

PHARMACEUTICAL COMMERCE

Business Strategies for
Pharma/Bio Success

The Packaging Contribution to Patient Adherence

PERHAPS CATCHING THE HINTS that the pharma industry is redoubling efforts in patient compliance, the contract packaging industry has announced a flurry of new designs and product-development initiatives on compliance packaging. This is occurring against a backdrop of a greater focus on effective sampling and starter-kit programs, as the importance of product samples in the sales reps' bags increases. Under new voluntary PhRMA guidelines (and a spate of state-level bans on gifts and office knickknacks), samples have become practically the exclusive item for reps to offer physicians.

But the bigger issue—with implications for both product marketing and for health outcomes—is the potential for better packaging to improve patient compliance. An investment in compliance packaging pays many returns in more consistent drug consumption, more refills and, ultimately, lower overall healthcare costs. Improved packaging also becomes a competitive feature in how drugs are distributed in various channels, as the impact of, for example, the WalMart compliance package (discussed below) is seen as an element of the company's widely publicized (and copied) \$4/month prescription program.

In the past year, several new programs have been initiated by contract packagers:

McKesson, drawing on resources in its McKesson Rx Pak repackaging business, along with McKesson Patient Relationship Solutions (see previous story), has partnered with the U.K.'s BurgoPak to introduce the latter's "slider pack" to the U.S. market.



Fig. 1. MeadWestvaco's Shellpak has been used by, among others, Wal-Mart for compliance packaging.

MWV

Colbert Packaging (Lake Forest, IL) has introduced two versions—ComplyPak and AlertPak—of a carton with a blister-packaged inner sheet.

Catalent Pharma Solutions (Somerset, NJ) has partnered with One World Design (Warren, NJ) to develop a dial-like container with chambers that can be keyed to days of the week or other time periods to improve adherence.

Anderson Packaging (Rockford, IL) kicked off 2008 with Compliance in a Bottle (CIAB), a plastic box with a snap cover for making it difficult for children to open the package, yet convenient for adults to open the package and draw out the blister pack. Last month, it announced an "extended dose" form that can contain multiple blister sheets.

Anderson's (and others') compliance packaging are required to meet safety standards set by the Consumer Products Safety Commission, which mandates testing for both "child resistance" and "senior-friendliness;" conventional pharmacy-issued bottles of pills generally

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meet these with a bottle cap that requires two actions to open (nevertheless, many complain of the difficulty of opening such bottles). The highest CPSC rating is F=1.

Notwithstanding the growth of technology offerings, there is no groundswell for adopting significantly more compliance packaging. A May 2008 pharma packaging study published by the Freedonia Group (Cleveland) projected total demand for unit dose containers and accessories to reach \$7.2 billion in 2012, up 6.9% from 2007. Efforts to reduce medication dispensing errors in hospitals and nursing homes are expected to favorably impact sales of blister packs, pouches, strip packs, and liquid medication cups.

Getting at patient issues

“Clinical trials show that a primary cause of patient non-compliance is forgetfulness; they simply get too busy and forget to take their medication,” notes Glenn Grosskopf, VP of product development for Colbert Packaging (Lake Forest, IL). “The problem can be compounded if patients simultaneously take multiple missed dosages, which can be life-threatening.”

Unit-dose packaging (UDP) is seen as a key method for improving patient compliance, what with only around half of patients maintaining their treatment regimen and refills. Blister packs, foil strips and other forms of UDP enable tablets to be coded for day of the week or other time periods to provide easy reminders. “The fact that nearly 50% of all consumers do not take their medications properly translates directly into lost sales for pharmaceutical manufacturers and the pharmacy industry,” observes Peter Mayberry, executive director, Healthcare Compliance Packaging Council (HCPC; Falls Church, VA). “It is not a direct correlation, however, because non-compliance takes many forms and the impacts are different.” HCPC attributes an estimated



Fig. 2. McKesson combines the Buropak carton with its own LoyaltyScript card.

Unit-dose demand in pharmaceuticals				
Item	2002	2007	2012	% change 2007-2012
Pharmaceutical Packaging Demand (million \$)	9120	12220	16000	30.1
% unit dose	38.2	41.9	44.7	
Unit dose Pharmaceutical Packaging	3480	5120	7150	39.6
Blister Packaging	1270	1630	2060	26.4
Parental Containers	994	1600	2380	48.7
Prefillable Syringes	430	770	1250	62.3
Vials & Ampuls	380	605	868	43.5
IV Containers	184	225	262	16.4
Pouches	353	570	830	45.6
Plastic Bottles	335	560	850	51.2
Prefillable Inhalers	310	465	665	43.0
Other Primary Containers	168	225	285	26.7
Secondary Containers	50	70	80	14.3

Fig. 3. Unit-dose packaging is gradually growing as a percentage of all pharma packaging.

Source: Freedonia Group

\$100 billion in lost drug sales and more than 300 deaths a day to patients failing to take their medications in the proper dosage or on time.

Adherence packaging has been used for years in short-term therapies or oral contraceptives, antibiotics or corticosteroids. But the healthcare industry is changing, and with it, the use of daily-dose blister packaging is becoming more needed and prevalent, observers say. More people are on medication than ever before, and Medicare’s prescription drug benefit has opened medication to more patients treated for chronic conditions, many of whom are older or on multiple medications, making them more likely

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Neopac

to need reminders to take their meds.

“This, combined with the enormous costs of poor patient adherence and the pressures on manufacturers’ and retailers’ supply chains, means the healthcare industry can’t afford to use the same packaging it has always used,” declares Eric Masters, global marketing director, MeadWestvaco (MWV) Healthcare (Mebane, NC). “Manufacturers and retailers, like Wal-Mart, are looking into alternatives to improve output, patient health and efficiency.”

Indeed, industry studies show markedly improved patient outcomes and drug refill sales when patients receive their Rx drugs in daily-dose blister packs. For example, MWV research found there is a series of functional and emotional factors packaging must address in order to positively impact adherence. “Patients need the motivation to take their medication, it must fit with their lifestyle, and they need to understand what the medication will do and why the prescribed regimen is important,” Masters noted. “Patients also need help remembering to take their medication; they need less complexity, and they need to be able to afford it.”

New UDP solutions

MWV’s adherence packaging solutions are designed to meet these needs. For example, both Dosepak Express and Shellpak are calendared unit-dose blister packs that provide a visual record of when the patient last took their medication. “Both formats incorporate educational materials and dosing instructions into the packaging so that it stays with patients wherever they go, and both provide pharma and retailers much better branding and bill-boarding space,” Masters explains.

The new AlertPak from Colbert Packaging offers the best of both worlds as well: It is primarily paper-based and enables pharma companies to fully brand the package and print dosage numbers, dates or other instructions used to serve as a reminder for patients. The compliance package “pops up” into a branded display that can set on a kitchen or bathroom countertop.

The integrated blister pack, which can be customized to accommodate a wide range of blister cavities, is encased



Fig. 4. Neopac offers a unit-dose dispensing system for creams or liquids.

in paperboard that can be enhanced with Colbert’s new PharmaGuard solution for added security. “New unit dose packaging solutions like AlertPak can remedy the non-compliance problem through tracking and accountability measures that make it easier for patients to remember to take their medication,” Grosskopf says.

One of the most innovative unit dose plastic bottles cited by the Freedonia report is AmerisourceBergen’s CIAB (Compliance in a Bottle), which holds an internal calendar blister pack that dispenses individual doses one at a time. This product combines the durability and convenience of the plastic bottle with the compliance prompting features of a unit dose blister. It also expands the real estate for patient education and branding as compared to a traditional bottle.

“The CIAB design actually has two versions, (including) one with a single blister for smaller sized products,” explains Justin Schroeder, director, marketing and business development at Anderson Packaging (Rockford, IL), part of the AmerisourceBergen Packaging Group. “That design is extremely sleek and portable.” Anderson is now offering a dual-blister design which enables larger sized products to achieve 30 doses in a compact compliance prompting format; it also accommodates extended dosing requirements and titration therapies.

In many cases, patient starter doses are presented in compliance packaging, especially if dosing titration is

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Anderson Packaging

required. Typically, wallet packaging is considered well-suited for this purpose. To that end, Howell Packaging provides various compliance wallet packages, including child-resistant/senior-friendly versions.

For instance, the Howell CRCIII is rated as F=1 and capable of high-speed, low-cost production. “The additional touch point is to include an opportunity for the patient to establish a direct relationship with the pharmaceutical company through use of a secure Web access feature included on the wallet compliance starter pack,” notes Joe Lally, marketing manager. “Howell Packaging has incorporated this feature into our wallet packages which enables the branded company to provide therapeutic category support and conduct ‘relationship marketing’ activities.”

Hurdles deter wider acceptance

While such new developments are promising, several hurdles stand in the way of greater adoption of compliance packaging by pharma. One of the biggest relates to cost, as production, shipping and storage expenses may be viewed as unnecessary. And there remains resistance in the pharmacy community, which is reluctant to change the way it does things.

“I think the economics will eventually work in favor of UDP,” HCPC’s Mayberry predicts. “There are already indications, for instance, that certain members of the pharmacy industry are willing to invest in UDP packaging operations in the United States as either joint ventures or to ‘pre-package’ prescriptions from their own inventory in advance of dispensing.”

An increasing number of retail and mail-order pharmacies are expected to offer patients the option of receiving Rx meds in unit-dose blister packs, Freedonia reports. One driver for the pharmacy industry in this area is the realization UDP also reduces dispensing costs considerably because pharmacy personnel do not have to repackage drugs behind the counter each time a prescription is presented. “By eliminating repackaging in the pharmacy,” Mayberry says, “it has also been proven that dispensing errors and other mistakes go down as well.”

MWV reports it is involved in strategic partnerships globally with other packaging companies to eliminate



Fig. 5. Anderson Packaging has updated its “Compliance in a Bottle” (CIAB) product for extended dosages.

inefficient steps in the distribution chain and help make adherence packaging available to patients throughout the marketplace. “For example, we’ve gotten prescription retailers on-board to use Shellpak adherence packaging for their generic and branded discount drug programs, such as Wal-Mart’s \$4 prescription program,” Masters says.

Better, faster, cheaper

Despite the fact that packaging is largely viewed as an afterthought in the price-sensitive generic market, some experts believe the opportunity exists for an innovative pharma company to differentiate itself by offering compliance packaging. This investment may not be far fetched when you consider many key Rx drugs for chronic conditions are now generic. “The company that can link the patient, physician, pharmacist and insurance providers through compliance packaging that achieves successful medical outcomes may just find the high ground of significant market share and become a ‘branded-generic,’” Howell Packaging’s Lally says.

Meanwhile, packaging solutions providers say they are investing heavily in technology platforms to support commercialization of new unit dose formats. This includes incorporation of robotics and high speed automation, with a keen focus on flexibility. Our ability to offer cost effective compliance packaging solutions is critical to the success of the brands we package for our customers, Anderson Packaging’s Schroeder says.

Not to be outdone, many of MWV’s solutions are

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designed to be manufactured efficiently. For example, the new Dosepak Express is made with less material so it can run at higher production speeds and easier for manufacturers to produce. “Dosepak Express and Shellpak both come in standard configurations that run easily on most existing processing line equipment,” Masters says. “Standardized sizes enable manufacturers to maintain efficient, speedy and economical processing on production lines, without having to use valuable resources to purchase all new equipment or reconfigure it to fit custom package sizes.”

The fact that unit dose formats can be designed with compliance-prompting features is helping physician’s samples get a leg up on setting compliance behavior for the eventual therapy. The mainstay for samples is blister packaging, especially when the requirements for the sample are to provide several oral-dose pills, and when promotional and safety information are a key component of the package. When you get below a 100-count bottle, blisters become economical compared to bottles, experts say.

More space, more messaging

One of the latest developments is vendors are incorporating more information space and utility into the blister packaging. This allows pharma companies to provide patient-education materials and clear instructions on dosage regimen, and, most recently, even technology-based cues to act as reminders/prompters for truly interactive solutions. “The expansion of the message is powerful in how you gain the ability to convey information about dosing instruction, potential side effects, drug interaction information, education on the disease state, or potentially something as simple as adding a ‘Notes’ section right on the package where the patient can capture and retain the highlights of their conversation,” Anderson Packaging’s Schroeder says.

Given the limited face time that the average patient spends with the doctor, a well designed physician supplied sample can play a vital role in facilitating a healthy outcome. Anderson packages some commercial products in starter kit physician sample formats that incorporate tools for driving education and compliance.

In a similar vein, many MWV packaging solutions are



Fig. 6. Howell Packaging’s compliance ‘wallets’ offer extending branding and communication possibilities.

designed with billboard space on the outer package and fold-out panel. This format provides ample room for branding, labeling, dosing instructions and patient education in large, readable fonts. “To ensure any additional important information stays with the prescription wherever it goes, the package contains a pocket for an insert or booklet,” Masters says. “We can also print additional information that is specific to the medication therapy on the blister itself or even next to each pill.”

Looking ahead, industry members concur the latest data concludes compliance prompting packages drive additional sales, and the ROI analysis supports this investment. At the same time, it helps ensure proper usage and successful medical outcomes. Says Howell Packaging’s Lally: “There is a great opportunity here to highlight the importance of packaging as an overall strategy throughout the life of the product, from research and development, clinical trials, marketing, patient acquisition, patient retention and successful medical outcomes.” PC Contract packagers are multiplying their product offerings to meet marketing and patient-safety concerns. **PC**

—By F.J. Quinn