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The Increasing Trend of Adherence Packaging and the Implications to Manufacturing

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This article presents data that highlights the increasing market trend to use adherence packaging and highlights the design and manufacturing options that should be considered to adopt this strategy.

Overview

The pharmaceutical industry has been facing immense challenges to well-established practices as it concludes the era of block buster products and enters a new era of smaller pipelines focused on specialty disease state therapies. From a commercial perspective, many companies have been forced to seek new avenues to drive growth of top line sales. In this new environment, the investment in both research and patient programs to increase the rate of patient adherence to medication has been significantly growing. One commercial tactic that has seen rapid growth over the last few years is to leverage packaging as a tool to increase patient adherence. This article reviews the concept of patient adherence and why it is important to the industry, highlights how packaging is being used to increase adherence, and provides insight on the manufacturing considerations for migrating packaging operations from bottles to adherence packaging.

Adherence or Compliance – *What Is the Difference*?

With any discussion on adherence or compliance packaging, it is important to be grounded on a common definition. The words patient compliance and patient adherence are often used interchangeably by the healthcare value chain. The preference to use one word over the other is often driven by company culture. In the last few years, thought leaders in the field of medication taking behavior research have been moving toward the use of adherence as the preferred term. In similar fashion, the use of compliance is now more often associated with the regulatory and legal aspects of the pharmaceutical industry.

In a recent publication, Vrijens, et al[1] propose a new nomenclature for medication taking behavior that leverages the word adherence. The recommendation is the result of an international collaboration of European research groups in the field of adherence to medications comprising 80 participants from 13 different countries. They define adherence to medications as the process by which patients take their medications as prescribed.

Adherence has three components: initiation, implementation, and discontinuation as seen in Figure 1.

- **Initiation** is when the patient takes the first dose of a prescribed medication.
- **Implementation** of the dosing regimen is defined as the extent to which a patient's actual dosing corresponds to the prescribed dosing regimen from initiation until the last dose is taken.
- **Discontinuation** marks the end of therapy when the next dose to be taken is omitted and no more doses are taken thereafter.

One other important term used in this adherence nomenclature is:

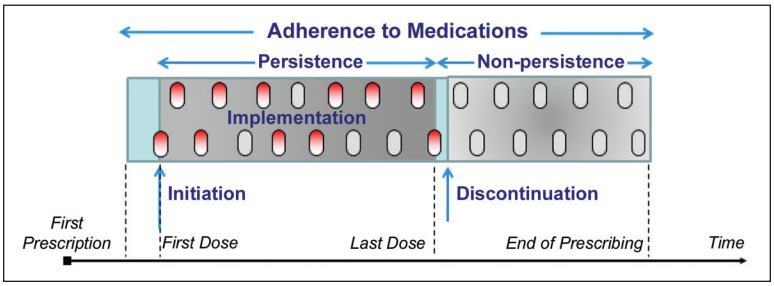

Figure 1. Three components of adherence: initiation, implementation, and discontinuation.

- **Persistence** which is the length of time between initiation and the last dose which immediately precedes discontinuation.

Looking at Figure 1, it is clear that non-adherence to medications can occur in a number of situations or in some cases a combination of situations. Specific situations might be a delayed initiation (patient does not fill their prescription in a timely manner); non-initiation (patient decides to not fill a prescription); sub-optimal implementation (patient misses doses); and early discontinuation (patient ceases taking medication prior the end of the prescribed treatment regimen).

Why Is Adherence Such a Hot Topic?

Alignment of Healthcare Value Chain Partners

The World Health Organization reports that the magnitude of medication non-adherence is so alarming that more worldwide benefits would result from improving adherence to existing treatments than from developing new medical treatments.[2] Because of the widespread effect of non-adherence, there has been unprecedented alignment among healthcare stakeholders including patients, providers, pharmacists, manufacturers, government agencies, and payors to work together to improve adherence. Recently, a diverse group of stakeholders representing consumers, health providers, the academic community, industry, and government, e.g., US Food and Drug Administration (FDA), National Institutes of Health (NIH), Veterans Administration (VA), convened to discuss the state of patient adherence and published a paper in the American Heart Journal entitled *Medication Adherence: A Call to Action*.[3]

Healthcare Systems and Manufacturers are Increasing Investment in Adherence Programs

With the advent of more sophisticated analysis conducted by health economists that measure the impact of non-adherence, payors (both insurance companies and governments) are becoming more aware of the high cost, lost revenues, and system burden that result from poor patient adherence. As a result, they are increasingly willing to fund programs focused on increasing patient adherence.

It Is Harder to Get New Drugs Covered by Payors

Payors are changing the way they evaluate drugs to be included in their formulary coverage by requiring comparative effectiveness research. This is placing new demands on pharmaceutical manufacturers to prove that new products add additional value versus other well accepted and more-often lower cost drugs. Research algorithms used to demonstrate differentiation include a number of variables: One of the most significant and hard to control variables is patient adherence rates.

Governments Are Demanding Better Adherence Rates

The US Government's Centers for Medicare and Medicaid Services recently enacted a five star rating for healthcare insurance plans that are serving patients that qualify for the Medicare Advantage and Prescription Drug Benefit programs (Part C and Part D of the Affordable Care Act). The star rating score is determined by how well they perform in a number of categories and provides a measure of quality and performance. A plan's star rating is publicly listed on the Medicare Plan Finder website which helps patients choose their desired plan. More importantly, quality bonus payments paid by the government are now based on the star rating system – the higher a plan's star rating, the greater the bonus payment percentage. Because patient adherence (or non-adherence) can affect many of the measures that are factored into the star ratings, plans are stepping up their resources to drive higher levels of patient adherence.

Patients and Adherence

Understanding why patients are non-adherent to their prescribed treatment is highly complicated. Hayden Bosworth, Associate Director at the Veterans Affairs' Center for Health Services Research in Primary Care states that, "there are over 100 factors that can be predictive of non-adherence." Research that he has conducted shows that these factors fall into the following five categories:[4-5]

1. Patient Characteristics:
   - Patient knowledge of the disease state
   - Coping skills/ego/strength/motivation
   - Cognition
   - Healthcare literacy level
   - Comorbidities
   - Side Effects
   - Depression/Mental Health
2. Provider/Physician Characteristics:
   - Medication Regimen (frequency, complexity, immediacy of beneficial effects)
   - Medication Intensity
   - Provider Communication (ability to help patients understand the why, how, when of taking their medicine)
3. Medical Environment
4. Social Environment
5. Government Policy

Adherence research focused on patients' medication usage and overall attitudes on taking medication also has been increasing over the last few years. Results from this research is now providing key insights to members of the healthcare value chain in creating programs and systems to increase levels of adherence. One insightful piece of research is an interview based study of 821 patients, conducted by JWM Chang that lists a number of self-reported patient reasons for non-adherence (Figure 2). Chief among them is simple forgetfulness.[6]

In addition to understanding the various factors related to medication adherence, research also has been conducted to expose misconceptions regarding medication adherence. The Outcomes Research Team at Merck recently presented the 10

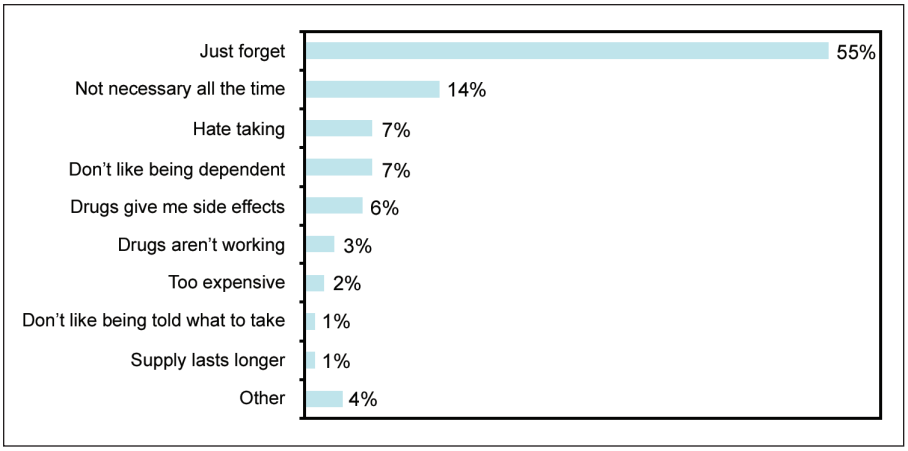

Figure 2. Patient self-reported reasons for non-adherence.

Tenets of Medication Adherence. These provide useful insights about patients' medication decision making and underscore the importance of patient beliefs in determining adherence behaviors. These tenets of medication adherence are:

1. Patients do not communicate their medication adherence intentions to their health care providers.
2. Healthcare providers assume that ***their*** patients are adherent.
3. A non-adherent personality does not exist.
4. Adherence to prescription medications is largely unrelated to adherence to self-care and lifestyle recommendations.
5. Medication adherence is largely unrelated to demographic characteristics.
6. Patients want information about their prescription medications and feel frustrated that not enough information is provided to them.
7. Healthcare providers can be inconsistent communicators about prescription medications.
8. Medication taking is a decision making process and patients actively make decisions about new and existing medications.
9. Non-adherence is rational behavior. It is driven by patients' beliefs about their treatment, disease, and prognosis as well as their objective-experiences with their treatment and disease.
10. Medication adherence involves "shades of gray." Patients can be faithfully adherent to one medication, non-fulfill another, and be non-persistent to another because they hold distinct medications and diseases.

Adherence Packaging Should Be Considered a Marketing Tactic

Within pharmaceutical commercial organizations, focused spending on field sales teams and Direct-to-Consumer (DTC) advertising, usually two of the largest budget items for the commercial team, has been decreasing. Many companies have been reallocating this budget toward programs that are designed to specifically impact adherence. Increasingly, companies are creating dedicated teams to focus solely on adherence. These teams usually have a mix of backgrounds that draw from both the commercial side as well as those with backgrounds in health economics and outcomes research.

These teams spend considerable effort to create, manage, and measure the effectiveness of different adherence programs. Table A lists the most common types of programs found in the market. Depending on the complexity of the disease state, many of these programs can be integrated together. It is not uncommon to see brands fund five to six programs at the same time to get their desired result.

Many of the programs listed in Table A are very expensive and often times cannot scale to include every eligible patient. For example, a program that uses nurses to call patients to check on progress of a highly complex treatment protocol may have a positive ROI and drive desired patient outcomes; however, it may be physically impossible to hire enough nurses to call every patient taking the medicine. Additionally, at a rate $50 to $100 per call, it becomes financially untenable to scale a successful program. The ability to scale and the relatively low cost profile of adherence packaging are the main reasons adherence teams are increasingly focused on incorporating package as a foundational tactic for any company's program.

Based on the definition of adherence used in Figure 1, initiation of the treatment is the pivotal step in building the proper habits to maintain adherence to treatment. Adherence teams know they have little control over the quality of the initiation message delivered by the prescriber or pharmacist (why they are taking the medicine, how to properly take the medicine, how long to take the medicine, etc., to ensure a positive outcome). One thing that they can control is developing preferred messages they want consumers to have. Historically, these messages have been delivered via patient starter kits, physician samples, websites, and physician office brochures.

Patient education	Branded web sites	DTC advertising with adherence message
Call center support	SMS text	Pharmacy intervention programs
Patient assistance programs	Drug discount and loyalty card programs	Patient experience/ sampling programs
Reminder systems and devices	Family involvement programs	Physician training
Patient letters/ direct mail	Email programs	Live calls from a healthcare professional (e.g., nurse)
Automated IVR calls	Public awareness/ celebrity campaigns	Medication counseling
Smart phone applications	Non-branded disease state websites	Packaging

Table A. Common patient adherence programs found in the global market.

Now, brand teams are starting to activate their commercial packaging as a vehicle to deliver important messages that they know impact the initiation phase of adherence. Additionally, packaging is being used as an entry point to other marketing tactics such as Customer Relationship Marketing (CRM) and loyalty card savings programs (i.e., prominent display of website). Marketing teams are becoming more enamored with using packaging as an adherence tool because they know, by default, the package will get into the hand of ***every*** patient that receives a prescription.

Adherence teams also are investigating ways to deliver messages on packaging that overcome health literacy barriers, exploring ways to convey messages through visual illustrations and icons. The Veterans Administration (VA) is conducting a large scale, prospective study utilizing adherence packaging incorporating patient educational information. Figure 3 depicts the graphics that will be used in the test. This package highlights the types of helpful patient information that can be incorporated into package graphics. The graphics on the VA package provide a number of benefits:

- Conveys important information on disease state treatment goals
- Provides a calendar feature that helps patients track medication usage and reduce dosing errors (i.e., missed dosage or over dosage)
- Provides graphics on when and how to take the medicine
- Includes important medical information that provides "reasons to believe" the dosing instructions
- States contraindications to limit safety issues that might not always be addressed by the physician or pharmacist

Data Highlighting the Impact of Adherence Packaging

A major piece of adherence packaging research worth highlighting is a recent study authored by Zedler, et al.[7] This study was the first large-scale pharmacoepidemiologic analysis of the effect of medication packaging alone on adherence. The objective of the study was to evaluate the effect of adherence packaging on long-term prescription refill behavior as compared to traditional amber vials. The retrospective analysis used pharmacy claims data from Wal-Mart retail pharmacies to assess the effect of calendar blister packaging on prescription refill adherence (frequency and timeliness) and duration (persistence). Data from more than three million patients filling prescriptions for the ACE-inhibitors (to treat hypertension) at Wal-Mart was included in the study.

Results from the study reveal some key conclusions of the effectiveness of adherence packaging:

- The use of adherence packaging in both new and ongoing medication users was associated with modest improvement in refill persistence and adherence. Results were measured by Length Of Therapy (LOT), Proportion Of Days Covered (PDC), and Medication Possession Ration (MPR) – all common measures used to analyze adherence.

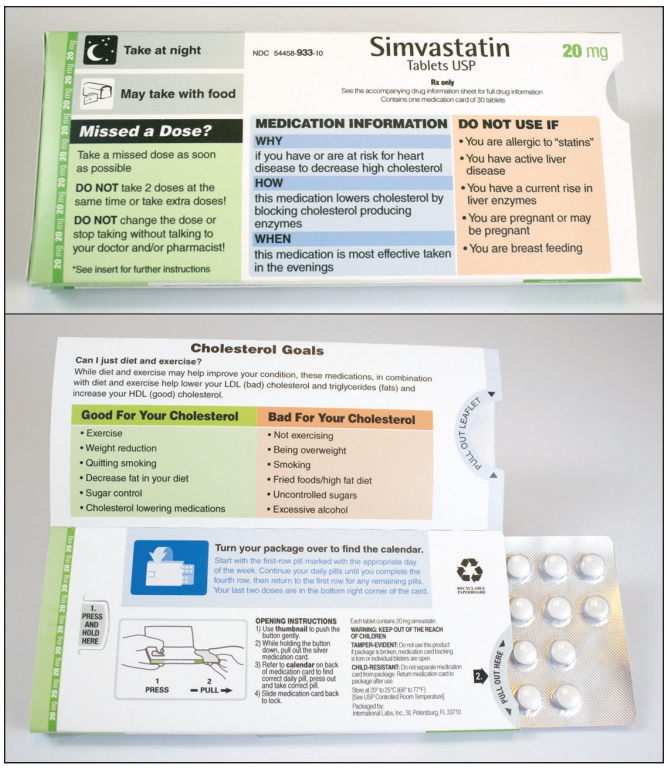

Figure 3. Graphics that will be used in the VA packaging test.

- Packaging alone made a positive impact on adherence – no other adherence programs or interventions such as education were used.
- Patients using adherence packaging were more likely to reach "full refill adherence" in a year than vial users with the greatest effect observed in new medication users.
- An adherence strategy of even small effect size at the patient level, such as found in a packages containing a calendar feature, which is broadly implemented on a population level (scaled to all patients taking a medicine) could significantly leverage therapeutic efficacy and provide substantial cumulative public health.

Sandy Kinsey, VP of Pharmacy Merchandising for Wal-Mart and Sam's Club, was recently quoted saying "Scientific studies have proven that statistically significant patient benefits result from adherence packaging programs and we are working to bring even more medications to our customers in adherence packaging."[8]

The Healthcare Compliance Packaging Council is a trade organization that promotes the greater use of adherence packaging to improve patient adherence rates and patient outcomes. Their website contains two decades of research studies that support the use of adherence packaging and can be found at www.hcpc.org. These studies all draw a similar conclusion that is best expressed by a quote from an Institutes of Medicine article entitled Preventing Medication Errors. "The strategy of using calendar blister packs [adherence packaging] could help large numbers of patients to take their medications more reliably and safely, and enhance their treatment outcomes."[9]

Considerations in the Design and Manufacturing of Adherence Packaging

From a packaging and procurement team's perspective, what's not to like about bottles: they're cheap, they're fast, and they're child resistant. The one thing they are not is a tool to help facilitate patient adherence. In global markets where blisters are preferred, medication is habitually separated from important patient information and labeling, thus reducing the odds for patients to have high levels of adherence. By re-considering older, established packaging paradigms and reward structures, manufacturing organizations can leverage their expertise to help the overall business health of the organization they serve. This can be accomplished in a much more impactful way, not by focusing on efficiencies and reduction in Cost of Goods (COGs), but rather by focusing on tactics that can drive top line sales. Relative to existing packaging, adherence packaging can be more expensive. Relative to the cost of current adherence programs, adherence packaging is extremely cost effective and scalable.

Adherence packaging is certainly not appropriate for every medicine. There are certain disease states and treatment protocols that require measured and dynamic dosing flexibility by both the prescriber and pharmacist. However, there are numerous medicines that can benefit from adherence packaging. These medicines typically treat chronic disease states and have static prescription counts.

Adherence packaging is defined by the adherence attributes that can be included in the design – most notably a dosing calendar feature, detailed dosing instructions, and/or patient information. There are other attributes that are common to adherence packaging:

- Each package is a prescribed or delivered unit.
- The package contains a primary package section (often times a blister) and a secondary outer container made from paperboard or another substrate such as plastic.
- Product stability is often very high due to the blister configuration.
- The package is not opened until the point of use.
- Prescription accuracy is high; product verification and prescription count can be verified by bar code or human readable graphical color schemes.
- Child resistant features are often integrated.
- Printing and verification systems used in manufacturing automation can be used to meet serialization and track and trace requirements.

Producing product in adherence packaging includes additional process steps as compared to operating in bottles. Below is a description of the common processes that are associate with adherence packages and a list of considerations.

Package Design

Since many of the design elements of the package are interlinked with each other, it is important to fully scope requirements into a design brief before development work begins. Adherence packaging typically has two components: the primary packaging (blister packaging) that physically contacts the medicine and the secondary package which secures the primary package.

Blister packaging primarily has two considerations that determine its design: 1) the dosing regimen and 2) the moisture barrier and stability requirements. Dosing regimen is set by how many tablets need to be taken per day and how many tablets need to fit in the blister. The tablet count per package is often set to deliver a specific price point. The moisture barrier and stability requirements have a direct impact on the material selected to form the blister. For drugs that require a complete moisture barrier, a Moisture Vapor Transmission (MTVR) (aluminum-aluminum) or Cold Form Foil (CFF) is used. The majority of product on the market does not require stringent moisture barrier requirements to maintain stability and therefore can leverage materials that are easier and more cost effective to work with. Examples of these are Polyvinyl Chloride (PVC) and Cyclic Olefin Copolymers (COC) materials that use a thermoforming process to shape the blister.

There are a few styles of secondary packaging associated with adherence packaging. The three main categories are 1) wallet cards (either heat sealed or glued), 2) paperboard Sleeve with folded heat sealed inner card containing the blister locked into the sleeve, or 3) paperboard or plastic sleeve that locks the blister. The requirement for a Child Resistance (CR) feature is the primary driver in choosing a style. For example, if no CR is required, a simple fold-over wallet may be optimal. Patient information to be included within the package also can dictate package style. The size and number of messages and graphics, and inclusion of Product Insert (PI) may point to using a packaging with a fifth and sixth panel. Lastly, if an **alu-alu** blister is selected for the primary blister, it typically requires that the secondary package is slightly bigger.

Package Development

Packaging development is sometimes handled in-house, but there is an increasing trend to use external package developers who are experts in CR features and material selection. Substrate selection is an important step to ensure the final package maintains the original intended structural rigidity. Developers will test different calipers of board thickness to meet the optimal cost per rigidity profile.

For packages that are designed for the US market, a major part of the package development process is passing Child Resistance (CR) testing. The US Consumer Product Safety Commission (CSPC) requires prescription medicine and certain oral solid dose medicines, as well as most investigational products used in clinical trials to be packed in child resistant packaging.

The CSPC regulations set specific protocol parameters for testing, and they must be conducted in accredited research facilities. Tests involve a panel of 50 children composed equally of male and female subjects. A package successfully passes the test if 85% of the children are unable to open the package in 5 minutes or 80% are unable to open the package after a demonstration is provided. The CSPC also requires a senior adult test that is similar in protocol to the CR testing. CR requirements are coded based on how many tablets a child would need to access to cause harm. If a child can be poisoned by accessing one tablet, the package requires an F=1 rating; eight tablets requires an F-8 rating and so on.

Figure 4. Paperboard sleeve package.

Package Production (Converting)

Production of the secondary package is typically conducted at an outside resource that specializes in paperboard converting or injection molded applications. The drug manufacturer will want to schedule at least one on-site check to validate the converting process and ensure that the agreed to quality controls are in place to meet specified tolerances of the packaging dimensions and more importantly that the printed graphics align with the approved master graphics file. For paperboard converting, there are three primary operations: printing, cutting, and gluing. The converting of pharmaceutical packages is often done in small batches (as compared to consumer products that have long continual runs). Printing machines that can perform quick changeovers to other print jobs are usually used to run the small batches. For the printing operation, color matching is the primary area of quality assurance focus. For the cutting phase, vision systems are employed to make sure that cutting tolerances are being maintained and to validate that there is no missing copy and that print registrations are within specifications. Gluing is the final phase and the step where product inserts or labels are attached as required. Sampling of product occurs at each step of the process.

Finished Product

This step of the manufacturing process combines the primary and secondary packages together. It can be done in house or at one of the many trusted contract packagers. Many of the manufacturing steps in this stage are similar, but there are subtle differences based on the type of secondary package that is being used that can affect the layout of the manufacturing line. Many of the steps described below can be automated by using modified standard equipment. There are four typical layouts for final assembly packaging lines that produce finished product. These are:

1. Heat sealed wallet
2. Glue sealed wallet
3. Paperboard sleeve with folded heat sealed inner card locked into sleeve
4. Paperboard or plastic sleeve with locked blister

For each layout, the blister former (thermoforming or cold forming) can be run separately or in-line with the rest of the manufacturing process. Table B highlights the line design impact of where the blister forming takes place depending on the package type. Table C highlights the different attributes of each manufacturing layout.

Paperboard sleeves, whether they are used with a locked blister or sealed inner card, can be fed, opened, and closed on a cartoning base with special features. The infeed and loading system of the blister into the sleeve typically uses a specialized piece of equipment. Downstream modules may be used to perform specialized printing, labeling, or attaching (outsert) functions.

Validation Process

Meeting internal QA requirements is a matter of following proven validation processes. Using a risk-based approach, quality critical items can be verified with standard bar code scanning and vision technology. It is always recommended and encouraged to leverage supplier documentation (GAMP® 5 and ASTM E2500) to minimize testing protocols and their execution. Other tips:

- Verification and inspection systems should reject non-complying products without stopping the equipment.

Figure 5. Paperboard wallet card package.

Heat Sealed Wallet and Paperboard Sleeve with folded heat sealed inner card locked into sleeve
• Blister former is operated as a stand-alone system. • Output from the blister former is usually batched in trays. • Automation to stack blisters in trays may be helpful. • As this is a stand-alone unit, it runs/produces at full speed as it is not dependent on downstream equipment. • Speeds as high as 400 blisters per minute are possible.
Glue Sealed Wallet and Paperboard or Plastic Sleeve with locked blister
• The blister former is often operated in-line with the system. • Speed is dependent on downstream equipment.

Table B. Blister former attributes by packaging line type.

Heat Sealed Wallet and Paperboard Sleeve with folded heat sealed inner card locked into sleeve
• Produced in a platen style heat seal machine. • Uses an indexing multiple product machine that feeds a base card, blister, and a secondary card. • The cards/blisters are sealed using heat and pressure at one or two stations. • Cycle rate of this equipment is 15 per minute; total output would be 120 cards per minute total using an eight up platen. • Equipment for heat sealing uses modified standard machines, the folders are custom machines. • Uses multiple magazines for card stocks and blisters which is labor intensive. • Output of the card heat sealer is difficult and expensive to automate if a variety of formats are being produced. • Cards are discharged unfolded requiring an external system of folding. • Cards may be folded in many sequences and formats. • Printing and verification of the lot and date codes as well as closing systems such as a wafer seal is included. • Speeds of 200 cards per minute can be obtained for wallets and 250 cards per minute for sleeves.
Glue Sealed Wallet and Paperboard or Plastic Sleeve with locked blister
• Blister feeder automatically feeds magazine. • Card with multiple panels and blister are simultaneously fed. • Hot melt adhesive is applied in conjunction with the folding sequence. • Final folding and closing are done within a single machine and discharged as a finished product. • Cards may be folded in many sequences and formats. • Printing and verification of the lot and date codes as well as closing systems such as a wafer seal is included. • Speed of this equipment may be as high as 300 to 400 wallets per minute. Paperboard sleeves with locking mechanisms are limited to about 250 to 300 finished products per hour due to the multiple layers of sleeve paperboard and inner card blister. • Equipment is highly customized but available from several manufacturers. • Multipack shippers and dispensers can easily be automated using standard equipment.

Table C. Manufacturing attributes by package line type.

- The secondary packaging equipment will determine the final package aesthetics that patients will see. A verification step should be included to ensure "look and feel" of the package meets specifications.
- Controls should be developed and maintained to meet target CR compliance levels (e.g., F=1).
- Production targets should be scrutinized to minimize capital requirements and investment considerations. Selecting intermittent motion equipment (slow to medium speed) vs. continuous motion equipment (high speed) can reduce capital requirements. Similarly, a phased approach to automation (moving from manual or semi-automatic to full automation) may decrease initial investments.

Conclusion

The trend of leveraging the unique characteristics of packaging to help patients better understand how and why to take their medicines is growing. Scientific data clearly shows that packaging alone can increase patient adherence to taking medicine correctly as prescribed. Never before have packaging and manufacturing engineers been in a better position to help their organizations by driving packaging decisions that drive top-line sales and positive business results – and ultimately helping patients reach better health outcomes.

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