Tamper-evident labelling for folding carton packaging
1. Introduction

Beguiling internet offers and irresistible advertising are inducing more and more consumers to adopt a bargain-hunter mentality and purchase medicines on the legal grey market or even illegally. The World Health Organization WHO has estimated that one in two medicines purchased on the internet worldwide is now falsified. Surprise would be an inappropriate response in view of the enormous profit margins of the counterfeiters. Depending on the medicine, the net profit can be as high as 20,000 percent – ten times the margin generated by the trade in heroin. ¹

The growing illegal online business is therefore seriously damaging drug manufacturers’ economic interests. According to estimates, the global loss could total as much as 35 billion euros. Counterfeit drugs also harbour considerable health risks. Consumers seldom realise that a click of the mouse can put their health at risk. Given the huge profits, drug counterfeiters often dilute or omit the active ingredients, or replace them with ineffective or even, in the worst case, dangerous substances. Especially in the case of patients who permanently depend on medicines, such as those who need blood thinners or HIV medication, the consequences can prove fatal. It is not only the internet trade that poses a danger to users – falsified medicines can also enter regular circulation in some circumstances. At present, counterfeit medicines are almost impossible to detect with an untrained eye.

The European Union has recognised this problem and responded by issuing the Falsified Medicines Directive 2011/62/EU. The final version of the Commission Delegated Regulation (EU) 2016/161 was published on 9 February 2016.² The provisions of the Directive will now become legally effective within a period of three years. Medicinal products or the packs containing them will then be required to bear an individual serial number and be traceable to the manufacturer. In addition, packs must be protected against tampering in future. Alongside the EU, other regions and markets, including China, the USA, Brazil and Turkey, are also in the process of taking, or already implementing, similar precautions.

The prospect of high profit margins and the existence of supply chains that lack seamless controls is giving rise to a dramatic increase in product piracy, which can have severe consequences, in other sectors as well. An especially extreme example was the baby food

¹ Cf. article entitled ‘Verfolgung ist die beste Medizin’ in F.A.Z. of 10 December 2013
scandal discovered in China in 2008. Melamine was being added to milk in order to give the appearance of a higher protein content while concealing dilution with water. When dairy products adulterated in this way were used in baby food, hundreds of thousands of infants became seriously ill and several died. In other segments, apart from luxury goods, such as watches and handbags, counterfeiters have long since taken a strong interest in car spares and electronic products, which can endanger life and limb as well.

Pharmaceutical companies now face the Herculean task of complying with the EU Directive seeking to protect against falsified medicinal products. The German securPharm initiative has described it as no less than one of the largest infrastructure projects in the drug supply industry. The cost burden imposed on manufacturers has been estimated at up to 100,000 euros – per production line. This figure does not include the companies’ ongoing additional costs. It has been pointed out on many occasions that the introduction of serialisation procedures will be accompanied by a review of merchandise management systems in most pharmaceutical companies. Although further costs will be incurred, the outcome will reap rewards not only relating to the key issue of counterfeit protection, but also as regards efficiency improvements.

It remains questionable whether this benefit can give rise to a competitive advantage, as is sometimes claimed. Given that other countries with large markets alongside the EU are likewise contemplating (or already implementing) similar serialisation projects, the number of unaffected pharmaceutical companies is likely to be small or, at best, significant only in niche markets to a growing extent.

2. Extensive autonomy in decision-making

Serialisation, typically in the form of a 2D matrix code containing an individual serial number among other elements, is only one of the two, safety features’ prescribed by the Directive. The other feature is described simply as an,‘anti-tampering device’. An explanatory commission document states, somewhat tersely: ‘It should be noted that the present Delegated Regulation does not set out the technical characteristics of the anti-tampering device since the Commission mandate, as delegated by the legislators, only covers the technical characteristics of the unique identifier.’ The Delegated Regulation of 2 October 2015 merely states, ‘The verification of the integrity of the anti-tampering device shows whether the packaging has been opened or altered since it left the manufacturer, thereby ensuring that the content of the packaging is authentic.’ Each manufacturer is therefore largely free to decide how to satisfy the requirement. Although manufacturers could benefit incidentally from complying with the,‘unique identifier’ requirement, there are unlikely to be any bonuses whatsoever for satisfying the ‘anti-tampering device’ stipulation – with the possible exception of being able to apply such a device to medicines that are currently outside the scope of the EU Directive. Pharmaceutical manufacturers and contract packers are therefore compelled to achieve maximum security by way of the anti-tampering feature, while attaching high priority to implementing the requirements as efficiently as possible in view of the absence of any currently foreseeable additional benefits.

5 Commission document C(2015)6601/F1, p. 4
3. European standard for anti-tampering features

Crucial guidance on the selection of an appropriate ‘anti-tampering feature’ is now provided by the European standard DIN EN 16679, entitled ‘Packaging – Tamper verification features for medicinal product packaging’. It was produced by Technical Committee CEN/TC 261 in consultation with German experts, and entered force in March 2015. The range of options outlined by the standard is relatively small.

They are as follows:

a) Folding boxes closed with glue
   These boxes must be cut or torn to gain access to the product. Although they can incorporate perforations to facilitate access, the first-time opening of the folding box must lead to visible damage of its integrity.

b) Specially constructed folding boxes
   The flaps are inserted in the body of the folding box in such a way that first-time opening leads to a visible change of appearance and remains clearly evident if the box is reclosed.

c) Film wrappers
   The product container is wrapped in film that cannot be removed without being ripped or broken.

7 DIN Deutsches Institut für Normung e.V.: Packaging - Tamper verification features for medicinal product packaging; English version EN 16679:2014; March 2015
d) Sealing labels

These permanently affix at least one flap to the body of the packaging. Only a label that has been neither torn nor ripped off indicates that the pack has not been opened for the first time.

Although fundamentally suitable for folding carton packaging, sophisticated display blister packs, as used for small electrical parts and memory cards in the retail trade (primarily to combat theft), are less suitable for practical and economic reasons. Flexible packaging with a sealing edge that seals the product inside a plastic and/or aluminium film are also likely to remain a rare occurrence in practice.

Other customary anti-tampering features that have already proven effective are also available, but unlikely to emerge as significant solutions for folding boxes simply for technical reasons. One such example is the sleeve. This is a particular type of film wrapping that is often shrunk only around the actual closure. Such sleeves are most popular for sealing glass or plastic bottles and similar items. A damaged or missing sleeve can provide an indication of tampering. A breakable or tear-away closure functions in much the same way as the sleeve, but is usually an integral part of the packaging. A typical application is bottled water. The cap of the bottle can be removed only after it has been turned and thus detached from a sealing ring. Finally, DIN EN 16679 also describes the blow-fill-and-seal (BFS) container, which is made from plastic material and formed, filled and sealed in a continuous process. In order to extract the – usually liquid – content, it must be visibly penetrated or broken.

4. Sealing labels give rise to marginal extra cost

If the options are restricted to folding carton packaging, as in the present case, only the variants a) to d) are relevant in principle. Variants a) and b) generally require major structural alterations to be made to folding cartons that are already in use, which can entail design and/or material changes. From an overall perspective, this can give rise to significant extra costs. The same applies, perhaps to a lesser extent, to variant c), namely film wrapping. In this case, the existing
folding cartons can usually remain in use. A difficulty remains, however, if the film has been completely removed and the doctor, pharmacist or patient is unaware that a wrapper was the primary defence against undetectable first-time opening. Unless a further verification criterion is applied, the package is vulnerable to tampering. Variant d) – the use of sealing labels – offers two advantages: the existing folding cartons can be retained, and the additional material and other costs are slight.

A popular means of enabling sealing labels to fulfil their intended role, however, has been the use of special materials, such as self-destructive films or void labels, which irreversibly display a void message on the substrate when removed. These special materials as well have drawbacks that arise in connection with high-speed machine dispensing. Furthermore, their use can give rise to substantial extra costs overall.

Labels can also play a key role – as an additional anti-tampering device – with variants a) to c). This applies in particular to folding boxes closed with a hot melt glue. It is common practice among product counterfeiters to melt the glue again by applying heat, and then to remove or exchange the product and re-use the original carton.

5. Label adhesive is a key factor

From the perspective of economic viability and technical ease, the most sensible means of ensuring tamper protection would be with conventional rectangular or round labels – possibly with the addition of security perforations. The crucial factor when such labels are being applied is their adhesive. It must be highly resistant to water, hot air and a variety of solvents. Only if
these conditions are met is the label impossible to peel off, even from highly varnished carton packs, without either being destroyed or visibly damaging the surface of the carton. Multi-purpose adhesives that fit the bill are now available; they are suitable for a wide variety of surfaces. The innovative adhesive HERMAsuperPerm 63S, for example\(^8\), allows one and the same sealing label variant to be used with an abundance of packing materials and numerous different surfaces. Given that sealing labels represent an economically viable solution, and that labelling technology has reached an advanced state of maturity, it is worth taking a closer look at their use as an anti-tampering feature.

6. Aspects of labelling

Whenever labels are to be used for tamper protection purposes, consideration must be given to several particular aspects. First, the folding cartons must be reliably separated – either in the upstream machine or by means of conveyor belts. The orientation of the cartons can likewise be controlled by the preceding machine; otherwise a cam chain or dimpled belt can be used for this purpose. Thereafter the cartons must be held fast between the conveyor belt and top belt in order to ensure precise label dispensing. In the pharmaceutical sector the line speed can be as high as 500 items a minute – if such a high output is to be maintained when labelling as well, experience with folding cartons is essential. In addition, the flaps of the folding cartons that are to be sealed can be in a variety of positions – top right and bottom left, top left and right, or on both sides at the bottom or top. The labels are applied to the sides of the cartons and initially protrude by about half their length. Rails or spring-loaded pressure rollers are used to bend or fold the labels reliably. Apart from being used to secure flaps that tuck in, in order to enhance protection against tampering, sealing labels can also be applied over flaps that are secured with hot-melt adhesive, which can be opened by applying heat.

7. Standard solutions for special tasks

The pharmaceutical industry probably occupies a unique position in having to address such complex requirements concerning product information and labelling. The sheer extent of information – which is already considerable – is only one of many challenging issues in this connection. Among the other aspects that are now presenting production managers with a demanding workload are the required absolute reliability of labelling, seamless traceability, and measures to prevent product piracy, such as serialisation and anti-tampering features. An abundance of different technologies – for printing, identification, labelling and monitoring – must interact within a very small footprint in order to ensure that every pharmaceutical manufacturer can achieve maximum security in an extremely diverse range of production conditions. In addition, country-specific particularities apply in many cases, and special labels that not only convey information but also perform other functions can further complicate the dispensing process.

Against this background it is no wonder that decision-makers, especially in the context of labelling pharmaceutical products, continue to believe that the necessary systems are not available off the shelf, but have to be built to order. In the knowledge that this approach entails many disadvantages, production managers reluctantly accept the consequences. The first major setback is a matter of cost – genuine specialty machines are expensive. Apart from the actual acquisition cost, purpose-built machines in particular are regularly accompanied by other drawbacks. After all, customised systems are generally built without the benefit of extensive practical experience. Sometimes the first opportunity to put specialty machines through their paces arises on the user’s premises. Given the lack of product maturity, in many instances they fail to meet the user’s expectations as regards efficiency, effectiveness, and
ease of operation and maintenance. Key factors in gauging the security of an investment are the certainty of spare parts being available even after several years and the ability to reproduce adopted processes if the machine has to be relocated.

If a modular design principle is applied, on the other hand, the disadvantages associated with custom-built machines can be avoided while resolving a comprehensive array of special tasks, including tamper-evident labelling. If this method is adopted, individual and well-proven functional components, many of which are produced in large quantities, can be combined in an end-to-end solution with other units in a variety of ways to suit customers’ requirements and thus overcome not only standard, but also exceptional challenges.

Included among the range of such functional units are:

- Labellers
- Printing systems
- Monitoring systems
- Ejectors
- Weighing modules
- Sensors

The labeller

A key component of every tamper-evident system is the labeller. One of the goals pursued within the modular design system is consistent dimensioning. As a consequence, individual units can easily be exchanged even after as long as ten years, upon the introduction of a faster model for example. This approach also contributes to enhanced reliability. HERMA now manufactures the same basic design of labeller, for instance, many thousands of times a year. In this case, all the electronics and software are fully integrated in the labeller. Updating the product to reflect the latest state of the art has practically no influence on the device dimensions. The labeller’s individual components, including the unwind and rewind units, separating systems and label sensors, are likewise produced in large quantities. Users requiring a high degree of flexibility simply need to procure the necessary variants of these units, such as left and right-hand versions, for different winding diameters, and for a variety of label types and widths.
The printing system

Printing variable data on pharmaceutical labels or folding cartons presents an enormous challenge in view of the continuously emerging requirements. Depending on the shape of the product, the size and type of label, and not least on the general production speed, different printing techniques can be economically viable. In view of the large quantities in which the uniformly dimensioned HERMA labellers are produced, practically all manufacturers of conventional hot foil and thermal transfer printers have now standardised the mounting frames of their printing units to facilitate their integration in these labellers. Users are thus offered maximum freedom – they can even convert an existing system to accommodate different printing techniques at a future date. Innovative processes with laser-activated labels and a laser marker can easily be integrated as well. Among their key benefits are minimal maintenance and the ability to produce exceptionally sharp images even with very small font sizes.

The monitoring or control system

Depending on users’ current wishes and needs, control systems may have to satisfy a variety of quality specifications. For the purposes of detecting missing print, for example, contrast, colour or simple camera sensors can be sufficient. If the print has to be read, however, OCV or OCR camera systems are used. For monitoring 1D or 2D codes, the most widely employed devices are scanners, camera sensors and other camera systems. In order to accommodate every possible requirement, a standardised mount is provided for the modular units. It is designed to accept all the customary sensors and camera systems.

The ejector

In the event of a label or product malfunction, it is essential that pharmaceuticals can be ejected from the production line in a controlled manner. In the case of expensive or fragile
products, it is generally desirable for the (defective) label to be ejected even before it is applied. Special ejector devices are available for this purpose, which dispense the defective labels to a collecting roll. If entire products are to be ejected, they are often segregated by the rotating star wheel and channelled into a lockable box. This is a space-saving operation but only suitable, of course, for products that cannot be damaged by falling a short distance. For especially sensitive products, other solutions are available with switches and accumulating belts for safely collecting ejected products.

**Sensors**

A high degree of precision is required to attach the small tamper-evident label to the side of the tuck-in flap in such a way that it protrudes by about half its length beyond the body of the folding carton (to the top or bottom). A mechanical folding rail then bends the initially unattached part of the label through 90 degrees, and a spring-loaded foam roller presses the label against the pack so that the tuck-in flap is permanently affixed to the carton. In order reliably to ensure that the anti-tampering feature is present, two control devices are required. A light barrier at each side of the carton initially monitors whether the label is protruding, and a second pair of light barriers activated after the folding operation establishes whether the label is still protruding or has now been properly flattened. In case of a defect, a gate controlled by a shift register inescapably ejects the relevant pack. If transparent sealing labels are used, the adhesive can be formulated with luminescent particles so that a UV sensor is able to distinguish between the carton and the label. This allows the proper attachment of the sealing labels to be examined directly. If the sealing labels are printed, this monitoring function can be performed by either a contrast scanner or a camera system. In case none of these techniques is suitable, gloss sensors are available that can detect the difference between the gloss finish of the carton and that of the sealing labels and thus establish whether or not the labels are attached.

The combination of modular design and a variety of functional units facilitates ‘mass customisation’ – tailor-made yet ‘off-the-shelf’ solutions – even for tamper-evident systems.
8. Print & apply modules for reliable aggregation

Although not expressly mentioned in the EU Directive, the requirement to ensure traceability inevitably triggers a need to aggregate the serialisation data in most cases. Aggregation is a method of making certain that the serial numbers on secondary packaging are collected and recorded for traceability reasons on the higher tiers of the packaging hierarchy as well. It provides a means of tracing the location of each pack, including the bundle, secondary packaging and pallet in and on which it is contained. Especially reliable print & apply systems are required on every aggregation level for printing the aggregated ‘group codes’ on labels and then applying the labels. In this connection as well, standard components belonging to HERMA’s modular design range ensure that the labels can be dispensed at high speed and placed with pinpoint accuracy. The devices can be positioned in any orientation and integrated in existing production lines in a variety of ways.

For the purposes of transferring the label after printing, two options are available:

- Transfer by vacuum stamp with direct contact
- Contactless transfer by vacuum/blower pad

In both cases, the label is detached from the liner immediately after printing and held by the vacuum. A print resolution of 300 dpi ensures outstanding image legibility.

As outlined above, reliability is a crucial factor when aggregation data are being printed. The label is the only medium on which this key information is recorded. It must remain machine-readable in the long term, and the image has to resist both smearing and mechanical degradation by abrasion or other influences. Alongside the classic techniques,
such as thermal transfer and inkjet printing, which are often susceptible to these problems, solutions utilising laser-activated label materials (LAM) are being used with increasing regularity. HERMA has developed an integrated system in this segment, comprising the labels, a labeller and a CO₂ laser. The new HERMA labels have a special finish that enables the laser in the labelling system to apply black inscriptions in the designated place – without any risk of smudging or scratching. Even with the smallest font sizes, the printed image is always very sharp, whether plain text, graphics and/or codes. Even demanding fonts, including those used for Asian scripts, are reproduced with extreme precision and clarity. Since the laser of the HERMA system does not remove any material, no smudgeable particles arise and the label is not damaged at all. The removal of residues or waste by suction is unnecessary. Furthermore, production interruptions occur less frequently because, apart from the labels, the laser system – unlike thermal transfer printers, for example – does not require any consumables or readjustment, and operates without wear.

9. About HERMA

- HERMA is a leading specialist in self-adhesive technology. In view of its comprehensive in-house expertise in self-adhesive materials, labels and labelling machines, it is thought to occupy a unique position worldwide.
- HERMA labellers are in service the world over – wherever the security, accuracy and speed of the labelling operation are regarded as the most crucial factors. The requirements demanded of labellers for healthcare products are higher than in any other sector. For more than 20 years HERMA has been finding solutions to the industry’s most challenging applications using highly flexible concepts with a reliability and efficiency that only a standardised system based on series-produced modular components can afford.
- As well as processing all conventional label types, HERMA labellers also dispense special materials such as booklet, documentation and hanging labels with precision, speed and exceptionally smooth operation. The modular design of the HERMA labellers also provides elevated security concerning the long-term and worldwide availability of spare parts.
• For the consistently high quality of the healthcare labellers, excellence in processes and manufacturing plays a crucial role, especially in the context of sharply increasing output. HERMA’s service engineers provide on-site support around the world. To ensure the high operational availability of the systems in international locations, components and spare parts can be ordered online around the clock: www.herma-components.com.

• You can count on HERMA: as a family-owned business for 110 years, we believe in the value of relationships that last – one more reason for our customers to trust in the long-term security of supply of all our support and maintenance offerings.
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