

# HOW HIGH-QUALITY PACKAGING KEEPS YOUR MEDICINE SAFE AND EFFECTIVE

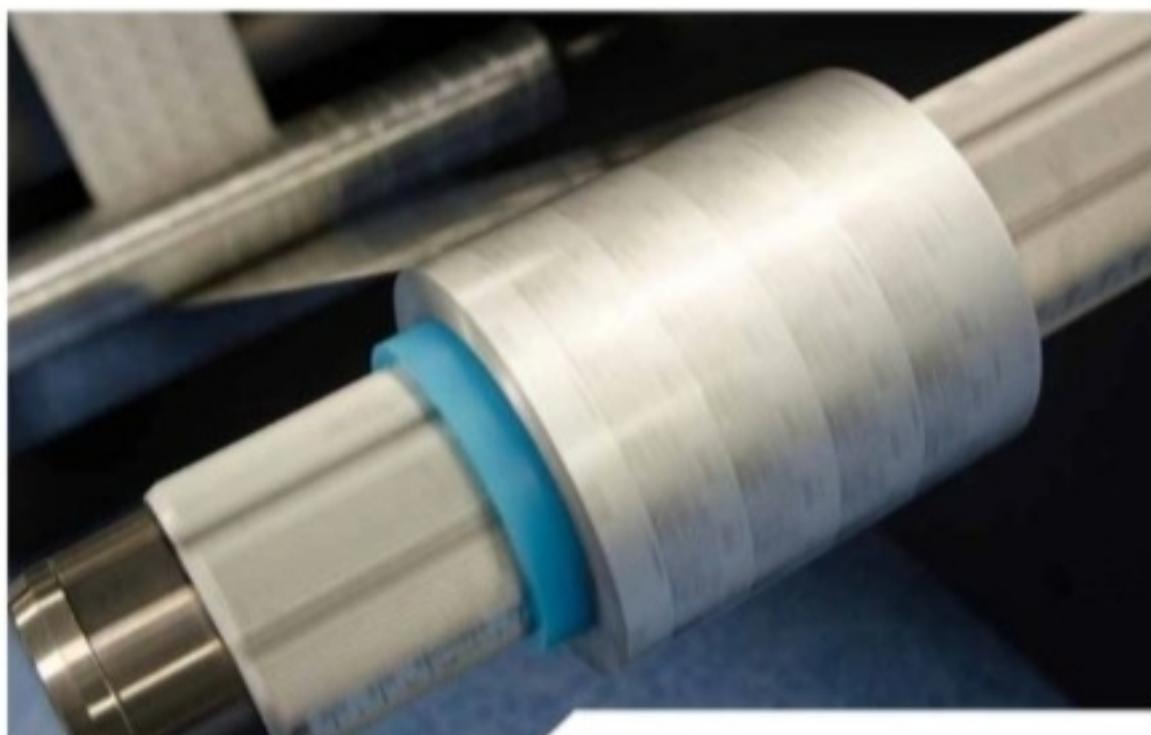
by Mr Kurt Zerafa

In the dynamic and highly regulated pharmaceutical industry, packaging plays a pivotal role in ensuring the safe storage, transportation and integrity of medicines. Given its direct impact on patient safety and regulatory compliance, pharmaceutical packaging is an essential aspect of the healthcare supply chain. This article looks into the critical challenges being addressed at Lewis Press Limited in order to providing innovative, high-quality packaging solutions that not only meet but exceed industry standards and customer expectations.

## Meeting Stringent Pharmaceutical Standards

To ensure the highest standards of quality and safety, manufacturing processes are subject to rigorous quality control measures that monitor every batch produced. Strictly adherence to internationally recognised pharmaceutical standards, including Good Manufacturing Practices (GMP), the PS9000:2016 Pharmaceutical Management System and ISO9001:2015 certification, are a must to remain competitive. These frameworks govern every aspect of a production process in a pharmaceutical packaging company, ensuring full compliance with industry regulations and best practices.

Adherence to above standards have materialised in various standard operating procedures (SOPs) that have been designed to control production processes and to guarantee consistency and compliance. One key example of this is the various documentation that is strictly controlled and utilised for every process being carried out. Combining this with the retention of key samples from production processes go a long way in achieving a high-level of transparency with our customers. This is a critical aspect that contribute positively to successful investigations in case of non-conformities and complaints.



Aluminium Foil for Blister Packs

## Key Functions of Pharmaceutical Packaging

Pharmaceutical packaging must fulfil multiple critical functions to guarantee product safety, regulatory compliance and efficiency in our customers' supply chain. The most important functions have been defined hereunder.

### 1. Containing and Protecting Pharmaceutical Products

The primary function of pharmaceutical packaging is to contain and protect medicinal products, ensuring their efficacy, stability and patient safety. The level of protection required depends on the type of packaging, which falls into three categories: primary, secondary and tertiary packaging.

**Primary Packaging:** This involves materials that come into direct contact with the medicine, such as blister packs, bottles, vials and ampoules. The printing of blister packs, for example, is a critical process that must take place in a controlled clean room environment to mitigate contamination risks. Aluminium foil is often used for such packaging due to its superior protective barrier against light, moisture, and oxygen, which contributes to the preservation of the medication's potency.

**Secondary Packaging:** This includes cartons, leaflets, booklets, and labels which provide important regulatory and informational content for both healthcare providers and patients. While these components do not come into direct contact with the medicine, they play a crucial role in ensuring that the right product reaches the right patient with the correct usage instructions.

### 2. Presenting Essential Information and Ensuring Accurate Identification

The artwork of a product is a critical aspect of pharmaceutical packaging and must be closely controlled to ensure that the information and

identification references displayed on the packaging comply with customer requirements. Close control of the artwork refinement process is achieved by conducting training and implementing SOPs that are focused to reduce non-conformities.

In pharmaceutical packaging, even the smallest defect—such as a missing letter or incorrect dosage information—can have severe consequences. Unlike other industries where minor defects may be tolerable, the pharmaceutical sector demands absolute precision. To maintain patient safety, the latest printing and print-finishing technologies are a must to ensure legibility and accuracy in every packaging component we produce. This is further supported by a number of quality checks that are implemented in critical stages of the product development process.



Flat cartons that are due to be glued and closed

### 3. Enhancing Efficiency for Pharmaceutical Manufacturers

Efficiency is a cornerstone of the pharmaceutical industry, where companies must ensure that their products reach the market promptly while maintaining the highest quality and safety standards. Lewis Press Limited is dedicated to supplying packaging solutions that not only meet strict regulatory requirements but also enhance the efficiency of our customers' operations.

A key aspect of efficiency in pharmaceutical packaging lies in adhering to precise product specifications. One notable example is the repeat length of primary packaging reels. These materials, delivered in continuous web form, must adhere to strict dimensional tolerances. Even slight variations in repeat length can lead to machine stoppages, production inefficiencies and delays in our customers' manufacturing processes.

Our ability to consistently meet these precise requirements relies on four essential factors:

1. Documented measurement of repeat lengths based on customer tolerances
2. Quality control checks performed by the flexo-printing and quality departments for each batch.
3. Investment in advanced technology to maintain consistent output and minimise non-conformities.
4. Highly skilled personnel – Our workforce is our greatest asset. Their expertise, attention to detail, and problem-solving abilities ensure that our packaging solutions meet the highest industry standards.

### Supporting Research and Innovative Product Development

Lewis Press Ltd. has always valued the importance of investing resources to improve our products with innovative packaging solutions whilst keeping in mind the needs and expectations of the customer. Due to this, our organisation is currently participating in a research funded project titled "*A User-Centred Smart Platform for Designing and MAnufactuRing Self-Sanitising and Sustainable PACKaging*" (SMARTSPACK) with the scope of developing a user-centric smart packaging solution that prioritises both user requirements and sustainability.

SMARTSPACK is led by Prof. Ing. Philip Farrugia from the Department of Industrial and Manufacturing Engineering at the University of Malta, alongside research team members Ms Tamasine Camilleri, Ms Essandra Bianco, Ms Svetlana Mifsud, Prof. Ing. Marvin Bugeja, Dr Maresca Attard Pizzuto, and Dr Margaret Camilleri Fenech. Besides the University of Malta and Lewis Press, Ltd., the project consortium includes Multi Packaging Ltd. and iAutomate (Malta) Ltd. SMARTSPACK is funded by the FUSION R&I: Technology Development Programme 2022, managed by Xjenza Malta (Project R&I-2021-005T). For more information, visit <https://um.edu.mt/projects/smarts pack>.



Leaflets that have been folded and slit