Highlights on the "Focus on Africa" session held on November 17, 2021
3rd GS1 Healthcare Online Summit, November 15-18, 2021

The 3rd GS1 Healthcare online summit was held between 15 and 18th November, 2021. The event featured 741 registrants from 89 countries and 45 speakers. The theme of this summit was "Global standards for global health".

This summit featured speakers from across the world including healthcare providers, distributors/wholesalers, manufacturers, solution providers and regulators of medicines and medical devices. Participants heard how GS1 standards help improve clinical outcomes and supply chain processes, how global standards are being used to help secure the supply chain. Participants also gained insights about important regulatory developments.

The Focus on Africa session, building on the Lagos Call to Action for Africa's strategy for pharmaceutical traceability was chaired by Tom Woods, chairman of the Global Steering Committee of the World Bank.

This session was an important platform for stakeholders from all around the world to learn about the progress being made by countries in Africa with regards to adoption and use of global standards to support pharmaceutical traceability and ultimately patient safety.

During this session, five speakers presented the progress from their countries including Ethiopia, Nigeria, Rwanda and Zambia. In addition, five speakers from development partner organisations including Global Fund, UNICEF and USAID and Vital Wave, a global digital technology company, shared information about a global verification & traceability initiative, popularly, the Global Trust Repository (GTR). This GTR will initially focus on supporting verification of COVID-19 vaccines and subsequently other products. Below are some session highlights.

➔ **Professor Mojisola Christianah Adeyeye – Director General, National Agency for Food and Drug Administration and control (NAFDAC)**

• Since the 2019 Lagos call to action, NAFDAC has led multiple initiatives to set up pharmaceutical traceability including developing and launching a 5-year implementation plan and allocating a traceability desk at NAFDAC.
• NAFDAC conducted a pilot of tracing COVID-19 vaccines from point of entry to multiple levels in the supply chain, to better understand the requirements for traceability in Nigeria.
• Nigeria is actively involved in the efforts to set up the GTR, a multi donor project that aims to set up a system to support verification & traceability of COVID-19 vaccines initially and subsequently other products.
• Officers from Ghana FDA recently visited Nigeria to learn on their approach for pharmaceutical traceability.

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➜ **Ms. Heran Gerba, Director General Ethiopia Food and Drug Authority (EFDA)**

• Digitalisation of the regulatory systems and processes used as an important stepping stone for pharmaceutical traceability in Ethiopia. They have developed an electronic regulatory information system (eRIS) and using this platform, registrations, import licenses, port clearance and others are coordinated within one platform and electronically.
• The importance of ensuring that stakeholders are actively engaged, routinely updated of the process to set up pharmaceutical traceability, could not be stressed enough.
• It helps to start with a limited scope i.e. pharmaceutical traceability. This gives the country an important opportunity to understand the effort required and to learn important lessons before expanding the scope.
• It is important to incorporate traceability as part of new and existing short and long term strategies – EFDA and the MOH in Ethiopia both have pharmaceutical traceability in their long term strategies.
• National regulatory and traceability information systems have been already designed, EFDA is working on defining architecture and other pieces.
• iVerify application, that enables patients to verify the authenticity of products, is developed and already in use by the population in Ethiopia. The app has recently been loaded with information for COVID-19 vaccines which has been made available to EFDA.

➜ **Mr. Makomani Siyanga, Acting Director General, Zambia Medicines Regulatory Authority (ZAMRA)**

• Zambia is part of ZAZIBONA effort (Zambia, Zimbabwe, Botswana and Namibia), an effort created initially by those countries to harmonize regulation but eventually expanded to include more countries.
• In order to set up the requisite regulatory framework to support traceability, the approach taken was to modify existing guidelines vs drafting an entire regulation where the former can be approved by the Authority and the latter is lengthy requiring multiple approvals from the government.
• The process of setting up the regulatory framework to support traceability is underway and key guidelines to be released early in 2022, draft guidelines already published and now collecting feedback. The presenter noted that this is an important enabler for traceability.
• Zambia is concurrently working on setting up master data, an important building block for traceability. The teams are manually collecting GTINs in collaboration with the Zambia Medicines and Medical Supplies Agency (ZAMMSA), they currently have close to 500 GTINS.
• Important lessons include the significance of government leadership and integration of traceability initiatives into other initiatives existing in the country.

➜ **Mr. Edouard Munyangaju, Medicines registration and variations assessment analyst, Rwanda Food and Drug Authority**

• Rwanda is working on master data as an important building block for traceability. National product catalogue has been officially launched. Currently working on guidelines and SOPs to standardize and sustain coordination of master data across the various in-country systems.
• Multiple information systems containing disparate information about product (master data) was an important challenge.
• Mobile application being worked on – this will provide users with the ability to verify authenticity of products.
• Coordination of various entities in the government is important. This is in addition to integrating traceability into existing initiatives in the countries.
• Rwanda will engage in the Global Trust Repository (GTR) effort.

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→ The WHO policy paper on traceability of medical products was presented as an important resource that WHO member states can use as they start thinking about traceability. The document is available in six languages including English, French and Arabic. Important considerations for member states thinking about traceability include these 11 items: Risk benefit analysis, governance and fundings, use of global standards, current state analysis, draft regulatory requirements, piloting systems and processes, defining key dates, exemptions, exceptions and waivers, enforcement planning, publication and communications planning.

→ **Mr. Derek Treatman, Vital Wave; Mr. Grant Courtney, UNICEF; Mr. Innocent Dube, UNICEF; Ms. Lindabeth Doby, USAID; Mr. Marasi Mwencha, Global Fund – Global verification & traceability initiative**

• Consortium of development partners are working together to set up a verification system that countries in LMICs (including Africa and beyond) to verify initially COVID-19 vaccines and ultimately other products.
• This solution that focuses on verification, built using GS1 standards, is seen as an important foundation for countries' national medicines traceability systems. Experiences based on existing traceability solutions will provide important input into this project.
• Countries encouraged to contact the various involved partners including Vital Wave, USAID, GAVI and Global Fund; or GS1 to express interest in this initiative.

→ **Dr. Sunil Gairola, Executive Director, Serum Institute**

• Counterfeit medication are especially prominent when there is a high demand for (a) particular medical product(s).
• The Serum institute demonstrated how they incorporate GS1 standards into their facilities including production, picking & packing process and how GS1 standards are of benefit for them.

Note: On November 18th, a ThinkTank provided an opportunity for stakeholders in Africa to actively discuss the opportunities, challenges and future of pharmaceutical traceability in the region. During this session attended by over 60 participants including heads of three regulatory authorities in Africa, regulatory authorities staff and development partners including various regulatory authorities had an opportunity to ask questions and receive experiences and responses from other regulatory authorities.

The ThinkTank was held under Chatham house rule, as such not recorded. Additional information regarding the next steps on this will be shared as and when it becomes available.

The recordings of these session are available on the event website. Contact Nuran Idris, Nuran.idris@gs1.org with questions or to learn more about GS1 standards and how they support pharmaceutical traceability.