Welcome to the Era of Smart Solid Dosages

On-dose authentication technology can help deter counterfeiters, while also helping patients better engage with their medicines

By Ali Rajabi-Siahboomi and Gary Pond

Globalization and increased outsourcing activities have led to some very complex supply chains for pharma manufacturers – and that means an increased risk of counterfeiting. And putting both brands and patients at risk. Today, many countries have implemented serialization requirements for secondary packaging to track and trace products throughout the supply chain, and many pharma companies also add additional security features, such as holograms and security inks to their packages to further deter counterfeiting. All these moves have huge benefits. But the industry needs to go even further.

One of the main channels for counterfeiting today is online illegal pharmacies – with hundreds of new outlets appearing online each month. These pharmacies have increased significantly during the COVID-19 pandemic – as today there is even more desire from consumers to shop online, with medicines being no exception. When searching for online pharmacies, it’s common to find links to both legal and illegal pharmacies, more worryingly, it can be hard for patients to tell the difference. Random sampling by the FDA of 10,000 online pharmacies, found 97 percent of them to be operating either illegally or not following regulations. The World Health Organization reports the chances of a patient getting a counterfeit drug product online is over 50 percent. At the same time, counterfeiters are becoming more adept at copying many aspects of a medicine, including the package, label, the foil induction seal, and even the appearance of the tablet itself. Moreover, counterfeit, and diverted medicines can also find their way into legitimate supply chains. In one recent example, Gilead warned of counterfeit versions of two of its top-selling HIV medicines in the USA. These drugs are expensive and considered specialty products; they are only distributed by a small number of authorized wholesalers in the USA, and the FDA requires them to be dispensed in their original packaging. You would expect that it would be highly difficult to counterfeit these medicines, but the counterfeiters used genuine Gilead bottles and added a counterfeit foil induction seal. The package looked genuine, and there wasn’t an easy way for patients or people in the supply chain to quickly determine if the actual tablets were real.

Not only can counterfeit medicines potentially contain dangerous ingredients, but they often have no therapeutic effect. HIV is a life-threatening disease and a patient’s viral load can quickly go out of control if they stop taking genuine medication. More and more, counterfeiters are targeting valuable medicines like this because of high demand from patients – and the high monetary rewards.

At Colorcon, we’ve been looking at ways to secure medicines at the individual dose level, so even if the original packaging is taken away, the actual tablet can still be authenticated.

For the patient

At Colorcon, our purpose is “To improve health and wellness through convenience, compliance and safety.” We offer a range of pharmaceutical coatings, excipients, and formulation development assistance, including process guidance, for oral solid dosages. We don’t work directly with patients, but our customers – the pharma companies – do! We feel it is our responsibility as a leader in solid oral dosage forms and coatings to innovate and bring solutions to the market that help pharma companies to protect patients. When thinking about innovations that can help prevent counterfeiting, we also realized that the same technologies could transform how patients engage with their medicines.

We believe there are opportunities to better secure medicines by targeting protection down to the dosage level. A film coating, such as Colorcon’s Opadry® system, already provides many positive benefits including functionality and differentiation. Now, we can also add molecular and microtags to the coatings. Our portfolio of on-dose authentication solutions, SoteriaRx®, brings to market the advanced technologies from TruTag and Applied DNA Sciences. The tags cannot be detected by the human eye, but the tablet can be scanned by an in-field reader to confirm the authenticity of individual tablets. The concealed signature of a tag can contain information such as product, dosage, and manufacturing site. Think of it as adding an invisible barcode to individual tablets – and, as the technology is so unique, it’s almost impossible to reverse engineer or copy.

But this technology doesn’t just help deter counterfeiters; it can also be used to better engage with patients. Some pharma customers we are working with want to use the tags to deliver content digitally – such as taking the tags to a website where patients can learn more about the medicine. You can also deliver links to other information such as patient support groups, resources, and educational materials. Companies can also use this information to monitor adherence patterns, allowing them to improve adherence rates. Many companies will offer personalized content to patients based on their demographic and geographic region. By this means, patients who are taking medications in ways prescribed by the doctor to improve their health, are also engaged with the health system to ensure their health and wellness. Our experience with pharmaceutical patients has shown that they are happy when they get personalized content, but other examples are consumer products. Just imagine the impact on engagement if a consumer product were to be personalized to the end customer. You can imagine all sorts of personalization options that can be delivered with this technology – including subscription services, e-commerce, and everyday products. We envision that this technology will not only help meet the needs of patients, but also help the providers feel more comfortable with how they take the medicine.

A smarter future

Smart medicine is an increasingly important topic for the pharma industry as companies look for ways to engage more with patients and encourage them to take their medicines as prescribed. Many factors contribute to making a medicine smart, including what goes into the packaging, what goes into the dosage form itself, and how the patient may engage with their medicine. All patients can benefit from greater information and support that ultimately improves safety and adherence. Wouldn’t it be fantastic if they could get this directly from the tablet through an integrated smartphone?

We’re very positive about the future of SoteriaRx®, especially following the FDA’s issuance of guidance on the use of physical-chemical identifiers (PCIDs) in solid oral dosage forms; in brief, PCIDs can be incorporated into already approved drugs as a Level 1 post-approval change. We’ve aligned our portfolio of authentication approaches with this guidance. We’ve also sought to ensure the transition to smart medicines is as smooth as possible for customers by demonstrating proof-of-concept with our coatings – and the manufacturing process is the same as for any film-coated tablet.

If you want to explore what smart medicine can do for you, then we’re happy to discuss your requirements and provide implementation support.

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