



REPUBLIC OF KENYA
MINISTRY OF HEALTH



PHARMACY AND POISONS BOARD

JOINT NEWS RELEASE

KENYA AND UGANDA PARTNER WITH INTERNATIONAL STAKEHOLDERS TO PROTECT CONSUMERS FROM ILLICIT MEDICAL PRODUCTS

Unprecedented Multilateral Initiative Brings Focus to the Shared Threat Posed by Illicit Medical Products

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Today, the Pharmacy and Poisons Board (PPB) of Kenya and the National Drug Authority (NDA) of Uganda announce a groundbreaking bilateral initiative. This collaborative effort involves participation from counterpart agencies in the United States, United Kingdom, and the European Union, as well as multinational organizations and the regulated pharmaceutical industry.

Over the course of four days, under an initiative known as Operation African Star, joint enforcement teams targeted violative shipments of health products encountered via postal and air cargo in both countries. In addition, reciprocal training was conducted. Partnering with key stakeholders in Africa, the international community, and private industry across all relevant sectors, Operation African Star aims to improve health outcomes by working collaboratively to better understand and disrupt the illicit trade in health products, pharmaceutical preparations, medical devices, and equipment across Africa.

Pharmacy and Poisons Board, Kenya, adopted the multi-Agency approach in addressing the issue of illicit trade with participating Authorities and Agencies being drawn from Kenya Revenue Authority, The Immigration services, Anti-Narcotics, National Intelligence Services, Directorate of Criminal Investigations, Kenya Airports Authority, the Post Master General, Communication Authority of Kenya and the Anti-Counterfeit Authority.

National Drug Authority, Uganda, leveraged its whole of government approach to protect public health and drew support and participation from the Uganda Revenue Authority, Uganda Civil Aviation Authority and the specialized units of the Uganda Police Force i.e., INTERPOL and Anti-Narcotics

Participating international counterpart agencies included the European Anti-Fraud Office; United Kingdom Intellectual Property Office; United States Agency for International Development, Office of Inspector General; United States Customs and Border Protection; United States Food and Drug Administration, Office of Criminal Investigations; United States Postal Inspection Service; and the United States Department of State, Diplomatic Security Service. Valuable contributions were provided by a host of international organizations, including the Organisation of Economic Co-operation and Development, the United Nations International Narcotics Control Board, Universal Postal Union, and the Pharmaceutical Security Institute.

During Operation African Star, joint enforcement teams examined shipments of human medicines, biologic products, and dietary supplements. These examinations revealed several pertinent observations that require synergies to stop, these include shipments of medicines which had been stored and shipped outside of approved conditions; prescription medicines lacking valid prescriptions and misdeclared to avoid detection; and dietary supplements known to contain undeclared active pharmaceutical ingredients and/or imported in violation of domestic regulations.

The participants also received training regarding emerging threats to public health and safety, such as psychotropic, precursor, and related chemicals. They also received training from the host countries on how violative shipments are identified and addressed via their respective regulatory and legal frameworks. This training was strengthened by opportunities for the participants to observe this dynamic firsthand as the hosts navigated through and explained their individual processes. Moreover, regulated industry assisted by providing critical information regarding the products encountered during the operation.

Speaking during the meeting, Chief Executive Officer of the PPB, Dr. Fred Siyoi, said, “The threat posed by illicit trade in health products and technologies impacts global public health, and consumers. This risk increases when health products and technologies are obtained outside of the unregulated supply chain. Safety and efficacy which cannot be assured threatens the East African Community and public health at large,” Additionally, he said that, “PPB is committed to protection of public health through collaboration with domestic and international partner agencies and organizations. PPB is proud to partner with the NDA to design and execute Operation African Star. We envision this as an iterative initiative with the potential to develop into an internationally recognized best practice.”

The Chairman of the NDA, Dr. Medard Bitekyerezo, said, “A multilateral initiative like Operation African Star allows us to exchange and develop best practices as we position ourselves to collectively combat current threats to

public health and safety and prepare for those yet to come. As evidenced by the wide array of support generated for this initiative, there is a growing recognition that to effectively combat these types of dangerous products requires crosscutting partnerships. The NDA is also committed to fighting these types of shared threats to public health and safety by working across sectors and governments to target bad actors distributing these types of dangerous products.”

Individuals who purchase prescription medicines from unauthorized sources may be putting their health at risk because these medicines may be falsified, substandard, expired, or otherwise unsafe for use. As many of these products are used to treat serious or life-threatening medical conditions, they could potentially be harmful if administered or ineffective when medical treatment is acutely necessary. Given that these types of products are often transshipped via third-party countries, they are likely to have been shipped and stored outside of approved conditions, making it difficult to determine if they are safe and effective if obtained from outside the regulated pharmaceutical supply chain.

“While the global supply chain has made medicines more accessible, it has simultaneously made it increasingly challenging to identify illicit products and hold bad actors accountable,” said United States Food and Drug Administration Assistant Commissioner for Criminal Investigations, Justin Green. “The FDA greatly appreciates the opportunity to work with Kenyan, Ugandan, and other key international partners to bring focus to a global public health threat and values the implementation of a pioneering initiative to combat it.”

Operation African Star benefited greatly from the existing strong and mutually beneficial relationships between the governments of Uganda and Kenya. Operational outcomes included the initiation of criminal investigations, seizures of violative products, and the exchange of actionable intelligence. Efforts are already underway regarding strategies to alert consumers of the dangers associated with illicit medicines and to aid in the decision-making of front-line personnel. Planning is ongoing regarding follow-on enforcement actions and training opportunities.