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STRATEGIES FOR EFFECTIVE MANAGEMENT OF CROSS-BORDER PRODUCT RECALLS

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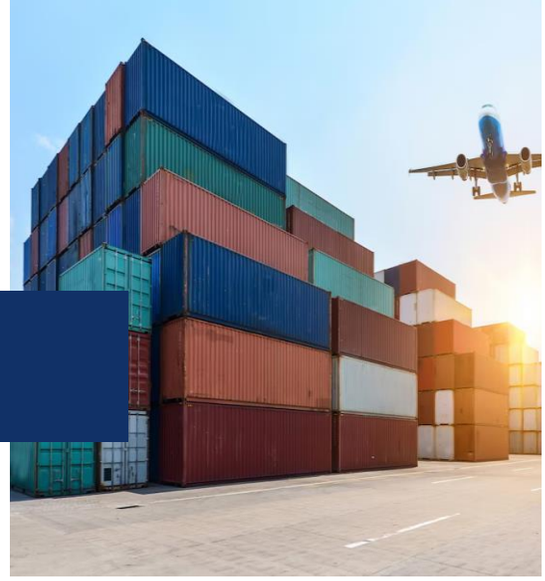

INTRODUCTION

With the ease of moving goods from one country to several other countries through global supply chains comes an increase in the risks for producers and distributors. In addition to the usual financial, operational, and political risks, there has been an increase in product liability claims arising from defects in such distributed products. Given the likelihood of product defects and liability claims, producers and global distributors have developed product recall plans that ensure that products are recalled as soon as defects are discovered. However, these recalls are often limited to the jurisdiction where the defect was found.

In Nigeria, for example, between 2023 and the first half of 2024, the National Agency for Food and Drug Administration and Control (NAFDAC) compulsorily recalled over thirty (30) products from the Nigerian market, with the most popular recall being a cough syrup of a major international pharmaceutical company by Public Alert No.13/2024. In most instances, products recalled in other countries including the United States of America, the United Kingdom, China, and other countries are recalled in Nigeria by NAFDAC.

In recent times, there has been an increase in product recalls in Nigeria. Compared to the total number of recalls in 2022, about 15 products, there has been over 100% increase in recalls in Nigeria. If this trajectory remains, NAFDAC recalls could reach as many as five hundred recalls a year within five years.

Product recalls cost financial and reputational damages to producers whose products are the subject of the recall. International companies may lose millions of dollars from defending lawsuits, settlements, and the loss of sales. While these losses may impair a producer in the short run; reputational damages from improperly managed product recalls may result in the complete collapse of the business.

Given the above, this article addresses the intricacies of product recall in Nigeria and the need for a comprehensive cross-border recall plan that seamlessly withdraws defective products from all countries, limiting the exposure of international companies to damages resulting from an ineffective product recall. It will also examine the legal framework for product recall, the roles and obligations of diverse stakeholders, and optimal strategies for effective recall management for products distributed globally.

BACKGROUND

On 10th April, 2024, the NAFDAC issued a public notification regarding the recall of a major cough syrup in Nigeria.[1] The recall was prompted by the discovery of an unacceptably high amount of diethylene glycol, a compound that has been linked to fatal outcomes in various countries since 2022, in the syrup. The presence of this toxic substance raised significant concerns among health officials worldwide due to tragic incidents of medication poisoning resulting from oral ingestion.

Diethylene glycol has been known to cause acute oral toxicity in laboratory animals and poses a serious health risk to humans when consumed.[2] The potential toxic effects on humans include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state, and acute kidney injury, which may lead to death.[3]

Following this discovery, NAFDAC mandated the Company to take immediate action and initiate a recall of the affected batch. NAFDAC also sent a Notice to the World Health Organization Global Surveillance and Monitoring System (GSMS) for further awareness and action. NAFDAC's recall of the product from the Nigerian market led to the recall of the drug by several other countries including South Africa, Kenya, Tanzania, Rwanda, and Zimbabwe.

[1] (2024, April 10). Public Alert No. 013/2024 NAFDAC/GOV.NG/PUBLIC-ALERT. Retrieved June 14, 2024, from https://nafdac.gov.ng/public-alert-no-013-2024-alert-on-recall-of-benylin-paediatrics-syrup-in-nigeria/.
[2] (2017, July 30). Human health assessment for long-term oral ingestion of diethylene glycol Public Alert No. 013/2024 PubMed. Retrieved May 14, 2024, from https://pubmed.ncbi.nlm.nih.gov/28465071/
[3] Ibid.

PRODUCT RECALL IN NIGERIA

Given the nature of product recalls and a product recalled in other countries, like the US, can lead to a consequential recall in Nigeria, it is imperative to understand and comply with product recalls in Nigeria. The execution of an effective product recall in Nigeria, however, entails complexity and necessitates a comprehensive understanding of the legal framework. Under Nigerian jurisprudence, several legislations and regulators regulate product recalls.

National Agency for Food and Drug Administration and Control Act, CAP N.1, Laws of the Federation of Nigeria 2004[4]

The Act establishes NAFDAC as the primary regulatory Agency for food, drugs, and related products. It further empowers the Agency to monitor product safety, investigate complaints, order recalls, impose penalties for non-compliance, require manufacturers, importers, and distributors to register their products with NAFDAC, and comply with safety and quality standards.

Section 30 of the NAFDAC Act, vests the Agency with powers to make regulations to carry out or give full effect to the provisions of this Act. In exercising its powers under the NAFDAC Act, the NAFDAC issued several guidelines and regulations covering product recalls in Nigeria. Such guidelines/regulations include the NAFDAC Good Manufacturing Practice Guidelines for Pharmaceutical Products (the "GMP Pharmaceutical Products Guidelines"), and the NAFDAC Guidelines for Inspection & Requirements for Pre-Packaged Food Manufacturing/Packaging Facilities in Nigeria (the "Food Manufacturing Guidelines").

NAFDAC Guideline on Recall and Alert Procedure

The NAFDAC Guideline on Recall and Alert Procedure provide that the Pharmacovigilance and Post Market Surveillance (PV/PMS) Directorate is responsible for receiving, reviewing, and promptly alerting the public about safety concerns and measures related to a product in the market.[5] Notifications may be disseminated to the Nigerian public through an Alert Notice and/or a Dear Healthcare Provider Letter (DHPL).

Upon reviewing the safety information received, timely alert notices and safety communication (Dear Healthcare Provider Letter) will be provided to the public and healthcare providers respectively. These alert notices and safety communications will contain safety measures and information that may impact treatment and diagnostic choices for healthcare providers and patients.

The Federal Competition and Consumer Protection Act (FCCPA) 2018

The Federal Competition and Consumer Protection Act (FCCPA) 2018 is the primary legislation governing consumer protection and responsible producer practices in Nigeria. Sections 130 and 131 of the FCCPA enshrine the consumer's right to products of assured safety and quality, encompassing usability, durability, compliance with specified standards, and freedom from defects.

Specifically, for product recalls, Section 135 of the FCCPA mandates manufacturers and distributors to promptly notify the public of any unforeseen hazards arising from the use of products introduced into the market and to take decisive measures to remove such items from circulation.

[4] Cap N.1 LFN 2004.
[5] NAFDAC (2024, February 15). Pharmacovigilance and Post Market Surveillance (PV/PMS). Nafdac.gov.ng. Retrieved July 14, 2024, from https://nafdac.gov.ng/about-nafdac/nafdac-organisation/directorates/pharmacovigilance-and-post-market-surveillance/

In cases where a company fails to recall its defective goods, the Act sanctions such failure by imposing a fine not exceeding 10% of its turnover in the preceding business year for companies. It is important to note that the turnover referred to is the turnover of the global company, and not its subsidiary if it has a subsidiary in Nigeria.

Likewise, any affected person retains the right to pursue legal recourse for consequential damages, with the company assuming full liability for compensatory obligations.

Standards Organization of Nigeria (SON) Act, 2015

The Standards Organization of Nigeria (SON) is the primary authority responsible for setting and implementing product standards in Nigeria. The SON Act, 2015 grants SON the authority to create and enforce standards for various products, as well as to certify products that meet these standards. Additionally, SON is empowered to investigate instances of non-compliance with the established standards.

Furthermore, the Act mandates that manufacturers, importers, and distributors adhere to SON standards, obtain SON certification for their products, and accurately label their products. These regulations are designed to ensure that products in Nigeria meet the necessary safety and quality standards. They also aim to hold manufacturers, importers, and distributors accountable for any breaches of these standards.

STRATEGIES FOR THE EFFECTIVE MANAGEMENT OF PRODUCT RECALLS IN NIGERIA

Product recalls have been utilised by various manufacturers when products in circulation have been discovered to have an inherent defect that negatively affects the consumers' health or the satisfactory use of the product; however, as noted earlier, these recalls are often limited to the territorial jurisdiction where the defect is discovered. International companies often overlook the need to recall products globally, particularly, the failure to recall products is often neglected in developing countries.

Regardless of the nature of the product recall, a product recall may result in severe damage to the reputation and credibility of a company if ineffectively managed. A comprehensive recall plan must extend to not only the territory within which the defect is discovered must extend to all countries where the products are shipped and used, as a failure to comprehensively recall all defective products may result in unexpected financial losses to a company.

A company that intends to maintain a good relationship with its global customers and the regulatory agencies across countries where its products are shipped and used, must have a strategy for the effective management of product recalls. Some of the strategies for effective management of cross-border product recalls are:

1. Proactive risk management: International companies must employ the services of professional product managers and lawyers to help them implement rigorous risk management systems aimed at identifying and mitigating potential hazards proactively, thereby limiting potential product recalls. A comprehensive recall plan for a company should address the specific requirements for the three distinct phases of a recall process: identifying the problem, executing the recall, and managing the aftermath and follow-up actions. [6]

2. Effective communication: An international company must be active in responding to either a regulatory agency's direction for the company to recall its product or a consumer's complaint about a defect in the product across all countries where its products are shipped and sold. A prompt response demonstrates that the company is empathetic to its consumers' plight regardless of their location and places the safety of its consumers over its reputation and profit margin.[7]

3. Compliance with the Regulatory Agencies: During a product recall, it is important to comply with the directions of the regulatory agencies. To this end, international companies should engage lawyers in all countries where their products are used. These lawyers can ensure compliance with both regulatory requirements and can provide prompt responses once a regulatory agency mandates a recall. Engaging in early communication and compliance with product specifications may limit the damage to the company's reputation. Having an open and constant engagement with the regulatory agencies demonstrates the company's transparency. Where a company has been complying with the legislations and regulations for product safety, it is easier for a regulatory agency to work with the company during the recall process.

4. Prioritize consumer safety: To maintain a strong and reputable business, international companies must take a proactive approach to identifying and addressing potential issues across the board before they escalate into major problems. The primary focus should always be on prioritizing the safety of all consumers and their well-being above all other concerns. This involves conducting regular risk assessments, implementing stringent quality control measures, and quickly responding to any consumer complaints or concerns. By placing consumer safety at the forefront of their operations, companies can ensure that they are providing products and services that meet the highest standards of safety and quality.

[6] Harvard Business Review (n.d.). A Strategic Approach to Managing Product Recalls. HBR.ORG. Retrieved July 14, 2024, from https://hbr.org/1996/09/a-strategic-approach-to-managing-product-recalls.
[7] Harvard Business Review (2024, June 4). Communication strategies in product recalls. FASTERCAPITAL. Retrieved June 14, 2024, from https://fastercapital.com/content/Communication-strategies-in-product-recalls.html

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5. Collaboration and Coordination: To successfully handle product recalls, it is essential to establish and nurture collaboration and cohesive actions among all relevant stakeholders. [8] This includes close coordination between regulatory bodies, manufacturers, distributors, and retailers. Such collaboration ensures that all parties involved are working together seamlessly to manage the recall process efficiently and effectively.

[6] GS1INDIA (2010, May 10). Communication strategies in product recalls. GS1INDIA.ORG. Retrieved July 14, 2024, from https://www.gs1india.org/media/joint-industry-recall-execution-effectiveness-report.pdf

CONCLUSION

As much as international companies that produce and ship their goods across several countries may try to ensure that their products are safe for their consumers and not defective, it is always safer to have a comprehensive recall plan that anticipates the chances of a defect and recall in countries that may not be within their immediate purview. A comprehensive product recall plan, therefore, involves employing lawyers and agents in all countries where the company's products are shipped and used to ensure compliance with local regulations and proactively prevent or limit the damage to the company's reputation as a result of a mandatory product recall.

Also, international companies should establish an extensive framework for cross-border product recall to prevent situations where products recalled in one country are left in another country and result in lawsuits and reputational damage to the company's business.

A comprehensive cross-border product recall plan is an integral part of a strategy to effectively handle product recalls whether voluntary or involuntary. A company with a comprehensive plan is ready to weather the storm and come out unscathed. Product recall plans should start at the point of product development and work through to the end of the recall.

Likewise, the implementation of product recalls plays a crucial role in guaranteeing consumer safety and upholding trust in the market. By comprehending the legal frameworks, roles, responsibilities, and optimal strategies for efficient recall management, corporations and regulatory bodies can collaborate to safeguard public health and mitigate the ramifications of product recalls. With the ongoing evolution of the global supply chain, the significance of proactive risk management, effective communication, and prompt actions is set to further increase.

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Stren & Blan Partners is a full-service commercial Law Firm that provides legal services to diverse local and multinational corporations. We have developed a clear vision for anticipating our client's business needs and surpassing their expectations, and we do this with an uncompromising commitment to Client service and legal excellence.

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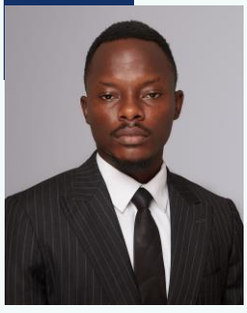

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