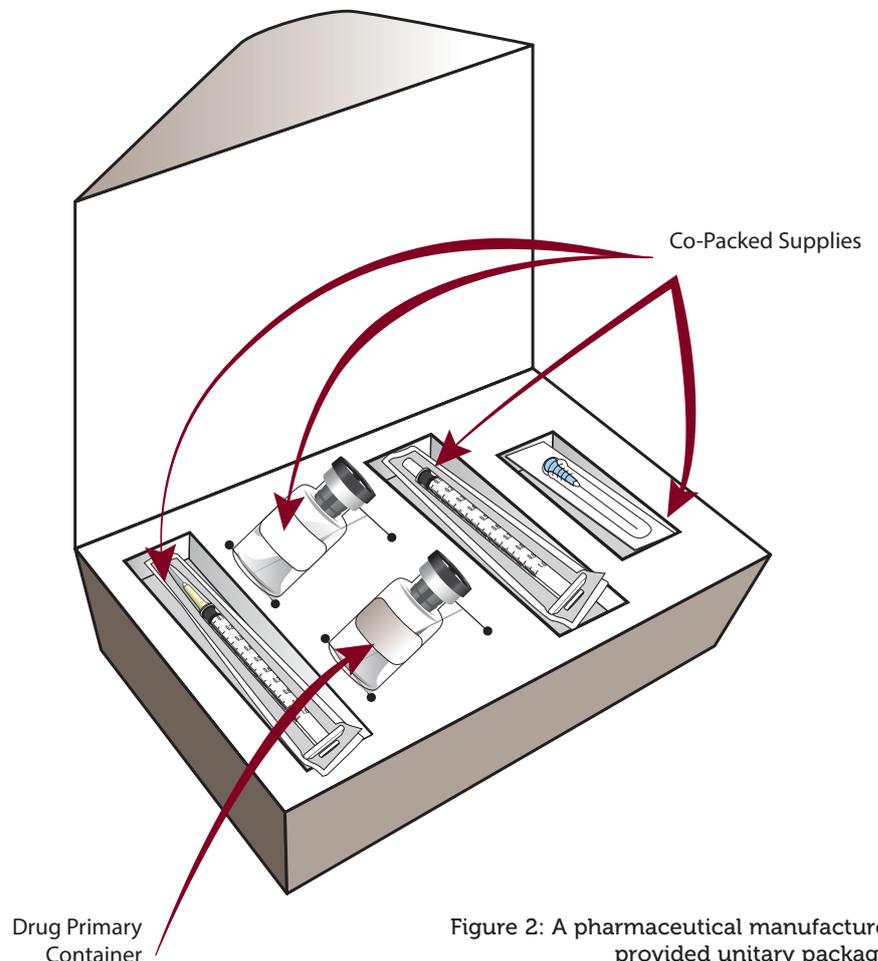


Figure 2: A pharmaceutical manufacturer provided unitary package.

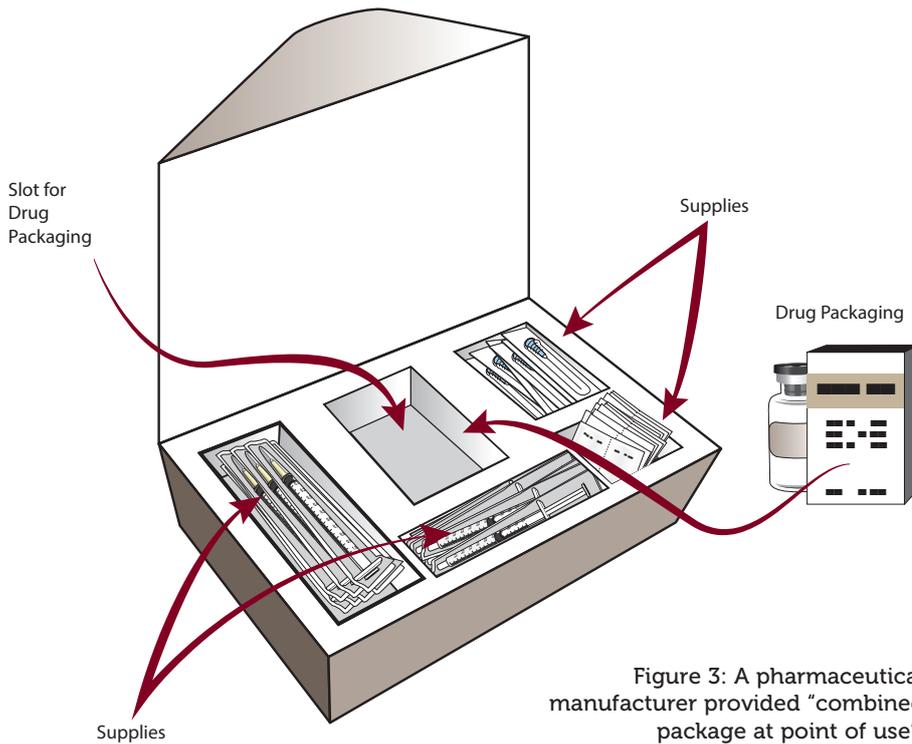


Figure 3: A pharmaceutical manufacturer provided "combined package at point of use".

discrete package, which is then combined with the drug packaging at the point of dispensing (Figure 3). This option minimises the burden on manufacturers and allows the drug product and devices to be treated separately in the supply chain.

Pharmaceutical Manufacturers – Quality Assurance and Consistency

As a partner in optimising drug preparation and delivery process, BD can be relied upon by manufacturers to provide performance quality assurance and supply assurance.

As drug preparation and administration demands continue to increase, pharmaceutical manufacturers will require an even higher degree of quality control for device specifications and performance

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data. When directly collaborating with pharmaceutical customers, BD can offer visibility on the product capabilities of its industry-leading devices to its direct partners. This becomes of key importance when specifications such as materials of construction and device performance are critical.

Finally, BD's broad portfolio of drug preparation and delivery solutions for co-packing can help pharmaceutical partners standardise clinical trial supply and ensure performance consistency as molecules progress towards commercialisation. Several organisations have reported challenges associated with managing clinical trial ancillary supplies, including difficulty sourcing the right supplies for each trial efficiently and cost-effectively, overlooked the make or manufacturer of supplies, and the need for expensive repacking.¹⁷⁻¹⁹ A clinical trial strategy that utilises co-packing to guarantee the right devices are supplied with investigational drugs can mitigate these risks, and a partnership with BD enables manufactures to study their medications with the supplies that patients and clinicians may ultimately use upon approval.

End-Users – Intuitiveness, Confidence and Convenience

From a patient perspective, a co-packaged offering utilising BD devices can help to encourage proper use and ensure that the

drug is prepared and delivered as intended by the manufacturer. This is especially important when patients are presented with unfamiliar use steps or when specific supplies are required. One representative example is Gattex[®] (teduglutide) from Shire (Lexington, MA, US), a medication that requires reconstitution with a supplied prefilled diluent syringe, withdrawal of very small dose volumes, and potential pooling of the contents of more than one drug vial before subcutaneous injection. To facilitate these use steps, patients are provided a kit that contains BD 22G 1.5" needles for attachment to the diluent syringe and reconstitution and BD disposable 1 mL graduated syringes with attached 26G 5/8" needles for dose withdrawal and injection.²⁰ Along with the product's instructions for use, co-packing of these two particular supplies (i.e. a fill needle and separate pre-attached needle and syringe) aids in the proper use steps to the user and may help prevent use errors, such as accidental injection with the incorrect needle and syringe.

Moreover, in situations where provided supplies are not standardised, device variation can have unintended implications. This may occur when a device is not co-packaged by the manufacturer but rather by another party, such as a specialty pharmacy, at the point of dispensing. In these cases, pharmacies may provide supplies that are intended to aid the patient in taking their medication but may not be ideal for the particular drug. Common examples of this include medications with complex preparation steps.

In addition to not necessarily being intended for use with particular products, pharmacy-provided supplies pose other challenges. First, because the devices are supplied in bulk, storage of such large quantities may be burdensome for patients. Second, there is likely a lack of standardisation of these provided supplies across pharmacies, or even within the same pharmacy, if purchasing is made solely based on product price. As a result, there could be differences in the particular device and associated training that patients receive, potentially causing unnecessary confusion.

For clinicians, the benefits of a BD co-packing strategy are two-fold: confidence and convenience. Due to BD's industry leadership, clinicians may be aware of BD products and may be already comfortable using these devices if provided

“Due to BD’s industry leadership, clinicians may be aware of BD products and may be already comfortable using these devices if provided alongside drug products.”

alongside drug products. Additionally, providing the appropriate devices at the point of use can increase convenience for clinicians, especially in acute clinical situations or those that require the use of special supplies, such as filter needles, filtered extension sets, closed-system transfer devices and vented vial adapters.

MAXIMISING THE VALUE OF PACKAGING SOLUTIONS

Although a BD co-packing solution offers a number of benefits, manufacturers can refer to the expected use environment characteristics to inform selection of which products would receive the greatest benefit from co-packing. Co-packing may add the most value when:

- Specific supplies are needed to support use steps, such as reconstitution, filtering, complex manipulation or large volume transfer.
- Dosing- or clinical practice-related circumstances require device standardisation, for example to protect the user from hazardous drug product and/or minimise device dead space.
- Use setting is a home or specialised clinic, rather than a general hospital environment, therefore favouring the convenience of co-supplied devices.
- Acute or emergency clinical situations demand that the correct devices are immediately accessible.
- Certain patient populations, for example psychiatric, paediatric or geriatric, mean that special device considerations are necessary.
- Required supplies are barriers to adoption into clinical practice.

BD is excited to work with the industry to navigate these factors and bring the highest-impact packaging solutions to market.

ABOUT THE COMPANY

BD is one of the largest global medical technology companies in the world and is advancing the world of health by

improving medical discovery, diagnostics and the delivery of care. The company develops innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD has 65,000 employees and a presence in virtually every country around the world to address some of the most challenging global health issues. BD helps customers enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to healthcare.

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THE DIFFERENCE IS SMARTER TO MARKET

WITH ONE TRUSTED PARTNER FOR YOUR DRUG PREPARATION AND DELIVERY SOLUTIONS. BD has a unique perspective on the needs of pharmaceutical companies. In developing the industry's most comprehensive portfolio of drug preparation and delivery solutions, we've learned what it takes to partner closely with leading companies worldwide. It's why you can rely on us to understand the demands of your business, the regulatory environments and your unique technical requirements at every stage—from the lab, through clinical trials, all the way to market. And why no other company combines the collaborative experience with the breadth and depth of safe and innovative delivery systems that BD brings to you. Discover the difference of one trusted partner. **Discover the new BD.**

Contact a BD consultant at MDS-B2B@BD.com

