



Spurious products menace in pharma industry

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THOUGH counterfeiting is increasing in various sectors, the increase of spurious products in the pharmaceutical sector is alarming. WHO estimates the value of the global trade in counterfeit drugs at \$75 billion, a huge amount that indicates not just the loss of revenue for the pharmaceutical industry but also the devastating impact to the health of the consumers who consume such counterfeit medicines. The problem is very serious in developing countries where consumer education is lacking.

About 85 per cent of the world

pharmaceutical market is in the developed world, where counterfeits are less than 0.2 per cent of the market. The incidence of counterfeiting in developing countries is, as expected, much higher. The Lancet estimated in 2012 that the rate of counterfeiting amongst malaria drugs was as high as 46 per cent. Roger Bate from the American Enterprise Institute along with some co-researchers published a paper in 2014 that indicated that about 32 per cent of all antibiotic and TB drugs sampled in India by their team had turned out to be falsified or sub-standard.

Government initiatives

Organisations such as the US Food and Drug Administration (FDA) and various Government authorities across the globe consider drug counterfeiting to be a major issue. In fact, the European Parliament has made the battle against falsified medicines one of its top aims. The Indian Government has also mandated for all pharmaceutical firms to build track and trace capability for exports using barcode technology at three levels of packaging: primary, secondary and tertiary. The Directorate General of Foreign Trade, within the Ministry of Commerce and Industry, had issued a Public Notice on January 10, 2011, requiring this functionality, and to date the tertiary and secondary levels have been completed with the primary due later this year. Although the Government is working at the policy level, there is a clear need to involve all stakeholders in the efforts in fighting this menace.

The role of standard bodies

This ever increasing menace has also energised the anti-counterfeiting solution providers to up the ante and develop solutions that allow the brand owners to help consumers identify a genuine medicine.

Today, there are over 100 product security technologies (holograms, digital watermarks, DNA taggants, security inks, serialisation etc) used by pharmaceutical manufacturers to combat counterfeiting. Such solutions can be applied on primary or secondary packaging.

With the availability of various authentication solutions, companies and Government authorities are facing problems in the selection of a specific authentication solution. The adoption of any given solution is a complex question involving issues, amongst others, of cost, compatibility, feasibility and reliability. There are different views on which technologies should be adopted and the timing for their adoption. Choosing an anti-counterfeiting security solution today is a complicated task. Although many options exist, a lack of harmonized requirements distorts comparison.

To resolve this issue, The International Standards Organisation (ISO) has recently published

a new ISO Standard entitled "Performance criteria for authentication solutions for anti-counterfeiting in the field of material goods" that addresses this concern. This new standard, referenced as ISO 12931, is objective-oriented and applicable to all anti-counterfeiting security solutions.

Similarly, GS1's Global Traceability Standard 27 defines how industries should maintain complete traceability (Track and Trace) of all products from raw material to finished products and their movement along the supply chain.

ASP's role in pharma industry

As an authentication solution providers association, it is our foremost duty to work with the industries facing the brunt of counterfeiting. The pharmaceuticals industry is plagued with the racket of fake medicines for decades together. The rising instances have led us to formulate and follow a four point agenda.

We aim to propagate the importance of ISO 12931 standards in the context of authentication methodologies with various national body association as well as industry specific trade association such as OPPI, IDMA etc. educating them about ISO and GS1 Standards and our activities. ASPA also works in tandem with global authorities such as International Hologram Manufacturers Association (IHMA), Counterfeit Intelligence Bureau (CIB) and Interpol, as well as industry bodies in India such as Ficci-Cascade, CII, ASSOCHAM and Indian Institute of Packaging to reiterate its commitment and ensure the highest level of standards as listed in the ASPA code of conduct. We also plan to enhance our relationship and collaborate with other anti-counterfeiting associations.

ASPA has most recently launched a new website- www.aspaglobal.com which includes educational material on various types of authentication solutions, tips on selecting the most relevant and effective authentication solution, case studies, white papers, industry news, member profiles, details of activities being undertaken by the association, reference material and access to ASPA's quarterly journal, The Authentication Times which

acts as a great tool to educate our readers. As an industry association of authentication solutions providers, we are committed to provide the best and optimal authentication solutions to the industry. Our members are developing latest generation solutions and are ready to support pharmaceutical industries in protecting brands and safeguarding consumer interest.

PharmaSecure's expertise

PharmaSecure is a US-based organisation that has been fighting the counterfeit drug problem in India for the past six years. By putting unique, random, alphanumeric codes onto each individual blister pack, bottle or injectable vial, PharmaSecure enables the verification of that product by simply SMSing the code. Over 1.2 billion products (i.e. one for every Indian citizen) have been protected to date through this technology, with close to 50 companies in India and other countries having already adopted the solution. With regulations being adopted by most governments, including India (as mentioned above), such solutions that incorporate unique identification of products with verification, and add a layer of track-and-trace, will be required in order to meet the regulatory demands and also protect consumers. PharmaSecure is at the forefront of this battle and is working with other members of ASPA to ensure that authentication solutions can be adopted as widely as possible.

The impact of counterfeit medicines is grave, with loss of life a distinct possibility. Governments around the world are working to formulate and implement regulations that protect consumers in their jurisdictions. Pharmaceutical companies are keenly aware of the loss of revenue and brand reputation that arises from counterfeiting, and have started allocating resources towards adopting authentication solutions. Organisations such as ASPA have a huge role to play in working with government and industry to ensure that the right solutions are adopted at the right time in order to win this fight once and for all.

(The author is Vice-President, Authentication Solution Providers' Association and COO, PharmaSecure)

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