



Pioneering data collection and policy research

RESEARCHING FALSIFICATION AND THE PHARMACEUTICAL SECURITY INSTITUTE

Accurate data and research on falsified medicines is critical for designing effective responses. However, it's difficult to collect, analyze and distribute data on this criminal activity, as counterfeiters conceal their operations. For example, the UN Office of Drugs and Crime (UNODC) has recognized that quantitative information on falsified crime and criminal justice is very limited. Therefore, global health policy stakeholders must build a fact-based infrastructure to understand the current and changing dynamics of this illicit activity, which threatens patient safety and public health.

In this regard, the Pharmaceutical Security Institute (PSI) is a pioneering organization that is directly addressing the need for data on falsified medicines. In 2002, the Security Directors of innovative pharmaceutical manufacturers established PSI to collect, analyze and disseminate information about falsified, illegally diverted and stolen medicines.

Established 10 years ago, this database includes 13,439 incidents of counterfeit, illegally diverted, and stolen medicines. Approximately 70% of this data is obtained from members, with additional data provided by credible and first-hand data sources. PSI utilizes this data through multi-lingual, open source reviews, liaison contacts with authorities, and special studies that provide a broader picture of the extent and dangers of the falsified medicines market.

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INNOVATIVE STUDIES ON FALSIFIED MEDICINES

The global health community must recognize preventing falsification as an integral element of efforts to protect public health worldwide. Prevention efforts are directly connected to improving access to authentic, effective, high-quality medicines. However, improving prevention will require greater efforts to collect data on this public health threat.

Two innovative studies provide insightful data and analysis on the global challenges of falsified medicines. The first was conducted by the University College London School of Pharmacy and the international research agency Matrix Insight, and it highlights opportunities for a better coordinated international response to falsified medicines. The report examines governments' growing recognition of the importance of preventing falsification and emphasizes the need for more collaborative action between all stakeholders. The report concludes that more investment is needed to both quantify falsification and provide early warning of potentially hazardous products when they are detected in legitimate supply chains.

The second report, from PSI and the University of California, San Diego School of Medicine, is a ground-breaking analysis of the penetration of counterfeit medicines into legitimate supply chains, published in April 2015.⁶ It assesses counterfeit reports involving the legitimate supply chain using 2009–2011 data from the PSI Counterfeit Incident System database.

REPORTS ON COUNTERFEIT MEDICINES ARE LACKING. BASED ON PSO REPORTING SYSTEM ANALYSIS FOUND THAT:



35.2%

more than one-third of the nations in the world had their legitimate supply chain compromised



51.3%

of the reports contained limited information precluding further classification

This study is part of a special supplement of *The American Journal of Tropical Medicine and Hygiene*, titled “The Global Pandemic of Falsified Medicines: Laboratory and Field Innovations and Policy Perspectives.” The supplement includes 17 articles on falsified and substandard medicines, creating a vital resource for information on this public health topic. This includes suggested policy interventions, such as an international framework and the adoption of stricter national laws against drug counterfeiting.