thoughtleadership

The new EU directive for pharmaceutical packaging: business-friendly compliance

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The new EU directive for pharmaceutical packaging: business-friendly compliance

The "EU Directive on Falsified Medicines" (Directive 2011/62/EU) was published in July 2011. It reflects an increasingly complex distribution network for medicinal products, with many different players – and a pressing need to ensure reliability across the entire supply chain.

Harmonised safety features across the entire EU are on their way. Legislation will be in force by the end of 2015, and manufacturers and other stakeholders will then have 3 years to decide on and implement a range of different safety features. It means new responsibilities for wholesalers and brokers, with written confirmation needed for APIs (active pharmaceutical ingredient) manufactured outside the EU and logos for legally operating online pharmacies.

What are the implications and what should all of those involved in pharmaceuticals packaging do next?

The threat

What the European Commission calls falsified medicines present very significant issues, which are becoming ever more significant. The word 'falsified' is used rather than 'counterfeit' in order to highlight challenges that extend well beyond IP violations. Falsified medicines can contain ingredients of bad quality or in the wrong dose, and so can pose a major risk to patient safety.

Following an original legal proposal by the Commission in 2008, a directive EU 2011/62 has been established to meet the growing threat from falsified medicines. This was a natural progression in the pharma segment. For some time, brand owners and converters have been paying more attention to safeguarding both customers and brand reputations. However, with formal regulations in place brand owners and converters must now be sure that the solutions they offer will be fully compliant.

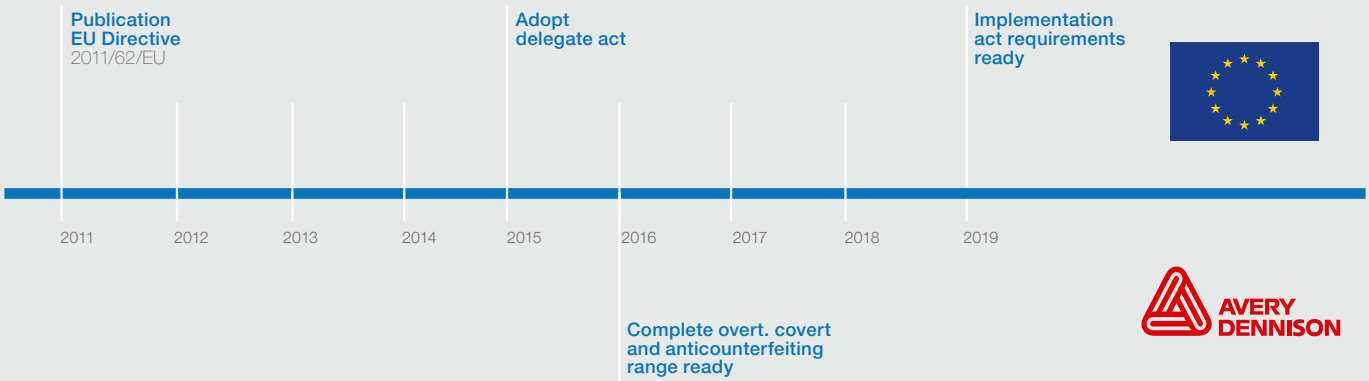
Article 54a requirements

European directive EU 2011/62 for medicinal products mandates a number of requirements, and Article 54a relates to safety features in packaging. These features involve obligations for wholesale distributors and persons authorised or entitled to supply medicinal products to the public. For medicines subject to prescription, those in the supply chain must ensure:

- **Product authentication : verify authenticity by assessing overt, covert or forensic devices**
- **Product identification : identify individual packs**
- **Product integrity : verify whether the outer packaging has been tampered with**
  For non-prescription medicines, individual packs must be identifiable.

Manufacturers and other stakeholders

will have three years, from the end of 2015 onwards, to implement the requirements in all European countries. Article 54a in the directive says that the Commission will leave open the precise nature of authentication/ anti-tamper measures. It requires the delegated Acts due in Q4 2015 to set out characteristics and technical specifications of these measures, with due consideration to cost effectiveness. The Acts will also set out lists of affected medicines.



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Layers of protection

Protection measures have to be designed with an awareness of the current capabilities of counterfeiters. Many fake medicines are very difficult to distinguish from the real thing, and resisting the falsified medicines threat depends on knowing first what will be difficult for a counterfeiter to reproduce, and secondly what will be easy for wholesalers, retailers and consumers of medicines to understand and use. The question of tampering is also very significant, and a properly designed labelling solution must show immediately whether or not a medicine's package has been opened or interfered with.

The right solution for a particular product will depend on many different factors, including product type, value and production volumes.

Avery Dennison is an advocate of 'layering' when designing security measures. Self-adhesive labels and seals allow a very broad range of measures to be designed, often with several protection methods working simultaneously. Technologies are available that range from simple but effective destructible labels through to high-end custom taggants. Making use of low-level anti-counterfeit technology that is visible to the consumer and also high-level security features using a covert or forensic technology allows brand owners to protect any medicine, no matter what its value or intended use.

Any measures for non-prescription drugs do not have to reduce shelf impact, and the use of self-adhesive labelling allows strong visual messages to be communicated including intricate designs and complex die-cuts. For prescription drugs, subject to much more stringent directive requirements, self-adhesive seals open up many possibilities for safety and brand protection. Such labels safeguard original products very effectively, in ways that are not available via -glue measures, and show counterfeiters that there is no practicable way to create a fake. Indeed self adhesive technology offers much more flexibility in manufacturing as glue does not like stop and go especially when the machine has to stop longer for a format change over. Furthermore the glue technology is a dirty process that requires more house keeping. Beside manufacturing flexibility, self adhesive offers an unique combination of tamper evidence and authentication features that no other technologies can deliver.

Finding the right solution

Even the most sophisticated anti-counterfeiting solutions cannot, on their own, prevent all counterfeiting. However, they can reliably alert brand owners to emerging problems and allow action to be taken.

Start with these five key questions when thinking about suitable protection:

1 **What level of security (low, medium or high) is needed in packaging design?**

2 **Is counterfeiting to be detected at the shelf or within supply chain processes?**

3 **Should patients be able to verify products at point-of-purchase with a visible authentication feature?**

4 **What is the level of investment available for brand security?**

5 **What will succeed at a global level?**

Obviously, the more layers of security a brand owner applies, the more resistant a product is to counterfeiting, pirating or diversion. A decision on appropriate measures will need to take into account both commercial and regulatory requirements. Above all, due diligence to protect a brand is vital. Security is an investment that directly impacts the bottom-line, safeguarding brand reputation and shielding a brand owner from potential liabilities if a counterfeit product results in patient injury.

Anti-counterfeiting technologies

Several anti-counterfeiting technologies employed by brand owners are shown below

Overt technology

This level of protection is visible to the naked eye, and allows the brand to be authenticated without the need of a special inspection tool. Overt technology offers only basic protection against counterfeiting. Examples include (but are not limited to) the following:

- Custom security papers using watermarks, paper colours or visible fibres embedded in the paper.
- Filmic security threads embedded into a paper, making a label hard to copy.
- 2D/3D custom holograms.
- Destructible/frangible films, papers and void materials that show tampering. A custom 'VOID' message (alphanumeric or geometrical shape) is left behind when a label is removed.

Covert technology

Covert technology gives advanced protection with hard-to-copy security features and some level of personalization. These security devices are not visible to the naked eye, but can be detected using an inspection device such as a UV light, magnifying glass or plastic film overlay. The type of tool depends on the specific protection technology used. Examples include (but are not limited to) the following:

- Customized security papers such as UV luminescent fibres embedded in the paper, chemical protection or verification with a special reactant pen.
- Non-visible custom security threads using UV reflection and microprints.
- UV prints using standard or custom colours and designs printed on the laminate of a facestock or liner.
- Infrared (IR) taggants – applied randomly in a paper/self-adhesive laminate, or using a custom spectrum that works as a unique signature. IR readers can be modified to give a signal when the right taggant percentages are detected. Uniquely encoded IR taggants are virtually impossible to duplicate.
- Inorganic taggants added to inks, coatings, varnishes, adhesives, plastics, etc. Authenticity is confirmed using a special reader that gives off signals when a particular taggant is detected.

Forensic technology

Forensic security devices are invisible to the naked eye. They are hidden within the product, and require laboratory analysis for authentication. This gives the highest level of protection using unique and personalized security features.

One example is the use of DNA taggants, which provide a forensic chain of evidence that is trusted by police and recognized by courts globally. To make the taggants, large botanical DNA is segmented, shuffled and reassembled to form a unique secure signature DNA marker (which becomes patented technology). DNA taggants are uniquely associated with the brand and cannot be counterfeited, digitally copied, scanned or re-engineered.

There are many potential pitfalls along the way, and effective deployment depends on close cooperation between the brand owner, the label converter and the materials supplier. Avery Dennison offers the technical support teams and the breadth of product options needed to stay at the forefront – to stay ahead of the counterfeiters while controlling costs.

This information is for guidance purposes only and should not be regarded as a substitute for taking legal advice on the EU Directive on Falsified Medicines" (Directive 2011/62/EU)

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