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Fight on sub-standard drugs

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Estimates of global counterfeit drug industry vary from $90 billion to $200 billion



India’s Central Drugs Standard Control Organisation (CDSCO), the apex body for regulatory control working under the health ministry, has adopted two prong strategy to control the spread and sale of sub-standard drugs. Recently, it conducted raids in the Delhi’s wholesale pharma market and seized medicines nearly worth Rs 50 million which were not stored with the required proper care. Some people were even arrested in this connection.

According to news reports, various types of irregularities like storing medicines and vaccines directly exposing to sunlight, at room temperature against the requirement of 2 to 8 degrees, and storing cough syrups in large containers and then selling it to retailers without proper labels were noticed. CDSCO has also issued draft standard operating procedure for handling of not of standard quality samples and has released the draft guidelines on post marketing surveillance of pharmaceutical products in India.

In US also, United State Food & Drug Administration (USFDA) is investigating sale of counterfeit drugs which was reported by alert patients. Just a few months back another news report said that US customs and border protection seized machines used for making fake pills at a rate 19 times higher than in 2011. In another incident USFDA issued notices to 14 drug companies for false claims of cancer cure and selling unapproved drugs.

Various estimates about the fake drug market in India have been made by different organisations. In some cases it was even noticed that India’s name was maligned by the exporters of the fake drugs from other countries. The drugs were exported from other countries, but the packets carried the Made in India tags.

Such incidences exhibit the magnitude of the problem of fake drugs. But many times it is just a tip of the iceberg. Data about the counterfeit drugs released by the USFDA itself was alarming. Approximately 10% of all pharmaceuticals sold globally are counterfeit. However, the further details are more worrying for Asia since the average figure of 10 % is not equal for all regions. While developed nations have only 1% penetration rate in Europe and the USA, developing nations have high level, up to even 30% in Africa and Far East.

Estimates of global counterfeit drug industry vary from $90 billion to $200 billion. Equally serious issue is the problems, including deaths, faced by patients due to fake drugs. Fake drugs contribute to rise of drug resistance and experts estimate that the counterfeit drugs cause the deaths of nearly one million people.

Authorities in different countries take anti-counterfeiting steps to stop the menace of fake drugs. Government are introducing legislations and initiating actions to prevent spread of fake drugs and attempting to stop them from reaching to patients. Even pharmaceutical companies too are developing methods to prevent sales of fake drugs as that harms their reputation and business. They are trying to use new technological developments.

Among various technological initiatives by the pharma companies, the one in China is printing 20-digit electronic drug monitoring code (EDMC) on each package of medicine or medical device to track the packets and test them for authenticity throughout the supply chain. However, one problem is that the EDMC coding does not correspond with other traceability systems in the world like Global Trade Item Number (GTIN). Serialisation is another method. But those are not found to be adequate. There are advance types of labels which can warn the drug buyers. Combination of such methods leading to multilayer security systems can help detect counterfeit drugs and prevent their spread. There are still challenges in all these systems for which solutions need to be found out. But most important vigilance could be alert buyer. Hence along with all precautionary steps and technical measures, educating people and creating awareness is important for other measures to be successful.