Journal of Pharmaceutical Care
jpc.tums.ac.ir

Counterfeit Drugs

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ARTICLE INFO

Article type:
Editorial

J Pharm Care 2015; 3(1-2): 1-2.

► Please cite this paper as:
Amouei A. Counterfeit Drugs. J Pharm Care 2015; 3(1-2): 1-2.
Received:2016-01-17, Revised: 2016-01-26, Accept: 2016-02-10, Published: 2016-05-31

Profits from the sale of counterfeit drugs were estimated more than US$75 billion that have increased 90% since 2010. India and China produce great extent of counterfeit drugs in the world. Generally Middle East Asian countries are final destination for these goods (1). WHO announced that "sixty percent of counterfeit drugs were distributed to developing countries in 2005" (2). Counterfeit drugs is defined as product which knowingly it's appearance is like original but it's safety and quality is lower (3). In spite of spreading counterfeit drugs in developing countries progressively, there are not practical supervision strategies to prohibit entering the market.so remain a question; did not the policy makers ,anywhere in the world, ever established practical system to terminate this problem?

Drug supply chain security act (DSCSA) was singed as law on November 17, 2013 in the United States. The ultimate goal of DSCSA is to create an electronic exchangeable process which would trace where pharmaceutical products have been, at the level of individual package number. The track and trace program simplify verification of correctness of drug identifier that imprinted on the drug packages. Also it enables the government to ascertain and eliminate counterfeit pharmaceutical products which are potentially unsafe for humans and recalled drugs as soon as practicable.

Up to 2017 all drug manufacturers shall provide the "unique product identifier" for all certain drugs and affix to or imprint upon packages. Unique product identifier consists of two-dimensional (2D) bar code which is readable by both humans and machine. The 2D bar code contains national drug code, serial number (20 characters), lot number and expiration date. Moreover each part is involved in drug supply chain shall buy and sell the drug with valid product identifier only.

Up to 2023, according to the law, gradually all entities in pharmaceutical supply chain- manufacturers, repackagers, wholesaler distributors and dispensers- would provide requirements which enable them to identify and quarantine the suspect products, rapidly determine that is illegitimate or not and subsequently notify FDA and trading partners at least in 24 hours after the detection. Each entity is supposed to verify and maintain transaction data for prescribed drugs which coming into its ownership or control and permit to assess by federal supervisors if occurrence problem. Also entity can't sale the products whiteout providing the transaction data for following holder. Transaction data that called 3Ts include: transaction information (TI), transaction history (TH) and transaction statement (TS). Transaction information contains: product's name, its strength and dosage form, national drug code, container size, number of containers, lot number, business date, delivery

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date and vender's and purchaser's name and contact details. Transaction history is made of all TI and TS in previous that go to back manufacturer. Transaction statement is an attestation declares the following: the seller is authorized under DSCSA, received the product from authorized person, complied with the law and purchased the legitimate products. The 3Ts must be stored at least 6 years after transaction by entity and trading partners (4).

These programs seem to be useful for combating and removing the counterfeit drugs from health system. It is suggested that developing countries as main victims of counterfeit drugs, make like these policies by adjusting with their domestic health system.

References

1. Webster N. People need to know about dangers of buying fake drugs online, Dubai conference hears. The National. April 20, 2015. ***Available from: http://www.thenational.ae/uae/health/people-need-to-know-about-dangers-of-buying-fake-drugs-online-dubai-conference-hears.***
2. O'Mathúna DP, McAuley A. Counterfeit Drugs: Towards an Irish Response to a Global Crisis. Academia. **Available from:**http://www.academia.edu/4934945/Counterfeit_Drugs_Towards_an_Irish_Response_to_a_Global_Crisis. December 12, 2005.
3. Shahverdi S, Hajimiri M, Pourmalek F, Torkamandi H, Gholami K, Hanafi S, et al. Iranian pharmacists' knowledge, attitude and practice regarding counterfeit drugs. Iran J Pharm Res 2012; 11(3):963-8.
4. Drug Supply Chain Security Act (DSCSA). U.S. Food and Drug Administration. Available from: http://www.fda.gov/Drugs/DrugSafety/Drug Integrity and Supply Chain Security/Drug Supply Chain Security Act. November 6, 2015.