

Surging Online Consumer Health Sales Shine Spotlight On Preventing Counterfeiting

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By Malcolm Spicer

Executive Summary:

"Chloroquine is OTC in many parts of the world," says TruTag Technology CEO Michael Bartholomeusz. In demand to treat malaria, chloroquine is "heavily counterfeited" and numerous deaths are attributed each year to patients receiving counterfeits for the actual ingredient. As the novel coronavirus pandemic accelerates online spending for consumer health products, the likelihood of counterfeits being provided also could grow, says the developer of an invisible tagging technology for drugs and dietary supplements.

Main Story:

The types of drugs available nonprescription vary among countries, with some pharmaceutical ingredients most commonly known to be available only Rx sold OTC and available online from pharmacies in some countries. Those ingredients include chloroquine, a malaria remedy that erroneously has been described as a potential COVID-19 treatment.

"Chloroquine is OTC in many parts of the world," said Michael Bartholomeusz, CEO of TruTag Technology Inc.

As a drug in demand to treat malaria, chloroquine is "heavily counterfeited" and numerous deaths are attributed each year to patients receiving counterfeits for the actual ingredient, Bartholomeusz said. "This provides some insights into what will happen when a drug is developed and launched to combat COVID-19," he said.



CEO MICHAEL BARTHOLOMEUSZ: TRUTAG OFFERS "A MEANS OF MASS DIGITIZATION OF MEDICINES AND NUTRACEUTICALS FOR THE PURPOSES OF AUTHENTICATION, SAFETY AND PATIENT COMMUNICATION."

Hydroxychloroquine sulfate and some versions of chloroquine phosphate are approved in the US to treat malaria; hydroxychloroquine sulfate is also approved to treat lupus and rheumatoid arthritis.

After President Trump and other uninformed sources touted chloroquine as a potential coronavirus treatment, the US Food and Drug Administrations published a warning against its use outside of a hospital or a clinical trial due to the risk of heart rhythm problems.

Additionally, the FDA's Center for Veterinary Medicine warned against using chloroquine phosphate made to treat disease in aquarium fish after learning some consumers, including a man who died, were attempting to prevent COVID-19 by consuming the fish drug.

Responding to questions from HBW Insight, Bartholomeusz also noted that no treatment for coronavirus currently is approved. "There is nothing to counterfeit. When it does become available, it will certainly be a target for counterfeiters," he said.

(The FDA on 1 May, following HBW Insight's contact with Bartholomeusz, approved an emergency use authorization for the investigational antiviral drug remdesivir for treating suspected or confirmed COVID-19 in adults and children in hospitals; see sidebar article.)

'Blur The Lines Between' Rx And OTC

Notwithstanding increased e-commerce purchases of OTC drugs sparked by the coronavirus pandemic, online pharmaceutical product sales allow a larger chance that counterfeit products will reach consumers, Bartholomeusz said. Counterfeiting drugs extends more commonly to OTCs in Asia, Africa, and South America, he said.

As well, some drugs are sold nonprescription online in some areas where the active ingredients are prescription-only.

"This is a large and encompassing problem exacerbated by the rapid rise in and prevalence of online pharmacies. Online pharmacies blur the lines between prescription and OTC drugs," he said.

Additionally, diversion during distribution prevents drugs from reaching their intended targets and could result in inappropriate or dangerous use. "Counterfeit is only part of the problem. Diversion is another significant issue, where drugs meant for distribution in specific markets or via specific distribution and retail channels are illegally diverted to unauthorized markets and channels," Bartholomeusz said.

Built on intellectual property and process knowledge from manufacturing and hardware to materials and software, TruTags are applied on tablets or capsules, invisible, difficult to replicate, cryptographically secure and can be read using with an app on standard mobile phones. The microtags allow pharma firms, their channel partners and law enforcement to monitor and manage supply chains to mitigate the influx of counterfeit or diverted drugs.

The microtags also allow consumers to directly verify they are taking an authentic and safe product. In cases of consumer harm, root cause determination as it pertains to the authenticity of the drug can result in faster issue resolution and risk management, Bartholomeusz said.

Unlike other pharma product tracking technologies, he said TruTags are more than serialization and packaging solutions, which don't ensure products' authentication and provenance once they're removed from packaging and containers.

"TruTag is the only company in the world that can offer a means of mass digitization of medicines and nutraceuticals for the purposes of authentication, safety and patient communication," he said.



TRUTAG CURRENTLY PROVIDES ITS TECHNOLOGY TO HEALTH CARE PRODUCT FIRMS INCLUDING SUPPLEMENT MANUFACTURER DAILY WELLNESS FOR USE IN ITS FERTILITY BLEND.

In addition to drugs and supplements, Emeryville, CA-based TruTag provides digital identification technology for security labels and documents, drug delivery systems and hyperspectral imaging.

Daily Wellness Supplement Has TruTags

TruTag currently provides its technology for firms including one consumer health product, Daily Wellness Co.'s Fertility Blend, which contains a proprietary blend of L-arginine, green tea and chasteberry in addition to vitamins E, B6 and B12, folate, iron, magnesium, selenium and zinc.

Bartholomeusz said nutritional supplement formulations such Fertility Blend have good reason for applying tags in their products. The products typically are higher-priced with wide brand recognition and made with expensive, high-quality ingredients.

"The nutraceutical products that can most benefit from the TruTag technology platform are ones that want to affirm the credibility and quality of their brands and products," he said.

"These are the products that are susceptible to counterfeiters and other bad actors seeking to either knock-off or divert the product to ride on the reputation of the innovator brand and pass off a cheaper or fake replacement."

Some traditional Chinese medicines, although typically made with botanical ingredients, fall into the category of counterfeit targets, Bartholomeusz said. He pointed out TCM remedies for the first time are included in the recently approved 11th version of "International Statistical Classification of Diseases and Related Health Problems" by the World Health Assembly, the governing body of the World Health Organization.

Some large TCM providers are "exerting significant efforts to ensure the authenticity and safety of their products from the farm to mouth ... Some TCM products are very susceptible to counterfeit – these are products that use ingredients like special mushrooms that are claimed to have cancer-fighting abilities, or high-end ginseng."