Indian pharmaceutical industry

Needs an effective strategy to combat counterfeiting

"One needs to understand that product identification technologies such as barcode and DMS tracking should be used to facilitate the overt, covert and other forensic technology, not to compete with these proven technologies"

Counterfeit pharmaceuticals are an ongoing problem worldwide and the labelling industry has been heavily regulated as a result. Different geographies can sometimes be at a higher risk than others, and in recent months, India has been cited as a source of counterfeits. The recent decision of Government of India of finalization of implementing bar code attract the attention of the industry. This comes on the heels of a discovery of "Made in India" labels on fake pharmaceutical products produced in China. To combat this, all Indian pharmaceutical exports will carry a barcode as of July 1, 2011 on primary, secondary and tertiary packaging.

Missing Element - No protection from fakes or tampering

The better-late-than-never rule will allow medicine to be traced and tracked to its source of origin. Bar code is a good solution for tracking and tracing of goods, but a problem will always remain if the product is counterfeit during the supply chain. As when the code is simply printed onto the packaging, it does not protect the pack against counterfeiting or tampering.

i. Traceability features are not immune against foregery and require additional anti-counterfeiting feature to ensure their own authenticity as well as the authenticity of the product they are attached to.
ii. The codes can simply be copied and printed on to illegal produced packaging, or the original product can be removed from the original pack and replaced by fake.
iii. The consumer is obvious to this if the produce pack itself is not properly protected.

One needs to understand that product identification technologies such as barcode and DMS[1] tracking should be used to facilitate the overt, covert and other forensic technology, not to compete with these proven technologies.

Example: EFPIA[2] product and verification project *(Figure 1)*

In May 2009, the EFPIA announced the pilot of its coding and identification solution in Sweden. The EFPIA

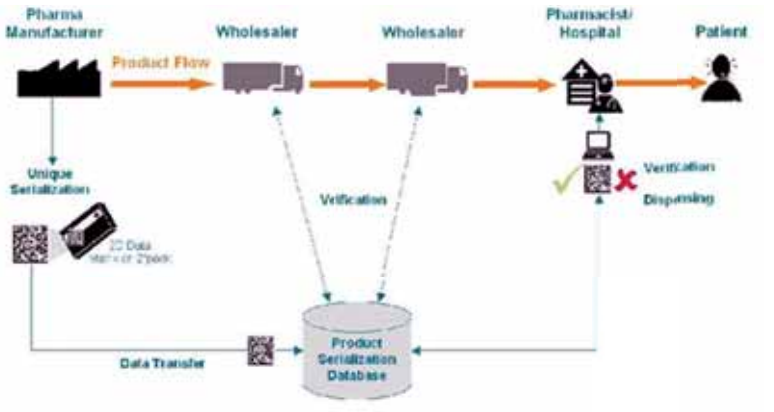

Figure 1 - EFPIA Product and Verification System: Product and data flow

Table1 : Overview of some security options

	Manufacturer	Distribution Cycle	Regional Distribution Centre	Pharmacist / Hospitals	End User
Holograms	Minimal cost	Easy to check	Easy to check	Easy to check	Easily recognized security
Micro-printing	Minimal cost	Easy to check with proper equipment	Easy to check with proper equipment	Easy to check with proper equipment	Education is important
Taggants	Moderate to high cost	Special reader required	Special reader required	Special reader required	Manufacturer would need to authenticate
Color shifting inks / Digital watermarks	Moderate to high cost	Easy visual inspection / reader required	Easy visual inspection / reader required	Easy to see / manufacturer authenticate	would need to Brand differentiation
Frangible and other security stocks	Minimal to moderate cost	Easy to detect tampering / reader required	Easy to detect tampering / reader required	Easy to detect tampering / reader required	Easy visual to detect tampering
Serialisation	Moderate to high cost	Special equipment needed, track-and-trace	Special equipment needed, track-and-trace	Special equipment needed, track-and-trace	Possible human code available
RFID	Moderate to high cost	Special equipment needed, track-and-trace	Special equipment needed, track-and-trace	Special equipment needed, track-and-trace	Manufacturer would need to authenticate

solution does not provide for verification by the patient, as it is the Pharmacists who will check a unique identification code on each individual pack when it is dispensed to patient.

These codes are generated and applied by manufacturers using a simple 2D Data Matrix Barcode, which contain a unique serial number. The scan revealed any duplication of data on packs and triggers the system to immediately alert the pharmacist to the possibility of a counterfeit product.

This solution presumes that all data collected in a central location in a timely fashion and can be queries against at anytime from almost anywhere. This opens up a list of question;

i. Who is going to be responsible for storing and managing this data?
ii. Who will pay for it?
iii. Are pharmaceuticals firms willing to share their data with everyone else in the supply chain?
iv. Most pharmaceutical products pass through many hands along the supply chain before they reach their finial destination, which increases the chances of product counterfeiting, especially in European market, where distribution involves many countries and languages. The long supply chain increases the risk of products being repackaged or exchanged at the temporary storage facilities.

With this solution, a pharmaceutical company still loses, because you cannot tell which product is the counterfeit, so if the fake product was dispensed first, then you are going to end up holding back the genuine product when you get a duplicate hit.

EFPIA had himself acknowledges that the system check the code, not the product, so it does not necessarily authenticate that the medicines is genuine, but it will identify that the code is genuine. *(see, Pharma Anti-counterfeiting news, Issue no1, August 2009).*

Anti-Counterfeiting is a multi-layered approach

Counterfeiters can quickly identified and duplicate many drugs and drug safety measures. This is why a multi-layered approach to counterfeiting is essential for opting drug security. Printers should provide both overt and covert anti-counterfeiting solution.

EFPIA and OPPI[3] (India) both have specified various safety elements for every drug unit. As per EFPIA, *first*, products should have a tamper-evident container closure system with overt and or covert authentication features, *second*, packaging should contain

An effective strategy
Malaysia Meditag

Introduction:
The Malaysian Government considers healthcare a priority and has introduced a number of schemes in past to help boost the sector. The most notable, and beneficial to OTC, was been the launch of "Meditag" holographic authentication sticker. It was introduced in 2005 by Malaysian Ministry of Health to confirm the authenticity of medicines registered with the Ministry.

What is Meditag?
The self-adhesive holographic Meditag measures 8mm x16mm and contains three levels of security. For unaided visual security, the label employs Hologram Industries (HI) proprietary diagram technique. A second level of security can be established through the use of a handheld instrument, and a third level for machine readability is also provided for forensics testing.

Result: Since the Ministry of health introduced meditag in 2005 instances of un-registered medicines (which are often counterfeit) on the market has fallen by up to one-third.

Source: Paper presented by Ministry of health at Global Forum on Pharmaceutical Anti-Counterfeiting held in Washington, DC, June 2008 and by Mediharta at Holopack-Holoprint, November 2010.

a randomized 2D barcode on each unit, and *lastly*, the supply chain should be transparent.

Further, the choice of technique should be depends on how the drug manufacturer intends to use security features, for example, a mandatory in favor of an individual technology, can backfire, once it fails.

Need of multi-layered security
In selecting a security feature, various tradeoffs are necessary between security and usability. It is possible to secure a document or product almost absolutely by applying layer after layer of complex security features, but to fully authenticate would require far more equipment and resources that is really feasable or necessary.

The most effective brand protection is a multi-layered solution, with sufficient barriers to deter criminal activity, ideally combing both overt and covert approaches. This strategy will go a long way towards, protecting patient safety, as well as country reputation and revenues of pharma companies.

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