



The Colour of Your Money

400
300
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100



With the annual cost of counterfeit pharmaceuticals running to billions of dollars – not to mention the cost to patients' health – the industry is always looking for innovations in secure packaging. Nicole Golomb at Simons Druck + Vertrieb GmbH investigates exciting developments in colour-code technology

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Nowadays almost every industry is affected by product piracy. The result: financial loss, damage to the original manufacturer's reputation and devaluation of quality brands, as well as cost-intensive product liability trials. Product piracy can jeopardise a company's very existence. Furthermore, counterfeit pharmaceuticals constitute a real danger to the life and health of consumers. Consequently, with a high demand for product protection, colour-code particles protect them by providing a unique traceable identity. They offer an effective means of protection – versatile in their application and reliable at the same time.

Product piracy is a lucrative business and, in many cases, the imposition of sanctions is quite insufficient – penalties are deliberately taken into account when counterfeiters calculate their profit margins. Counterfeiters do not incur expenses for research and development; the more extensive and cost-intensive the product's development, the more attractive it becomes for forgers. State-of-the-art technology enables counterfeiters to reconstruct even the most intricate particles and, on the face of it, the counterfeited product is almost identical to its original except for some minor modifications. Patents provide construction details – free of charge for counterfeiters – as every detail of the manufacturing process has to be laid open for each patent, thus simplifying the work of counterfeiters enormously. In fact, about 10 per cent of the pharmaceuticals sold worldwide are counterfeit. Financial losses are only one part of the story – the other part is the negative effect on

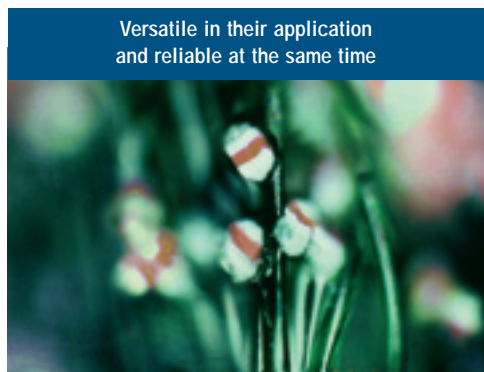
the brand owner's reputation caused by the glut of imitations and counterfeits available on the market. Product imitations disrupt brand confidence and will finally alienate customers if the product does not meet their expectations. Of course, a negative image and high financial losses take a back seat when people's lives and health are at stake. Often, inferior material and



Colour-codes to combine with Braille against counterfeiting



Unique colour-code under the microscope



Versatile in their application and reliable at the same time

poor production processes are used for manufacturing counterfeits; consumers are unable to detect the fraud and must simply trust that they are getting the genuine product.

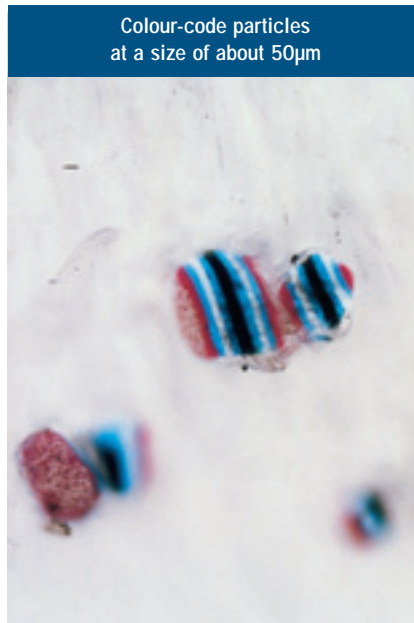
PHARMACEUTICAL PIRACY IS NOT A PECCADILLO

Pharmaceutical counterfeiting exposes consumers to danger – forged products are often mixed with substances which have toxic effects or cause allergic reactions. According to the World Health Organization (WHO) more than half of all forged products worldwide have no active ingredients at all and a fifth are compounded with wrong or inferior substances to camouflage the act of counterfeiting. Besides forging ingredients and dosages of drugs, counterfeiters reproduce labels, packaging and package inserts. Manipulating use-by dates is also a well-established practice; expired drugs are simply placed into new packaging. Consumers will not be suspicious of drugs if the forged or manipulated packaging looks and feels original. Pharmaceutical piracy is a criminal offence with disastrous results – an estimated 100,000 people die annually in China as a result of counterfeit drugs. Pills made of baking powder, poisonous chemical cocktails in cough syrup or malaria prophylaxis consisting of acetylsalicylic acid are all too common. Developing countries have the highest proportion of pharmaceutical piracy; in these countries, about a quarter of all available drugs are produced illegally. For example, in Nigeria almost every second medicament purchased has been forged. However, European pharmaceutical markets are not without risk: underdosed drugs have already been shipped through German freeports. Additionally, legal controls fall far short for drugs sold via the Internet, making their intake more like a lottery with incalculable side effects.

REQUIREMENTS FOR ANTI-COUNTERFEIT GUIDELINES

Consumers who purchase pharmaceuticals via the Internet will find it increasingly important to be able to identify that the delivered goods are genuine. Companies who communicate their products' identification and anti-counterfeit systems

allow their users to become active in identifying the original products for themselves. But disclosing this information is pointless if that product protection is not forgery-proof. A company that openly communicates their anti-counterfeit strategy establishes the quality of both the product and the protection system, and consumers and producers both benefit as they are able to clearly identify genuine product. At the same time, efficient product protection serves as a barrier against potential counterfeiters.



The global proliferation of counterfeit pharmaceuticals has resulted in increased demand for anti-counterfeiting strategies, and more product protection systems on the marketplace. But which system works most effectively? Is it able to accomplish the operational requirements? What about the cost-benefit ratio? And, finally, what does the anti-counterfeit system do exactly? Firstly, product protection cycles shorten with almost every system that is tested, implemented and rejected. These systems often turn out to be ineffective, creating unnecessary expenses in the production process. The implementation of new anti-counterfeiting systems requires a lot of time, money and labour in terms of: technical changes in the production line; the protection system itself; and expenses for investigation, gathering information on respective systems and introducing and monitoring it.

APPLICATION OF ANTI-COUNTERFEIT COLOUR-CODES

What brand owners are looking for is a product protection system that combines guaranteed anti-counterfeiting capability with legal certainty. One protection system which achieves this is based on micro colour-code particles in different sizes of between 5 and 45 micrometers (μm). Between 4 and 11 resistant melamine alkyd colour coatings are layered one upon another and form a specific colour-code with an individual selection and sequence of colours. The colour-code is invisible to the naked eye, but a standard pen microscope with about 100x magnification is sufficient to identify the code. Each user receives an individual unique colour-code. Once the product has been tagged with the code, immediate identification is easily accomplished on the spot, either by the manufacturer, custom

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authorities or customers. Coded identification tags can also include information about place of manufacture and destination. By securing both product and transport units, production and distribution channels can be traced back from manufacturer via wholesaler and retailer. Like a genetic fingerprint, the colour-code identifies each product as genuine or counterfeit.

RELIABLE IDENTIFICATION OF PHARMACEUTICALS

Possible applications for colour-code particles in the pharmaceutical industry are versatile because of their microscopic size and flexibility. In print processes, the colour-code particles can be applied on almost every substrate. They secure all parts of the primary and secondary packaging: aluminium and plastic tubes, blister packaging, caps, cardboard packaging, labels, package inserts and many more. Transmission occurs via a clear varnish which is adjusted to the respective product. The particles generate a simple and cost-effective anti-counterfeit system and can easily be integrated either directly in the packaging manufacturing process or in the packaging process of the pharmaceutical company. Security features, such as holograms, ultraviolet inks or seals, are effectively completed by colour-code particles – especially if non-visible product protection is required. The melamine alkyd polymers can be applied on labels and seals, or by heat-transfer and direct printing onto cardboard packaging. The actual cost per product amounts to the fraction of a cent.

LOGISTIC EFFICIENCY WITH RFID AND COLOUR-CODING

Experience has shown that counterfeiting is increasingly aiming at products in everyday use. Since the place of origin and transport routes of counterfeits are extremely hard to locate, putting a stop to these criminal activities is a difficult task. Radio frequency identification (RFID) allows uninterrupted traceability of distribution channels and control of imports and exports. Yet, there is one thing for which RFID cannot provide a 100 per cent guarantee: unambiguous identification of the genuine product. Although RFID transponders feature an electronic product code (short EPC), they can be tampered with by counterfeiters. Additionally, RFID chips can be removed from the products, and their price is so high that a company can often not equip a complete product line with them. This problem can be solved by combining different protection systems – micro colour-code particles can close the security gap between the transponder and the product. Melamine alkyd polymers make sure that genuine products are identified as such. Therefore, if transport documents and units are tagged with the same code as the product, all of them can be unmistakably linked together. The

pharmaceutical industry in particular can benefit from these flexible and complex identification systems that can be used both to ensure authentication, and for the track and trace process. For example, if a brand owner and holder of IP rights receives recurring imports from foreign countries, he can apply for seizure of products that infringe his IP rights at the border. If controls are carried out by customs authorities, they will then be obliged to check and – if an infringement of rights is obvious – stop the incoming goods. If it is confirmed that these products are fakes, customs procedures can be initiated and power of disposition denied. In this instance, product protection with micro colour-codes allows fast and target-oriented action of custom authorities and facilitates easy identification of either genuine or fake product. The traffic of counterfeited products can thus be stopped right at the border.

Forgery-proof packaging ensures consumer protection



BRAILLE ON FORGERY-PROOF FOLDED BOXES

From 1st September, 2006, pharmaceutical packaging in the EU must additionally be labelled in Braille, with the name and strength of the respective drug. Many pharmaceutical companies are prepared for this new law as they are internationally positioned and have encountered similar regulations in other countries. Studies have shown that it will cost roughly €100 million to meet these Braille regulations, due to technical changes in production processes, and the development of technical standards and manufacturing guidelines. To ease the burden, product protection systems based on colour-codes can combine anti-counterfeit measures with the application of Braille writing. The technology allows dots as well as danger symbols to be applied with the colour-code particles integrated in clear lacquer. The Braille anti-counterfeit dots are transferred by means of silk-screen printing or dot dispensers. These new regulations demanding Braille on every folded box offer the unique chance to combine legal requirements with anti-counterfeit action.

CONCLUSION

For more than 10 years, the micro colour-code system has proven to be forgery-proof and is even admissible in court as evidence in many cases – this can help protect the manufacturer in the event of any legal action. Product protection with colour coding also shortens and simplifies product liability trials, helping to fend off unjustified claims. In addition to legal regulations and guidelines that protect against product piracy, individual low-price product protection, which integrates legal certainty, will set the pace in the future. ♦

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