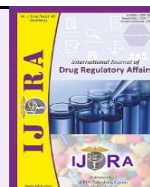


Available online on 15 Dec, 2024 at <https://ijdra.com/index.php/journal>**International Journal of Drug Regulatory Affairs**Published by Diva Enterprises Pvt. Ltd., New Delhi
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Review Article

**Recall of Drug in India and United Kingdom: A Comparative Review**

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Abstract

Recall is the action which is taken to withdraw drug from distribution. If the product is defected in terms of quality, safety, efficacy. Recall can be voluntary or statutory recall. There are different classes of recall based on severity of the recall. In India recall is guided by CDSCO where as in UK done by MHRA (medicines and healthcare products regulatory agency). There are three levels of recall which can be done at consumer, retail, wholesale. Distributors and healthcare professionals play important role in recall of drug. Generally, company initiate the recall with the help of regulatory authorities, distributors and healthcare professionals. Recall is carried out by using different steps with the help of Drug Inspector, marketing company and investigational team. In this review, we are mainly focusing on comparison of recall in regulatory authorities of India and United Kingdom, in terms of level, classes of recall and their similarities and differences.

Keywords: Recall; CDSCO; MHRA; Regulatory authorities; Quality Assurance**Article Info:** Received 03 Dec 2024; Review Completed 14 Dec 2024; Accepted 15 Dec 2024**Cite this article as:**Pangavhane PS, Shinde SP, Bhusal SB. Recall of Drug in India and United Kingdom: A Comparative Review. Int. J. Drug Reg. Affairs [Internet]. 2024 Dec15 [cited 2024 Dec 15]; 12(4):97-102. Available from: <http://ijdra.com/index.php/journal/article/view/726>**DOI:** <https://doi.org/10.22270/ijdra.v12i4.726>

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1. Introduction

Recalls include corrective measures for pharmaceuticals with reported quality, effectiveness, or safety issues as well as actions to remove the drugs from distribution or usage. Drugs that are not of standard quality, contaminated, or illicit are examples of quality-related defects. Recalls pertaining to safety and efficacy include fatalities and severe adverse reactions. Drugs that are forbidden by the Drugs & Cosmetics Act as well as products for whose product licenses have been suspended or revoked are also included in recalls. Only those signals whose importance and urgency cannot allow for a transmission delay are to be sent by the Rapid Alert System. The severity of the flaw, its potential to endanger patients or animals (in the case of a veterinary product), customers, operators, and the environment must all be evaluated.

Product recalls, complaints, and adverse reactions are covered in Paragraphs 27 and 28 of Schedule M of the Drugs & Cosmetics Act & Rules, as well as the license requirements for defective product recalls in Rule 74(j) and Rule 78(i). However, an efficient and consistent recall process with timelines at every stage of the supply chain is necessary, and auditing and accountability are currently lacking. This has been noted in cases where government analysts have declared drugs to be of substandard quality, when reports of severe side effects or fatalities have been made, when drugs are prohibited under Section 26 A, when

defects occur and the manufacturer voluntarily removes drugs from the market, etc.

2. Types of Recall**2.1 Voluntary recall**

Any event that compromises the quality, safety, or effectiveness of the batch or product in question, such as

- If a batch or batches are discovered to be noncompliant with regulatory standards during the post-marketing stability study, this can initiate a voluntary recall.
- If a market complaint inquiry reveals that the batch is flawed.
- If a failure under investigation is found to have the potential to negatively affect the quality of a batch that has already been released, such as through contamination, mix-up, degradation, etc., they should be investigated.
- If, upon investigation, any odd findings are found during the visual examination of retention samples that point to a potential influence on product quality.
- If pharmacovigilance or post-marketing monitoring data show a significant safety risk with the product.

2.2 Statutory recall:

In one or more of the following circumstances, statutory recall may be initiated in response to a directive or mandate from the Central or State Drug Regulatory Authorities:

- To recall a drug product or batch that is deemed to be illegal, such as one that is not of a standard quality, etc.
- To remember the prohibited substances.
- Materials used for promotion and/or labelling that are thought to be illegal. (1)

3. Level of recall

Consumer level: The recall classification and the extent of distribution will define the level (or depth) of recall for a product or batch. Retail, wholesale, and consumer/user are the three levels of recall. The consumer or user level, which can include any intermediate wholesale or retail level, might change depending on the product. Individual customers, patients, doctors, and hospitals can all be considered consumers or users.

Retail Level: refers to the level that comes right before the user or customer level. Retail supermarkets, pharmacies, hospital pharmacies, dispensing doctors, clinics, assisted living facilities, etc. are all included.

Wholesale Level: All distribution levels between the manufacturer and the store are referred to as wholesale levels. Every Class I recall must be carried out at the wholesale/distributors, retail, and consumer levels. In these situations, print and electronic media tools, such as newspapers, radio, and television, must be used to make public announcements. Every Class II recall must be carried out up to the wholesale and retail levels. Every Class III recall must be carried out up to the wholesale level. (2)

4. Recall procedure in India

The licensee, the licensee's representative, or the Quality Head in charge must record the information in the "Recall Log" and provide a distinct recall reference number that corresponds to the serial number for the specific year the recall was started.

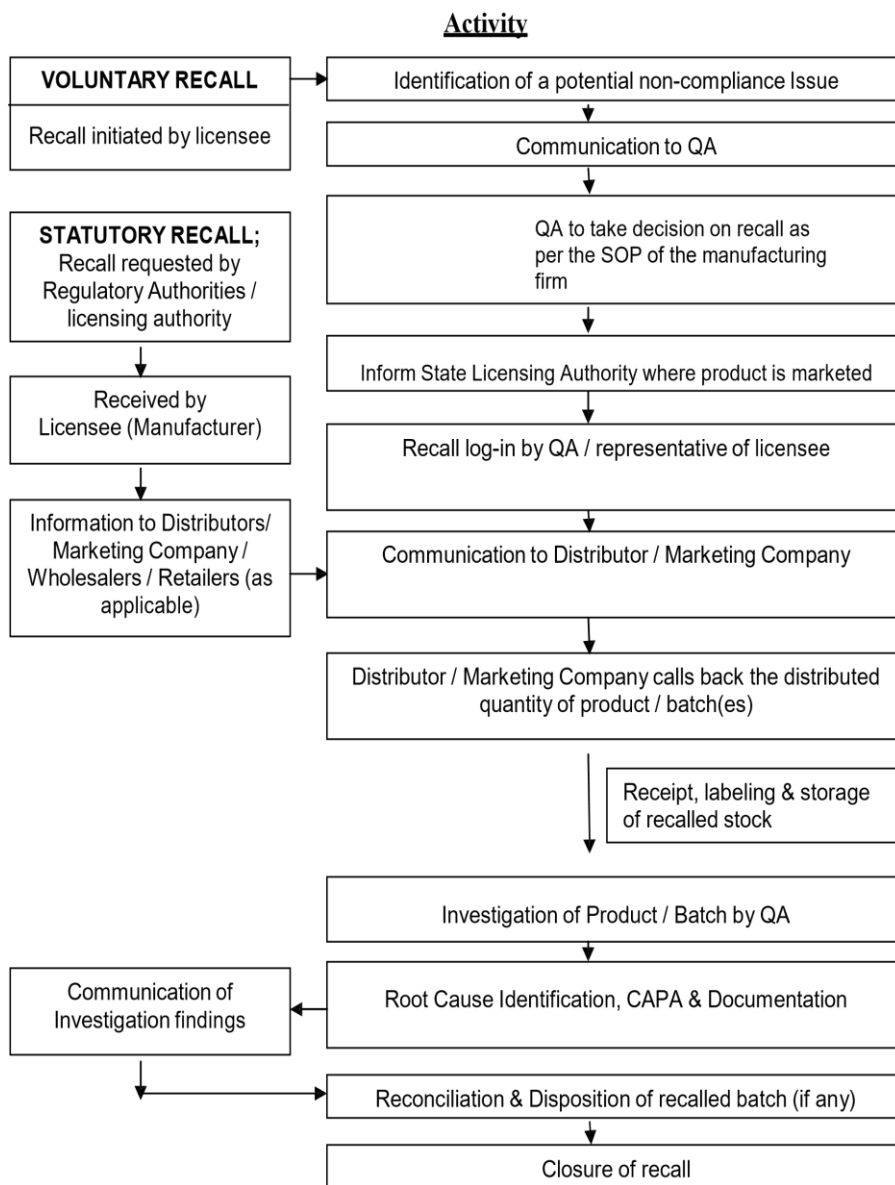


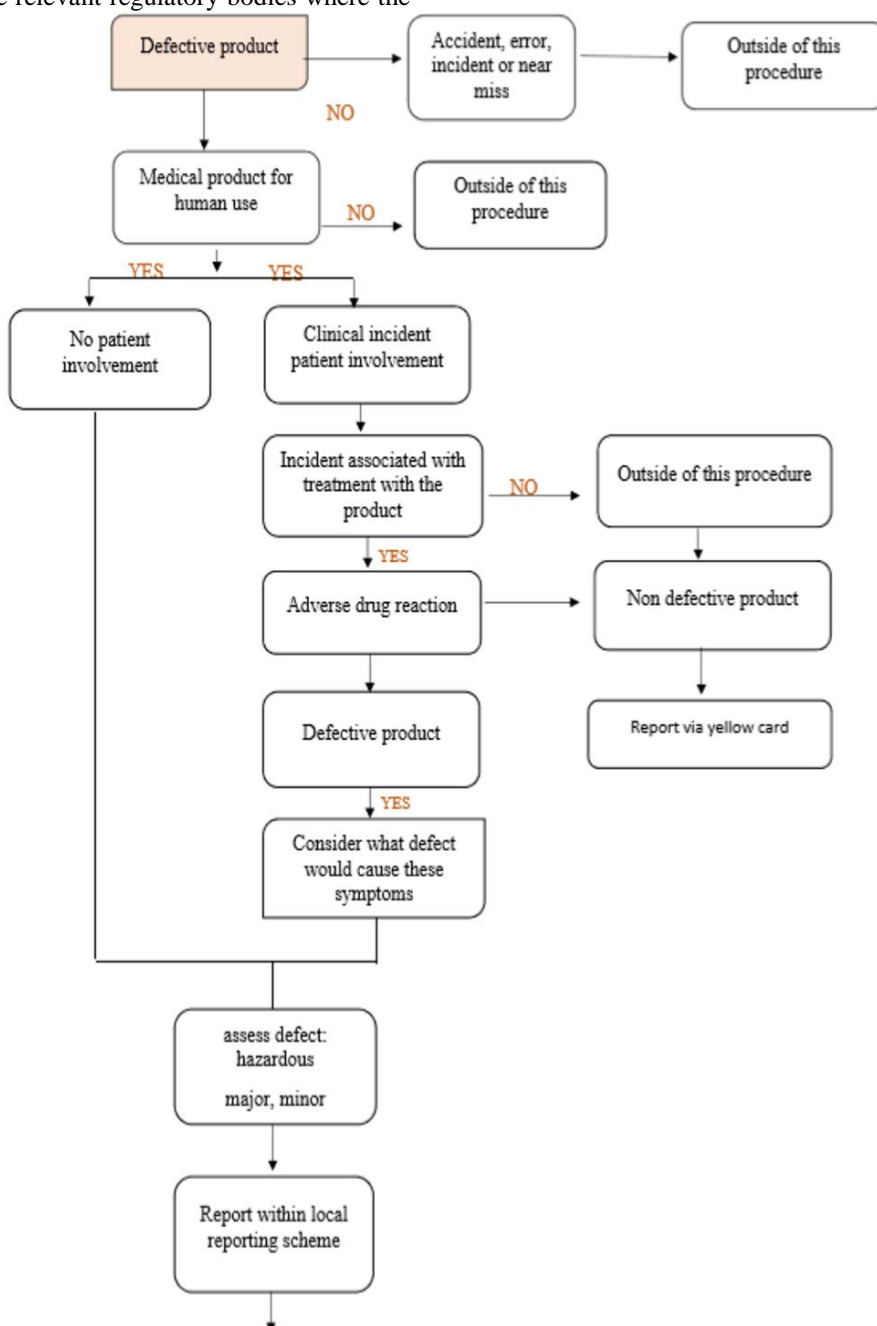
Figure 1. Recall procedure in India

Depending on how serious the defect is, the licensee, licensee representative, or quality head in charge must notify the distributor or marketing company via the quickest possible method of communication, which may include email, phone, fax, SMS, etc., to halt the distribution of the batch or batches in stock and call back the stock that is available with the distributors, retailers, etc. The licensee, their representative, or the Quality Head in charge must fill up and send the "Product/batch Recall Notice" to the distributor or marketing company. Following the identification of the product or batches that need to be recalled, the licensee, licensee representative, or QA in charge must analyse the information pertaining to the defective product or batches and make a recall decision in accordance with the approved procedure.

As soon as the recall decision is made, the licensee or licensee representative in the market where the product is sold must notify the relevant regulatory bodies where the

product batch or batches in question were distributed. Depending on the recall class, additional recall-related measures will be conducted.

In accordance with the recall classification specified in the definition, the product or batch in question must be recalled based on the risk assessment. The manufacturer and marketing firm will be in charge of notifying retailers of the recall's cause in their freeze stock notice. Distributors, marketing firms, and retailers are responsible for informing their immediate suppliers, manufacturers, and local drug inspectors about the stock situation of recalled products. The distributor or retailer is responsible for keeping track of the recall notification received, the stock at that time, the freezing process, and the returned back records. The area Drugs Inspector will then be able to verify and report on the prompt freezing and return of the merchandise. (2)



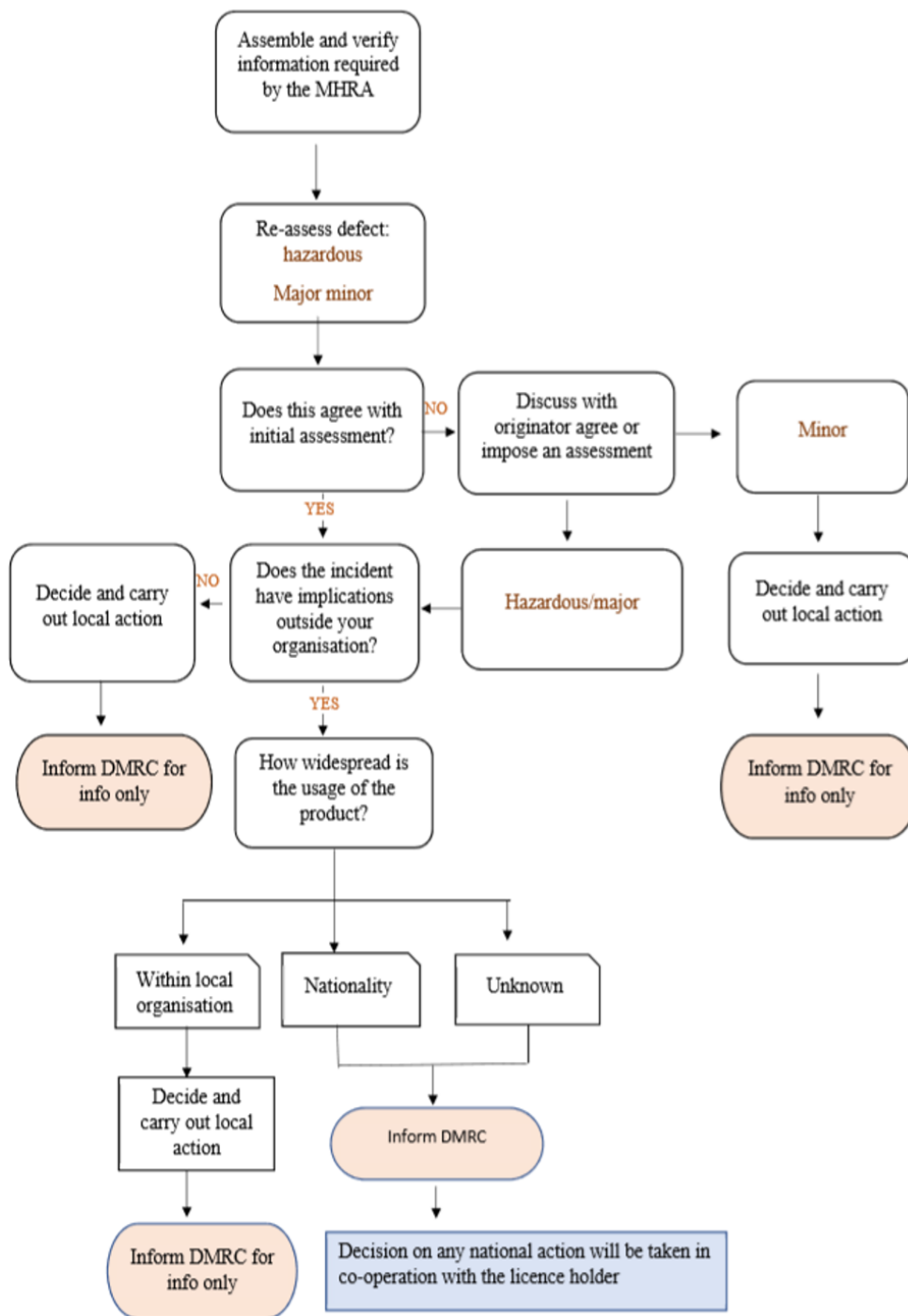


Figure 2. Recall procedure in United Kingdom

Table 1. Country Profile (3)

Parameter	United Kingdom	India
Country name	United Kingdom of Great Britain	Bharat Ganrajya
Capital	London	Delhi
Largest city	London	Delhi
Population	62.8 million	1441.72 million
Area	242,514sq.km (93,638 sq. miles)	3.3 million sq.km (1269219 sq. miles)
Major language	English	Hindi
Major religious	Christianity	Hindu
Currency	Pound sterling (1.52 American Dollar= 1 Pound)	Indian Rupee (1 American Dollar= 84 INR)
Government	Unitary parliamentary constitutional monarchy	Republic of India
Regulatory authority	Medicines and Healthcare products Regulatory Agency (MHRA)	Central Drug Standard Control Organisation

Role of health care professionals

In United Kingdom role of healthcare professional in recall is as follows:



Figure 3. Role of healthcare professionals

Role of distributors

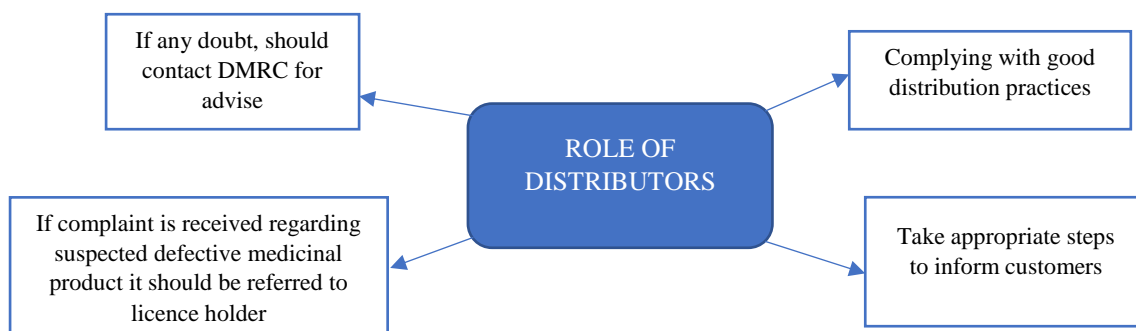


Figure 4. Role of distributors (4)

Table 2. Classes of drug recall: (5)

United Kingdom	India
4 Classes	3 Classes
Class I- Life threatening	Class I- Serious adverse health consequences
Class II- Mistreatment or harm to patient	Class II- Temporary adverse health consequences
Class III- Unlikely to cause harm to patient	Class III- Not likely to cause any adverse health consequences
Class IV- "Caution in use" called class IV drug alert	

5. Recall procedure in United Kingdom

Recalling Medicinal Products with Flaws in nearly all situations, the DMRC and the license holder communicate before deciding to recall a product or batch. As long as license holders work carefully and honestly with the MHRA, the agency's legislative authority to mandate a recall is rarely exercised. After deciding to recall a batch or batches of products, several other decisions need to be made. Following table displays the United Kingdom's recall classification according to classes I through IV. (6,7)

6. Conclusion

To protect the public's health from subpar or damaged items, the product recall includes defined written protocols and systems to record, access, investigate, and review any potential quality flaws. The regulatory authority and enforcement should be in charge of managing the medication recall. They should also be aware of the type

of recall action and classify the product according to the possible risk that the deficiency poses to patients or consumers. The product recall should be managed by the regulatory body, enforcement, and inspection. Recall should be done in according to the guidelines so that it should not harm patient health.

Acknowledgements

I would like to express my sincere gratitude to the editorial team and reviewers of International Journal of Drug Regulatory Affairs for their valuable feedback and support throughout the review and publication process. Their constructive comments have significantly enhanced the quality of article. I also thankful to my colleagues and co-authors for their support and assistance during the process.

Financial Disclosure statement:

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject

matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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