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Counterfeiting of medicine is no more incurable now

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Counterfeit drugs are a menacing and deadly problem worldwide contributing to morbidity, mortality, toxicity, and drug resistance among the individuals. The proliferation of fake drugs is astounding, with over 100 countries reporting incidents of fake drugs according to a 2008 report from the Pharmaceutical Security Institute. The incidents of drug counterfeiting show no evidence of declining: some industry people suggest that the number of counterfeit medicines in market has increased to as much as 25% each year over the past several years. Counterfeiting medicines is not a new issue, in Graham Greene's 1948 novel The Third Man was a story about a search for a smuggler of counterfeit penicillin in postwar Vienna. Although the literatures on counterfeit medicines in the medical and scientific communities aren't vast, there's a lot in newspapers and magazines because journalists have picked up high-profile stories.

A counterfeit medicine is a compound that is not made by an authorized manufacturer but is presented to the consumer as if it were. The global estimates of drug counterfeiting are somewhat ambiguous, depending on geographic region, but proportions range from 1% of sales in developed countries to >10% in developing countries. Medicines counterfeiting is highly sophisticated and it is almost impossible for patients and dispensing healthcare professionals to spot the fakes. There is also a lack of transparency in the legitimate medicines supply chain, which makes it vulnerable to infiltration by counterfeiters. This puts lives at risk. From the manufacturer to the dispensing healthcare professional, the safe supply of medicines can only be achieved if each and every stage of the supply chain enforces safe practice. This is not currently the case. The existing system makes it almost impossible to establish the pedigree of a medicine dispensed to a patient. This is made worse by repackaging and re-labelling medicines within the supply chain which contributes to uncertainty and is exploited by counterfeiters. Counterfeit medicines contain wrong ingredients, insufficient ingredients and sometimes no active ingredients at all. The consequences of taking counterfeit medicines include treatment failure, drug resistance and sometimes death. It is the right of every patient to receive quality medicines. To achieve this, changes are needed in the existing Indian regulations to preserve a medicine's integrity and stop intermediaries tampering with them. We therefore strongly urge the Indian Commissions to consider the benefits to all stakeholders of medicines traceability and authentication through its review of medicines distribution in India as other developed nations like Europe etc. In order to check the adulteracy an industry-wide solution has been proposed in the form of barcode to protect patient safety through a more transparent medicine supply chain, thereby attempting to tackle the rise in counterfeit duplicate medicines entering the market. Championing 2D Data-Matrix Bar Coding should be done on the wrapper of the medicines as a technological solution to support its call for tighter regulation and better enforcement in the supply chain to protect patient safety.

There is need for a transparent and secure medicines supply chain that puts the patient first and where all stakeholders take responsibility for guaranteeing the integrity of medicines. “A unique bar-coding should be done on every medicine pack before it leaves its manufacturer”. This way, at every stage of its distribution, up to the point at which it reaches the patient, the medicine can be authenticated to make sure it is genuine.” DataBar Barcode is a type of linear barcode symbol. DataBar when linked with 2D barcode, especially Micro PDF barcode with linkage character is called 2D Data-Matrix Bar-Code. When linkage character is turned on, scanner will read both barcode one after another.

The encrypted 2D Data Matrix Bar-Code can also carry a randomized number unique to the individual pack, making it even harder for counterfeiters to successfully

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copy and bring their fakes to market. By using a hand held bar-code reader which very common in most European pharmacies, Indian markets should also employ such technology so that the dispenser will be free to scan the encrypted 2-D data matrix code and check vital data including recall information and the details of every trader who has handled that pack in the supply chain. The introduction of unique coding for each pack of medicine, together with authentication, track and trace systems and physical security in the form of tamper resistant packaging will dramatically improve the safety of medicines supply. This involves the integration of four key elements.

Tamper resistant packaging

Medicines currently lack the type of tamper resistant devices now taken for granted in other sectors such as the food and drinks industry. All medicines should possess special features to show whether the packaging has been opened. This includes bottles with external seals or tampers evident screw caps, and boxes with seals or perforated panels.

2D Bar Codes

2D data matrix bar codes printed on packaging during manufacture can provide each medicine with a unique identity before it enters the supply chain. Significant quantities of encrypted information can be stored this way to support pharmacists, regulators and government authorities in the authentication and tracing of individual medicines. 2D data matrix bar codes help prevent dispensing errors and make counterfeit medicines easily identifiable. Existing scanners found in most pharmacies can read the bar codes and no additional work is required by the pharmacist. Scanned information is transmitted to an independent electronic data hub and a verification message is quickly returned to the dispensing pharmacist.

Dispensing authentication and transparency

No part of the supply chain should accept medicines without validation. With tamper resistant packaging and 2D data matrix bar codes in place, a unified system with agreed responsibilities across the country will allow each individual medicine pack to be traced. This will take the place of existing systems which is not of much significance in preventing counterfeiting and do not allow the pedigree of medicines imported across national boundaries to be checked. A safe medicine supply is one in which every stakeholder is able to trace and authenticate the medicine back to the manufacturer.

Integrity of manufacturers packaging

Removing or interfering with manufacturers packaging can never be in the interests of patient safety. Parallel traders repackage and over-label medicines. These practices may have to be reviewed with the introduction of a new, safer medicines tracing and authentification system.

The consequences of counterfeiting:

Counterfeiting is of grave concern for consumers, governments, and legitimate manufacturers as well. It has significant social and economic consequences. The important one is that the consumers don't get the safe and effective products they pay for and, instead, may be put at significant risk. On the economic point of view, legitimate manufacturers of pharmaceuticals suffer from patent and copyright infringement. Counterfeiting, in reality, "hijacks" the brand. For these reasons, this should be strictly handled by employing science and technology and in this context 'Bar coding' seems to be a highly promising and reliable solution to fight away this menace.

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