

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

The Cabinet,

- Having reviewed the Constitution;
- Federal Law No. (1) of 1972 on the Competences of Ministries and the Powers of Ministers, as amended;
- Federal Law No. (14) of 1995 on the Control of Narcotic and Psychotropic Substances, as amended;
- Federal Law No. (1) of 2006 on Electronic Transactions and Commerce;
- Federal Law No. (24) of 2006 on Consumer Protection, as amended;
- Federal Decree-Law No. (5) of 2012 on Combating Cybercrimes, as amended;
- 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 Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Facilities;
- Federal Law No. (2) of 2019 on the Use of Information and Communication Technology in Health Areas; and
- Based on the Proposal of the Minister of Health and Prevention and the Cabinet's approval thereof,

Hereby resolves as follows:

Article (1)

Definitions

For the purpose of applying the provisions of this Resolution, the following words and expressions shall have the meanings assigned thereto respectively, unless the context requires otherwise:

State : The United Arab Emirates.

Ministry : The Ministry of Health and Prevention.

- Minister** : The Minister of Health and Prevention.
- Health Authorities** : Any federal or local government authority in charge of health affairs in the State.
- Electronic Platform** : A central electronic system in the Ministry aiming at tracking and/or monitoring drugs from the plant until the product reaches the consumer and/or patient, through the interconnection between health authorities, pharmaceutical facilities and health facilities.
- Medical Product** : Any medicinal product, medical equipment or product designated for healthcare.
- Medicinal Product** : Any product that contains an active substance or combination of active substances that achieve the intended purpose of its use in or on human beings or animals through a biological effect. Such product is manufactured, sold or offered for use in the following cases:
1. Diagnosis, treatment, curing, alleviation or prevention of diseases; and
 2. Restoration, regeneration, modification or correction of physiological functions.
- Medical Device** : A medical product that any material, apparatus, instrument, machine, implant, reagent or system, including its accessories and software, that achieves the intended purpose of its use in or on human beings or animals without having a pharmaceutical or immunological effect or metabolism. Such product is manufactured, sold or offered for use in the following cases:
1. Diagnosis, treatment, curing, alleviation, monitoring or prevention of a disease, injury or disability.
 2. Investigation, compensation or modification of an anatomical position.
 3. Control of conception.
- Pharmaceutical Product** : A medical product manufactured in a particular pharmaceutical form and designated for specific uses in human beings or animals.

Narcotic and Psychotropic Substances : Medical and medicinal products and other products that contain any active substance, pursuant to Federal Law No. (14) of 1995 on the Control of Narcotic and Psychotropic Substances, as amended.

Dangerous Medical Products : The products which are identified and whose prohibited uses are determined by a resolution to be issued by the Minister.

Defective Product : Any medical product that neither meets the quality requirements nor the requirements set out in Federal Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Facilities, or the implementing regulations or resolutions.

Adulterated Product : A medical product that has been prepared with a deliberate intent of fraud or disinformation, including:

1. Labelling false or incorrect information on its cover, package, label or package insert, concerning its identity or source in an unreal way.
2. Imitating another medical product using the same art forms and colors of the original product package and label.
3. Adding or removing one or more active or inactive components from its formulation labelled on its cover, package, label or package insert without the approval of the competent department of the Ministry.
4. Changing the amount and volume of one or more of its active and inactive components without the approval of the competent department of the Ministry.

Pharmaceutical Facility : A facility licensed to operate in any area of the profession of pharmacy in the State, including any pharmacy, chain of pharmacies, medical warehouse, pharmaceutical lab, pharmaceutical research center, pharmaceutical plant and other facilities defined by the Executive Regulations of Federal Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Facilities.

- Pharmacy** : A facility licensed to store, prepare, formulate, dispense, offer or sell medical products directly to the public, through a fixed or mobile, permanent or temporary facility.
- Chain of Pharmacies** : A group of pharmacies owned by a natural or legal person bearing the same name.
- Medical Warehouse** : A place licensed to store a medical product, pursuant to the provisions of Federal Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Facilities, and the Executive Regulations thereof. A warehouse may be licensed for the purpose of importation and distribution or only for the purpose of distribution.
- Plant** : A facility intended for manufacturing Medical Products in whole or in part.
- Compounding Pharmacy** : A pharmacy licensed to prepare Medical Products, based on medical prescriptions, or to meet the health facilities' needs for the necessary formulations.
- Health Facility** : Any place intended and licensed for conducting medical examination on patients, providing advice to them, assisting in diagnosing their diseases, treating or nursing them, accommodating them for treatment or carrying out any function related to prevention, treatment or rehabilitation, whether such place is owned or managed by a natural or legal person. This definition also includes health facilities of the medical schools operating in the State if they provide any of the abovementioned health services or clinical examinations to patients.

Article (2)

Tracking Drugs

The Ministry shall track, through the Electronic Platform, the manufacture, importation, storage, supply and distribution of Medical Products, Medicinal Products, Pharmaceutical Products, Narcotic and Psychotropic Substances, Dangerous Medical Products and any other Medical Product identified by a resolution of the Minister, in order to monitor the circulation, importation, marketing or distribution of such products by the Pharmaceutical Facilities or Health Facilities to determine all phases of the circulation thereof.

Article (3)

Liabilities

Health Authorities, Pharmaceutical Facilities, Health Facilities and any other authority identified by the Minister, each within its respective area of competence, shall:

1. Use the Ministry's system for the unified coding of Medical Products, Medicinal Products, Pharmaceutical Products, Narcotic and Psychotropic Substances, Dangerous Medical Products according to the international standards adopted in the State.
2. Verify the validity and license of drugs in order to quickly detect Defective Products and Adulterated Products.
3. Track the medicinal stock at the State's level, in the light of a strategic time-bound plan for drug needs.

Article (4)

Issuance of Implementing Resolutions

The Minister shall issue, in coordination with the Health Authorities, the resolutions necessary for implementing the provisions of this Resolution.

Article (5)

Publication and Entry into Force of the Resolution

This Resolution shall be published in the Official Gazette, and shall enter into force as of the day following the date of its publication.

Mohammed bin Rashid Al Maktoum

Prime Minister

Dated: 12th Muharram 1442 AH,

Corresponding to: 31st August 2020 A.D