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A Comparative Analysis of Pharmaceutical Product Recall Guidelines followed by East African Regulatory Authorities

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Pharmaceutical product recalls are carried out in response to defective products or adverse events occasioned by use of a product. Recalls are necessary to safeguard the health of the consumer, hence they need to be timely and effective. The objective of this study was to compare pharmaceutical product recall procedures and requirements followed by the Pharmacy and Poisons Board (PPB) of Kenya with those followed by the National Drug Authority (NDA) of Uganda and the Tanzania Medicines and Medical Devices Authority (TMDA). This cross-sectional study reviewed and thematically analyzed guidelines for product recall accessed from the websites of the three regulatory bodies. There were similarities in three out of twelve parameters (initial communication and final progress report contents as well as depth of recall) for all three regulators. The PPB and NDA had similar guidelines for two parameters while TMDA and PPB had similar requirements for four parameters. Both the NDA and TMDA lacked specifications for six parameters. Overall, the product recall procedures followed by the PPB, TMDA and NDA were found to be divergent. Adoption of harmonized guidelines will streamline product recall procedures within the East African region which share a political and economic ecosystem.

Keywords: Drug products safety; recall procedures; Pharmacy and Poisons Board; Tanzania Medicines and Medical Devices Authority; Ugandan National Drug Authority

INTRODUCTION

Quality-assured medicines are a critical component of an effective healthcare system.[1] For this reason, the manufacture, distribution and sale of health products is regulated by governments through competent regulatory authorities.[2] Pharmaceutical manufacturers are required to adhere to current good manufacturing practices (cGMP) enforced through regular inspections.[3] Despite the best efforts to ensure that only quality pharmaceutical products enter the market, falsified and substandard medicines still account for as much as 10% of medicines in low- and middle-income countries.[4,5] One of the basic cGMP requirements is a system for recall of products known or suspected to be defective from the market.[6]

A drug recall refers to removal from the market and return to the manufacturer of a defective or harmful product.[7] Recalls of pharmaceutical products can be initiated as a result of customer complaints about product quality or adverse reactions, detection of failure of cGMP after the product has been released, stability issues observed during ongoing stability studies or inspection processes, detection of dangerous contaminants and known counterfeiting or tampering with product.[8–10] Recalls may be initiated by the manufacturer or market authorization holder (MAH), or, for purposes of safeguarding public safety, by competent medicines regulatory authorities (MRA).[8] Drug recalls can have far reaching impacts on the availability of essential medicines in addition to affecting the manufacturers income and reputation.[11,12]

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Drug regulatory authorities outline procedures to be followed by manufacturers, MAH, wholesalers, retailers and patients in the event of a product recall. The procedures prescribed vary among different regulatory bodies. In the European Union, the European Medicines Agency (EMA) coordinates recalls for centrally regulated products while relevant national regulatory authorities are responsible for locally regulated products.[11] In addition, EMA maintains a rapid alert list, including partner European states and the World Health Organization, that allows for rapid communication when serious quality defects in medicines are reported. The Canadian MRA, Health Canada, denotes the responsible party during the recall as the manufacturers, distributors and sellers of medicine.[13] Responsible parties are required to take full responsibility of product recalls including initiating the recall, determining the risk involved, classifying the recall as well as monitoring and reporting the progress and effectiveness of the recall.[13]

The United States Food and Drug Administration (US-FDA) oversees the manufacturers' recall strategies and assesses adequacy of the company's action.[14] When initiating a recall, the firm must provide the US-FDA with the product identity, reason for the recall, quantity of the batch produced and in circulation, risk assessment report, distributor details and any recall strategy as well as name and contacts of person tasked with the recall at the firm.[15] Additionally, the firm needs to submit periodic status reports with details such as number of consignees notified, number of consignees who have responded and quantity of affected products retrieved at the time of reporting.[15]

In Kenya, the Pharmacy and Poisons Board (PPB), established under the Pharmacy and Poisons Act (Chapter 244) of the laws of Kenya, is mandated to regulate the manufacture, sale and distribution of drugs, poisons and medical devices and the practice of pharmacy.[16,17] The Board oversees company-initiated product recalls usually handled by MAH but may initiate a product recall when critical defects or adverse reactions are reported.[18] The Tanzania Medicines and Medical Devices Authority (TMDA) is similarly tasked with overseeing recalls in Tanzania.[19] In Uganda, the National Drug Authority (NDA) oversees recall of medicines deemed defective in accordance with procedures detailed in the guidelines for the recall and withdrawal of medical products.[20]

The manufacturing, distribution and consumption of pharmaceuticals is not restricted to national borders.[21] This holds especially true for the three East African countries, Uganda, Tanzania and Kenya which have extensive common borders and engage in cross border trade, including that of pharmaceutical products. Consequently, any quality issues affecting pharmaceutical products in one country have a high probability of being detected in the neighboring countries. Thus, it would be beneficial to evaluate product recall procedures among the three countries and identify any gaps and differences. The aim of this study was to compare pharmaceutical product recall procedures and requirements followed by the PPB with those followed by the NDA and the TMDA.

METHODS

The study was cross-sectional and compared pharmaceutical product recalls protocols and standards adopted by the PPB, NDA and TMDA. Guidelines for product recalls available on the three publicly accessible websites were studied.[19,20,22] Twelve parameters were assessed namely, recall classification, communication content, progress report timelines, final progress report content, health risk assessment, termination of recall, timeline for initial notification of the regulator, mode of communication, depth of recall, method of recall, duration of recall and public warnings. The data extracted from the websites was compared for similarities, differences, and gaps.

RESULTS AND DISCUSSION

The recall procedures adopted by the PBB, NDA and TMDA are compared in Tables 1 and 2. The PPB and TMDA adopt a similar classification of product recalls, namely class I, II and III recalls. Class I recalls involve products with critical defects that could cause life-threatening effects or

serious injury. On the other hand, class II recalls involve products with major defects that pose serious health risks while class III recalls involve products that pose minor health risks. The NDA, however, classifies recalls as class A, B and C with class A recalls involving products with critical defects while class C involves products with minor defects and minor health risks. This difference in recall designation may indicate different methods of determining the gravity of the product defects between the NDA and the other two regulatory authorities. Interestingly, the TMDA uses the ABC designation for levels of recalls. The classification of drug recalls into class I, II and III is widely adopted, being used by USA, European Union and Japanese regulatory authorities.[15,23,24] This classification was instituted by FDA, EMA and Japanese regulatory authorities in the sixties following the thalidomide tragedy. The classification was adopted by several national pharmaceutical regulatory authorities.

Clear and timely communication are very important when managing an effective recall.[12] Upon detection of defect, PPB requires initial communication to include description of defect, brand name, international non-proprietary name (INN), Active Pharmaceutical Ingredient (API), product strength, dosage form, description of the package, batch number, manufacturing and expiry date, finished product manufacturer's name and address, name and address of the MAH and contact details, total quantity in circulation, list of customers and areas of distribution of the product. The TMDA requirements are virtually similar to those of the PPB but with an additional requirement to state reasons for recall as well as date and circumstance of discovery of defect. The NDA on its part has fewer requirements namely, product characteristics, nature of defect and reason for recall. Unlike the PPB and TMDA, the NDA requires an indication of health risk and clear instructions on what to do with the recalled product.

The PPB and TMDA guidelines require submission of progress reports while the NDA only requires a final report after 30 days. The PPB requires submission of an initial report at 1 week, a follow-up report after 2 weeks and a final report at the end of 4 weeks, while the TMDA requires specifies weekly progress reports. Contents of the final reports are similar for PPB and TMDA capturing product particulars, quantity distributed, root cause analysis, corrective and preventive action as key components. Furthermore, the PPB requires a detailed timeline of corrective action and steps for disposal. The NDA prescribed final report should include product particulars, details of the defect, actions taken, copies of recall correspondence and steps taken to prevent recurrence of the problem. It is imperative that NDA makes submission of progress reports mandatory for drug recalls to ensure effectiveness of the process. This will align with regulatory requirements of stringent bodies such as the US-FDA which requires a report to be made not more than 15 days after the recall on the progress of the steps taken.[15]

Both the PPB and NDA require a health risk assessment by the MAH/manufacturer. Considerations for health risk assessment for both regulatory bodies are diseases/injuries that have occurred due to product use, health risk to particular population segments, degree of seriousness of health hazard to the population at greatest risk, likelihood of risk occurring and immediate and long-term consequences. The PPB also requires listing of available alternative products as part of the health risk assessment. Termination of the recall by PPB and NDA occurs after all stocks have been removed from circulation, reconciliation has been carried out and appropriate corrective and preventive actions have been instituted. TMDA recall guidelines do not specify the procedure and requirements for termination of recall. The PPB and NDA termination requirements are similar to those of the Health Canada and US-FDA which mandate the termination of a recall when the regulator and the recalling entities are in concurrence that the recalled product has been removed and safely disposed or corrected.[13,15]

Only the PPB specifies timelines for initial notification upon detection of a potential defect as 24 hours (initiation of recall), 72 hours and 5 days, respectively, for class I, II and III recalls. The initiation timeline is similar to that adopted by the Rwanda Food and Drug Authority for class

I and II recalls but differs for class III recalls where the latter specifies 72 hours.[18] Timely action dependent on the class of recall is important to safeguard patient health.[25] It is thus imperative for regulators to specify timelines for handling different classes of recalls.

The depth of recall, which refers to how far affected products are drawn out of trade, was similar for all the three regulators. For PPB and NDA, the depth of recall for class I/class A was consumer/user level, class II/ class B was retail level, while class III/class C was wholesale/distributor level. On the other hand, TMDA class I recalls extended to consumer/user level but included health facilities, class II to drug outlets and health facilities while class III to retail and wholesale level. The TMDA uses levels A, B and C to describe recall depths for the respective recall classes.

There were minor differences in the mode of communication regulators required manufacturers/MAH to use to reach stakeholders. The PPB requires class I recalls to be communicated via phone, email, radio and TV followed by letter while class II and III recalls are to be communicated via letters, emails and phone. TMDA specifies that class I recalls be communicated via media release and letters to facilities and individuals, class II recalls via letters to private and public drug outlets and wholesale and retailers while class III recalls via both telephone calls and letters. The NDA requires all recalls regardless of class to be communicated via telephone, fax, email, telegram and public media as well as letters marked as URGENT and MEDICINAL RECALL in bold red.

The procedures adopted by the three regulatory authorities are similar to those of the European Union which requires the timely relay of drug recalls (24 hours for class I and II recalls) through a rapid alert system.[23] Similarly, the US-FDA and Health Canada recall processes stipulate open communications to all stakeholders including formal letters to all parties.[13,15] Wang *et al.* recommended the need to ensure class I recalls are communicated in using a dedicated system that is not also handling less critical information.[26] With regard to method of recall, the PPB specifies direct uplift of stocks for class I recalls and wholesaler collection for class II and III recalls, whilst the TMDA and NDA do not specify the method of recall. While the PPB and TMDA limits the duration of class I recalls to 14 days, class II recalls to 21 days and class III to 28 and 30 days, respectively, although the NDA has no specification. The PPB requires public warning in form of rapid alerts for class I recalls and none for class II and III recalls. Press releases are required by the NDA for class A and B recalls. The TMDA does not specify need for public warnings for any of the three classes of recalls.

Overall, for all the twelve parameters assessed, there was no harmonized approach to the handling of recalls by the three regulatory authorities. A degree of similarity was seen for initial communication and final progress report contents as well as depth of recall for the different classes. For several parameters, there were similarities between two authorities only. The PPB and NDA had similar requirements for health risk assessment and termination of recall. The PPB and TMDA requirements for classification of recalls, submission of initial report, mode of communication and duration of recalls were closely related. Obvious gaps were seen where the NDA and TMDA guidelines failed to specify progress report timelines, health risk assessment, termination of recall, timelines for initial notification of regulator, method of recall and duration of recall. Even slight deviations in procedure such as classification of recalls using Roman numerals or letters can result in misunderstanding or confusion. Considering the shared social and economic ecosystem of the three East African Countries, it would be advantageous to establish a harmonized system for handling recalls.

Table 1: Comparison of PPB, TMDA and NDA recall procedures and requirements

Parameter	PPB	TMDA	NDA
Recall classification	**Class I, II and III**	**Class I, II and III**	**Class A, B and C**
Content of initial communication	Description of quality **defect** **Product details** (Brand name, INN name, API, Product strength, Dosage form, Description of package, batch number, manufacturing date, expiry date) Finished product **manufacturers** name and address Name and address of MAH and contact details Total **quantity** of medical product in circulation List of **customers** **Area** of distribution of product	Nature of **defectiveness**/possible defectiveness, Date and circumstances of discovery of defect, Reasons for recall **Product details** (Proprietary name/generic name, Dosage form, Strength, Batch number, Pack size, Manufacturing date and expiry date) Name and address of **manufacturer** Total **quantity** of product to be recalled/has been distributed List of **customers** to whom the product was distributed **Area** of distribution of the product	Nature of **defect** Urgency of recall Reason for recall Product details (Name of product, Strength, Pack size) Indication of health risk Specific clear instructions on what to do with the product recalled
Progress report timelines			
Initial report	One week	Weekly	Not specified
Follow-up report	Two weeks	Weekly	Not specified
Final report	Four weeks	Not specified	30 days
Final report content	Mechanism of recall notification and communication Extent of recall Distributed quantity of affected batches Root cause analysis/investigative report Corrective and preventive action Timelines for corrective action Steps for disposal of recalled product	Reconciliation between distributed and recovered quantities Investigative report on causes Corrective and Preventive actions taken	Nature of defect Action taken Urgency of action taken Reason for action taken Indication for degree of health risk and reported health problems Copies of recall correspondence Steps taken to prevent recurrence of problem

Considerations for assessment of health risk	Diseases/injuries that have occurred due to product use Health risk to particular population segments Degree of seriousness of health hazard to which population at greatest risk is exposed Likelihood of occurrence of risk Immediate and long-term consequences Available alternative products	Not specified	If disease/injury has already occurred Risk to various population groups Seriousness of risk to the population at risk Likelihood of risk occurring Immediate/long-term consequences of exposure to the risk
Considerations for termination of recall	Reconciliation report for all stocks under recall Detailed investigative report leading to recall Corrective action preventive action plan and report Destruction certificate issued by PPB	Not specified	All stocks removed from circulation Appropriate corrective measures instituted

NDA = National Drug Authority (Uganda); PPB= Pharmacy and Poisons Board (Kenya); TMDA = Tanzania Medicines and Medical Devices Authority.

Table 2: Comparison of PPB, TMDA and NDA class-specific recall procedures and requirements

Parameter	PPB	TMDA	NDA
Timelines for initial notification to regulator			
Class I/A*	24 hours	Not specified	Not specified
Class II/B	72 hours	Not specified	Not specified
Class III/C	5 days	Not specified	Not specified
Depth of recall			
Class I/A*	Consumer level	Health facilities, individual suppliers, customers	Consumer level
Class II/B	Retail level	Public and private drug outlets, health facilities	Retail level
Class III/C	Wholesale level	Wholesale, retail level	Wholesale/distributor level

Mode of communication			
Class I/A	Phone, email, radio, TV, Press announcement, followed by letter	Media release, letters	Telephone, Fax, Email, Telegram, Public media, Letters marked URGENT and MEDICINAL RECALL in bold red
Class II/B	Letter, email, phone	Letter	Telephone, Fax, Email, Telegram, Public media, Letters marked URGENT and MEDICINAL RECALL in bold red
Class III/C	Letter, email, phone	Letter, phone	Telephone, Fax, Email, Telegram, Public media, Letters marked MEDICINAL RECALL in bold red
Method of recall			
Class I/A	Direct uplift of stocks	Not specified	Not specified
Class II/B	Via wholesaler	Not specified	Not specified
Class III/C	Via wholesaler	Not specified	Not specified
Duration of recall			
Class I/A	14 days	14 days	Not specified
Class II/B	21 days	21 days	Not specified
Class III/C	28 days	30 days	Not specified
Public warning			
Class I/A	Rapid alerts	Not specified	Press release
Class II/B	None	Not specified	Press release
Class III/C	None	Not specified	Not specified

PPB= Pharmacy and Poisons Board (Kenya); TMDA = Tanzania Medicines and Medical Devices Authority; NDA = National Drug Authority (Uganda).

CONCLUSION

The three East African regulatory authorities have fundamentally dissimilar guidelines for handling drug recalls. Only three out of twelve parameters had a level of similarity. In view of the social, political and economic interdependence of the three countries, harmonization of recall guidelines will strengthen regional integration and enhance public safety with regard to access to quality pharmaceutical products.

REFERENCES

(1) Ozawa, S.; Higgins, C. R.; Yemeke, T. T.; Nwokike, J. I.; Evans, L.; Hajjou, M.; Pribluda, V. S. Importance of Medicine Quality in Achieving Universal Health Coverage. *PLoS One* **2020**, *15* (7), e0232966. https://doi.org/10.1371/journal.pone.0232966.

(2) Rägo, L.; Sillo, H.; Hoen, E. ‘t; Zweygarth, M. Regulatory Framework for Access to Safe, Effective Quality Medicines. *Antivir. Ther.* **2014**, *19* (3_suppl), 69–77. https://doi.org/10.3851/IMP2902.

(3) Abdullayev, R.; Valiyeva, M.; Nasibova, T. INTERNATIONAL PRACTICES ON GMP IN PHARMACEUTICALS. *Nat. Sci.* **2024**, *6* (4), 5–8. https://doi.org/10.36719/2707-1146/43/5-8.

(4) Nayyar, G. M. L.; Breman, J. G.; Mackey, T. K.; Clark, J. P.; Hajjou, M.; Littrell, M.; Herrington, J. E. Falsified and Substandard Drugs: Stopping the Pandemic. *Am. J. Trop. Med. Hyg.* **2019**, *100* (5), 1058–1065. https://doi.org/10.4269/ajtmh.18-0981.

(5) Johnston, A.; Holt, D. W. Substandard Drugs: A Potential Crisis for Public Health. *Br. J. Clin. Pharmacol.* **2014**, *78* (2), 218–243. https://doi.org/10.1111/bcp.12298.

(6) Gouveia, B.; Rijo, P.; Gonçalo, T.; Reis, C. Good Manufacturing Practices for Medicinal Products for Human Use. *J. Pharm. Bioallied Sci.* **2015**, *7* (2), 87. https://doi.org/10.4103/0975-7406.154424.

(7) Sadhna, D.; Nagaich, U. Drug Recall: An Incubus for Pharmaceutical Companies and Most Serious Drug Recall of History. *Int. J. Pharm. Investig.* **2015**, *5* (1), 13. https://doi.org/10.4103/2230-973X.147222.

(8) Cheah, E. T.; Chan, W. L.; Chieng, C. L. L. The Corporate Social Responsibility of Pharmaceutical Product Recalls: An Empirical Examination of U.S. and U.K. Markets. *J. Bus. Ethics* **2007**, *76* (4), 427–449. https://doi.org/10.1007/s10551-006-9292-1.

(9) Farrukh, M. J.; Tariq, M. H.; Malik, O.; Khan, T. M. Valsartan Recall: Global Regulatory Overview and Future Challenges. *Ther. Adv. Drug Saf.* **2019**, *10*, 204209861882345. https://doi.org/10.1177/2042098618823458.

(10) Świeczkowski, D.; Zdanowski, S.; Merks, P.; Szarpak, Ł.; Vaillancourt, R.; Jaguszewski, M. J. The Plague of Unexpected Drug Recalls and the Pandemic of Falsified Medications in Cardiovascular Medicine as a Threat to Patient Safety and Global Public Health: A Brief Review. *Cardiol. J.* **2022**, *29* (1), 133–139. https://doi.org/10.5603/CJ.a2020.0168.

(11) Annema, P. A.; Derijks, H. J.; Bouvy, M. L.; van Marum, R. J. Impact of Drug Recalls on Patients in The Netherlands: A <scp>5-Year</Scp> Retrospective Data Analysis. *Clin. Pharmacol. Ther.* **2024**, *115* (6), 1365–1371. https://doi.org/10.1002/cpt.3220.

(12) Ghijs, S.; Wynendaele, E.; De Spiegeleer, B. The Continuing Challenge of Drug Recalls: Insights from a Ten-Year FDA Data Analysis. *J. Pharm. Biomed. Anal.* **2024**, *249*, 116349. https://doi.org/10.1016/j.jpba.2024.116349.

(13) Health Canada. *Recall policy for health products*. https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-

enforcement/information-health-product/drugs/recall-policy-0016/policy.html (accessed 2024-08-20).

(14) Food and Drug Administration. *FDA's Role in Drug Recalls*. FDA's Role in Drug Recalls. https://www.fda.gov/drugs/drug-recalls/fdas-role-drug-recalls (accessed 2024-08-29).

(15) Food and Drug Administration. *Product Recalls, Including Removals and Corrections*. Product Recalls, Including Removals and Corrections Guidance for Industry. https://www.fda.gov/media/136987/download.

(16) Moscou, K.; Kohler, J. C. Matching Safety to Access: Global Actors and Pharmacogovernance in Kenya- a Case Study. *Global. Health* **2017**, *13* (1), 20. https://doi.org/10.1186/s12992-017-0232-x.

(17) Abuga, K.; Ongarora, D.; Karumbi, J.; Olulo, M.; Minnaard, W.; Kibwage, I. Sub-Standard Pharmaceutical Services in Private Healthcare Facilities Serving Low-Income Settlements in Nairobi County, Kenya. *Pharm. (Basel, Switzerland)* **2019**, *7* (4). https://doi.org/10.3390/pharmacy7040167.

(18) Bahizi, M.; Nyirimigabo, E.; Ntirenganya, L.; Umuhoza, M. I.; Habyalimana, V.; Bikorimana, G.; Ukwishaka, J. A Four-Year Assessment of the Characteristics of Rwandan FDA Drug Recalls. *BMC Public Health* **2024**, *24* (1), 1784. https://doi.org/10.1186/s12889-024-19245-8.

(19) TMDA. *Guidelines for recall, handling and disposal of unfit medicinal products*. https://www.tmda.go.tz/uploads/publications/en1626772826-en1623839245-GUIDELINE FOR RECALL,HANDLING-final most (1).pdf (accessed 2024-09-03).

(20) National Drug Authority. *Guidelines for the Recall or Withdrawal of a Medical Product*. https://www.nda.or.ug/Wp-Content/Uploads/2022/02/INS-GDL-37-Guideline-For-Recall-of-a-Medical-Product.pdf (accessed 2024-09-03).

(21) Ravinetto, R.; Vandenbergh, D.; Macé, C.; Pouget, C.; Renchon, B.; Rigal, J.; Schiavetti, B.; Caudron, J.-M. Fighting Poor-Quality Medicines in Low- and Middle-Income Countries: The Importance of Advocacy and Pedagogy. *J. Pharm. Policy Pract.* **2016**, *9* (1), 36. https://doi.org/10.1186/s40545-016-0088-0.

(22) Pharmacy and Poisons Board. *Guidelines for Recall and Withdrawal of Medical Products and Health Technologies*. https://web.pharmacyboardkenya.org/download/guidelines-for-recall-and-withdrawal-of-medical-products-and-health-technologies/ (accessed 2024-11-13).

(23) European Medicines Agency. *No Title*. Quality defects and recalls. https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/compliance-post-authorisation/quality-defects-recalls (accessed 2024-09-04).

(24) Jabeen, S.; Sridhar, S.; Balamuralidhara, V. Drug Recall Procedure in ASEAN Countries. *Res. J. Pharm. Technol.* **2019**, *12* (12), 6041. https://doi.org/10.5958/0974-360X.2019.01049.7.

(25) Jayaraman, R.; AlHammadi, F.; Simsekler, M. C. E. Managing Product Recalls in Healthcare Supply Chain. In *2018 IEEE International Conference on Industrial Engineering and Engineering Management (IEEM)*; IEEE, 2018; pp 293–297. https://doi.org/10.1109/IEEM.2018.8607403.

(26) Wang, B.; Gagne, J. J.; Choudhry, N. K. The Epidemiology of Drug Recalls in the United States. *Arch. Intern. Med.* **2012**, *172* (14). https://doi.org/10.1001/archinternmed.2012.2013.