REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Frequently asked questions on recalls

1. What does the board mean by the word, "Recall"?

*Recall is the removal of **specific batch(es)** of a medical product and health technologies from the market because they have been found not to meet marketing authorization requirements.*

2. What does it mean when a product is said not to meet the prescribed market authorization requirements?

This means that the product fails to comply with the regulatory standards and specifications set by the PPB in view of quality, safety, and efficacy of the medical product.

3. How does the board know that product needs to be recalled?

The decision to recall a product is usually based on the findings of the risk assessment and regulatory compliance assessment by the board. This decision considers the potential safety to patients and the severity of the issue.

4. Why is a recalled product dangerous?

The recalled product may be considered dangerous due to identified safety concerns and quality defects that could pose risks to the health and well-being of patients or consumers. The recall is initiated to mitigate these potential dangers.

5. What informed the board's decision to recall a product in the market?

The decision to recall a product is usually informed by various factors, including reports of adverse events, product quality defects, non-compliance with regulatory requirements, or identified safety concerns. The primary goal is to protect public health and safety.

6. **How does the board ensure the identification of batches after a recall notification?**

The board ensures the identification of batches through strict record-keeping requirements imposed on manufacturers and distributors. Each batch of a product is assigned a unique identification number, which is used to trace and identify products in the event of a recall.

7. **What does PPB mean with the words 'sub-standard and falsified product'?**

A "sub-standard" product refers to a product that does not meet the quality standards and specifications established by regulatory authorities. A "falsified" product is one that is deliberately misrepresented or counterfeited, often with the intent to deceive or defraud.

8. **How does the board take action after receiving 'multiple market complaints' from a product?**

When the board receives multiple market complaints, it takes immediate action by implementing a recall. This response is prompted by the recognition that numerous complaints suggest a possible widespread issue with the product. Multiple complaints serve as a significant indicator of safety or quality concerns that require urgent attention to protect safety and health of the public.

9. **Is there a mechanism to continuously monitor the quality of medicines being sold in the Kenyan market?**

Yes, the PPB has mechanisms in place to continuously monitor the quality of medicines in the Kenyan market. These mechanisms include active surveillance through online and mobile phone platforms for collection of reports submitted. By healthcare workers and members of the public, post-market surveillance through pro-active quality surveys, inspections of pharmaceutical outlets and products at the ports of entry, and continuous sampling and testing of products to ensure compliance with quality and safety standards.

10. **Does PPB need to carry out a quality assessment in case of a recalled product?**

Yes, conducting a comprehensive quality assessment is crucial in the recall process. Quality assessments help identify any defects, deviations, or safety concerns related to the recalled product. It ensures that all necessary actions are taken to address the issue effectively.

11. **Can you please tell us what the specific problem was with the product being recalled?**

Tamedol

The PPB is in receipt of several market complaints on Tamedol suspension, manufactured by Biopharma Ltd, the nature of the complaint was color change from pink to black/dark color of the suspension. Following the market complaints, the PPB initiated investigations which entailed sampling and analysis of the complaint samples. On analysis the product, it was found the product FAILED to meet market authorization requirements. (Photos are attached)

Visipaque

The product is suspected substandard and falsified (SF)

Vials with broken seals, rubber stopper with punctures and glue, compromised integrity of the bottles, leaking vials, dirty and dusty vials, missing user manual in the boxes, QR Codes on the contrast vials did not contain information upon scanning, same boxes of contrast had vials with different expiry dates, different batch numbers on bottles within the same box, disparity in labels from the known product, suspected adverse drug reaction on some of the patients administered with the contrast media (patients showing signs of fever immediately following injection of the contrast and septicemia in some patients).

12. What is the use of drugs being recalled?

The intended use of the drug is usually specified in its labeling and product information. If you have questions about the intended use of a specific drug, you can refer to its package insert, consult a healthcare professional, or contact the manufacturer.

Tamedol suspension (Paracetamol) and is used in management of pain and fever in children.

Visipaque is used as a special X-ray dye for diagnostic purposes ONLY. It's typically given to adults during procedures like heart checks, brain scans, leg artery exams, kidney tests, and to make CT scans work better.

13. The Visipaque in question is manufactured in China and Ireland. How is it possible that they are available in Kenyan markets?

The presence of substandard and falsified (SF) batches of Visipaque radio contrast media in Kenyan market is through importation via illegal and unauthorized route, the PPB is carrying out investigations in view of preventing future occurrence of such incidents.

14. Which action does PPB expect when they advise pharmaceutical outlets, healthcare facilities, and healthcare professionals to take immediate action?

They are expected to stop using, distributing, or dispensing the recalled product, and to follow the specific instructions provided in the recall notification.

15. Who compensates the pharmacy outlet / healthcare facilities in case of a recall?

Compensation for pharmaceutical outlets / healthcare facilities affected by recalls may vary depending on the circumstances and agreements between the manufacturer, distributor, and the affected parties. It is advisable for affected entities to communicate with their suppliers for potential compensation.

16. What will happen with similar products if pharmacy outlet / healthcare facilities have from the same company?

Similar products from the same company are closely being examined for potential issues by the Pharmacy and Poisons Board (PPB) in view of compliance with quality and safety standards.

17. What should members of the public who have already bought these products do?

Members of the public who have already purchased the recalled products should stop using them immediately and follow any instructions provided in the recall notification. They may also contact healthcare professionals or the manufacturer for further guidance or assistance.

18. *Should healthcare providers follow-up with patients who have received recalled products?*

At this time PPB are not urging healthcare professionals to follow-up with patients who received Recalled products. However, healthcare providers should remain vigilant, and report any adverse events and complaints believed to be associated with use of a recalled product through the board's electronic reporting system called the Pharmacovigilance Electronic Reporting System (PvERS) available online and can be accessed through mobile phone.

19. Where was the board when this product was being dispatched to the public?

The board is responsible for regulatory oversight and monitoring of products in the market. However, lapses in quality or safety may occur at various stages of the supply chain. The board takes action upon receiving reports or evidence of non-compliance to protect public health and safety.