

**PHARMACEUTICAL BATCH RECALL SYSTEM: GLOBAL ISSUE
AND REGULATORY CONTROL**

Rajendra K. Songara, Manmohan Singhal*, Pratibha chauhan, Ajay K. Tiwari

School of Pharmaceutical Sciences, Jaipur National University, Jaipur,
Rajasthan, India 302025

Summary

The objective to prepare this article is to guide to the management of batch recall or product withdrawal by companies in world's Pharmaceutical industry. Consequently, it is most likely that the affected product may be restricted by law to supply by, on the prescription of a doctor or dentist and its stocks held at various point in the distribution chain for the purpose of NHS use. Similar considerations may be appropriate to the management of recall of pharmacy and general sale list medicines, have due regard in each case to the nature of the product concerned and its distribution outlets.

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***Author for correspondance:**

E mail: manu_research2@rediffmail.com

Introduction

Effective batch recall or product recall assumes that the product has been conveyed in accord with good distribution practice through legitimate channels. It is essential that recalls and withdrawals are managed promptly from the time of reporting of a possible defect, in a manner commensurate with a degree of potential risk to the patient. As a prerequisite, therefore the necessary procedures will already have been put up in place, tested, reviewed, and made known to all concerned in the recall process.^[1]

A company cannot conduct the batch recall or product withdrawal in isolation, however. It relies on its customer and agents including health authorities, to act with due diligence at the time of discovery of a possible defect; to provide all reasonable assistance in locating and, if necessary, embargoing the suspect material; to supply a sample if available immediately on request for the purpose of examination and analysis; and to co-operate as appropriate in the dissemination of recall information.^[2]

It is likely that new power under the centralized procedure, for instance will give further statutory force to the good practice already pertaining as advocated. Any such changes introduced will be notified to member companies via the normal channels. Companies are advised to take due account of all relevant legislative changes.

This article applies to the medicines for human use that are licensed medicinal products as defined in the Medicines Act 1968, and which are withdrawn or recalled from sale or supply for safety, quality and efficacy reasons. It does not cover withdrawal from sale or supply for commercial reasons, even though the license holder is obliged to notify the Medicines Control Agency of such withdrawal. If a company is discontinuing the product without immediate withdrawal of stock then the market will be notified accordingly.^[2]

Recalled drugs

The term "recalled drugs" refers to any type of medication, whether it is prescription or over the counter, that has been withdrawn from the market, either by the particular drugs manufacturer or the FDA, also known as the Food and Drug Administration. The Food and Drug administration is a business entity that is responsible for making sure that foods, drugs and medical devices are safe for consumers. When it has been determined that a drug has such adverse side effects that injury or death could be a result of their use, the Food and Drug Administration will issue a recall. In addition to the two types of drug recalls that can be issued, which include Class I and Class II Recalls, the Food and Drug Administration also issues safety alerts, notices and warnings. They also have the ability to implement labeling changes for certain drugs that may pose an inherent risk.

Recalled drugs that fall under a Class I Recall carry the reasonable possibility that their use or exposure to them may cause serious injury and maybe even death. Recalled drugs that fall under a Class II Recall have the potential to cause temporary or medically reversible injury.^[3]

Defective drug lawsuits

In the recent past there have been many research studies conducted regarding recalled drugs, and it was found that since 1993, there have been over 1,000 deaths can be linked to pharmaceutical drugs. It is also a widely reported fact that over 20 million people have at

one time taken a drug that was eventually recalled. Newspapers and television alike are constantly reporting on recalled drugs and the lawsuits that are filed because of them. Billions of dollars are awarded every year to patients, as well as their surviving family members, who have incurred serious loss or injury due to the adverse effects of recalled drugs.^[4]

Recalled drugs have been known to cause birth defects, heart attacks, strokes, deadly breathing problems, death, and many, many more potentially dangerous adverse affects. While drugs do undergo lengthy testing procedures and resting phases before being approved for public use, it sometimes is not apparent just what the effects will be until a large, diverse group of people have begun to use the drug. Sometimes, at this point it is too late, as they drug may have been responsible for someone's death.

The list of recalled drugs keeps growing as time goes by, and many consumers are beginning to wonder just how safe the drugs are that they take on a daily basis.

Medicines act regulation

Regulations made under the medicines Act in 1968 impose certain obligations on license holders with regard to withdrawal and recall from sale.

The following extract is taken from Part I, schedule 1 to the medicines Regulations 1971 as amended.

Para 6 : The license holder shall keep such documents as will facilitate the withdrawal or recall from the sale, supply or the exportation of any medicinal product to which the license relates.

Para 7: Where the license holder has been informed by the licensing authority that any batch of any medicinal product to which the license relates has been found not to conform as regards strength, quality or purity with the specification of that product or with the provisions of the act that are applicable to the medicinal products, he shall, if so directed, with hold such batch from sale, supply or exportation, so far as may be reasonably practical, for such period not exceeding six weeks as may be specified by the licensing authority.

Para 8: The license holder shall notify the licensing authority forthwith of any decision to withdraw from sale, supply or exportation any medicinal product to which the license relates and shall state the reason for that decision.^[5]

Schedule 2 to the regulations (Standard Provisions for Manufacturers licensing including Manufacturers Licenses of Rights) was amended in 1992 by SI no. 2486, in order to implement Directive 91/356/EEC "Principles and Guidelines of Good Manufacturing Practice for Medicinal Products for Human Use "(GMP Directive)

The holder of the manufacturer's license is required to have in place a system fir recording and reviewing complaints and for recalling medicinal products in the distribution system. The manufacturer must inform the Defective Medicines Report Centre (DMRC) of the MCA immediately of nay defect that could result in a recall or restriction of supply.

Where the product is manufacturer by a contract manufacturer, then it is advisable that the product license holder should clearly define the roles and responsibilities for a recall or withdrawal in the contract between the two parties. The product license holder should be

informed at the earliest opportunity if a problem arises that could result in a recall or withdrawal.

Amendments to schedule 3 to the regulations (Standard Provisions for Wholesalers Dealers Licenses of Right) place requirements on holders of wholesale dealers to license to have recall plans and to assist in the event of recall or withdrawal.^[5]

Liability

Civil liability issues should be taken into account when considering the necessity for a batch recall or product withdrawal.

Claims under common law negligence could allege a failure by the manufacturer to discharge his duty of care to customers by not initiating a batch recall or product withdrawal and that, as a result, injury was caused to claimants. It is more likely, however, that claims would be based on strict liability under the consumer protection Act, 1987 which provides for liability in the event of injury or damage caused by a defective product. There is no need to prove that the manufacturer is negligent and a product is to be deemed effective, "if the stability of the product is not such as persons generally are entitled to expect" while liability under the act is strict. It is not absolute and a manufacturer may, in appropriate circumstances, rely on the so called development risks defense whereby there will be no liability, if at the relevant time, the state scientific and technical knowledge was such that the defect could not have been detected. Compensation levels under both negligence and the 1987 Act are unlimited.^[6]

Whatever the decision is taken by the recall committee, it is important from a liability point of view for the committee to be seen to have acted reasonably and on the basis of an informed risks-benefit analysis.

Recalls are action taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a volatile product will cause serious health consequences or death. A Class II recall is a situation in which use of or exposure to a volatile product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of or exposure to a volatile product is not likely to cause adverse health consequences.^[7]

Positions affected

1. Lead Pharmacy Technician, Procurement and Inventory Management.
2. Delivery technicians per Technician Area and Assignments list posted on the Pharmacy Services Share Point site.
3. Pharmacists per TJC Readiness/Rx Checks/Outdate Assignments list posted on the Pharmacy Services Share Point site.
4. The Clinic Pharmacy (CP) is also notified for recall notification of appropriate sites according to the CP policy.^[8]

Instructions for recall

1. The Lead Pharmacy Technician, Procurement and Inventory Management (PIM) will receive the notice of drug recall from the vendor or FDA.
2. The PIM will revise the drug product in the stations to a Recalled (G) Security Group in the hospital console to prevent access prior to being checked.
3. The PIM will send out a recall notice on the Pharmacy-IP LISTSERV and also fax a copy to Central, Markey Outpatient, OR, and Pediatric Satellite Pharmacies. The *Hospital Wide Medication Summary* information will be included in the notice to allow focused checking of the stations. The Clinic Pharmacy (CP) is also notified for recall notification of appropriate sites according to the CP policy.
4. Pharmacy technicians are to check their assigned areas, including Med Stations and floor Stock areas. A copy of the notice should be printed out, filled out, signed, and returned via fax to the PIM by the end of their current shift. E-Mail communication is acceptable if the notice information is contained in the e-mail (copy/pasted function utilized).^[9]
5. If the PIM has not received notification that an area has been checked by the technicians, a second notice will be emailed to the Pharmacists-IP LISTSERV with running total of what has been received. At this point, it becomes the Pharmacist assigned to the area to check that area for the recalled product. A copy of the notice should be printed out, filled out, signed, and returned via fax to the PIM by the end of their current shift. E-Mail communication is acceptable if the notice information is contained in the e-mail (copy/pasted function utilized).
6. Once the PIM has received documentation that all Pyxis stations have been checked for recalled product, the PIM will run a transactions report for the drug product(s) and confirm an inventory transaction was completed at each station (per hospital wide summary). Once this inventory transaction step is confirmed, the PIM will revise the security group back to its original category.
7. All recalled drugs should be returned to the purchasing technician, placed in a bag, and marked as recalled.
8. Items returned to the Pharmacy from other departments will be replaced or credited. The PIM will notify an area based on interdepartmental billing data and will document returns by these areas. If an area has not responded, the PIM will work with the area manager to complete the recall process.
9. The purchasing technician will isolate the recalled drug products until they can be returned to the vendor or destroyed. The PIM will forward return information to the purchasing technician.
10. The PIM will maintain a hard copy file of all drug recall notices and the actions taken. A master checklist indicating that all areas have been checked will be maintained in this hard copy file. Files will be stored for three years with a cross reference master file of drug, manufacturer and date.^[10]

URGENT!!!*****RECALL NOTIFICATION*******Date:** ----- **Time:** -----*This form MUST be responded to by the end of your shift today. See below for Instructions and assigned areas.***Drug Name:****Manufacturer:****Cardinal item number:****NDC:****Lot(s):****Reason for recall:****Instructions:**

1. Check your area(s) (see next page) thoroughly for product.
2. Print this form, fill in by hand, sign, and fax back to no. provided.
3. Clearly mark products as “**RECALLED-DO NOT USE**” and put on Purchasing Technician’s desk. Use the pneumatic tube system only if you have a commitment from a pharmacy employee to get the product to the Purchasing Technician’s desk.

[6]

Complaints logging and monitoring

A potential batch recall or product withdrawal may be initiated by receipt of a complaint from customers, distributors, and the company’s own quality control organization or from DMRC. It is consequently essential for an effective procedure to exist in order to respond to all customer complaints in a timely manner. The existence of such a procedure should be made clear to all company employees (including representatives, receptionists and possibly security staff) and agents who may be the first recipient of a complaint.

FDA-Industry Co-operation

The manufacturers or distributors of the product carry out most recalls of products regulated by FDA voluntarily. In some instances, a company discovers that one of its products is defective and recalls it entirely on its own. In others, FDA informs a company of findings that one of its products is defective and suggests or requests a recall. Usually, the company will comply.^[11]

If the firm does not recall the product, then FDA can seek legal action under the *FD&C Act*. These include seizure of available product, and/or injunction of the firm, including a court request for recall of the product.

This cooperation between FDA and its regulated industries has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market. This method has been successful because it is in the interest of FDA, as well as industry, to get unsafe and defective products out of consumer hands as soon as possible.

FDA Guidelines for recall system

FDA guidelines for companies to follow when recalling defective products under the Agency's jurisdiction are published in Title 21 of the *Code of Federal Regulations*, Part 7. These guidelines make clear that FDA expects these firms to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful. Under the guidelines, companies are expected to notify FDA when recalls are started, to make progress reports to FDA on recalls, and to undertake recalls when asked to do so by the Agency.

The guidelines also call on manufacturers and distributors to develop contingency plans for product recalls that can be put into effect if, and when needed. FDA's role under the guidelines is to monitor company recalls and assess the adequacy of a firm's action. After a recall is completed, FDA makes sure that the product is destroyed or suitably reconditioned and investigates why the product was defective.

Generally, FDA accepts reports and other necessary recall information submitted by e-mail. In many cases, this has become routine for some firms and FDA district offices. However, FDA maintains the prerogative for investigational visits and other in-person communications where the agency considers it appropriate.^[12]

Recall classes

The guidelines categorize all recalls into one of three classes according to the level of hazard involved.

Class I

Class I recalls are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are a food found to contain botulinal toxin, food with undeclared allergens, a label mix-up on a life saving drug, or a defective artificial heart valve.^[13]

Class II

Class II recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a drug that is under-strength but that is not used to treat life-threatening situations.

Class III

Class III recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labelling or manufacturing regulations. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a bottled drink, and lack of English labeling in a retail food.

Recall information

FDA develops a strategy for each individual recall that sets forth how extensively it will check on a company's performance in recalling the product in question. For a Class I recall, for example, FDA would check to make sure that each defective product has been recalled or reconditioned. In contrast, for a Class III recall, the Agency may decide that it only needs to spot check to make sure the product is off the market.

Even though the firm recalling the product may issue a press release, FDA seeks publicity about a recall only when it believes the public needs to be alerted about a serious hazard. For example, if a canned food product, purchased by a consumer at a retail store, were found by FDA to contain botulinal toxin, an effort would be made to retrieve all the cans in circulation, including those in the hands of consumers. As part of this effort, the Agency also could issue a public warning via the news media to alert as many consumers as possible to the potential hazard. ^[14]

Receipt

Complaints cover a range of concerns and may be broadly divided into 'product' complaints or 'service' complaints (e.g. marketing and distribution). They may be received either orally or in writing from various sources by a wide variety of individuals and departments within the company.

There must exist the defined procedure that prescribes the route of directing complaints to those assigned the responsibility of handling them. The procedure should require prompt notification to all relevant personnel, including a qualified person.

A system must be developed which allows for the recording of complaints and their individual identification. In the case of oral complaint, a written record of the contact should be made and the complainant identified. ^[14]

Receipt of the complaint must be acknowledged without prejudice pending an investigation. If it is necessary to seek clarification, or relevant to recover any material associated with the complaint, this should be requested a juncture.

It is reasonable to expect that samples will be supplied promptly unless there is insufficient of the possibly defective material. ^[14]

Various issues related to recall

A manufacturer of over-the-counter drugs has voluntarily recalled six products, including acetaminophen, sinus-relief medication and back-pain tablets sold in drug stores and supermarkets.

The six products being recalled are acetaminophen 500 mg extra-strength tablets, acetaminophen, caffeine and 8 mg codeine phosphate tablets, allergy and sinus relief extra-strength tablets, daytime sinus-relief extra-strength tablets, muscle and back-pain-relief extra-strength tablets, and sinus medication extra-strength night tablets.

The drugs are sold under various brands, including Exact and Life, at Shoppers Drug Mart, Loblaw's, Rexall, Jean Coutu, Safeway, Procuracy, Federated Coop, Proxim, and Value Drug Mart.

Company spokesman Jacques Bibeau said the products were manufactured in 2007-08, and usually has a three-year shelf life. So, he said, the six products being recalled would either have been consumed by now or expired. He couldn't estimate how many bottles of the medication were affected by the recall, saying the company is still in discussions with Health Canada.

Canadians who have used the affected products and are concerned about their health should speak with their doctor, Health Canada advises. Paramedics are advising pharmacies that consumers should return products to their place of purchase, Health Canada said. ^[15]

Phenylpropanolamine (PPA) Recall

In November 2000, the FDA issued a public health advisory about Phenylpropanolamine hydrochloride (PPA), the drug mentioned in the email. This drug is found in many over the counter (OTC) medicines, specifically in cold and flu remedies, as well as appetite suppressants. The drug will likely be banned, but because this process takes time, the FDA issued the health advisory in the meantime and manufacturers are voluntarily recalling and/or reformulating medicines containing PPA.

The main problem with this drug is that it elevates your risk of having a hemorrhagic stroke, especially with (but not limited to) first time use among women. Because the uses of PPA are not serious enough to warrant taking even that small chance, the FDA recommends that you stop taking any medications containing the drug.

Rather than looking at a limited list such as the one contained in the above email, you'd be better off checking the package of any cold, flu or appetite suppressant medication for the drug, which will appear in the list of active ingredients and may be listed as Phenylpropanolamine, Phenylpropanolamine hydrochloride, or Phenylpropanolamine bitartrate. Many manufacturers offer several formulations of their cold and flu remedies, some of which do not contain PPA. Pseudoephedrine is an effective alternative to PPA for use in cold and flu preparations, but unfortunately, there is no approved alternative OTC drug for use in appetite suppressants. Therefore, if you are using any OTC medications to suppress your appetite for weight loss or other reasons, you should stop using the medicine and talk to your doctor about getting a prescription drug instead. ^[15]

Investigation

Complaints must be thoroughly investigated by the nominated person or persons in a timely fashion in order to determine their validity and potential risks. The person named on manufacturer's license is responsible for the quality control should be involved in the review of product quality complaints. The investigation should include the laboratory evaluation of any returned material along with control keeping sample of specific batch, if known. Other batches may also need to be checked (particularly any batches containing rework of the defective batch).

An internal technical report containing full complaints, nature of the complaint, material returned and laboratory findings should be prepared and referenced to the corresponding batch records.

Possible causes of the complaint should be explored and corrective actions identified.

Previous complaints of a similar nature should be reviewed to help determine if the complaints is an isolated occurrence or if a pattern or trend exists. Where the investigation indicates that corrective action is necessary, management should review the results of investigation to determine and implement the required actions. ^[16]

The FDA's Role in the Tylenol Recalls

Finally, on May 1 of 2010, McNeil issued another Tylenol recall because of what were described as 'serious safety concerns' regarding 50 children's versions of these same products.

Based on these recalls and concurrent with other investigations that were ongoing with McNeil, the FDA has announced that it will expand its earlier investigation of a plant in Fort Washington, Pennsylvania in which the FDA uncovered serious problems with safety protocols, quality assurance steps and the potential for the contamination of products based on manufacturing practices. In its report on this initial investigation, the FDA excoriated the plant's conditions and the potential for harm for those who used these products.

Overall, anyone who has used these recalled Tylenol products could be at risk. If you or someone you love has been harmed as a result of using any of these products, you need to seek the help of experienced Tylenol recall lawyers who have a long track record of holding those responsible for the dissemination of dangerous drugs into the consumer marketplace accountable.^[17]

Children's Tylenol Recall, FDA Investigation

Tylenol, Motrin, Zyrtec and Benadryl; what parent doesn't have at least one of these pain relievers in the house if they've got kids? It's time for more spring cleaning, and that includes the medicine cabinet.

More than 40 over-the-counter infant's and children's liquid medications are being recalled by McNeil Consumer Healthcare, based in Fort Washington, PA. The recall involves 43 various children's versions of Tylenol, Motrin, Zyrtec and Benadryl.

They don't meet quality standards?

Tylenol, Motrin, Zyrtec and Benadryl products met Johnson & Johnson's McNeil Consumer Healthcare division quality standards just fine until the Food and Drug Administration showed up.

The FDA said it was reviewing procedures at McNeil, which appears to be the sole source of the problems. "We are following through with the facility to make certain that everything has been checked," said FDA spokeswoman Elaine Gansz Bobo.

According to McNeil and the FDA, some of the products recalled may have a higher concentration of active ingredient than is specified on the bottle. Others may contain particles, while still others may contain inactive ingredients that do not meet internal testing requirements.^[17]

The FDA regulates approximately 25 cents of every dollar spent annually by American consumers

The FDA is responsible for regulating products to ensure the safety of foods, drugs, biological products, medical devices, cosmetics, radiation-emitting devices, and more. FDA's Special Agents frequently investigate criminal wrongdoing by large companies. If these investigations lead to prosecution, the guilty officers and employees often receive federal prison sentences, while the company can expect to receive multimillion-dollar fines and restitution payments.^[17]

To produce 43 different drugs at one facility, even if they operated at full steam means that there was a problem for a very long time. When was the last FDA inspection?

“A \$1.8 million 2006 Institute of Medicine report on pharmaceutical regulation in the U.S. found major deficiencies in the current FDA system for ensuring the safety of drugs on the American market.

Response

All complaints must be responded to regardless of their validity. The company must be sensitive to customer’s perceptions of the quality of its products by being responsive to their concerns. To reply to the complainants should be based upon the internal technical report and contain sufficient detail as is reasonable to satisfy the complaint of the company’s concern and determination to assure the safety and efficacy of its products. In this regard, account should be taken of the particular product source of complaint (e.g. patient, pharmacist, doctor, health authority or DMRC)

Copies of all correspondence, including the investigation summary, must be retained for a period consistent with the company’s documentation retention policy. If samples either accompanied the complaint or were subsequently, they also needed to be retained for the definite period. ^[18]

Complaint analysis

A regular written summary report of the number and type of formal complaints received should be prepared for presentation to management. The data should be analyzed in such a manner as to render visible in any additional corrective action required.

Risk assesment

The Company should have effective procedures for the efficient batch recall or product withdrawal of any of its product from market. Designated senior executive, or their appointed deputies with a responsibility for the patient safety and or quality assurance, may be performed the risk assessment.

If a recall committee is appointed to perform this task may consist of the of some or all of the following as appropriate medical director, technical director, business operations director, a qualified person, person’s name on manufacturing license as responsible for production and quality control, regulatory affairs manager, distribution manger, legal affairs manager, public affairs manager and product strategy manager.

Decision to recall a batch

A decision to recall a batch or withdraw a product may be taken for any of the following reasons:

- ❖ If the quality of the product does not conform to the registered specification during its shelf life, for example the quality of the active ingredients or excipients in the product, or the degree of degradation on storage.
- ❖ If the packaging of the product is found (or can be expected) to lead to deterioration of the product within its declared shelf life.
- ❖ If the statement made on the label or leaflet is not in accordance with the requirements of the product as registered.
- ❖ As a result of the adverse reaction that may have been reported as occurring with the product.
- ❖ Any other factor which might render the unsuitable for he intended use and which may present a hazard to the user.

❖ If the product is known or expected to be counterfeit or tampered.^[18]

Procedure for recall

Recommendations for batch recall or product withdrawal procedures

The association makes the following recommendations with the following view to the establishments of practices which would ensure the efficient operation of the batch recall or product withdrawal procedure.

Company responsibilities

Responsibility for the decision to recall the batch or withdraw the product must remain with the company holding the United Kingdom product license, irrespective that how the product is distributed and by whom. For parallel imported products the PL (PI) holder is responsible for placing the product in the market and for cooperating with DMRC in the event of recall. However, the DMRC has given an undertaking that it will inform the company marketing the corresponding UK so that it may take any action necessary to protect and may consider whether that product may be affected.^[18]

Liaison with DMRC

Liaison with DMRC must be established at an early stage. The information required by DMRC in the event of batch recall or product withdrawal is set out in the form. This information is generally given over the phone. In case of patient risk immediate notification to the DMRC is essential. The DMRC has 24hrs telephone lines in operation as noted.

The DMRC will inform by facsimile the health authorities and the department of health of a drug alert.

The DMRC will also inform other EC member states via the 'rapid alert system', if appropriate. The other EC members states may similarly inform the DMRC of recalled or withdrawal product.

Written procedures

Each company should ensure that its batch recall or product withdrawal systems and procedures are set out in written form and their details made known to all who may be concerned in their operation.

Such written procedures should nominate a responsible individual, or a group of individuals (the recall committee) to deal with all incoming reports which call for consideration of a need for batch recall or product withdrawal. The procedure should include named deputies and/ or out of hours contact (e.g. security staff). The contact details of the responsible individual, the deputy and out of the hours contact should be known to the DMRC. The DMRC maintains a file of these contacts which is updated. Companies are advised to review their contact details as appropriate and notify the DMRC for any changes, since they are of critical importance to DMRC when it needs to communicate urgently.

The recall committee should appoint a "recall co-ordinator" with appropriate secretarial assistance in order to co- ordinate all the necessary actions and communications and to keep a detailed log of events and the precise time at which they occur.

The procedures should be revised at regular intervals to take account of changes in procedures and the recall committee listed therein.

The procedures should be validated at regular intervals to assess effectiveness.

Immediate action upon receipt of report suggesting a need for a batch recall or product withdrawal

Reports should be referred immediately on receipt to recall committee for risk assessment and appropriate action.

Monitoring systems

A system for monitoring the progress of the batch recall or product withdrawal must be instituted to ensure, as far as possible, that the original batch quantity must be reconciled with the amount which is either embargoed or returned from purchasers or users as a result of recall or withdrawal action.

Where there is patient risk, such arrangements are particularly essential to provide information, both for the company and for the DMRC, on the extents of risks for the patients which may remain. An initial statement should be prepared giving the amount packaged, amount distributed and the quantity remaining in the stock. ^[18]

Distribution records

Adequate distribution records are essential to the efficient operations of the measures outlined above. The records should contain sufficient information on whole sale dealers and direct customers and be readily available to the recall committee.

There may be special customer requirements to record batch documentation for large volume parenteral and vaccines.

Companies engaged in cross- border distribution are advised to ensure that an efficient batch traceability system is in place.

Post recall or withdrawal review

A final analysis of the recall or the withdrawal operations should be produced and a copy sent to the DMRC.

Conclusion

The batch recall procedure thus should identify the person or persons responsible for communicating the need for recall. The communication methods to be used as media (radio, press), direct mail shot, and electronic data interchange (EDI) etc to whom the recalled withdrawal notification should be sent. Appropriate liaison with the DMRC is advisable regarding the content of the recall notification and the communication methods to be used. Depending on the situation, consideration should be given to providing telephone back-up to supply further information.

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