



Pharmaceutical Product Recall Procedures in India, South Africa and China

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ABSTRACT

Drug regulatory authorities assure that drug products are rigorously tested for safety and efficacy before marketing. As per WHO, the prevalence of spurious, falsely-labelled, falsified or counterfeit medicines that are deliberately and fraudulently produced, packaged and/or mislabeled is a growing trend worldwide. Drug recalls are conducted for seriously defective products that pose health risks to patients by voluntarily by manufacturers or by mandate of regulatory authorities. The aim of this article is to compile and analyze the recall procedure for India, South Africa and China and to assess the actions taken in the NSQ cases. The regulatory provisions adopted by the drug regulatory authorities of these countries were investigated for recall notification, type, classification, health hazard assessment, strategy, rapid alert system, evaluation system and termination. Recall guidelines are well developed in all three countries with peer recall classification, health hazard assessment system, strategy and public warning methods. Recall timeline is very specifically defined in India China; where as in South Africa suitable timeline is agreed upon by Department of Health, and in. In India and South Africa, termination of recall process is notified after satisfactory recall completion. In China, licensee followed by final reporting of recall after successful completion licensee need to submit analytical report of the new batch manufactured ensuring rectification defect.

Keywords: China, India, Pharmaceutical product, Recall, South Africa.

INTRODUCTION

Drug recalls are common for countries with well-defined regulatory guidelines that often involve totally defective products that pose health risks to patients. Clinically important drug recalls usually involve thousands of affected units distributed nationwide or beyond. Given the large number of affected units per recall and the widespread distribution of these units, a measure /procedure is needed to minimize patient harm when recalls occur. A comprehensive strategy ensures that health care providers are properly notified about all clinically important drug recalls. Little is known about the public health burden of drug recalls, though the pharmaceutical companies face issues with finance as well market reputation.¹

The FDA makes sure that drug products are rigorously tested for safety and efficacy before grant of marketing authorization and making available to the consumer. The FDA, along with the manufacturer continues to monitor the drug products for any unforeseen problems while in market. If in case any issue related to safety comes into question, the manufacture or the FDA initiate market withdrawal or recall of the market distributed products. When drug products are reported to have caused potentially harmful effect on users due to defective quality, safety or efficacy issues are subjected to a recall. The recalls are usually due to company's notice, customer's complaint or FDA observation. Nevertheless, the manufacture's put their best efforts in manufacturing and selling of safe and authentic products, the possibility

still exists that dangerously defective products may reach to the consumer. A recall is an expensive undertaking, not only in apparent costs, but also disservice to the reputation and the risk of litigation. A number of factors can cause a drug to be recalled:

Health hazard

The health risks associated with certain medications like deaths, diseases, injuries, or other adverse reactions occurs while the product was used according to its labeled directions, due to a) product malfunction, b) product formulation, c) product quality (including potency, contamination, etc.), d) product design, e) inadequate directions for use, or f) other known or unknown causes. Occurrence of any life threatening, painful symptoms, toxicities or disease like clinical situation that could expose humans or animals to a health hazard are considered for health hazard evaluation with data support and information to determine the recall emergency status.

Mislabeled or poor packaging

Medicinal products released in market with wrong dosing instructions or mistakes in the labelling, problem with the dosing tool provided and packaging related defects are recalled.

Potential contamination

Any report of contamination of drug product with any harmful or non-harmful substance that can occur during production or distribution is subjected to recall.



Counterfeit

Any report or complaint of efficacy related issue with a drug product that ultimately proved by laboratory analysis calls for recall of product. These types of defects stand for fake medicine and product that contain wrong or no active ingredient.

Manufacturing defects

Manufacturing defects related to a product's quality, purity and potency cause for a drug recall. According to the WHO, the prevalence of spurious, falsely-labelled, falsified or counterfeit (SFFC) medicines that are deliberately and fraudulently produced, packaged and/or mislabelled is a growing trend worldwide threatening both patient safety as well as public confidence in the health systems.² SFFC medicines are illegal and results in treatment failure or even death. Antimalarial and antibiotics are amongst the most commonly reported SFFC medical products. Both Generic and proprietary medicines are falsified including very expensive products for cancer to very inexpensive products for treatment of pain.³

DISCUSSION

Pharmaceutical Product Recall in India

A defective product in relation to quality includes Not of Standard Quality (NSQ), Adulterated or Spurious drugs. Report of serious adverse reactions and death related to use of any particular drug results into safety and efficacy related recalls. Recalls also include drugs that are prohibited under the Provisions of Drugs & Cosmetics Act and those products for which product licenses are suspended/cancelled. In Schedule M of the Drugs & Cosmetics Act & Rules reference of product recalls, complaint and adverse reactions are in Para 27 & 28 and the conditions of license for defective product recall are described in Rule 74(j) and Rule 78(i). Recalls may be conducted as manufacturer's own initiative, by FDA request or by FDA order under statutory authority. In case quality related defects or complaints manufacturer may voluntarily withdraw drug from the market. FDA declares a drug as NSQ based on Government Analyst report or in incidents where serious adverse effects or death have been reported or in case of banned drugs sold under Section 26 A and order compulsory recall.

The Central Drugs Standard Control Organization (CDSCO) is the national regulatory body for Indian pharmaceuticals and medical devices regulations. Within the CDSCO, the Drug Controller General of India (DCGI) regulates pharmaceutical and medical devices, under the gamut of Ministry of Health and Family Welfare. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). The DCC is an advisory committee to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout in the administration of this D & C Act. DCC

guidelines categorize NSQ drugs as Category A and Category B defects and differentiate out the action to be taken on NSQ drugs based on defect category.

Recall guideline

Guidelines on Recall and Rapid Alert System for Drugs (including Biologicals & Vaccines) published in 2012 is applicable to all quality defective product reports and reported incidents of safety and efficacy received for drugs vaccines and biological. This guideline is followed by licensees (manufacturers, importers, stockists, distributors, retailers) for voluntary or statutory recalls. The procedure is also used by Drugs Control Authorities of Central or State when urgent recall action is required to protect public or animal health. This guideline provides stepwise procedures to be followed in recall strategy recall evaluation at every level and achieve compliance within a specified time frame.⁴

Recall classification

Recall is classified by regulatory authorities to a particular product recall indicating relative degree of health hazard.

- **Class I** is a situation in which there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death and as well as banned under 26A of Drugs and Cosmetics Act 1940.
- **Class II** is situation in which the use of, or exposure to, a defective product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III** is a situation in which the use of, or exposure to, a defective product is not likely to cause any adverse health consequences.

Recall is of two types Voluntary Recall and Statutory Recall.

- **Voluntary recall** is triggered by manufacturer in response to incident affecting the quality, safety and efficacy of a batch/product of drug.
- **Statutory recall** is done in response to direction or mandate of the Drug Regulatory Authorities (Central/State) in situations as violation of the laws such as NSQ, banned drugs or violation Rule 106 (Diseases under Schedule J).

Levels of recall

The level (or depth) of recall of a product/batch is determined based on recall classification and level to which distribution has taken place.

- **Consumer or user level** including any intermediate wholesale or retail level, consumer including individual consumers, patients, physicians and hospitals.



- **Retail level** includes retail groceries, pharmacies, hospital pharmacies, dispensing physician, institutions such as clinics and nursing homes, etc.
- **Wholesale level** includes levels between the manufacturer and retailer. All Class I recalls are executed to the levels of distributors, wholesaler, retailer and consumer. Public announcements are made using print/electronic media aids viz. Newspapers, Television, Radio etc. All Class II recalls are executed up to the levels of wholesale and retail and Class III only up to the levels of wholesale.

Recall procedure

Recall decision of the product/ batch (es) is taken within 24 hours of receipt of intimation. Communication sent using the fastest mode including email, telephone, fax, SMS etc to the entire supply chain. The licensee informs the concerned regulatory authorities about the distribution of defective product batch (es) and further actions on recall are undertaken according to class of recall. The recall notice received the stock at that time, the procedure for freezing the stock and returned back records are maintained by the distributor/retailer and made available for verification by area Drugs Inspector.

Follow-up action of recalled goods

The follow-up action consists of a check on the effectiveness of the recall, investigation of the reason for the recall and remedial action taken to prevent a recurrence of the defect. The stocks of recalled goods are placed under "Quarantine", sample investigated to establish the root cause of the product quality defect and corrective and preventive actions are initiated. Based on conclusion of the investigation findings, the QA Head / representative of licensee direct the distributor / marketing company for appropriate disposition of the batch (es) of the recalled goods as per the regulations.

Time lines for effective recall system and rapid alert

Based on the category of risks involved, time line of within 24 hours to a maximum of 72 hours is given for Class I recall. For class II recall up to maximum of 10 days and for Class III recall up to maximum of 30 days is allowed. The recall must be initiated immediately without any prejudice of the outcome of Section 25(3) and Section 25(4) of the Drugs & Cosmetics Act 1940 for adducing the evidence.⁵

Pharmaceutical Product Recall in South Africa

Medicines Control Council (MCC) in South Africa is responsible for recall / withdrawal of medicines, medical devices and *In Vitro* Devices (IVDs); monitor the effectiveness of recall actions and also provides a scientific, technical and operational advice. Most recalls are conducted on voluntary basis. The MCC recall medicines/medical devices/IVDs when registration

thereof has been cancelled or are sold illegally in South Africa or are no longer of proper quality, safe, efficacious or lacks performance. As per the Medicines and Related Substances Act, 101 of 1965, no person shall sell any medicine, medical device or IVD unless it complies with the prescribed requirements.

Notification of recall

A report related to *inter alia* an adverse drug reaction to a particular batch (es), product quality deficiency, technical complaints experienced with regard to the printed packaging material, contamination, mislabeling, counterfeit including adulterated medicines, faulty medical devices or IVDs, non performance of a medical device or IVD etc from various sources, e.g. manufacturers, wholesalers, retail and hospital pharmacists, doctors can initiate recall. Regardless of the level, medicine recall cannot be undertaken without consultation with the MCC and without agreement on the recall strategy. However, in case of a potential significant health hazard to patients, during the weekend/public holidays the holder of a certificate of registration (HCR)/parallel importer may within 24 hours disseminate information on the recall.

Recall classification

Recalls are classified into both the classes according to the level of health hazard involved (risk to the patient) and types which denotes the depth or extent to which the product should be recalled from the distribution chain, e.g. Class I, Type C recall, etc. Class I or Class II recalls are considered to be urgent safety-related recalls. Class III recalls is considered to be routine on safety-related recalls.

- *Type A recall* is designed to reach all suppliers of medicines/medical devices /IVDs, i.e. wholesalers throughout the country, directors of hospital services, retail outlets, doctors, nurses, pharmacists, authorized prescribers and dispensers and individual customers or patients through media release (radio, television, regional and national press).
- *Type B recall* is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorized prescribers and dispenser.
- *Type C recall* is designed to reach wholesale level and other distribution points e.g. pharmacies, doctors, hospitals). Decisions on the Class and Type of a recall are based on the evidence and/or expert opinion of the MCC and High Commission for Refugees (HCR).

Post recall procedures

Within two weeks (or at other agreed times) of recall implementation the importer/distributor has to provide



the MCC with an interim report on the effectiveness of the recall and within 30 days a final recall report should be furnished. These reports may include details on the investigation defect cause, corrective actions implemented extent of distribution, success of the recall, method of destruction or disposal of the recalled goods.

Follow up action

The follow up action consists of evaluation recall effectiveness and investigation of reason along with corrective actions taken to prevent a recurrence. The Medicines Control Officer evaluates the reports received from the recalling site and make assessment. Apparent follow up actions are taken by the MCC or Inspectorate and Law Enforcement directorate on behalf of the MCC as directed by Council. Once the recall has been handled satisfactory, the MCC will determine closure of the recall.⁶

Pharmaceutical Products Recall in China

The China Food and Drug Administration (CFDA) under the State Council of the People's Republic of China is in charge of comprehensive supervision on the safety management of food, health food and cosmetics and is the competent authority of drug regulation in mainland China. The Pharmaceutical Products Recall Guidelines is intended to ensure that recall operations are effectively and efficiently carried out by the manufacturer, importer, distributor or certificate holder of pharmaceutical product in order to safe guard public health. Regulation 28(8) & 33(5) of the Pharmacy and Poisons Regulations require a holder of a wholesale dealer licence and a manufacturer to set up and maintain a system of control that will enable the rapid and, so far as practicable, complete recall of any pharmaceutical product from sale to the public in the event of the pharmaceutical substance or product being found to be dangerous or injurious to health. Procedure is divided into six stages, with a reference to the Section in which detailed information is given.

Receipt of pharmaceutical product problem report

Recall is initiated as a result of reports or complaints on quality, safety or efficacy on a pharmaceutical product by manufacturers, wholesalers, retailers and hospital pharmacies, research institutes, medical practitioners, dentists or patients. Serious problems which may lead to recall of Class I or Class II must be reported to the Department of Health within 24 hours after receipt of the complaint or report for investigation. The Pharmaceutical Product Problem Report Form together with opinions on toxicological or therapeutic hazards and the action proposed by the authorities/organization are referred to Department of Health. For less serious problems results in Class III recall, the Pharmaceutical Product Problem Report Form is sent to Department of Health no later than 72 hours. When the need for recall has been established, additional information is required so that an appropriate recall strategy may be devised.

Initiation of a recall

It is required to notify the recall situations in Recall Notification Form including detailed information to the Department of Health immediately after the decision to recall is made and the Senior Pharmacist (LC-M), Department of Health is notified. The information required include, details of the problem, details of the product, health hazard evaluation and proposed action.

Assessment of recall

The classification, level and strategy of recall are determined depending on the potential hazard of the defective product and the extent of product distribution.

Recall

An appropriate recall strategy include, the nature of the deficiency in the product, the incidence of complaints, public safety, distribution networks, recovery procedures, resources for corrective action and availability of alternative products. The proposed recall strategy should be agreed by the Department of Health before implementation and recall should be completed by the date as directed. Licensee prepare recall letters with a factual statement of the reasons for the recall together with specific details that is sent by mail, facsimile or e-mail to the clients. Rapid alert to public is usually reserved for hazards classified as Class I, and where appropriate Class II, or situation where other means for controlling the hazard appear inadequate.

Progress of recall and report

Licensee has the prime responsibility for implementing recall action, and for ensuring compliance with the recall procedure at its various stages. However, no recall, regardless of level, should be undertaken without consultation with the Department of Health. For Class I recall, Licensee should notify its clients within 24 hours upon the decision of recall. All Class I recall should complete within a time as found suitable for the case agreed by Department of Health. For consumer level recall, the Licensee should set up sufficient recall spots for collection of recalled products. Licensee provides the Department of Health with an interim report during recall process for the monitoring of progress within 7 days after initiation of recall. A final report is submitted to Department of Health within 14 days after commencing of the recall. After completion of the recall, a report on investigation results on the problem and the action proposed to be implemented in future to prevent a recurrence of the problem should be submitted to Department of Health in a timely manner. These reports establish the effectiveness of the recall and unless satisfactory reports are received, further recall action may have to be considered.

Evaluation of the recall

The evaluation consists of a check on the effectiveness of the recall and an investigation of the reason for the recall



as well as the remedial action taken to prevent a recurrence of the problem. The Department of Health examines the recall reports and the signed Recall Reply Forms submitted by the Licensee and assess the effectiveness of the recall action. If Department of Health finds the Recall to be ineffective, the Licensee will be asked to take appropriate steps, including Re-issuing recall letters on completion of a recall, the Licensee is

requested to provide a report with investigation on the problem and details of the remedial action proposed to prevent recurrence of the problem. After implementing the remedial action and subsequent manufacturing or importing the new batch of the product, the Licensee shall submit analytical report(s) of the new batch tested by external accredited laboratory to Department of Health as a proof of product quality.⁷

Table 1: Comparative account of drug recall guidelines implemented in India, South Africa and China

Recall Procedures	India	South Africa	China
Recall definition	Removal or correction of marketed products for the reasons relating to deficiencies in quality, safety or efficacy, including labeling considered to be in violation of the laws.	The removal of specific batch/batches of a medicinal product from the market for reasons relating to deficiencies in the quality, safety or efficacy.	A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/ or concerns that the product is or maybe counterfeit.
Regulatory body	Central Drugs Standard Control Organization (CDSCO)	Medicine Control Council (MCC)	China Food and Drug Administration (CFDA)
Legal requirement	Para 27, 28 of Schedule M and conditions of license for defective product recall in Rule 74(j) and Rule 78(i) of the Drugs and Cosmetics Act, 1940 and Rules	Section 19 (1) of the Medicines and Related Substances Act, Act 101 of 1965 and Regulation 43(1) of the Medicines and Related Substances Control Act, Act 101 of 1965	Regulation 28(8) & 33(5) of the Pharmacy and Poisons Regulations and Regulation 28(8) & 33(5) of the Pharmacy and Poisons Regulations 1965
Initiation of Recall	Voluntary or Statutory recall	Voluntary or MCC mandated recall	Manufacturer, wholesale dealer, licence holder or Department of Health. Voluntary (only after Pharmaceutical Product Problem Report Form submission to Department of Health) or CFDA mandated
Recall Classification	Class I, II and III	Class I, II and III	Class I, II and III
Health hazard evaluation	By relative degree of health hazard	Level of health hazard involved (risk to the patient)	Type of hazard and evaluation of health hazard to user
Recall strategy	Recall guideline provide recall strategy, but not mandatorily required to be followed	No recall should be undertaken without consultation with the MCC and without agreement on the recall strategy	The proposed recall strategy should be agreed by the Department of Health before implementation
Notification and Public Warning	Newspapers, Television, Radio warning only for Class I	Notification and public warning by media release depends on the recall strategy or MCC release on Cluster: Communication of the Department of Health	Recall letter release by mail, facsimile or e-mail to the clients, for public through appropriate channels including press release
Recall timeline	Class I – within 24 hours up to maximum of 72 hours. Class II - up to a maximum of 10 days. Class III - up to a maximum of 30 days is allowed.	Within a time as found suitable for the case agreed by Department of Health	Within 7 days
Monitoring and Auditing the Recall	Investigation report	Assessment interim report on the effectiveness of the recall	Assessment of recall reports and the signed Recall Reply Forms submitted by the Licensee
Termination of a Recall	May be show cause notice or legal action against firm as required	After satisfactory recall completion, the MCC determine closure of the recall	Licensee provide investigation report with details of the remedial action proposed and CFDA further follow up action



Pharmaceutical industry is one of the very important commercial sectors for the economy of any country. Drug product recall is not a desirable event for any pharmaceutical company; also recalling a product is not an easy task once released into the market as recovery from different levels are difficult and tedious job. Recall of any product adversely affect the financial status and commercial goodwill of the manufacturing company.⁸ The regulatory bodies ensure proper fulfillment of recalling by implementing strict guideline defining procedure from notification to termination.

The definition of recall is on an average similar for all the countries that is, removal of specific batch/batches of a medicinal product from the market due to deficiencies in the quality, safety or efficacy, complaints of serious adverse reactions or concerns related to counterfeit. Mostly recalls are initiated as Voluntary by the manufacturer or as statutory recall following FDA mandate for all the countries but in China voluntary recall can only be undertaken after Pharmaceutical Product Problem Report Form submission to Department of Health. In all the countries recall is classified as Class I, II and III with slight difference in terminologies that depends on health hazard evaluation relating to relative degree of risk involved to the patient. Mostly all the countries provide recall strategy in the respective recall guidelines. In South Africa and China a recall must be conducted in accordance with the approved recall strategy but in India it is not mandatorily required to be followed.

Recall notification and public warnings are provided in newspapers, television, radio, press release and in FDA's web site mostly for Class I recall only. Recall timeline is very specifically defined in India as 24 to 72 hours for Class I, maximum 10 days for Class II and maximum 30 days for Class III where as in South Africa suitable timeline is agreed upon by Department of Health and in China it is normally 7 days. In India after completion of recall process a show cause notice or legal action can be initiated against the firm as required. The MCC determine closure of the recall after satisfactory recall completion. In China, licensee should provide investigation report with details of the remedial action proposed and CFDA takes follow up action before subsequent manufacturing or importing the new batch of the product. The Licensee shall submit analytical report(s) of the new batch tested by external accredited laboratory to Department of Health as a proof of product quality making the CFDA a step ahead in ensuring rectification defect. CDSCO has provides a comprehensive list of drugs, medical devices and cosmetics declared as NSQ/Spurious/Adulterated/Misbranded for the year 2014 to 2016 (Figure 1)⁹. Detailed literature search has revealed that list of drug recall data for MCC, South Africa and CFDA, China is not available online.

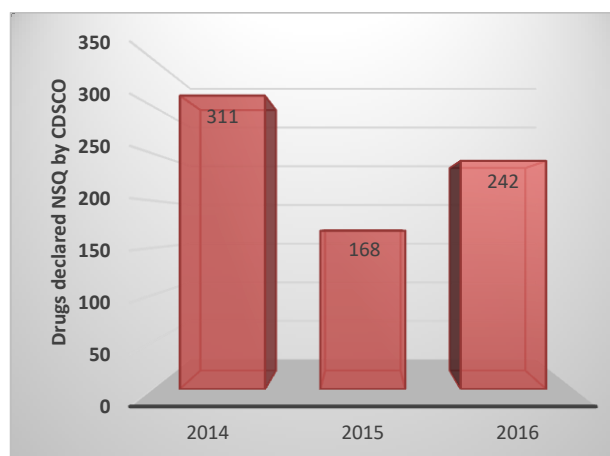


Figure 1: Drug product recall data of CDSCO for year 2014 to 2016

Summary and Conclusion

Recalling can be done smoothly when company management follows guideline, and do all the recalling activities as defined. As the number of recalls are increasing year by year greatly affecting the public health, the regulatory authorities and pharmacovigilance should monitor the pharmaceutical firms closely to decrease the number of recall. The regulatory authorities' should also monitor proper disposal of recalled product to ensure protection of environment and human health. Every pharmaceutical company conduct mock recalls to ensure effectiveness of the arrangements of recall and conduct internal inspections, audits to find any mistakes/mishappenings during manufacturing process. Indian regulatory CDSCO has implemented recall guideline at par with other countries, still it should be made mandatory that recall to be undertaken in consultation with the CDSCO and without formal approval of the recall strategy it should not be undertaken. In termination of recall process though licensee provide investigation report with details of the disposal action done and CDSCO may issue show cause notice or legal action as required. Follow up in respect to manufacturing of subsequent new batch of the recalled product by assessing analytical reports or by external audit as proof of product quality will ensure further safe guard of public health.

Government may take following steps to reduce manufacturing, sale and distribution of Not of Standard quality drugs:

- ✓ Uniform implementation of Schedule M GMP & Schedule L-1 GLP provisions in all states of India.
- ✓ Up gradation of drug testing laboratories of all states.
- ✓ Education/training of regulators and manufacturer.
- ✓ There is urgent need to improve guidance document of recall procedure. Need to develop some recall formats/procedure/information forms etc.

- ✓ In some states, sufficient regulatory staff is not available. Government has to provide some funds to the state to develop their infrastructure and appoint more regulators.
 - ✓ There is need to develop some clear guidance documents for destruction of recall products.
 - ✓ In case of delay in class I recall, there must be some strict provisions against the manufacturer.
 - ✓ Regulators need to upgrade/trained for NSQ investigations.
 - ✓ There is need to improve interstate communication.
 - ✓ There is need to develop line on software. Once the drug has declared NSQ by any state or central drug testing lab, the report to be made available to all regulators and also to the public
 - ✓ Improve our vigilance system for imported drugs.
 - ✓ Need a separate wing to track NSQ/Spurious or Adulteration cases.
 - ✓ There is need to provide some funds to the informers.
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