Question 2: *What are effective and sustainable mechanisms or processes to integrate local, community, sub-national, national, and regional voices, priorities, and contributions into health system strengthening efforts?*

Strengthening Pharmacovigilance to Improve Product Safety Surveillance and Reporting in Kenya

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HEALTH SYSTEMS STRENGTHENING ACCELERATOR

Context

Safety surveillance following the market authorization of health products and technologies (HPTs), along with ongoing quality and effectiveness monitoring and reporting, are integral for maintaining patient safety and achieving the goals of the health system. However, Kenya in the past has experienced irregular and infrequent reporting of adverse events following immunization (AEFIs) to the national pharmacovigilance system maintained by the Pharmacy and Poisons Board (PPB). Limited access to reporting tools by health care professionals and members of the public alike, a tendency to misplace manual reporting forms before the data they contain is uploaded to the web-based Pharmacovigilance Electronic Reporting System (PvERS), and inadequate knowledge on the use of that system were all major factors contributing to the challenges. In March 2021, for example, when COVID-19 vaccination was introduced in Kenya, health care workers needed to be trained on the features of the multiple vaccines to ensure their effective administration. It was also critical to ensure patient safety, track the vaccine uptake and epidemiology trends, and manage vaccine stock for the success of the immunization campaign—all of which demand proper reporting and data accuracy.

To improve patient safety, policies, procedures, and systems need to be in place to support pharmacovigilance—activities relating to the detection, assessment, understanding, and evaluation of adverse effects or other HPT-related problems. Moreover, HPTs must be handled in compliance with applicable laws and regulations. Vaccine safety monitoring enables the early detection, investigation, and analysis of AEFIs, as well as adverse events of special interest. The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program is collaborating with the PPB to strengthen pharmacovigilance systems and improve safety surveillance and the reporting of health product-related problems, including AEFIs.

Activity Description

Development of mPvERS
To address the system weaknesses that challenged COVID vaccine introduction, in 2021 Kenya upgraded PvERS —which was developed with support from a USAID-funded predecessor program, the Health Commodities and Services Management Program—to include the reporting of AEFIs, medication errors, transfusion reactions, and medical device incidents. In 2022, MTaPS supported the PPB in developing a mobile Pharmacovigilance Electronic Reporting System (mPvERS), which interlinks with PvERS and allows for the real-time transmission of pharmacovigilance reports from handheld mobile devices, thereby enabling even users from remote parts of the country to easily access the system. The PPB, with MTaPS support, trained health care workers on using mPvERS to send the safety reports and designed, printed, and disseminated brochures and posters on how to use the app that targeted health care workers and members of the public.

Complementary Surveillance Activities
To ensure a successful COVID-19 immunization campaign, it was important to ensure proper reporting and data accuracy in tracking vaccine uptake, epidemiological trends, and overall patient safety. MTaPS assisted the Ministry of Health on multiple fronts of vaccine deployment: policy, planning, and coordination; supply chain logistics management; pharmacovigilance to monitor AEFIs; and capacity building.

- **Capacity Building.** MTaPS, in collaboration with the National Vaccines and Immunization Program and other implementing partners, developed training materials for COVID-19 vaccine deployment on topics such as cold storage, transportation, administration, safety surveillance, and data management and reporting. The program trained 101 master trainers who cascaded the knowledge down to the county and sub-county levels, and eventually to the health facilities, reaching a total of 1,323 health professionals in all 10 MTaPS-supported counties. In addition, MTaPS trained 1,355 health care workers on spontaneous reporting of AEFIs with COVID-19 vaccines and investigation of serious AEFIs.
- **Improving Data Quality and Reporting on Vaccine Stock and Safety.** To address the COVID-19 vaccine data quality concerns at the facility level (e.g., missing stock data, high wastage of vaccines, and low levels of AEFI reporting), MTaPS worked with the Sub-County Expanded Program on Immunization logisticians and the sub-county health records and information officers to ensure all COVID-19 vaccinating facilities within their sub-counties could access the national reporting system to enter vaccination data directly. Additionally, MTaPS supported the focus counties to review the data and conduct focused support supervision on COVID-19 vaccines administration and data entry at health facilities, printing and distributing vaccines ledger books to improve documentation of vaccine inventory management.
- **Support for the Development of National- and County-Level COVID-19 Vaccines Micro Plans.** During vaccine introduction, planning was carried out centrally for deploying COVID-19 vaccines to the counties. MTaPS supported the national COVID-19 vaccines procurement and logistics subcommittee to develop and roll out a standardized micro plan template in the country's 47 counties, enabling decentralized planning for vaccine rollout. Partners were able to further cascade these micro plans to the health facilities.

Activity Impact

The PvERS upgrades have made some fields mandatory to ensure the inclusion of minimum required information. This, along with continuous capacity building of healthcare workers, has helped to improve report quality. In some counties, increased reporting has led to investigations of serious adverse events, including AEFIs, with review and feedback from the pharmacovigilance expert review and advisory committee.

MTaPS' technical assistance provided a platform for sustained roll out and support of COVID-19 vaccines both in the focus counties and nationally. As the country worked toward designating all the facilities offering routine immunization as COVID-19 vaccination centers, lessons learned from MTaPS' work informed the scaling up efforts to address gaps. As new information emerges on COVID-19 and other vaccines, ongoing facility-level mentorship and support supervision, AEFI reporting, and awareness building will continue to strengthen new and existing interventions targeting health workers and the public. This will be done by PPB in collaboration with the National Vaccines and Immunization Program (NVIP), counties, and implementing partners.

The reports received from the national pharmacovigilance system inform policy changes aimed at improving patient safety, including the review of treatment guidelines and various regulatory actions and interventions across the country.

This case focuses on HPTs and demonstrates the importance of proper information management for decision-making while promoting good governance and transparency in national health systems. The reporting system is key for promoting access to quality, safe, and efficacious medicines, other HPTs, and vaccines. The entire process was led and has since been owned and sustained by the PPB. Further, the system is integrated and not parallel, hence all products across the various vertical programs (e.g., HIV, malaria) are captured in the system.

"The Pharmacovigilance electronic reporting system will go a long way in strengthening reporting and vigilance on safety quality issues for health products and technologies in Kenya both by healthcare providers and the general public."
– Dr. Siyoi, PPB CEO


Kenya Unveils New, Easier Way To Report Medical Side Effects Through Your Phone

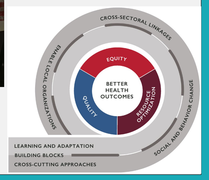
By Peace Hinger
Published on: April 13, 2022 01:23 (EAT)

The mobile-based solution provides a reporting platform in form of a mobile application for both android and iPhone Operating Systems as well as a USSD solution.

Chief Administrative Secretary for Health Dr. Rashid Aman, lauded the system terming it as a step in the right direction in enabling the public to enjoy quality, safe, and efficacious health products and technologies.

"The solution is developed to supplement the existing national reporting system PvERS II, launched in March 2021 to increase and improve consumer reporting and AEFI reporting.," Dr. Rashid said on Wednesday.


A healthcare worker interacting with the mPvERS application on 6th September 2022
Photo credit: Barbara Jepkorir



Evidence

The number of safety reports submitted to PvERS annually increased from 2318 in 2021 to 2999 in 2022 and subsequently to 2981 between January and April 2023. The number of adults fully vaccinated for COVID-19 in the 10 MTaPS focus counties increased from 460,807 (4.59% of the target population above 18 years) on September 2, 2021, to 4,058,653 (40.5% of the target population above 18 years) on August 31, 2022—an almost nine-fold increase. These reports have led to the PPB taking various regulatory actions regarding product safety and efficacy.

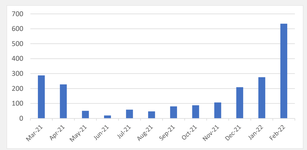
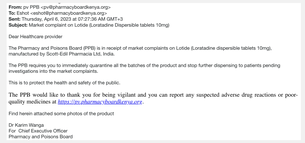


Figure 1. Number of AEFIs (all vaccines) reported by month.
Note: COVID-19-related: 96.2%; non-COVID-19-related AEFIs: 3.8%


From: pv PPB <pv@pharmacyboardkenya.org>
To: ExPol <expol@pharmacyboardkenya.org>
Sent: Thursday, April 6, 2023 at 07:27:56 AM GMT+3
Subject: Market complaint on Lotide (Loratadine Dispersible tablets 10mg)

Dear Healthcare provider

The Pharmacy and Poisons Board (PPB) is in receipt of market complaints on Lotide (Loratadine dispersible tablets 10mg), manufactured by Scott-Edil Pharmacia Ltd, India.

The PPB requires you to immediately quarantine all the batches of the product and stop further dispensing to patients pending investigations into the market complaints.

This is to protect the health and safety of the public.

The PPB would like to thank you for being vigilant and you can report any suspected adverse drug reactions or poor-quality medicines at https://pv.pharmacyboardkenya.org.

Find herein attached some photos of the product

Dr Karim Wonga
For: Chief Executive Officer
Pharmacy and Poisons Board

Example of alert generated based on PvERS safety reports


PHARMACY AND POISONS BOARD

PUBLIC ALERT ON FALSIFIED MEDICAL PRODUCT

The Pharmacy and Poisons Board in collaboration with other government agencies have detected falsified medical product circulating in the Kenyan market. The details of the product are as follows;

Product Name	Ashton & Parsons Matricaria Infant's Powder			
Stated manufacturer on secondary packaging	Made by Smith Kline Beecham Nigeria plc 20 Industrial Avenue, Pojepji Lagos, Nigeria Under Licence from SmithKline Beecham Consumer Brands Brandford, England Trademark owner,			
Stated manufacturer on primary packaging	Made by Smith Kline Beecham Nigeria P/C 20 industrial Avenue. Lingeju Lagos, Nigeria Under Licence from SmithKline Beecham Consumer Brands Brandford, england Trade Mark Owner.			
Stated active ingredients	Tincture of Matricaria(1in10)4mg & Lactose B.P 125mg			
BN/Lot	**PA 4328C**	**PA 4318C**	**PA2011C**	**AP 061W**
Mfg. date	JAN 2021	JULY 2020		MAY 2018
Exp. Date	MAR. 2024	JUNE 2023	MAY 2022	MAY 2022
Packaging language	English	English	English	English
Identified in	Kenya	Kenya	Kenya	Kenya

Example of sections from a public alert issued by the PPB regarding product safety
Source: PPB Kenya

Falsified Ashton & Parsons Matricaria Infant's Powder BN. PA 4328C

The members of the public are encouraged to be vigilant and report any suspected substandard or falsified medical products to the Pharmacy and Poisons Board Website: https://pv.pharmacyboardkenya.org/psubv/add, mobile application: mPvERS both android & iOS and USSD code at *727#, Email: pv@pharmacyboardkenya.org

CHIEF EXECUTIVE OFFICER

24th June 2022

Facilitators

- The USAID-funded and MSH-implemented Health Commodities and Services Management Program (HCSM) had earlier supported the development of PvERS in 2013, which was used for reporting suspected adverse events and falsified medical products. This system was maintained and sustained by the PPB using their own resources. In 2020/2021, the World Health Organization supported the PPB to expand the scope of the PvERS to include medical devices, blood products, AEFIs, and medication errors. As such, MTaPS was able to leverage the existing PvERS to develop the mobile version.
- The PVERS and mPvERS are E2B format compatible with the WHO reporting system—VigiFlow—allowing Kenya to easily transmit safety reports to WHO.
- System development and deployment included extensive engagement with a range of stakeholders: key national Ministry of Health and county-level stakeholders, public health programs, pharmaceutical industry, academia, research institutions, health professional associations, the Pharmacovigilance Expert Review and Advisory Committee, donors, implementing partners, and research institutions. During deployment, these various stakeholders were oriented on the use of the reporting system and USSD codes. Building public awareness and making mPvERS and USSD codes accessible to everyone via the PPB website were also critical.
- The use of mPvERS has been embedded in all pharmacovigilance-related trainings for health care workers and stakeholders' meetings, including the orientation of county pharmacovigilance focal persons and training for pharmaceutical industry-based qualified persons for pharmacovigilance (QPPV).
- MTaPS paid for the development, launch, and sensitization of mPvERS; however, the PPB immediately took responsibility for the maintenance, additional trainings, and other costs (e.g., hosting with iOS and Android, USSD provider costs).

Challenges

- Health care workers and the public at large were not adequately aware of the system. This was addressed through an awareness campaign that included the development and dissemination of printed materials with guidance on how to use the mobile app. Additionally, MTaPS trained health care workers in its focus counties on the use of mPvERS and USSD codes for safety reporting.
- Reports were often of poor quality due to health care workers' limited knowledge on how to correctly fill in the forms. MTaPS has addressed this through continually orienting the 41 county vigilance focal persons, who could then cascade the information to health care workers in their respective counties.
- A high workload burden made it difficult for health care workers to document and submit the safety reports. One mitigation was to encourage health care workers to contact the county vigilance focal person or other pharmacy staff for assistance if they had a case to report but were unable to do so.
- Health care workers feared the consequences of reporting cases. It was therefore critical to assure them that the reports they submitted would be handled in confidence and to also work at the facility level to encourage a just culture.

Lessons Learned

- Establishing pharmacovigilance is critical for determining a product's safety and efficacy profile. Although the role of pharmacovigilance lies largely within the national medicines regulatory authority, it requires participation and awareness of a wide spectrum of actors for reporting suspected adverse drug reactions and the use of safety data to inform regulatory actions, policy decisions, and clinical care.
- The integration of electronic systems helps to improve functioning of systems. Though the interest was on improving AEFIs, strengthening the existing system for reporting ensured that other adverse events on HPTs could be improved. The implementation of the trainings was also integrated, which reduced the costs for rolling out the overall pharmacovigilance reporting.
- The involvement of all stakeholders is key for buy-in during implementation. For example, various public health programs in Kenya (NVIP, NLTP, NBTS)—which had parallel channels for the reporting of adverse events—had to be engaged so they could embrace PvERS as the single national pharmacovigilance reporting platform.
- Contextualization and regional dynamics need to be carefully considered when deploying new technologies. Despite advances in technology, there are still regions in Kenya with poor internet connectivity or electricity. In such cases, a mix of both physical hard copy forms and electronic reporting are needed.

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