

THE USA AND A SHIFT FROM BOTTLES TO BLISTERS

What the Rest of the World Already Knows

We have put together the “3-Ps”, Protection, Product, and Patient, to consider for packaging cannabis, prescription, and over-the-counter medications.



PHARMAWORKS™

“As an American ex-pat living in the United Kingdom, I was astounded at the dominance of blister packs for packaging medications. Estimates show that 85% of dispensed medications find their way into a blister package in Europe. The USA continues to package in bottles and blister packs. In contrast to Europe, bottles dominate the US market as the preferred packaging, whereas blister packs represent roughly 20% market share for packaging medications. That brings us to the “3-Ps”; Protection, Product, and Patient. Consider these three concepts when packaging cannabis, prescriptions, and other over-the-counter medications.”

— Chad Tyler, Sales Director, Pharmaworks

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KEY TAKEAWAYS:

How the “3-Ps” impact your packaging solution.

Understand the versatility and advantage of blister packaging.

Your products and blister packs.



PROTECTION, CHILD SAFETY AND ANTI-COUNTERFEIT TECHNOLOGY

When it comes to protection, child safety is at the top of the list. Studies have shown that blister packaging outperforms child-resistant (CR) bottles. It is estimated that blister packaging is 65% more effective in preventing child access to medication. In May of 2021, Pediatric Research reported, “Pediatric overdose deaths rose from 0.08/100,000 children in 1999 to a peak of 0.19/100,000 children in 2016, with opioids accounting for an increasing proportion of deaths.”¹

Data indicated an uptick for overdoses in children when opioids arrived on the scene. What will the data show for the arrival of cannabis? More and more countries and states are moving to legalize cannabis. Many young children who consume cannabis edibles require hospital admission due to the severity of their symptoms.

What child-resistant features are available for each packaging format? A bottle must be resealable at the most fundamental level. The most notable method of resealing a bottle, and enhancement for child safety, is the safety cap. This CR feature commonly requires an individual to push and turn or squeeze and turn to open the container. To access the contents of a blister pack, consumers must tear into the package to access the product inside. A comment we hear from consumers all the time is just how hard it is, even for an adult, to open. Of course, the blister packages they are referring to are those with CR features. Multiple types of packaging material provide a tough semi-rigid structure

that must be punctured and torn to access the contents. These examples and descriptions of other CR features for bottles and blisters are available on the United States Consumer Product Safety Commission website.²

Both package types can be tough for children to open, but there is a major flaw that is often overlooked when only comparing the mechanical implementation of each method. Child-resistant features are irrelevant when bottle caps are not closed or properly applied. Open containers leave medication exposed and provide easier access for a curious child. Due to the placement of separate doses into a single sealed cavity of a blister package, consumers must open each blister cavity separately to access the contents.

Another aspect of protection is counterfeit drug prevention. A counterfeit medication or drug is a medication or pharmaceutical product produced and sold with the intent to deceptively represent its origin, authenticity, or effectiveness. Resulting counterfeits may not be as effective as an authentic drug or have no effect. In other instances, counterfeits can be dangerous and pose serious health concerns.

As listed on the FDA’s website, “The Drug Quality and Security Act (DQSA), was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace





certain prescription drugs as they are distributed in the United States.”³ Focusing on Track & Trace technology is particularly important for the manufacturer. Track & Trace regulations around the globe protect the end user from counterfeit products and improve the recall process.

Understanding the process is key to identifying the advantage of blister packaging. A high-level explanation describes a Unique Identifier (UID) created at the beginning of the packaging process, recorded in a database, and tracked downstream. Each step throughout the production and supply chain is recorded all the way to shipment. Track and trace solutions integrated with blister packaging applications can trace an individual dose of product back to a single blister cavity. Such a capable solution provides high precision if a review or audit is required. It also gives the manufacturer, pharmacists, and patient a means to verify and confirm if their product is authentic.

1 Pediatric Research Report (<https://www.nature.com/articles/s41390-021-01567-7>)

2 Child-Resistant Packaging Index: ASTM Package Type (<https://www.cpsc.gov/Regulations-Laws--Standards/Statutes/Poison-Prevention-Packaging-Act/CRP-ASTM-Package>)

3 Drug Supply Chain Security Act (DSCSA) (<https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>)

PRODUCT, QUALITY AND INTEGRITY

Product integrity is another priority. Every packaging application, both bottle and blister, must

go through stability testing to ensure an adequate barrier of protection. Adequate packaging must protect the medication from environmental factors such as moisture, oxygen, or chemical migration. Exposure to the environment could negatively impact product chemical assay and reduce the efficacy of the medication.

A key characteristic of blister packages is the capability of sealing individual tablets or capsules within dedicated cavities for each dose. Typically made of thermo-formed plastics or cold-form aluminum, blister packages protect the drug from contaminants such as moisture, oxygen, and even light utilizing the barrier of foil, film, or paperboard. In addition, the entire form, fill, and seal process can be completed on a single machine reducing environmental exposure which can alter the efficacy of the medication. This ensures optimal quality of the product until a patient removes each dose.

The protection provided by bottles can be deceptive. Prior to a manufacturer packaging, for example, a 500-count bottle of tablets for dispensing at a pharmacy, studies are required verifying product stability using adequate barrier protection prior to the initial opening of the bottle. The initial level of protection provided by the original induction seal can never be achieved again once a cap is removed to fill the first prescription. Filling recurring prescriptions further exposes remaining product to ambient air and humidity. Medications and product filled in a traditional amber bottle and sent home with a patient only compounds the issue.

PATIENT ADHERENCE TO DOSAGE AND SCHEDULE

Medications and other drugs must be taken as directed for multiple reasons. The Centers for Disease Control and Prevention (CDC) previously provided estimates that non-adherence causes 30%-50% of chronic disease treatment failures and 125,000 yearly deaths in the United States.¹ Adherence refers to the correct dosage amount, at the correct time, and in a suitable way.

While medication adherence is a sophisticated subject, calendarized blister packs directly counteract patient forgetfulness by providing a visual dose history for each day of the prescribed medication regimen. Several published studies have shown a direct connection between calendarized blister packaging marked with dates or other information, resulting in improved patient compliance/adherence to dosing regimens.

One study measured a sample size of 4,500 patients who received medication in a calendarized package. In contrast, the same number of patients did not receive their medication in a calendarized package. The study referenced on Healthcare Packaging states " ...patients with the reminder package had a 7% higher MPR [medication possession ratio], a 13% higher proportion of days covered, as well as a refill timing that was 4 days earlier than those without the reminder package."²

Another example is the unit-of-dose blister package. This application produces blister packages that are simple to use, particularly for patients taking multiple medications per dose and those who have difficulty remembering proper dosage protocols. Adding printed instructions on the package near each sealed dosage provides a clear vision of dosing history and an "alert package". After interfacing with a physician and pharmacy staff, the medication package is the remaining source of information the patient interacts with regularly. Printing relevant information directly on the blister pack is perfect for reinforcing adherence.

The oral contraceptive market is a prime example of successful adherence packaging. Birth control

requires a specific schedule of different dosages to remain effective. Adherence packaging is necessary to reinforce proper dosing intervals. A typical bottling solution is not capable of the required patient adherence to such a prescribed medication regimen.

Blister-packed medications allow prescriptions to be filled quickly as no medication counting and repackaging by pharmacy staff is required, eliminating medication count errors. If pharmacy staff mistakenly pulls the wrong prescription from the shelf, the name and strength of the drug are visible to the patient providing the patient an opportunity to verify they have received the correct medication. In the case of the typical amber bottle, the patient contends with a label printed by the pharmacy and must rely on pharmacy staff to fill the bottle with the right amount and correct dosage.

Blister packages also provide a way for patients and end-users to manage their supplies. Patients often do not realize a refill is required until only one or two doses remain. Such mismanagement can lead to delays in refilling prescriptions and cause missed doses. Again, information printed on blister packages indicates when it is time for a refill, providing ample time according to the regimen.

Data collected by the US Census Bureau projects more than 73 million seniors aged 65 and older will be living in the United States by 2030.³ That is 1 in 5 Americans. Canadian population projections reflect a similar trend calling 1 in 4 people a senior



by 2030.⁴ This demographic consumes a far greater number of over the counter (OTC) and pharmacy-dispensed medications than other groups. It is easy to establish that this age group will continue to impact the North American pharmaceutical manufacturing and packaging industries.

Baby Boomers have clear-cut expectations which align with the characteristics offered by blister packaging. As they continue to be a generation on the go, seniors want convenient and portable unit-dose packages of medications and supplements rather than bottles, expect packaging to be discreet, and prefer blisters for their subtlety. Day and time labeling on blisters to improve adherence is necessary for daily dosing regimens, and easy-to-open blister packs are a welcome alternative for those who have difficulty opening bottles.

1 Study shows reminder packaging improves patient adherence | Healthcare Packaging (<https://www.healthcarepackaging.com/machinery-materials/adherence-delivery/press-release/13285022/study-shows-reminder-packaging-improves-patient-adherence>)

2 Why You Need to Take Your Medications as Prescribed or Instructed | FDA (<https://www.fda.gov/drugs/special-features/why-you-need-to-take-your-medications-prescribed-or-instructed#:~:text=Taking%20your%20medicine%20as%20prescribed%20or%20medication%20adherence%20is%20important,important%20part%20of%20medication%20adherence.>)

3 Demographic Turning Points for the United States: Population Projections for 2020 to 2060 (<https://www.census.gov/content/dam/Census/library/publications/2020/demo/p25-1144.pdf>)

4 Government of Canada - Action for Seniors Report (<https://www.canada.ca/en/employment-social-development/programs/seniors-action-report.html>)

MAKING THE MOVE FROM BOTTLE TO BLISTER

How difficult is it to shift from bottles to blisters? Often the only regulatory requirement is filing a CBE 30 form with stability data to the FDA to convert your packaging to blisters in a relatively short timeframe. Many contract packagers can also adjust for a rapid change to the packaging format if you do not currently have blister packaging

capabilities. There is also an increase in retailers who purchase drugs in bulk from manufacturers or wholesalers and either blister pack themselves or have contract packagers manage the process. In this case, the only requirement would be compliance with the state board of pharmacy guidelines.

With about 80% of the U.S. pharmaceutical products delivered and dispensed in bottles today, as opposed to the 15% in bottles in Europe, there is a huge opportunity to utilize more blisters and have a meaningful impact on products, protection, and patient outcomes. Consider the “3-Ps” for packaging your cannabis, prescription, and over-the-counter medications.

ABOUT PHARMAWORKS

Clients around the globe have trusted Pharmaworks for over two decades for blister packaging solutions. Pharmaworks began with rebuilding and upgrading blister packaging and cartoning equipment. Starting with a strong understanding of the blister packaging process, we went on to innovate our own line of world-leading blister packaging equipment, feeders, and cartoners. Today, Pharmaworks is the premier manufacturer for anything blister packaging equipment related. Pharmaworks provides tooling, vision inspection solutions, product handling solutions, blister machines, cartoners, validation services, rebuilds, field upgrades, training, and more. Often clients have partnered with us on their journey from product stability runs to production. Pharmaworks has a product range that can grow with our client's demands and is also backed by a world-class service team that is passionate about customer service. Visit [Pharmaworks.com](https://www.pharmaworks.com) to learn more about our products and services.



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