

The Verification & Traceability Initiative

Supporting countries to reduce the urgent risk of falsified and diverted COVID-19 products in national supply chains with a vision toward national traceability of all vaccines, medicines, and health products.

WHY

As COVID-19 vaccine distribution ramps up worldwide, there has been an upsurge in the production and distribution of falsified and sub-standard vaccines and related COVID-19 supplies. The development of one of the most valuable and highest-demand vaccines in history has already been cited as a risk by the COVAX Facility, the GAVI Audit and Finance Committee, and UNICEF, and evidence from Interpol and the Oxford Data Observatory has corroborated this.

The need for product quality verification and traceability extends beyond COVID-19 vaccines to all health products. The highest risk is in low- and middle-income country (LMIC) national supply chains, where governance structures, tools, and technical capacity for active monitoring for falsification are limited and traceability systems are either non-existent or in the early stages of development. Falsified vaccines and medicines cost LMICs \$30billion/year and over \$200billion globally¹.

COVID-19 pandemic investments can accelerate implementation of traceability to protect beneficiaries from falsified health products while strengthening the digital foundations supply chains for all public health and routine healthcare use cases.

WHAT

The **Verification & Traceability Initiative**, will establish a global repository of trusted health product information that can verify the authenticity of health product information sent to its application programming interface (API) or scanned using a complementary, off-the-shelf verification application. The global repository will initially be loaded with COVID-19 vaccine data from manufacturers to address the urgent risk of falsified or diverted COVID-19 vaccines. However, the repository will be designed to support end-to-end (E2E) traceability of all vaccines, HIV, TB, and malaria medicines, and other health products. The Verification & Traceability Initiative will also support country deployment in alignment with existing verification and traceability efforts. Utilization of the global repository of trusted health product information or verification application are options in the suite of WHO recommended and current country approaches to protect patient safety.

Verification can be integrated into existing supply chain management and vaccination campaign workflows by supply chain and health worker cadres without requiring a significant change in existing processes. Additionally, a secure and password-protected global dashboard will allow authorized users to monitor trends in verification events and suspect activity, and utilize as a proxy for product movement in the supply chain. Investigation of suspicious scans by decision makers will require in-country procedures to be adapted and/or drafted.

Importantly, the global repository and mobile verification application are **built on the GS1 supply chain standard**, ensuring their interoperability with other GS1-enabled supply chain information systems. While the repository will initially support verification of COVID-19 vaccines, its use of the GS1 standard will allow its functionality and scope to be expanded over time to cover other health products and use cases, including traceability, product recall, and supply chain automation and analysis.

Depending on the existing digital health ecosystem, the repository can be used through two different modalities:

- (1) **Standalone mobile application:** For countries where no existing national traceability system exists. Supply chain and health system workers can scan vaccines with a smart phone application to validate their authenticity at any time. This application will be easy to use and require minimal additional training.
- (2) **Integrated with traceability system:** For countries with an existing national traceability or health product management system. Supply chain and health system workers can use their existing product scanning system, which can interface with the global repository's API to verify products registered in the repository.

¹ WHO, A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products, 2017.

WHEN

Immediate Term: By mid 2022 the global repository of trusted health product information will be tested and ready to be adopted and scaled by countries. The initiative will provide direct technical and financial support to early adopter country partners in two-to-five countries, to implement and use the global repository and share lessons learned to improve the solution for other geographies. Thereafter, the global repository and related tools and guidelines will be made available in a self-service fashion.

Additional bridge funding for immediate deployments may also be available through the following COVID-19 response funding mechanisms. Interested country partners should contact their local partner offices for more information on how to use existing funding to support the global repository of trusted health product information deployment.

- GAVI: [COVID-19 Vaccine Delivery Support \(CDS\)](#)
- USAID: [American Rescue Plan Act \(APRA\)](#)
- Global Fund: [Procurement and Supply Chain Strategic Initiatives](#)

For long-term operations and scaling of the solution to cover additional health products and use cases, countries can work with initiative partners to leverage existing long-term funding vehicles, for example through Health Systems Strengthening funding provided by USAID, the Global Fund, and the World Bank to provide ongoing support to the appropriate government ministry and/or regulatory agencies.

Medium to Long Term: The Verification & Traceability Initiative will serve as a platform for discussions on traceability and as a catalyst for the digitization of health product supply chain systems over the next three-to-five years. The global repository of trusted health product information, the global repository API, mobile verification application, and verification SDK are key digital components designed specifically to integrate within a broader, standards-based digital health ecosystem that supports other supply chain and health system functions. Successful implementation of the verification use case opens the door to additional use cases and traceability of routine vaccines, medicines, and other health products in the future, including:

- **Monitoring the supply chain** for identification of falsified vaccines and other medicines as a mechanism for product recalls in post-marketing surveillance.
- **Expanded track-and-trace functionality**, including integration with logistics management information systems (LMIS) to enable real-time identification of inventory positions across the supply chain network.
- **Innovation and development of new GS1-enabled applications** for consumers, supply chain partners, and healthcare providers.
- **Integration with electronic health record systems (EHRs)** to facilitate pharmacovigilance, adverse event reporting, health outcomes analysis, ordering, and billing.

WHO

The effective prevention of falsified, sub-standard products, and diversion requires collaborative partnership across all organizations involved in public health programming and routine supply chain management. The Verification & Traceability Initiative invites discussion with country partners involved in ensuring the quality and veracity of health products, including:

- Ministries of health, regulatory authorities in health and technologies, and public-sector healthcare providers
- Private-sector healthcare providers, supply chain operators, and NGOs
- Global donors providing financial or in-kind support for health product procurement or distribution
- Vaccine and other health product manufacturers
- Technology providers and software developers

To learn more about the Verification & Traceability Initiative, please contact the Project Management Unit for the Verification & Traceability Initiative (Vital Wave): traceability@vitalwave.com