

Circular No. (42) 2020

Date: September 24, 2020

To: All Pharmaceutical Manufacturers (MAHs)

Sub: 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, you are required to register with the NHRA-MVC Traceability Hub by January 2021 and be certified with GS1 standards no later than 1st October 2021.

All Pharmaceutical Manufacturers (MAHs) are required to register with the NHRA-MVC Traceability Hub by 1st January 2021.

All MAHs are required to sign a Participation Agreement with NHRA-MVC and pay initial registration and annual renewal fees in support of Bahrain's traceability initiative. The fee table will be available on the NHRA-MVC website for your review. The MAHs must be registered and make payments by 1st January 2021. Once processed, the NHRA-MVC team will assist MAHs through the certification process to ensure that their systems have the ability to send appropriate GS1 standard data files to the NHRA-MVC Traceability Hub.

We expect all MAHs to be registered by 1st January 2021

We expect all MAH's to be fully certified no later 1st October, 2021

All system requirements, serialization procedures, reporting specifications, and registration process requirements will be handled by the NHRA-MVC team, with details available on the NHRA-MVC website.

Beginning October 15th 2020, a series of webinars will be hosted by the NHRA-MVC team to explain the benefits of the Traceability Hub.

Additional information regarding registration, submission of information to the NHRA-MVC Traceability Hub, and other topics can be found at www.nhra-mvc.bh You may also contact the NHRA-MVC Team at nhra-mvc-support@rfxcel.com with any questions or comments.



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