**Official Gazette**

**No. 3342 – Thursday 30 November 2017**

**Supreme Council of Health**

## Legislative Decree No. 41 of 2017

## Issuing a Track and Trace System for the Supply Chain of Medicine within the Kingdom of Bahrain

The President of the Supreme Council of Health:

Having reviewed Law No. (18) of 1997 with respect to the Practice of Pharmacists and Pharmaceutical Centers, as amended by Law No. (20) of 2015,

Law No. (38) of 2009 regarding the establishment of the National Health Regulatory Authority (NHRA), as amended by Law No. (32) of 2015,

Legislative Decree No. (5) of 2013 establishing the Supreme Council of Health and its amendments,

The Regulations for the Medicine Registration System in the National Health Regulatory Authority (NHRA) promulgated by Legislative Decree No. (12) of 2015, as amended by Legislative Decree No. (8) of 2017,

And to ensure the quality of medicines in the Kingdom of Bahrain,

And based upon the submission of the Chief Executive Officer of the National Health Regulatory Authority (NHRA), and

Subsequent to the approval of the Supreme Council of Health,

has resolved the following:

### Article (1)

The National Health Regulatory Authority (NHRA) shall apply the Track and Trace system for the supply chain of medicine within the Kingdom of Bahrain from the manufacturing site to the patient (Track and Trace) in accordance with the bylaws and regulations attached hereto.

**Article (2)**

The Chief Executive Officer of the National Health Regulatory Authority (NHRA) shall implement this Decree, which shall come into force from the day following the date of publication in the Official Gazette.

**President of the Supreme Council of Health**
**Lieutenant General**

**Dr. Mohammed bin Abdullah Al Khalifa**

Issued on: 5 Rabia Al-Awwal 1439 Hijri
Corresponding to: 23 November 2017

## Track and Trace System

## For the Supply Chain of Medicine within the Kingdom of Bahrain

### Article (1)

In implementing the provisions of this Decree, the following terms and expressions shall have the below definitions assigned to them, unless the context requires otherwise:

**Kingdom**: Kingdom of Bahrain

**Medicine**: Every pharmaceutical product that is classified, registered and authorised to be circulated as a medicine by the National Health Regulatory Authority (NHRA).

**A Two-Dimensional (2D) Barcode**: A matrix that can accommodate a large number of letters and numbers. It has a high storage capacity for information in a very small space. The data stored in such a matrix can be retrieved through designated barcode readers.

**Authority**: National Health Regulatory Authority (NHRA)

**Distributor**: Manufacturing sites, companies, distributors, importers and storage keepers of medicines, pharmaceutical products and pharmaceutical institutions of all kinds.

### Article (2)

A Distributor shall use the Global Trade Item Number (GTIN) for all Medicines circulated in the Kingdom, whether they are locally produced or finished products imported from abroad, or Medicines manufactured abroad and packaged in manufacturing sites inside the Kingdom.

### Article (3)

Barcode specifications shall be organised as follows:

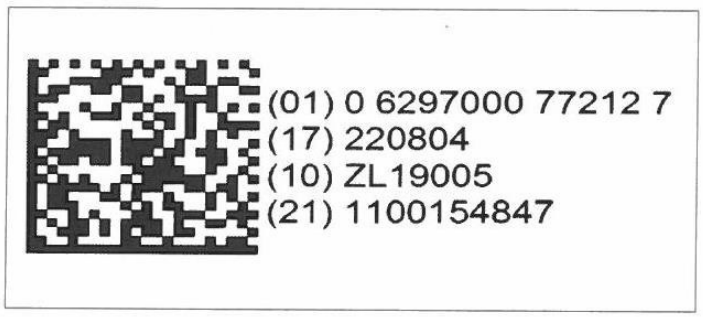
(a) A Two-Dimensional Barcode shall be printed on the packaging of the product in accordance with the specimen issued by Global Standards One (GS1).

(b) The barcode shall contain the following:

1. The Global Trade Item Number (GTIN) of the Medicine.
2. The expiry date of the Medicine.
3. The batch number.

4. The serial number of each package.

This should be completed as follows:




**Article (4)**

The Distributor must comply with the provisions of this Decree as of January 2018, provided that the program shall be fully implemented by no later than 31 December 2019.

**Article (5)**

Subject to Article (4) of this Decree, the Medicine will not be circulated in the Kingdom unless it has a Global Trade Item Number (GTIN).

**Article (6)**

The relevant entity within the Authority shall follow up with the Distributor's implementation of the stages of the Decree and shall prepare comprehensive quarterly periodic reports for the Chief Executive Officer of the Authority to allow him to undertake any necessary procedures in this regard.

**Article (7)**

The Distributor may add any other mark to ensure the quality or safety of its products such as watermarks or any such marks.

**Article (8)**

All Distributors must begin uploading the basic information of their products through the company (GS1UAE) from 1 November 2017, provided that the deadline for the provision of information shall be at the end of April 2018.