United Arab Emirates

Ministry of Health & Prevention

Office of the Minister

[Code: MIO-MOD/2021/88]

Ministerial Decree No. (73) of 2021 Regarding Pharmaceutical Products Traceability

The Minister of Health and Prevention,

Having taken cognizance of:

- Federal Law No. (1) of 1972 Concerning the mandates of ministries and powers of ministers, and its amendments,
- Federal Law No. (18) of 1981 Regulating Commercial Agencies, and its amendments.
- Federal Law No. (3) of 1987 Promulgating the Penal Code, and its amendments.
- Federal Law No. (11) of 1992 promulgating the Civil Procedures Law, and its amendments.
- And Federal Law No. (14) 1995 on Narcotics and Psychotropic Substances, and its amendments.
- Federal Law No. (1) of 2006 on Electronic Commerce and Transactions.
- Federal Law Decree No. (5) of 2012 on Combating Cybercrimes, and its amendments.
- Federal Law No. (4) of 2015 on Private Health Facilities.
- Federal Law No. (8) of 2015 on the Federal Customs Authority.
- Federal Decree-Law No. (4) of 2016 on Medical Liability.
- Federal Law No. (19) of 2016 on Combating Commercial Fraud.
- Federal Law No. 9 of 2017 on Veterinary Products.
- Federal Decree-Law No. (15) of 2018 on the Collection of Revenues and Public Funds.
- Federal Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments.
- Federal Law No. 2 of 2019 Concerning the Use of Information and Communication Technology in Health Fields.
- Federal Law No. (15) of 2020 Regarding Consumer Protection, and its amendments.
- Cabinet Resolution No. (57) of 2018 Concerning the Executive Regulations of Federal Law No. (11) of 1992 on the Civil Procedures Law.
- Cabinet Resolution No. (4) of 2019 on the Procurement and Warehouse Management Regulations at the Federal Government.
- Cabinet Resolution No. 21 of 2019 on the Combat of Narcotics and Psychotropic Substances.
- Cabinet Resolution No. 32 of 2020 Concerning the Executive Regulations of Federal Law No. 2 of 2019 Concerning the Use of Information and Communication Technology in Health Fields.

*In case of any misinterpretation, the Arabic version of this legislation prevails.

- Cabinet Resolution No. (59) of 2020 Regarding Tracking and Monitoring Medications.

And based on the requirements of the public interest,

Have decided as follows:

Article No. (1)

Definitions

1.1 The definitions of the words and expressions contained in Cabinet Resolution No. (59) of 2020 Regarding Tracking and Monitoring Medications referred hereto shall have the same the definitions of the same words and expressions contained in this ministerial decree.

1.2 In the implementation of the provisions of this ministerial decree, the following words and expressions shall have the meanings assigned to each of them, unless the context requires otherwise:

'Tatmeen' Platform	:	It is an e- system that tracks and/or monitors medicines from production place to consumer and/or patient, by linking health authorities, pharmaceutical facilities, health facilities and other entities concerned with trading pharmaceutical products.
Global Trade Item Number (GTIN)	:	It is an internationally recognized identifier placed on the product for the purpose of coding pharmaceutical products.
Uniform Code for Medical Products (UCMP)	:	It is a uniform, non-repeating identifier given to pharmaceutical products, used to identify each medicinal unit or product.
2D Coding System or QR Code	:	"It is a coding method that depends on the photosynthesis of data, such as numbers and letters, that are readable by the electronic devices applicable in this regard."
Global Location Number (GLN)	:	It is an international unified code for the location used in the chain of pharmaceutical products trade, issued by GS1 for the purpose of tracking the transportation of pharmaceutical products among different places.

Article No. (2)

Scope of Application

The provisions of this ministerial decree shall apply to pharmaceutical products that are being traded in the country, subject to the provisions related to the Status Adjustment Time-Limit and Exceptions referred to in Article (6) hereof.

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Article No. (3)

Linking to "Tatmeen" Platform

It is prohibited to import and trade any medicinal product within the country, or to trade any locally manufactured medicinal product, except after linking it to Tatmeen platform and including the medicinal product details in the platform, subject to the provisions related to the Status Adjustment Time-Limit and Exceptions referred to in Article (6) hereof.

Article No. (4)

Coding Mechanism

1. The 2D coding system is applied to all pharmaceutical products in the country, including the Global Trade Item Number (GTIN), which is based on the GS1 standard, as a unified coding for pharmaceutical products that all pharmaceutical facilities, health facilities and other entities concerned with trading in pharmaceutical products shall abide by.
2. The Global Location Number (GLN) is used for the purpose of necessary monitoring of the places where pharmaceutical products are traded from the manufacturing place to the consumer.

Article No. (5)

Coding Specification

The 2D coding specifications include the following details and any future updates made or added thereto:

1. Global Trade Item Number (GTIN) for Pharmaceutical Products.
2. Batch Number.
3. Medicine Expiry Date.
4. The Serial Number of Each Separate Package.

The general form of coding is as follows:

Article No. (6)

Status Adjustment Time-Limit and Exceptions

1. A Status adjustment time-limit of 6 months shall be given from the date of issuance of this ministerial decree, during which all drug manufacturers and holders of marketing rights, desiring to market their pharmaceutical products in the country, must apply the 2D coding system on their pharmaceutical products and upload their product information through the GS1 platform in the country, provided that this information is consistent with the requirements of this ministerial decree. It is prohibited to trade any pharmaceutical products that are not consistent with the provisions of this ministerial decree after the expiry of the aforementioned time-

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limit. Local import and manufacturing can be exempted from the application of this ministerial decree based on the justifications approved by the Drug department at the Ministry of Health and Prevention, as per the evidence approved in this regard.

2. The provisions of this ministerial decree do not apply to pharmaceutical products traded in the country before the expiry of the status adjustment time-limit referred to in Paragraph (1) of this Article, until the quantities supplied of these products at various trading points run out.
3. All entities and establishments that trade in pharmaceutical products in the State must obtain the Global Location Number (GLN). A time-limit of 18 months is given from the date of issuance of this ministerial decree to implement the provisions of this paragraph.

Article No. (7)

Publication and Enforceability of this ministerial decree

This ministerial decree shall be published in the Official Gazette and shall come into force on the day following the date of its publication.

Abdul Rahman Bin Mohammed Al Owais

Minister of Health & Prevention

#Signed#

Issued on: 14/06/2021

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