No scope for manipulation

How to use safe and efficient tamper-evident labels?

In this interview, HERMA product manager Ulrich Fischer provides answers to the most important questions.

What exactly does the EU prescribe with respect to tamper-evident labels?

The use of tamper-evident labels is mandatory for all peelable labels. The EU sets these standards by various regulations: the EU regulations 1223/2009 and 69/2008. User-friendly tamper-evident labels are required and they must be reliable and cannot be removed from the package after opening. This means that the label must be intact and not have any gaps or breaks.

In contrast to serialisation, for which the requirements have been extensively described in the EU guideline 2016/161, the prescriptions with respect to the anti-tampering marking have been very vague. At least the DIN EN 16679 standard shows the range of possibilities. It’s not a long list.

What would be permitted, for example?

For the current pharmaceutical folding box, four solutions in particular are available. These are folding boxes sealed with glue, special folding box constructions, shrink-wrapping and seal labels. Expensive blister display packages are in principle conceivable for folding boxes, but they don’t make sense for practical and economic reasons. Flexible packaging with plastic and/or aluminium foil and a sealing edge would in practice remain the exception rather than the rule. In addition there are manipulation characteristics that would hardly play a role for folding box packaging, for technical reasons alone, such as the sleeve or similar elements.

What are the criteria by which a pharmaceutical company should decide on the most appropriate solution?

Of course this always depends on the individual case. It should be considered, however, that when implementing the anti-manipulation mechanism, a pharmaceutical company will not experience any positive side effect beyond having met the guideline itself. For pharmaceutical manufacturers or contract packagers, this would mean that a maximum level of security must be achieved, but at the same time great value must be placed on an economically feasible implementation, since no other benefit is currently apparent.

What does this mean in concrete terms?

To be able to continue to use the existing folding boxes, when you look at cost/benefit aspects, the use of seal labels is particularly interesting, specifically given the fact that labelling technology has matured and corresponds to the know-how that is already widely distributed in the pharmaceutical industry.

Doesn’t one need special materials for these purposes? And doesn’t that represent a cost factor?

In the past, that was certainly the case. In order for seal labels to work reliably, often very special materials are used, such as foils that virtually dissolve when someone attempts to manipulate them, or so-called “void” labels that irreversibly unveil a piece of text when an attempt is made to open the container. Aside from the costs involved, these special materials also exhibit weaknesses when using machines to process containers at high speed.

The most economically feasible and technically useful protections against manipulation would be completely conventional rectangular or round labels – maybe with an additional safety perforation. The decisive factor for this use is the pressure-sensitive adhesive. It must be highly resistant to water, hot air and different solvents. Only then is it guaranteed that the conventional label cannot be removed from strongly lacquered folding box packaging without visibly destroying itself or the carton surface.

Is this system of the future or an option that can be realised today?

HERMA has a separate, very successful business division that deals with the development of self-adhesive materials for different challenges. At HERMA, such pressure-sensitive adhesives are now available for universal use, that is to say for very different surfaces. With the innovative HERMA SuperPerm 635 adhesive, for example, one and the same seal label variation can be used for a multitude of packaging materials and surfaces. This solution is already in use in the pharmaceutical industry, for example at a very well-known manufacturer of folding boxes and labels. That is why it’s worth looking at the label as a manipulation marker more intensively, even if it’s not one’s initial focus.

What do you mean by that?

Even in the previously named variations, labels can play an important role – as an additional anti-manipulation marker. For example, this is the case for folding boxes with an adhesive seal based on hot glue. It is current practice of product forgers to dissolve hot glue by adding heat, then removing or exchanging the product and replacing the original folding box again. Such manipulation attempts make corresponding seal labels immediately recognisable.

What happens if

In question.

To optimally ensure the presence of the anti-manipulation marker, two control units are necessary. A light barrier on each side of the folding box checks for the presence of a protruding label part, a second pair of light barriers checks whether the label still protrudes after the pressing or whether the pressing was successful. If an error is detected, a slider, controlled over a shift register, invariably separates the packaging in question.

Who do you manage

In what to current changes?

At HERMA, the electronics and software are completely integrated in the labelers. Keeping them up to date has practically no influence on the device geometry. The individual units of the labelers, such as winders and unwinders, separating systems and label sensors are in turn also manufactured in large quantities. To maintain high flexibility on the users’ side, it is enough to maintain these units in different forms. For example in right-oriented/left-oriented models, for different winding diameters, label types and widths.

What are the special challenges that need to be solved in tamper-evident systems?

A high level of precision is required. It’s about applying rather small tamper-evident labels sideways to the insertable tags in such a way that they just put about 50 percent above the body of the folding box either upwards or downwards. A mechanical folding rail then presses the two protruding label parts by 90 degrees and spring-loaded foam materials press the labels so that the insertable tags are firmly connected to the bodies of the folding boxes.