TACKLING PARENTERAL DRUG LABELLING'S SURGING COMPLEXITY

Lars Skole, Managing Director of LSS Labelling Systems Scandinavia, discusses emerging trends and challenges associated with growing parenteral packaging and labelling complexity – and how pharmaceutical developers and manufacturers can meet the challenges ahead.

Pharma and biotech development is expanding at a tremendous rate following sustained growth of pharmaceutical-based healthcare around the world. To maintain health and deal with chronic disease, more people are taking prescriptions and over-the-counter (OTC) medications than ever before.

Billions of doses will continue to be dispensed from basic packaging. But millions more doses will be delivered to patients in single-unit doses and specialised functional combinations that marry the drug with the delivery device – or the patient to a personalised therapy.

PACKAGING'S NEW ROLE IN THERAPEUTIC PERFORMANCE

For a long time, most consumer drug labelling involved mass-scale printing and application operations and the high-speed capacity to efficiently mark the packaging of large quantities of common products. Most drugs were packaged in very simple primary containers – essentially, jars and bottles for oral solid dose drugs and vials for liquid or parenteral medications.

A pharmaceutical packaging market study by Freedonia Group in 2020 notes the increasing importance of packaging as more sophisticated therapeutics penetrate the market.[1] Study data shows an expanding use of what was termed "high-value" containers, closures and accessories, with the goal of drug developers "to enhance drug delivery and security and promote better patient adherence with prescribed medication schedules".

PERSONALLY ADMINISTERED PARENTERALS GROWING

In its report "Pharmaceutical Packaging – Demand and Sales Forecasts, Market Share, Market Size, Market Leaders", Freedonia projects that parenteral containers (injectable, infusible liquid therapeutics) will post the fastest rate of growth among primary pharmaceutical packaging.

The analysts say advances in parenteral therapies for cancer, diabetes, viral diseases, neurological disorders and similar conditions will support gains in the segment. Accordingly, the report says the use of prefillable syringes – especially self-administering combinations like epipens – are expected to grow the fastest. However, vials will continue to be parenteral drugs' dominant package form for the foreseeable future.

INCREASED LABELLING COMPLEXITY TO SIMPLIFY CARE

Clearly labelled and marked primary drug packaging and devices help clinicians and

> "Clearly labelled and marked primary drug packaging and devices help clinicians and patients accurately administer treatments and simplify delivery, especially for parenteral injectables."

Lars Skole
Managing Director
T: +45 7020 2500
E: lsk@lss-dk.com

LSS Etikettering A/S
Normansvej 8
8920 Randers NV
Denmark

www.nemera.net

patients accurately administer treatments and simplify delivery, especially for parenteral injectables.

Many of these combination devices have limited label real estate and challenging surface characteristics and are tough to label. These circumstances explain why parenteral labelling, in particular, is growing more complex and technically challenging.[2]

MORE INDIVIDUAL PRODUCT LABELLING REQUIREMENTS ON THE HORIZON

Freedonia notes trends favouring the use of smaller-sized medication containers and single-unit dosing will increase the overall number of labels pharmaceutical manufacturers will be processing for a given product. This number, according to Freedonia, will also be magnified by the increases in the overall quantities of drugs produced.[3]

All of these development trends are pointing to one thing: higher numbers of more discrete product lines and more frequent but smaller batch sizes – all of which drive vial and parenteral labelling operation complexity. Regardless, there is a desire from contract packagers and pharma manufacturers to have more flexible lines (Figure 1).

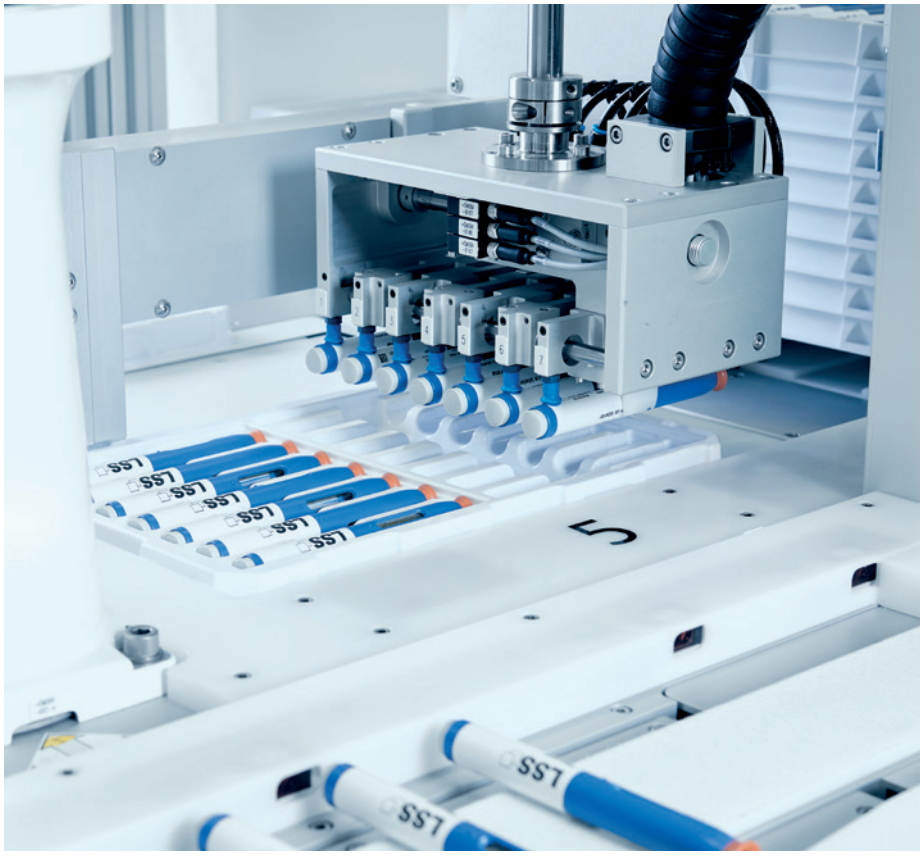

Figure 1: Device labelling.

"Requirements for labelling prescription drugs are extensive because regulators want to provide both the prescriber and user with the best information in support of administering the medication effectively."

LABELLING KEY TO PATIENT CENTRICITY AND BETTER OUTCOMES

Driving the development of all drug products is the concept of patient centricity. Essentially, that means providing people with affordable access to safer, more effective drugs that deliver better results more efficiently than alternatives like surgery or a hospital stay.

Requirements for labelling prescription drugs are extensive because regulators want to provide both the prescriber and user with the best information in support of administering the medication effectively.

Patients are increasingly administering their own parenteral treatments as well. To pharma and its regulators, that means clear markings, instructions and safety or administration guidance must appear on the label and be legible on the package at the point of care.

Labelling plays an even more critical role in dose compliance and is an inherently patient-centric strategy because it assures the precise prescription and dosing by physicians and accurate administration and delivery by clinicians and patients. Several studies have shown a clear correlation between dose compliance and improved health outcomes, as well as a lowering of the overall cost of care for a given condition.

Patients who can't or won't take their medications often get sicker, requiring expensive hospitalisations or surgeries.[4] When patients take their medications as prescribed, they get better faster and at significantly lower cost to payers.

SECURITY IN THE SPOTLIGHT

Among other things, the covid-19 pandemic has put parenteral drug supply chain security in the spotlight, so expect greater attention to labelling and labelling operations in support of supply chain integrity and resiliency in this area from all players.

For example, every primary package (vial or combination device) and label now carries information that assures both source and quality to global regulators. Label technology is also offering other security functionality to help assure supply chain integrity, including heat-sensitive and smart labels to thwart drug counterfeiting and diversion.

Pharmaceutical companies, notes Freedonia analyst Mike Richardson, will be increasing their purchase of label technologies featuring high visibility and tamper-evident features, because the perception of safety enhances the perception of product value. He says these value-added labels are finding increased use in the OTC drug segment, where greater competition is boosting demand for labels that enhance the perceived value of products.

Freedonia says this trend will shift consumption towards label technologies with enhanced security features such as radio-frequency identification tags, serialisation codes, holograms, colour-shifting inks and other anti-piracy measures.

INDUSTRY 4.0 AND DATA INTENSITY

Serialising pharmaceutical packaging with an individual product identifier is now law in most established global pharma markets. This and a number of variables related to primary packaging – including its size and the product's data and physical handling requirements – are making labelling and marking operations more challenging to manage effectively.

In the face of Industry 4.0 and global serialisation compliance, companies are compelled to either develop and implement labelling operations that meet their products' packaging and labelling complexities or hire commercial partners who can. Either way, pharma and biotech manufacturers need access to sophisticated systems capable of integrating digital and information technologies currently disrupting pharma manufacturing and supporting data acquisition requirements.

MEETING REQUIREMENTS REQUIRES INTEGRATION AND EXPERTISE

Finding and integrating the capacity and capabilities to handle anticipated demand and meet emerging data requirements will likely be challenging manufacturers the most. Capable technologies are available but acquiring systems in high demand takes time, as buyers reserve their place in the production queue. Delivery time for new equipment and completing internal validation can impinge on timely access to processing and manufacturing systems.

Manufacturers are seeking faster, more flexible machines with increased throughput and integrated quality assurance technologies. Because many of the new biologic drugs are parenteral, including pandemic-fighting vaccines, they require processing in highly controlled cold environments (as low as -80°C in some cases). This is placing even more technical demands on labelling operations that require developed, integrated technologies to accomplish.

In the wake of the pandemic, and as current trends gain momentum, specialised vial and device labelling equipment procurement will become an imperative – all of which calls for defining the purchasing strategy.

When talking with suppliers, the dialogue needs to be open and forthcoming to determine optimal system specifications that create a comprehensive solution purchase and not just an equipment buy. Pharma's regulatory environment is one of the strictest there is – and that attenuates the need to develop a robust procurement strategy.

SPEED IS KEY, ACCURACY AND QUALITY ESSENTIAL

Pharma and biotech developers are under pressure to respond faster to market demands. That means timing the delivery of needed capability is critical. Details of the machine, the number of systems purchased and other variables also help set the timeline – as does the order book of the vendor. All of these variables can add weeks and months to delivery timing and clash with business plans if not sorted beforehand.

Purchasing capital equipment is a challenging process in its own right. It needs to be done with a straightforward, planned approach to ensure the investment is not wasted. Aligning manufacturing business interests with experienced vendors who have already considered the above will yield the best machine for the investment and meet the projected demands of global markets and the needs of patients around the world.

> "In the wake of the pandemic, and as current trends gain momentum, specialised vial and device labelling equipment procurement will become an imperative."

ABOUT THE COMPANY

For more than 40 years, LSS (Labelling Systems Scandinavia) has delivered automatic labelling solutions around the world and for all kinds of pharmaceutical products. Its individually designed and customised labelling solutions meet the unique requirements of the pharmaceutical industry. With decades of experience in developing, designing, manufacturing and installing pharmaceutical labelling machines, the company's versatile solutions range from simple offline systems and automatic label dispensers to integrated labelling systems that interface with other equipment and software. It has standard solutions for vials, ampoules, small bottles, syringes, autoinjectors, pens and boxes.

REFERENCES

1. *"Pharmaceutical Packaging – Demand and Sales Forecasts, Market Share, Market Size, Market Leaders". Report, Freedonia, April 2020.*
2. *"New Regulations And Safety Complicate Drug Labeling". Pharmaceutical Online, July 2, 2018.*
3. *"Pharmaceutical Label Demand to Grow Over 7 Percent Annually Through 2020". Pharmaceutical Processing World, February 8, 2017.*
4. *Claxton AJ, Cramer J, Pierce C, "A systematic review of the associations between dose regimens and medication compliance". Clin Ther, 2001, Vol 23(8), pp 1296–1310.*

ABOUT THE AUTHOR

After more than 15 years leading technology companies and 12 years devoted to the packaging industry, **Lars Skole**, managing director of LSS, has deep experience of integrating labelling technologies and systems to create high-performance packaging operations. He has an MSc degree in Technology Management from the University of Aalborg (Denmark) and international experience developing comprehensive labelling solutions for label manufacturing (converting) and marking and labelling primary pharmaceutical packaging, including parenterals, prefilled syringes, autoinjectors and combination devices.