

مكتب الرئيس التنفيذي Chief Executive Office



Circular No. (46) 2020

Date: 11th November 2020

To: All Invoicing Companies representing Manufacturers/MAHs

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.

All Invoicing Companies representing Manufacturers/MAHs are required to:

- 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 by **1st January 2021**.
- 2. All Invoicing Companies representing Manufacturers/MAHs are required to be fully reporting traceability events no later than **October 2021.**
- 3. All Invoicing Companies representing Manufacturers/MAHs are required to be compliant with Aggregation reporting requirements by **1st May 2022.**
- 4. A All Invoicing Companies representing Manufacturers/MAHs shall email the name of their contact person, their email address, their phone number and the names of the Manufacturers/MAHs that they represent, **by 15th November 2020**, to: nhra-mvc-support@rfxcel.com

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 representing Manufacturers/MAHs 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.

A series of webinars will be hosted by the NHRA-MVC team to explain the sign-up, fee payment, and onboarding process of the Traceability Hub.

You may contact the NHRA-MVC Team at nhra-mvc-support@rfxcel.com with any questions or to register for upcoming webinars.

Dr. Mariam Athbi Al Jalahma Chief Executive Officer