

# Pharmaceutical Labelling Solutions

Labels + Packaging  
Brochure  
Europe  
2020



# Tested, proven, compliant label materials for the pharmaceutical industry

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With the latest pharmaceutical trends in mind, we help industry manufacturers meet compliance and performance requirements, with a customer-ready portfolio and a team of experts ready to find solutions to any challenge. As a global leader in pharmaceutical labelling, we're looking towards the future to ensure you have the solutions you need today and tomorrow.

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– Ewa Weglinska  
Product Manager Pharmaceutical Solutions, Avery Dennison

## Industry Trends

As the world focuses on the importance of healthcare and pharmaceuticals, keeping up with industry trends is more important than ever. Global pharmaceutical manufacturers and brand owners must innovate to maintain their competitive edge.



## Patient Safety + Brand Protection

In 2016, counterfeited products accounted for more than three percent of global trade, or about \$590 billion, according to a report from the Organisation for Economic Co-operation and Development. That figure is growing and is estimated to reach about \$2.3 trillion by 2022. Also, according to OECD, fake medicines kill hundreds thousands of people every year.

Anti-counterfeiting measures help ensure healthcare professionals and patients are getting the products they need from the brands they trust – and it protects brands from losing millions each year.

## Engaging Patients

Healthcare practitioners are increasingly interested in pharmaceutical packaging that enhances the overall treatment experience, including easier dosage management and drug compliance. Patient-friendly packaging and devices including auto-injectors, smart packaging, and prefilled syringes are a few examples. Increased personalization in the industry, including biologics and individualized treatment plans will likely drive smaller production lots.

## The Internet of Medical Things (IoMT)

Prescription drugs are one of the most recent additions to the Internet of Medical Things (IoMT). Intelligent labels using UHF and NFC technology enable both traceability and patient compliance, making it easier for pharmaceutical brands to meet global compliance demands.

The US Food and Drug Administration (FDA) implemented the Drug Supply Chain Security Act (DSCSA), while the EU now mandates pharmaceutical serialization. These efforts aim to put a complete, automated chain of custody for the industry in place – efforts that will require pharmaceuticals to be traceable at the unit level and make intelligent labels a smart choice for brands.

## Sustainability

Like other consumer packaged goods, pharmaceutical consumers are increasingly interested in sustainable packaging – which has led to an increased interest in the development of more compliant pharmaceutical packaging materials.

Recycled content and recyclable packaging materials, carbon-footprint reduction, and lifecycle analysis – like the Avery Dennison product life cycle assessment (LCA) tool – are all expected to increase in utilization in the pharmaceutical industry. In-store recycling for prescription drugs and single-use medical devices is likely to gain in popularity and adoption.

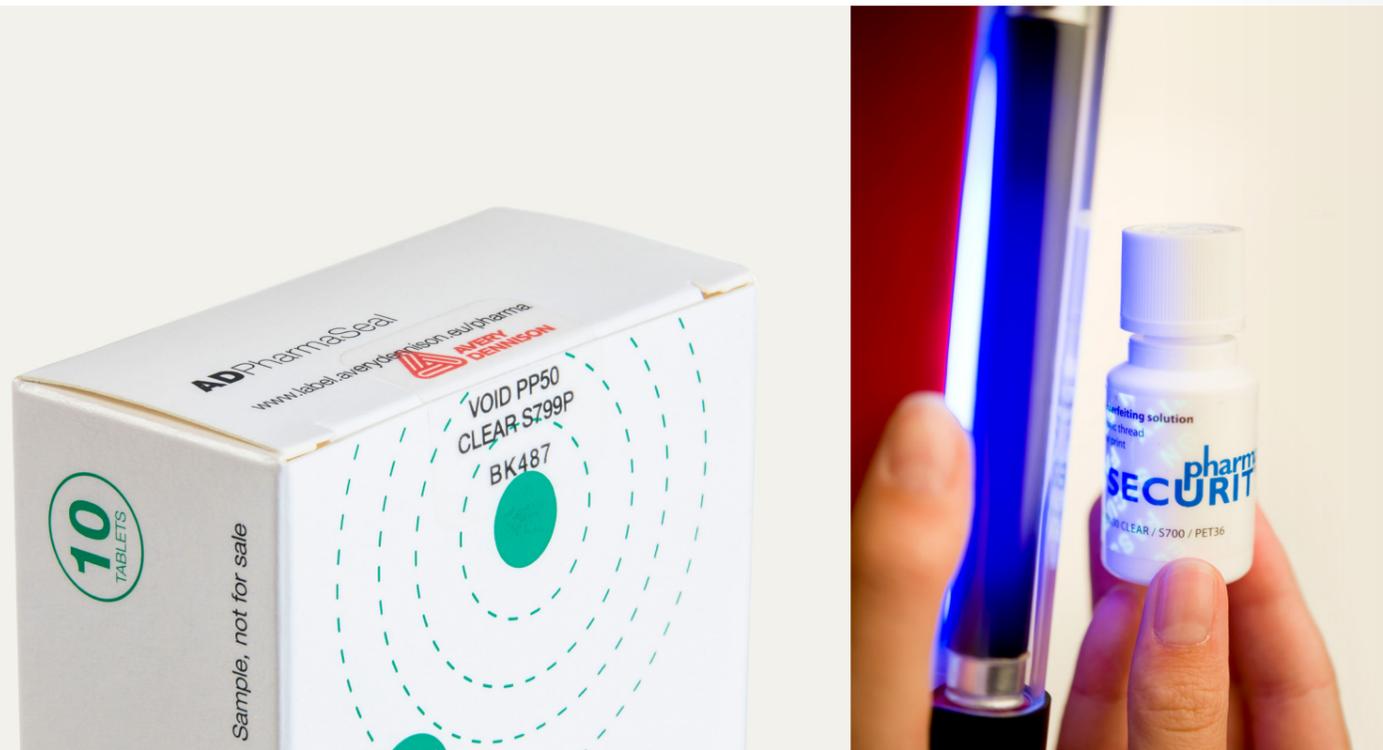
## Global Compliance

As a vital part of pharmaceutical packaging, labels must comply with both local and global regulations, depending on the market in which they're sold and consumed. The European Medicines Agency (EMA) and FDA specify the main requirements for packaging materials.

Working with global suppliers with change management processes in place and local production facilities in every region will be increasingly popular as global trends in compliance policy shifts toward more sustainable materials and intelligent labelling solutions.

## Labels and Packaging Legislation

Pharmaceutical regulations are constantly changing. Our global team of labels and packaging experts remain vigilant about staying up-to-date on regulatory and legislative changes that affect your packaging.



## Guidelines on Plastic Packaging Materials

Plastic-based containers are increasingly replacing glass containers and bottles for pharmaceutical packaging. However, migration is an issue for plastic containers. Components from inks, lacquer, top coats, adhesives, substrate (paper/film) or even the container itself may leach, and contaminate or react with the contents.

Label and plastic packaging solutions should comply with:

- European food regulation 1935/2004/EC, including 10/2011/EU guidance on plastic materials and articles intended to come into contact with food
- ISO 3826-1 a norm that explains how to test plastics collapsible containers for human blood and blood components
- ISO 10993-5 testing for cytotoxicity and ISO 10993-17 testing for leachables
- FDA 175.105 Food and Drug Administration (FDA) concerning indirect food additives, adhesives and components of coatings

## Guidelines on Falsified Medicine Directive (FMD)

Drug counterfeiting is a growing problem for both pharmaceutical manufacturers and the patients they serve. Manufacturers of these drugs experience damage to their brand image, sales and revenue. Directive 2011/62/EU was amended in order to prevent falsified medicines entering the legal supply chain and reaching patients. Directive 2011/62/EU in article 54(o), which has come into force on Feb 9th 2019, requires that every package of prescription medicine must have an anti-tampering device. One of the most popular alternatives is a label seal which can cause box damage, label damage or leave visible signs after label removal.

## Guidelines on medical devices including cytotoxicity

For any medical device, such as auto injectors, or for any materials in contact with a patient, biological evaluation and biocompatibility testing is needed. This testing assesses interactions with a patient's tissues, cells, or body fluids - and helps to prevent potential biological risks. A test we consider to be most relevant for labelling materials to meet this evaluation and testing within a Risk Management Process (ISO 10993-1) is ISO 10993-5, a dedicated test for vitro cytotoxicity.

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# Pharmaceutical Labelling Solutions

With new technologies and legislation, there's a need for new materials that can meet your pharmaceutical packaging needs of today and tomorrow. Our ready-made labelling solutions are designed to meet strict regulations, and our global team is ready to ensure you have tested and proven materials.



### Cold chain labels

The durability of materials is of utmost importance for biological and pharmaceutical products such as blood, stem cells, and whole tissues that are preserved by cooling to low sub-zero temperatures, such as  $-196^{\circ}\text{C}$  (the boiling point of liquid nitrogen). At temperatures below  $-130^{\circ}\text{C}$ , biological activity ceases and therefore storage at these temperatures is necessary to preserve the material in its unaltered state.

Our materials for cryogenic applications were designed for applications ranging from room temperature to storage in liquid nitrogen and harsh deep-freeze environments. Our C2050P adhesive offers application temperatures as low as  $-50^{\circ}\text{C}$  and is suitable for labelling containers during clinical trials. Our cold chain labels can be applied on containers, tubes, vials, aluminum canisters, and other challenging surfaces.



### Syringe labels

Syringes have a very specific combination of requirements for labelling, including their small diameter, surface coating, dispensing speed during packaging, no-label appearance, regulatory requirements, migration safety, and storage and application temperature.

Our syringe labels are designed for all of these applications, with labelling materials and adhesive engineered for small diameter vessels and high speed applications. They can be applied on syringes, autoinjectors, ampoules, vials, and more.

### Ethical and OTC

Small containers with diameters typically between 10-25mm made of plastics like HDPE or LDPE are commonly used. For those containers our portfolio includes products that have excellent adhesion and hold on tight curvature (mandrel), low migration properties, and high shelf appeal. Our blister labelling films can be distinguished by their high opacity and ultradestructibility.

Applications include pill bottles, nasal sprays, eye drops, and inhalers.

### Intelligent labels

In pharmacies, clinics, and hospitals, intelligent labels with RFID technology can enhance inventory management by helping to itemize and sort stock – helping pharmaceutical brands ensure quality, prevent waste, and save lives.

Pharmaceutical labels with an NFC inlay have a unique digital identity – one that can be tracked and traced online across the supply chain. Combining NFC tagging and blockchain recordkeeping can provide brands and consumers alike with a complete, tamper-proof, easily-accessible view into a product's provenance and journey through the supply chain.

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Intelligent labels like NFC deliver the added benefit of meeting increasing government and consumer demands for visibility into every step of a product's journey from source to shelf.

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We offer a broad portfolio and the in-depth technical support needed to create dependable, compliant, and unique solutions for pharmaceutical applications.

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### Security labels

To counteract pharmaceutical counterfeiters, we have created tamper-evident and void labels that comply with European Union Directive 2011/62/EU requirements. Our security labels reduce the risk of packaging falsification and include destructible labels, box damage films, and void labels.

### Temperature controlled packaging

Temperature control is essential for quality control. Our TT Sensor Plus 2 data logger uses NFC technology to transfer temperature data wirelessly to mobile devices to ensure the quality of products, and to identify any supply chain issues. The label is about the size of half a credit card, which makes it viable for a variety of applications. For temperature controlled packaging, where temperature is critical, we offer Vacuum Insulation Panels (VIPs), which can be put in a box to keep contents cold during shipment.



## Labelling Materials for Today and Tomorrow

We help pharmaceutical industry manufacturers meet compliance and performance requirements, with a customer-ready portfolio and a team of experts ready to find solutions to any challenge.



### Patient Safety

**When regulations change, you create a new product, or you have a new labelling need, we'll work with you to find or create a solution that meets all of your patient safety needs.**

- Universally compliant packaging materials for products sold in the global marketplace
- Extractables and Leachables testing with stringent standards to meet your regulatory compliance including REACH regulations, EU Directive 94/62/EC, regulation 1935/2004/EC, and FDA requirements
- Global R&D resources to create new solutions when necessary for compliance and unique applications
- Additional testing for cytotoxicity with negative results

### Change Management

**As a global manufacturer serving the pharmaceutical industry, we understand the changing nature of the regulations, performance standards, and compliance needs.**

- Specially developed adhesives for small diameter containers, syringes, blood bags, cryogenic applications and security seals to ensure compliance and security of supply of unchanged product for an extended period of time
- Change management service with one year of prenotification
- Insurance that performance requirements of the new product are on par or better than the previous product
- Complete change management documentation to include test reports, certification, and validation reports

### Innovation and R&D

**Strategically positioned across the globe, our centers of technology and research support major innovation initiatives for new products that meet the changing needs of the pharmaceutical industry.**

- Unique pharmaceutical testing methods including extensive customer application simulation testing, prototyping, as well as analysis and engineering of labels and packaging
- Dozens of research laboratories around the globe with a team of approximately 300 engineers and scientists
- Dedicated team of R&D and compliance experts with years of experience

### Engineered Solutions

Our engineered solutions service helps you develop custom-made labels that differentiate your business and grow your bottom line. Our team includes some of the industry's most experienced professionals. They'll explain the latest market developments and trends in innovation, and then use that knowledge as the foundation for developing your unique solution. After eight decades of innovation and pioneering change in the labels and packaging materials industry, we still love a challenge. So if we don't already have a solution for your specific needs, we'd love to work with you to create one.



**Let's start a new project together!**

Scan the QR code, or visit [label.averydennison.com/pharma](http://label.averydennison.com/pharma) to contact Ewa Weglinska, Product Manager for Pharmaceutical Solutions

# Avery Dennison: Your Partner for Patient Safety

We have a wide range of tested, proven, compliant label materials for the pharmaceutical industry. With a solution for every application, we help manufacturers throughout the pharmaceutical industry track products, inform customers, and comply with regulations. And we want to work with you.

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## Who we are

As the pioneer in the pressure-sensitive industry, we bring one-of-a-kind capabilities to labels for the automotive industry. We combine decades of innovation with deep knowledge of both regulatory and legal requirements. We know about the real-world conditions in which our labels must perform, and the technical challenges they have to meet. Whatever your product, wherever it's going, we can help you develop a label that sticks with it.

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## What we stand for

**Sustainability. Innovation. Quality. Service.**

In 1935, we invented the first self-adhesive label, and we've never looked back. With each passing decade, our innovations have further shaped our industry by lifting the limits on what labels can do. The world's most successful brands know that innovation and evolution are the lifeblood of longevity and success. We're proud to help our clients continually expand the boundaries of what's possible.

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## Work with us

You're the expert in your business; we're the expert in pharmaceutical labelling. Contact your business development manager today to find out how Avery Dennison Pharmaceutical Labelling Solutions can meet and exceed your needs.

[label.averydennison.com](http://label.averydennison.com)

Avery Dennison Corporate (NYSE:AVY) is a global materials science manufacturing company specializing in the design and manufacture of a wide variety of labeling and functional materials. The company's products, which are used in nearly every major industry, include pressure-sensitive materials for labels and graphic applications; tapes and other bonding solutions for industrial, medical, and retail applications; tags, labels, and embellishments for apparel; and radio frequency identification (RFID) solutions serving retail apparel and other markets. Headquartered in Glendale, California, the company employs approximately 30,000 employees in more than 50 countries. Reported sales in 2018 were \$7.2 billion.

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