IICC 2021 International Industrial Chemistry Conference

Virtual
1st International Industrial Chemistry Conference
26-28th February 2021

Investigation Process of Pharmaceutical Drug Recall

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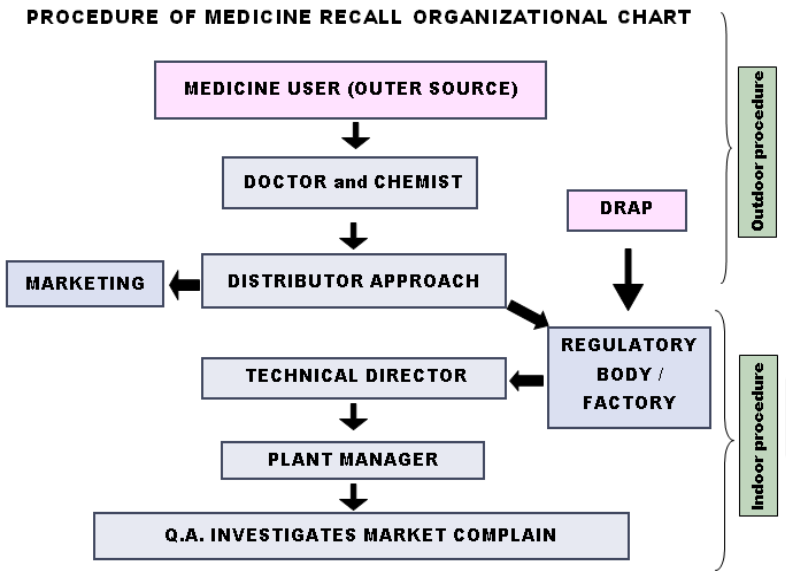
Background/Objectives:

Healthcare system is one of the basic issues, both for the developed and the developing countries too. In this regard, Pharmaceutical Drug Recall (PDR) plays a crucial rule in monitoring and maintaining public health [1]. PDR is the collection of marketed sub-standard, mishandled drugs, etc., back to the company it manufactures. This may be due to the market complaints and drug side effects, etc., [2]. Failure of PDR may give birth to moral, social, religious, mental, financial, and hygiene issues. European countries deal it effectively and punish the responsible company through different penalties including heavy amount of fine, etc. Similarly, medicine regulatory authority of several countries monitors this issue through patient and market survey, and deals as per law. On the contrary, this is not the situation of developing countries where relaxed law practicing conditions, poverty, poor economy, etc., are some of the major barriers identified for PDR monitoring in these regions [3]. The United States Food and Drug Administration (FDA), a federal agency of the Department of Health and Human Services) and Drug Regulatory Authority of Pakistan (DRAP) monitor drug recalls in USA and Pakistan, respectively [4][5]. Present study is aimed to investigate PDR procedure in Pakistan.

Experimental:



Results:

*COMPLAIN FAKE ⟶ REPORT CLOSED
*COMPLAIN GENUINE ⟶ IF GOODS RETURN, ROOT CAUSE & COMPLAIN NATURE ANALYSIS BY Q.C. (PHYSICAL AND CHEMICAL TESTING)
*COMPLAIN MINOR & MAJOR ⟶ REPROCESS TO PRODUCTION AREA
*COMPLAIN CRITICAL ⟶ NO REPROCESS

Conclusion:

Collection of sub-standard drug from market may be a temporary financial loss for the company but it gets good market repute in return. Conclusively, strict implementation of law at governmental level may control this issue in developing countries too. Moreover, it is to be ensured that companies are better equipped to analyze quality defects of drugs and sub-standard products are properly investigated through effective monitoring of the overall process.

References:

1. *International Pharmaceutical Industry,* **2014,** 6, 16-17.
2. *The Pharmaceutical and Chemical Journal*, **2020**, 7,16-22.
3. *Investigations Operations Manual*, **2021,** Chapter 7, 425-430
4. *The Gazette of Pakistan*, **2012,** Chapter-1,1265-1268.
5.https://www.fda.gov/drugs/drug-recalls/fdas-role-drug-recalls Accessed, Feb. 02, 2021.