

Chief Executive Office

مكتب الرئيس التنفيذي

## **Circular No.: (38) 2021**

Date: 13<sup>th</sup> December 2021

**TO: All Invoicing Companies (MAHs, Manufacturers, Exporting Distributors), and All Agents/Distributors (Importers), Dispensers (Hospitals, Pharmacies, Clinics) in the Kingdom of Bahrain.**

**Subject: Update Regarding the Phased Approach to Implementing the NHRA-MVC Traceability Hub for Pharmaceutical Product Traceability**

As per Resolution No. 41 of the year 2017, and in accordance with the National Health Regulatory Authority (NHRA) Medicines Barcoding and Serialization Guideline; Kingdom of Bahrain; May 2021 Version 1.3, the Bahrain National Health Regulatory Authority (NHRA) has contracted with MVC W.L.L to establish and manage the "NHRA-MVC" Traceability Hub track and trace system for the Kingdom of Bahrain as per Circular (46) 2020, 11th November 2020.

NHRA understands that implementing end-to-end traceability of medicines without aggregated shipments, introduces some inventory management challenges for Customs, Agents/Distributors, Import Pharmacies, and Dispensers (Pharmacies, Clinics, Hospitals).

We will address these challenges by continuing our phased approach to tracking serial numbers; allowing these groups to utilize the aggregated information related to shipments when scanning their deliveries.

**Phase 1:** Manufacturers/MAHs to implement serialization (per GS1 standards) and send the EPCIS events to the Traceability Hub, by 31st December, 2021. (Reference Circular No. (29) 2021, published 31st October, 2021). **COMPLETED**

**Phase 2:** As stated in Circular No. (46) 2020; Manufacturers/MAHs must aggregate all medicines to cases and pallets, no later than 1st May, 2022. **IN PROCESS**

**Phase 3:** The Aggregation and Blockchain Validation Phase addresses what Customs, Agents/Distributors and Import Pharmacies, and Dispensers (Pharmacies, Clinics, Hospitals) are required to do.

- **For Customs:** Beginning 1st June, 2022, Customs Agents will scan the 2D barcode of the aggregated shipments to authenticate medicine shipments arriving in the Kingdom of Bahrain.
- **For Agents/Distributors and Import Pharmacies:** Beginning 1st June, 2022 Agents/Distributors and Import Pharmacies will scan the 2D barcode on each medicine pallet label shipment received and send that data to the Traceability Hub for validation and also perform this requirement when fulfilling orders for Dispensers.
- **For Dispensers (Pharmacies, Clinics, Hospitals):** Beginning 1st June, 2022 Dispensers (Pharmacies, Clinics, Hospitals) will scan the 2D barcode(s) of delivers they receive for validation by the Traceability Hub. When dispensing medications, the relevant 2D barcode(s) will be further scanned.

Training Guides on how to perform the required scanning will be provided and the NHRA-MVC Team will conduct LIVE testing during February 2022, for those Manufacturers that are already sending aggregation information with their shipments to Agents/Distributors, which all relevant interested parties will be invited to attend. Additional information regarding these live testing events will be provided in January 2022.

**For any questions feel free to contact the NHRA-MVC Team at:**

[nhra-mvc-support@rfxcel.com](mailto:nhra-mvc-support@rfxcel.com).



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