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KENYA ASSOCIATION OF PHARMACEUTICAL INDUSTRY

Introduction to Serialization, Track and Trace

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Rapporteur's Report

The session began with an introduction to Serialization, Track and Trace that was done by the team from GS1 led by Ms. Nuran Idris from GS1 Global Office and Mr. Nelson John Uyirwoth from GS1 Kenya. Their presentation focused on the critical role of GS1 standards in enhancing traceability within the healthcare supply chain. The speakers emphasized that GS1 standards facilitate efficient supply chain operations and improve patient safety by ensuring accurate product identification and data integrity, with the GS1 DataMatrix being a pivotal tool that incorporates essential data elements such as GTIN, serial number, expiry date, and lot number. They highlighted the distinction between traceability—tracking the movement of products through the supply chain—and verification, which ensures product authenticity at the point of dispense, citing the European Union's verification process as an exemplary model. Furthermore, the global adoption of GS1 standards was discussed, noting that over 70 countries are now integrating the GS1 DataMatrix into their traceability systems, with countries like Kenya, Nigeria, and Ethiopia considering integrating these standards into their serialization, track & trace processes. While acknowledging the costs associated with implementing these standards – including hardware, software, training, and process enhancements – the speakers stressed the importance of collaboration among stakeholders to share these burdens. Successful case studies, such as Turkey's Pharmaceutical Track and Trace System and Nigeria's narcotics pilot, illustrated practical steps taken towards compliance with GS1 standards. The session concluded by underscoring the necessity for continuous improvement and adaptation of systems to meet evolving regulatory and supply chain environment, encouraging local stakeholders to engage in pilot projects for gradual implementation.

The second presentation by Ms. Merryl Riley of National Bioproducts Institute (NBI), South Africa, showcased the implementation of track and trace solutions at the National Bioproducts Institute (NBI) in South Africa. Merryl introduced NBI as a nonprofit organization dedicated to manufacturing human plasma-derived medicinal products for patients in Southern Africa and emphasized the critical need for effective track and trace systems to ensure the safety and integrity of their products. She outlined NBI's comprehensive

approach, starting with a clear understanding of GS1 terminology, including application identifiers, GS1-128 barcodes, and 2D DataMatrix barcodes, while highlighting the importance of both human-readable interpretation (HRI) and non-human-readable interpretation (nHRI) information on packaging. The discussion covered the packaging hierarchy, the classification of trade items versus logistics units, and the necessity of assigning Global Trade Item Numbers (GTIN-14) to every item, detailing the complexities of managing these identifiers. Merryl also stressed the need to determine the information to be printed on each item, considering regulatory requirements and trading partner specifications, and discussed packaging considerations such as space for barcodes, ink durability, and integration with packing lines. She shared insights into the development of an in-house system that included user requirements specifications, functional specifications, and design specifications, ensuring compliance with current good manufacturing practices (cGMP) and relevant health authority guidelines. Demonstrating the practical implementation of the track and trace system, Merryl showcased the manual assembly of packages, the generation of serial numbers, and the process of retrieving information from SAP, followed by printing and verifying the encoded data. She also played a video that demonstrated the aggregation process, where individual units are scanned into shippers, ensuring accurate tracking throughout the supply chain. In her conclusion, Merryl highlighted the collaborative nature of the initiative and the importance of ongoing dialogue among stakeholders to enhance track and trace capabilities. Her presentation provided valuable insights into NBI's practical approach to implementing a robust track and trace system.

The third presentation by Mr. Shaun Pillay, General Manager from Pyrotec Company, provided valuable insights into serialization and traceability solutions in the pharmaceutical industry. Shaun introduced Pyrotec, a company with 59 years of experience, specializing in smart factory solutions and track and trace initiatives, and highlighted their multiple divisions that cater to various aspects of coding, labeling, and packaging. He emphasized the importance of serialization, which involves applying unique identifiers to retail units in accordance with GS1 standards and detailed the processes of authentication and traceability as products move through the supply chain. Shaun explained the functionality of their custom-designed serialization and verification systems, which integrate seamlessly with NBI’s existing ERP system, SAP. He outlined the steps involved in generating unique serialized numbers, applying aggregation rules, and creating labels that conform to customer specifications. Shaun also discussed the critical role of camera systems equipped

with Optical Character Recognition (OCR) and Optical Character Verification (OCV) technologies to ensure data accuracy and compliance, emphasizing their significance in preventing counterfeit products in the pharmaceutical sector. He concluded by discussing the potential of RFID technology for product tracking and authentication.

The final presentation for the session was by the regulator, the Pharmacy and Poisons Board of Kenya, that was represented by Mr. Gedion Murimi. His presentation focused on the proposed pathway for implementing a track and trace system in Kenya. In his presentation, Mr. Murimi outlined the history, status, and future phases of the initiative. The discussion highlighted the origins of the track and trace concept, initiated by Parliament in 2019 due to the need for standardized marking systems, leading to the development of a centralized system that unfortunately faced legal and financial hurdles. Currently, a draft blueprint for traceability has been created, and batch traceability has begun, with integration into the Kenya Trade Authority's (KENTRADE) system. The proposed pathway consists of three phases: the first phase (12-48 months) aims to establish basic visibility and record capabilities for tracking products, including data capturing and a central batch repository; the second phase (48-72 months) focuses on unique level traceability with serialized numbers for high-risk health products and event-based reporting; and the third phase (72-120 months) will implement universal serialization and advanced analytics, including AI for data-driven regulation. Murimi emphasized the importance of stakeholder collaboration, education, and compliance in achieving these goals, as well as the need for a robust legal framework and infrastructure to support the implementation of the system. The session concluded with a Q&A segment addressing concerns about the central batch repository and the responsibilities of manufacturers in generating serial numbers, and a highlight of ongoing efforts toward regional harmonization of serialization requirements within the East African Community.

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