Full-on pharma

As one of the most stringent end-use markets for labels and packaging, pharmaceuticals demand a lot of the digital print supply chain. *David Pittman* investigates

Of all the end-uses for labels and packaging, the pharmaceuticals market is no doubt one of the toughest and strictest that the industry serves.

Bernd Sauter, managing director at Kama, says, 'While batch sizes are getting smaller and delivery times are shortening, the requirements for quality, safety features, serialisation and validation are increasing. Zero defect is on everyone's lips and is becoming the standard.'

Bart Vansteenkiste of Domino Printing Sciences, adds, 'It is essential that all pharmaceutical products use the appropriate packaging, and have labels that depict all the important information about the contents in order to keep up with new legislation centred around patient safety and anti-counterfeiting.

'These details are generally displayed via printed serialisation embedded in either a data matrix or QR code – and this is now a requirement for all prescription pharmaceuticals in Europe and the US, and for prescription and over-the-counter (OTC) medicines in Russia, as specified by the Chestny Znak regulation.'

Mr Vansteenkiste, who is Domino's global life sciences sector business development manager, also warns that incorrect or poorly displayed information can have 'disastrous consequences', with patients potentially being handed the wrong product by a pharmacy, or an incorrect drug or dose of drug being administered in a hospital.

> Zero defect is on everyone's lips and is becoming the standard

Kama sales manager Stefan Kleditzsch notes that for printing a minimum font size of 4pt applies, and that negative font is not allowed for the important instructions on dosage, use and storage.

'The regulations for marking with Braille vary internationally and are mandatory for the European market according to the local pharmaceutical legislation there. Usually, 4-6 lines of Braille are embossed, sometimes only one line and placed on one to three sides of a folding carton with a defined distance of 8mm to the creasing and cutting edges. The height of the Braille dots must be at least 0.4mm (optimally 0.5-0.7mm), and the surface must not break.'

Kama's AutoBraille unit, an inline Braille embossing module that can be moved automatically to any position across the full width of the company's FlexFold 52i Pharma, is contributing to the machine being regarded a highly efficient converting system for producing pharmaceutical folding cartons.

The Domino K600G is capable of printing 2D codes on each individual pocket in a blister pack

'The requirements must be met consistently at the specified levels,' continues Mr Kleditzsch. 'All codes and fonts, images, etc, must be checked pixel by pixel – ideally by PDF comparison –, and defective products must be ejected and all processes must be documented in detail. The entire inspection process must be validatable.'

Philippe Voet, CEO at label printer Etivoet Belgium, sees labels and packaging's role in compliance, protection, stability, convenience, presentation and integrity being as important as information dissemination. From the way we as consumers and patients touch and interact with brands and their products, the role of labels and packaging goes far further than a mere means of delivering information.

Then there are the issues of counterfeiting and brand protection. According to Smithers, estimates from Interpol and the World Health Organization (WHO) place 10% of the global pharma drug supply chain as counterfeit, costing up to $200 billion annually. The WHO has previously calculated that such a volume of counterfeit drugs accounts for one million deaths every year. Pete Smallwood, business development manager at Eltronis, examples cases of his company experiencing projects where the counterfeiting of a specific medication has become so

widespread that medical practitioners refused to prescribe it.

The recent coronavirus pandemic has exacerbated the situation, with the rise in e-commerce having made selling counterfeit drugs easier, and counterfeiters also exploiting Covid-19 through the sale of fake vaccines. This, says Smithers, examples why the pharma market is one of the chief users of anti-counterfeiting packaging, which alone will be worth $200 million globally by 2026. The pharmaceutical security packaging segment is likewise forecast to grow year-on-year at a rate of 5.6% to reach $269.8 million in 2026.

'Brands want visible and invisible counterfeit protection, tamper and resistance evidence, child resistance, and protection against wrong use,' says Mr Voet, who has also recently been appointed as the new president of industry association Finat.

Dave Stone, senior consultant, print security at Smithers, identifies that, 'The best approach is to have levels/layers of security starting with visible.'

Overt options could include foils and holograms, and colour changing elements. Next might come assisted viewing/detection techniques, such as fluorescent inks or taggants. Tamper-evident features go on to play a direct role for the consumer as, 'if a simple tamper-evident void tape is used to seal a package, the end user can detect a counterfeit at the point of opening,' says Mr Stone.

'Where pharmaceuticals are opened by the end user, then the packaging has a direct impact on reducing counterfeiting,' advises Mr Smallwood. 'Effective solutions need to focus on two specific areas: allowing the end user to have the capability to easily authenticate their purchase; and showing that the packaging is intact when it reaches the end user, provide evidence of tampering, and ideally allow the end user to easily open the packaging.'

Eltronis has introduced a combination product, Enseal, that combines a tamper-evident label with an easy opening strip that cannot be reattached; it carries encrypted, unique QR codes that allow the end user to verify their purchase with a standard smartphone. The QR codes can also carry additional information such as shelf-life, dosage, etc. The authentication has a geo-location element, which shows the pharmaceutical brand clear evidence where the code was authenticated, so making it a valuable weapon against grey import. This functionality is delivered through its Engage secure Cloud-based platform.

Mr Vansteenkiste sees tamper-evident labelling combined with serialisation as, 'one of the most effective methods of protecting products and brand integrity.

'The combination of these two tools is crucial in preventing counterfeiting and ensuring patient safety. With serialisation, when buying products from a pharmacy you can be sure that the product is genuine, and tamper-evident labelling ensures that the product has not been compromised in any way and is safe to use.'

Russia's Chestny Znak supply chain track-and-trace system is one of the newer, more complex pieces of legislation that the pharma supply chain must respond to

Regulatory landscape

As Mr Vansteenkiste has already detailed, legislation and regulations the world over are constantly being updated and introduced, such as the Chestny Znak supply chain track-and-trace system in Russia. In Europe, the Falsified Medicines Directive has already been implemented, whilst in North America the Drug Supply Chain Security Act (DSCSA) comes into force in November 2023. This will include mandated unique identifiers in the form of two-dimensional data matrix barcodes. Mr Vansteenkiste predicts that in the near future it will become a legal requirement to have a 2D code on every pharmaceutical product, as well as its packaging.

> "Patient safety is paramount, meaning this kind of coding could become a legislative requirement"

Mr Voet suggests purely pharmaceutical regulatory and legislative changes, 'will probably not be the main driver for change.'

Rather, 'I believe sustainability will be of bigger importance. If you look at the tsunami of new legislation towards all industries, the pharmaceutical and packaging industries shall also steer towards the needed Circular Economy.'

Mr Smallwood sees one of the major issues with regulation and legislation being that it sets a bar for companies to achieve. 'This can have the tendency to instil a mindset that as long as the manufacturer has met the regulation then they have met their responsibilities,' he says. 'However, this tends to absorb any budget for additional anti-counterfeit measures, there is no understanding of the specific counterfeit issues of an individual market, and these imposed solutions become the focus for cost cutting programmes.'

'If you look at the tamper-evidence element of the Falsified Medicines Directive, it has been a target for companies to drive the price down regardless of the quality, and as it tries to be a one-size-fits-all solution ▶

The combination of Eltronis' technologies serves to provide authentication and brand protection plays to the pharma supply chain

these tamper evident labels become readily available and easily procured by counterfeiters.'

To deliver success and the desired ROI, Mr Vansteenkiste goes on, 'Accuracy and readability are crucial to serialisation and coding's success, but of equal importance is the availability of the relevant equipment on a global scale. Tracking and tracing is of paramount importance across the world, regardless of localised pharmaceutical legislations. Any manufacturer of medical goods must have access to serialisation and coding equipment of the highest quality, not only to ensure they can keep up with production demands and keep waste to an absolute minimum, but for health and safety purposes as well. Equipment durability, substrate flexibility and overall versatility are also essential considerations for pharmaceutical companies. Close interrogation of the production line and local legislations must be performed first to gather an understanding of what the minimum requirements will be.'

The right choice

To further increase ROI, Mr Smallwood calls on pharmaceutical companies to design anti-counterfeit elements into packaging from the off, rather than trying to integrate them into an existing package. 'That way printing and converting should be seen as an integral partner in the design of the anti-counterfeit solution rather than simply a supplier.'

For Mr Voet, 'Digital printing should be the ideal technology for the pharmaceutical industry as the advantages are fully in line with the specification, as well as being ideal for small runs, having no fixed costs, stability of quality, and the ability to serialise. But pharmaceutical products do have an important step before being able to use digital print – proof of safety of the digital technology. Product safety and patient safety are critical. That's why water-based conventional technologies are widely used for pharmaceutical products. Newer technologies like water-based digital presses will most probably give the perfect combination of both worlds.'

Etivoet has itself invested in a new water-based inkjet press, and can also offer 100% VOC-free labels. A 100% camera inspection is used to ensure accuracy and quality of its labels for pharmaceutical customers. These are produced in a specific and separate building, where in addition to ISO 9001 and BRC audits, the company receives detailed audits from its pharma customers on a regular basis.

> The pharmaceutical and packaging industries shall also steer towards the needed Circular Economy

Domino has added K600G to its family of monochrome inkjet digital printing systems, and which is capable of printing 2D codes on each individual pocket in a blister pack. In the past, coding at the pocket level would typically be limited to a product name and weight. With K600G, Domino can offer a solution to print a 2D code, which can contain information including batch code, expiry date, and further product identification at the individual item level.

'This will enable doctors and consumers to scan and check whether an item is the right medication, in the right dosage, and that it has not expired,' says Mr Vansteenkiste. 'Patient safety is paramount, and Domino anticipates that this kind of coding could become a legislative requirement in the coming years – the next obvious step would be to introduce serialisation at the individual item level to provide even higher security.' •

Becton Dickinson has used Domino's digital printing technology to combat counterfeiting of Covid-19 vaccines