

مكتب الرئيس التنفيذي Chief Executive Office



Circular No. (17) 2022

Date: 10 May 2022

To: All Agents/Distributors (Importers) in the Kingdom of Bahrain and All Invoicing Companies (MAHs, Manufacturers, Exporting Distributors)

Subject: Use of 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 2019 Version 1.2,

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**. The NHRA- MVC team will handle all track and trace system requirements, procedures, reporting specifications, including the registration sign-up process and fee requirements for all Invoicing Companies representing Manufacturers/MAHs.

AGENTS/DISTRIBUTORS should remind all Invoicing Companies (MAHs, Manufacturers, Exporting Distributors) supplying them medicines; that sign-up with NHRA-MVC Traceability Hub is absolutely mandatory. If the Invoicing Company has not signed-up yet; the shipments will be put on hold.

Each Invoicing Company is required to do the following, regardless of any extensions or exemptions their Company has been granted:

- 1. Register in the NHRA-MVC Traceability Hub, which requires a signed Participation Agreement with NHRA-MVC, pay a one-time sign-up fee and pay the annual fee in support of Bahrain's traceability initiative.
- 2. All Invoicing Companies (MAHs, Manufacturers, Exporting Distributors) were required to be fully reporting traceability events no later than **October 2021.**
- **3.** All Invoicing Companies were required to be compliant with Aggregation reporting requirements by **1st May 2022.**

The NHRA-MVC sign-up process, including the Participation Agreement and fee table, are available on the NHRA-MVC website. The One-time sign-up and annual fee are collected during the sign-up process at www.nhra-mvc.bh

Once processed, the NHRA-MVC team will assist all Invoicing Companies through the traceability reporting process, to ensure that their systems have the ability to send appropriate GS1 standard data files to the NHRA-MVC Traceability Hub.

You may contact the NHRA-MVC Team at nhra-mvc-support@rfxcel.com with any questions.

Dr. Mariam Athbi Al Jalahma Chief Executive Officer