

Federal Decree-Law No. (28) of 2023 On the Establishment of the UAE Drug Corporation

We, Mohammed Bin Zayed Al Nahyan, President of the United Arab Emirates;

- Upon reviewing the Constitution;
- Federal Law No. (1) of 1972 Concerning the Competences of Ministries and Powers of Ministers, as amended;
- Federal Law No. (2) of 2019 Concerning the Information and Communication Technology in the Health Field;
- Federal Law No. (8) of 2019 Concerning Medical Products, Profession of Pharmacy and Pharmaceutical Facilities, as amended; and
- Based on the proposals of the Ministry of Health and Prevention and the approval of the Cabinet;

Have promulgated the following Federal Decree-Law:

Article (1)

Definitions

In application of the provisions of this Decree by Law, the following terms and expressions shall have the meanings ascribed thereto, unless the context requires otherwise:

State	: United Arab Emirates.
Ministry	: Ministry of Health and Prevention or Ministry of Climate Change and Environment, as the case may be.
Corporation	: The UAE Drug Corporation
Board of Directors (BOD)	: The Corporation Board of Directors

Chairman	: Corporation Chairman of the Board of Directors
Director General	: Director General of the Corporation
Health Authorities	: Federal and local government authorities concerned with health affairs, each within its jurisdiction.
Medical Product	: The product described in Article (2) herein.
Pharmacological product	: Any product that contains an active substance or group of substances that achieves the intended purpose of use thereof in or on the human or animal body through a biological effect, and is manufactured, sold, or offered for use, either with or without a prescription, in the following cases: - Diagnosis, treatment, cure, relief, or prevention of a disease; and - Restoring, renewing, modifying, or correcting the physiological functions. The following shall also be included in Pharmacological Products: Biopharmaceutical Products: Substances made from a living organism, such as vaccines, blood products and derivatives, cell and gene therapy products, and allergen testing products. Food Supplements. Cosmetic products
Medical Equipment	: A medical product that contains a substance, device, instrument, engine, implant, detector, or system, including accessories, and operating software thereof. It shall include wearable devices and products based on AI technology, which shall achieve the intended purpose of its use in or on the human or animal body without a pharmaceutical, immune, or metabolic effect. In

	<p>addition, it is manufactured, sold, or offered for use in the following cases:</p> <ul style="list-style-type: none"> - Diagnosis, treatment, cure, relief, or prevention of a disease, an injury, or a disability; - Detection, modification, or replacement of an anatomical position; and - Birth Control.
Health Care Product	: Any medical product that is used for the general health care of humans or is not intended for the diagnosis, treatment, cure, or prevention of any disease, and does not require a prescription or direct medical supervision when used.
Pharmaceutical Product	: A medical product manufactured in a specific pharmaceutical form and has specific uses in humans or animals.
Veterinary Product	: A substance, a composition of substances, or a material intended for the treatment, prevention, or diagnosis of medical conditions in animals, or for the repair or modification of physiological functions in animals.
Fertilizers	: Materials that are used in any way to provide plants with their nutritional needs, improve growth, increase productivity, and improve the quality of products thereof. They shall include the following: Chemical Fertilizers: Any chemical compounds that are manufactured, either wholly or in part, and supplied to the plant—whether through soil, irrigation water, or leaves—to fulfil its nutritional needs and promote growth, improvement, and increased production. These compounds shall be classified into:

	<p>Compound Chemical Fertilizers: Any manufactured or naturally occurring chemical compounds that contain more than one nutrient that the plant needs for natural growth and development thereof.</p> <p>Simple Chemical Fertilizers: Any manufactured chemical compounds containing a single nutrient that the plant needs for natural growth and development thereof, such as nitrogen, phosphorus, potassium, and micronutrient fertilizers.</p> <p>Organic Fertilizers: Fertilizers and amendments produced from plant or animal waste or a mixture thereof, which contain nutrients for plants and organic substances necessary to improve the biological, physical, and chemical properties of the soil.</p>
Agricultural amendments	: Materials that work to restore the soil, improve properties, and increase productivity thereof, including agricultural environments and beneficial microorganisms.
Plant Growth Regulators	: Compounds with physiological effects that regulate the biological processes in the plant and products thereof. They are used in small quantities to improve plant growth, quantity, and value of production to achieve the best return, such as auxins, cytokinin's, gibberellins, abscisic acid, and ethylene.
Pesticides	: Any chemical, biological or organic substance or mix of substances that contains the active ingredient and the additive in order to prevent, expel, reduce the spread of the pest, control or regulate growth thereof. It shall include the following: Agricultural Pesticides: Materials used to control agricultural pests, such as insecticides, fungicides, herbicides, acaricides, rodenticides, molluscicides, nematocides, bactericides, oils, soil disinfectants, storage disinfectants, and seed disinfectants.

	Public Health Pesticides: Materials used to control public health pests, including pesticides used to control disease vectors inside and outside houses and in public places, and pesticides used to control pests in animal sheds.
Genetically Modified Organism (GMO)	: A living organism that has a new genetic composition that differs from original composition thereof, obtained by using modern biotechnology.
Organism products	: Materials prepared from genetically modified organisms or contain living organisms.
Genetically modified	: Genetically modified, or its derivatives, waste, other products containing it or containing a percentage of the genetically modified component.
Alternative Product	: A pharmaceutical product that is similar to another pharmaceutical product, having the same qualitative and quantitative composition of active ingredients, the same pharmaceutical form, and being bioequivalent thereto.
Innovative product	: Pharmacological products that contain a new active ingredient in whole or in part, and the owner of which holds a patent document.
Pharmacogenomics	: A branch of pharmacology that deals with the impact of genetic variation on drug response in patients by linking gene expression or single nucleotide polymorphisms with drug efficacy or toxicity. The goal of pharmacogenomics is to develop and improve methods to reach the highest level of drug efficacy, taking into

	consideration the patient genetic makeup in order to ensure maximum efficacy with minimal side effects.
Personalized Medicine	: A model of precise medicine that takes into account the variation in genes, environment, and lifestyle to determine the treatment and prevention of disease. This approach aims to accurately predict the most effective personalized interventions for each individual patient, optimizing both treatment outcomes and preventive measures.
Controlled products	: Products and substances whose medical and commercial circulation requires control actions such as: toxic substances and plants, prohibited veterinary substances, narcotic and psychotropic substances, whether they are raw materials or medical products, and dangerous medical products.
Semi-controlled products	: Substances or drugs that are not classified as narcotic or psychotropic substances, but circulation thereof in the state shall be controlled because their misuse may lead to harm to public health.
Chemical precursors	: A chemical substance that is used in any stage of the manufacturing or production of narcotic or psychotropic substances, dangerous substances, psychoactive substances, or toxic substances, in accordance with the specified lists.
Batches	: A specific quantity of a medical product that has been manufactured in a single batch and carries a unique identification number as well as a manufacturing date after passing the necessary inspection and testing stages.

<p>Non-clinical trials</p>	<p>: Toxicology and pharmacological studies to assess the safety of a medical product. Such trials are not conducted on humans.</p>
<p>Clinical trials</p>	<p>: Controlled trials or research on a specific medical product that are conducted on groups of humans to determine how it is absorbed, metabolized, distributed, and eliminated from the body, to identify basic effects, side effects, and adverse interactions thereof. With the aim of verifying the effectiveness, efficiency, quality, and safety of using the medical product within the approved uses according to the marketing approval granted to the medical product, or for new uses or drugs under research and development. Such trials include clinical trials without intervention. They are clinical trials using medical products within the dosages and methods of use for uses that are consistent with marketing approval thereof in the State. They do not require any change in the participant medical prescription or normal lifestyle thereof.</p>
<p>Marketing approval</p>	<p>: The approval granted by the Corporation to a legal entity licensed in the State to market a specific medical product. This legal entity shall be responsible for all aspects of marketing, promotion, and follow-up of the product in the State. The approval shall include a special appendix that contains all the details related to the product, prescription thereof, the composition of the active and inactive ingredients and their quantities; as well as the use and dosages, the methods of use, the effects and side effects, and any other details in accordance with the legislation applicable in this regard.</p>
<p>Contract</p>	<p>: Companies contracted to re-engineer and accelerate the</p>

**development and
Manufacturing
Organizations
(CDMOs)**

processes of innovation, development, and manufacturing of medical products. CDMOs include:

Contract Research Organizations (CROs): A person or company that is contracted to carry out one or more of the obligations of a clinical trial sponsor.

Contract Site Management Organizations: A person or company that is contracted to provide administrative services related to the management of clinical trial sites, and shall not bear any of the regulatory obligations of the clinical trial sponsor. It may have a network of clinical research sites managed thereby, and its services include: identifying or managing principal and secondary researchers, recruiting study staff, preparing submissions to institutional review committees and boards, assisting in project feasibility, patient recruitment, study site launch and close-out, or any other study-related activities at the study site.

Contract Development and Manufacturing Organizations: Companies contracted by major pharmaceutical companies to provide comprehensive services from development to manufacturing of medical products. These services can help with scalability or allow the major company to focus on drug discovery and drug marketing instead. The services shall include: Pre-product development services, technical studies related to the product, materials, manufacturing methods, registration, and commercial production.

Article (2)

Scope of Application

1. This Decree by Law shall apply to the following medical products in all areas of the State, including free zones:
 - a. Pharmacological products;

- b. Medical Equipment;
 - c. Pharmaceutical Products;
 - d. Health Care Products;
 - e. Biopharmaceutical Products;
 - f. Food Supplements;
 - g. Cosmetics;
 - h. Veterinary Products;
 - i. Fertilizers;
 - j. Agricultural Amendments;
 - k. Plant Growth Regulators;
 - l. Pesticides; and
 - m. Genetically Modified Organisms (GMOs) and products thereof.
2. The Cabinet may add any other medical products to those referred to in paragraph (1) of this Article.

Article (3)

Corporation Establishment

Pursuant to the provisions of this Decree by Law, a federal institution called “UAE Drug Corporation” shall be established. It shall be affiliated to the Cabinet, and shall have independent legal personality, financial and administrative independence, and the legal capacity necessary to carry out all legal acts and transactions that ensure the implementation of powers thereof.

Article (4)

Corporation Headquarters

The Corporation headquarters shall be within the Emirate of Abu Dhabi. The Corporation may establish branches or other offices thereof within the State or abroad, upon a resolution by the BOD.

Article (5)

Corporation Purposes

The Corporation aims to contribute to improving public health levels and making the State a trusted global center for the pharmacological and medical industries by achieving the following:

1. Promoting research and development in the pharmacological and medical products sector and attracting leading investments in the research and pharmacological and medical industries sector.
2. Strengthening the local industrial capacity in the areas of developing, producing, and exporting high-quality medical and pharmacological products at an efficient cost.
3. Supporting medicine security in the State and ensuring the availability, quality, efficacy, safety, and reliability of medical and pharmacological products, as well as their effectiveness and impact on therapeutic and preventive health and the overall health level of the State.
4. Effective national management of the procedures for developing, approving, manufacturing, marketing, and trading medical and pharmacological products at standard times and costs, and in accordance with the best international standards and practices.

Article (6)

Corporation Powers

The Corporation shall be the federal authority responsible for regulating medical products in the State. To this end, the corporation shall be entitled to the following:

1. Propose and develop policies, strategies, and legislation related to medical products in the State, in coordination with the Ministry, Health Authorities, and relevant entities, and work to implement them after they are approved by the Cabinet;
2. Prepare and issue the national framework for pharmacological research and clinical and non-clinical trials, including identifying research and clinical and non-clinical trial priorities, ethical rules, procedures, funding mechanisms, and governance thereof in accordance with the best international standards and practices. In Addition to

- supervising implementation thereof;
3. Approve entities authorized to conduct pharmacological research and clinical and non-clinical trials in the State, issue the necessary permits and approvals for conducting those research and studies, and monitor and supervise compliance with the terms of the licenses and approvals issued in accordance with the relevant legislations;
 4. Establish specialized research centers in partnership and coordination with hospitals, specialized centers, and academic, research, and scientific institutions concerned inside and outside the State;
 5. Develop and issue the national framework for testing medical products at all stages, and to supervise implementation thereof, after coordination with the Ministry, Health Authorities, and relevant entities;
 6. Conduct tests on medical products at all stages, approve medical product testing laboratories, and monitor and supervise them in accordance with the relevant legislations;
 7. Approve and register medical products and supervise them in accordance with the relevant legislations;
 8. Establish a pricing system for medical products in the State, in coordination with the relevant entities;
 9. Establish the conditions, standards, and requirements for good manufacturing practice and the development and innovation of medical products, and supervise them in accordance with the relevant legislations;
 10. Issue licenses for factories, compounding pharmacies, contract companies supporting the development and manufacture of medical products, medical product companies, pharmacies, pharmaceutical consulting offices, warehouses, stores, marketing offices, blood banks, and cord blood and stem cell storage centers. In addition to supervising the compliance of such facilities with the conditions and standards of licensing in accordance with the relevant legislations;
 11. Issue marketing approvals for medical products and license marketing advertisements thereof, and supervise compliance with the conditions of the approvals and licenses issued in accordance with the relevant legislations;
 12. Issue permits and approvals related to the import, export, re-export, manufacture, sale,

- distribution, display, possession, trade, storage, and disposal of medical products, including controlled products, semi-controlled products, and chemical precursors used in the manufacture of medical products. In addition to monitoring and supervising compliance with the conditions of the permits and approvals issued in accordance with the relevant legislations;
13. Propose and prepare lists of controlled products, semi-controlled products, and chemical precursors used in the manufacture of medical products, as well as any updates thereto, in coordination with Health Authorities and relevant entities, and submit them to the Cabinet for approval;
 14. Establish and manage a national system for tracking and monitoring medical products from the manufacturer to the consumer;
 15. Create a national pharmacogenomics database that contributes to the development of more efficient drugs and treatments, and enhances the application of personalized medicine in the State;
 16. Propose incentives and financial and non-financial benefits that enhance the attractiveness of investment in the medical industries sector, and submit them to the Cabinet for approval;
 17. Develop a national pharmacovigilance system to ensure the quality, efficacy, and safety of medical products, including mechanisms for managing reports of negative and harmful outcomes of these products at any stage of development and circulation thereof, mechanisms for investigation and field inspection. As well as resulting procedures of banning import, suspending distribution, preventing circulation, suspending, withdrawing, or recalling products, and supervising the implementation of the national system, in coordination with Health Authorities, entities, and regional and international organizations concerned.
 18. Develop the national policy related to determining the levels of the strategic stock of medicines and medical supplies, and follow up on implementation thereof, in coordination with the National Emergency Crisis and Disaster Management Authority, Health Authorities, and relevant entities at the federal and local levels;
 19. Regulate and manage medical product data, in accordance with the highest international standards for data protection and maintaining confidentiality thereof. In

- addition to organizing the scope and purposes of data processing, use, and disclosure, in a manner that supports the protection of data owners within and outside the State, without prejudice to the applicable legislation on data and information protection;
20. Conduct specialized studies and researches in the fields related to the powers of the Corporation including, monitoring and analyzing the regional and international phenomena, risks, and guidelines;
 21. Propose the accession to, the international treaties and agreements or signing thereon, as well as suggesting the memoranda of understanding and partnership agreements with countries and regional and international organizations and bodies related to the Corporation powers, or joining them, in coordination with the Ministry of Foreign Affairs.
 22. Represent the State in the regional and international organizations, exhibitions and conferences in the Corporation areas of competence, in coordination with Ministry of Foreign Affairs;
 23. Hold conferences, seminars and workshops related to the Corporation field of work, in coordination with the relevant entities in the State;
 24. Establish and manage a comprehensive database of data and information related to the Corporation powers, in coordination with the Ministry, Health Authorities, and relevant entities, and to achieve integration in the exchange of data and information;
 25. Establish institutions and companies on its own or in partnership with others, both inside and outside the State. As well as owning shares in companies and institutions, in accordance with the regulations approved by the Cabinet in this regard;
 26. Impose administrative penalties on violators of the laws and regulations related to medical products, in accordance with the relevant legislations; and
 27. Any other powers assigned thereto in accordance with laws or regulations and resolutions issued by the Cabinet.

Article (7)

Board of Directors (BOD)

1. The Corporation shall have a BOD to be formed by a Cabinet resolution. The said resolution shall determine the Chairman and deputy thereof, the remuneration of its members, the term of membership, working system, and the mechanism for decision-making thereof.
2. The Board of Directors shall have a chairman, whose rank shall be determined in the appointment resolution thereof.

Article (8)

Powers of the Board of Directors (BOD)

The Board of Directors shall be the supreme authority of the Corporation, and it shall be responsible for managing affairs thereof. To that end, it shall undertake the following:

1. Approve the policies, strategies, and legislations related to the powers entrusted to the Corporation, in coordination with the relevant entities in the State, and submit them to the Cabinet for approval;
2. Approve the general policy of the Corporation, strategic plans, programs, and projects thereof, in accordance with the procedures followed in this regard;
3. Approve the laws, regulations and work plans necessary for the proper progress of work in the Corporation;
4. Approve the organizational structure of the Corporation and submit it to the Cabinet for approval;
5. Approve the Corporation draft annual budget and final account and submit them to the Ministry of Finance to include them in the Budget Law and Consolidated Final Accounts Law;
6. Issue a table of financial powers, delineating spending limits, expenditure categories, and authorized signatories at banks;
7. Approve the financial and human resources regulations of the Corporation, and submit the same to the Cabinet for approval;
8. Propose to sign or join international agreements and treaties related to activities and

- competencies of the Corporation, in coordination with the Ministry of Foreign Affairs and other concerned authorities;
9. Seek the assistance of technical experts, scientists, and specialists it deems appropriate to assist the Corporation in carrying out tasks thereof;
 10. Nominate of the Corporation Director General;
 11. Appoint one or more external auditors, if necessary, and determine fees thereof, to audit the Corporation accounts in accordance with generally accepted accounting laws, regulations, and principles.
 12. Form permanent or temporary committees and work teams to enable the Corporation to carry out powers thereof, and to define the functions of such committees, work teams, and work system thereof;
 13. Suggest fees for the services provided by the Corporation and raise the same to the Minister of Finance for presentation to the Cabinet for approval;
 14. Accept gifts, donations, grants, and aid in accordance with the powers of the Corporation, and in accordance with the relevant legislation; and
 15. Any other powers authorized thereto in accordance by virtue of the laws or regulations or the resolutions issued by the Cabinet.

Article (9)

Director General

The Corporation shall have a Director General with the rank of Under-secretary, whose appointment shall be by a federal decree, based on the recommendation of the BOD. Director General shall undertake the following tasks:

1. Propose the Corporation policies, strategies, plans, and programs, submit them to the BOD, and supervise implementation thereof after being approved;
2. Propose draft laws, decrees, regulations and executive resolutions related to the Corporation, and submit them to the BOD to take the necessary actions in their regard;
3. Propose the Corporation organizational structure and present it to the BOD to take the necessary measures regarding it;
4. Follow up on the preparation of the annual budget draft and the final account of the

Corporation and submit them to the BOD, and follow up on the implementation of the budget within the appropriations established for it;

5. Supervise and empower the organizational units affiliated thereto, follow up on their achievements and performance results, and propose the necessary systems and procedures to contribute to improve and develop performance;
6. Represent the Corporation before all parties inside or outside the State, and in its relationship with others and before the judiciary;
7. Submit periodic and annual reports related to the Corporation work progress, and present the same to the BOD; and
8. Any other duties, competencies, and powers assigned to the Corporation by virtue of laws or regulations, or by the Chairman.
9. The Director General may delegate some of duties or powers thereof to any staff member of the Corporation as appropriate, provided that the delegation shall be in writing and specific.

Article (10)

The human resources, financial, contractual, accounting, and procurement legislation applicable in the federal government shall apply to the Corporation, unless a special provision is provided for herein or in the rules and regulations issued in implementation thereof.

Article (11)

Financial Resources

The Financial resources of the Corporation shall consist of the following:

1. The annual appropriations allocated to the Corporation in the State general budget;
2. The annual revenues and returns that achieved by the Corporation from the activities carries out thereby and fees for the services provided thereby;
3. Gifts, donations, grants and aid accepted by the BOD;
4. Any other resources the Corporation achieves from exercising powers thereof;

Article (12)

Fiscal Year

Fiscal Year of the Corporation shall commence on the first of January and end on the thirty-first of December of each year, provided that the first fiscal year of the Corporation shall commence on the date the provisions of this Decree by Law come into force and end on the thirty-first day of December of the following year.

Article (13)

Oversight of the Corporation

The Corporation shall be subject to the oversight of the Supreme Audit Institution, and it shall provide the Supreme Audit Institution with all the data or information requested thereby regarding the Corporation business.

Article (14)

Judicial Enforcement

The Corporation employees who are designated by a resolution of the Minister of Justice in agreement with the Chairman shall have the capacity of judicial control officers in establishing violations within their jurisdiction of the provisions of this Decree by Law and other resolutions and laws issued in implementation thereof.

Article (15)

General Provisions

1. The Corporation shall succeed the Ministry of Health and Prevention and the Ministry of Climate Change and Environment in all rights, obligations, and legal matters pertaining to the regulation and management of medical products. This includes the rights and obligations outlined in any contracts, agreements, or memoranda of understanding associated with such affairs.
2. The employees of the organizational units concerned with the competences of the Corporation at the Ministry of Health and Prevention and the Ministry of Climate Change and Environment, who are to be transferred in coordination between the

Ministry and the Corporation, shall be transferred to the Corporation by virtue of a Cabinet resolution, with the same ranks, total salaries, and benefits determined for them upon the issuance of this Decree by Law.

3. All assets, appropriations, allocations and financial budgets allocated for the affairs of regulating and managing medical products at the Ministry of Health and Prevention and the Ministry of Climate Change and Environment shall be transferred to the Corporation by virtue of a Cabinet resolution.

Article (16)

Executive Resolutions

The Cabinet shall issue the resolutions necessary to implement the provisions of this Decree by Law, and for that effect, the Cabinet may assign the Ministry of Health and Prevention and the Ministry of Climate Change and Environment or any other entity to exercise the competences stipulated herein until the Corporation carries out all its operations.

Article (17)

Delegation of Competences and Outsourcing Services

The Corporation may, upon the approval of the Cabinet, delegate some of its competences to any federal or local government entity. The Corporation may also outsource some of its and services to any other government or private entity upon the approval of the Cabinet.

Article (18)

Repeals

1. Any provision that violates or contradicts the provisions of this Decree by Law shall be repealed.
2. The resolutions and laws related to the affairs of regulation and management of medical products issued prior to the enforcement of the provisions herein, shall remain in force until the issuance of resolutions and laws that replace them in accordance with the provisions outlined in this Decree by Law

Article (19)

Publication and Entry Into Force of Decree by Law

This Decree-Law shall be published in the Official Gazette, and shall come into effect from the day following the date of its publication.

Mohammed Bin Zayed Al Nahyan
President of the United Arab Emirates

Issued by us at the Presidential Palace in Abu Dhabi:

Dated: 10 Rabi' I 1445 H

Corresponding to: 25 September 2023