

In the Name of Allah, the Most Merciful, the Compassionate,

**Arab Republic of Egypt**

**Presidency of the Republic**

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**Egyptian Drug Authority (EDA)**

**Decree No.315 of 2021**

**On Regulating Scientific Offices**

**President of Egyptian Drug Authority,**

**After perusing Law No. (127) of 1955 on Pharmacy Profession Practice and its amendments;**

**Law No. (212) of 1960 on Regulating, Trading and Distributing Drugs, Chemicals, and Medical & Chemical Devices and its amendments;**

**Law No. (113) of 1962 on Reorganizing Importation, Manufacturing, and Trading of Drugs, Medical and Chemical Devices;**

**Law No. (120) of 1982 on Regulating Activities of Commercial Intermediary and Mandate and its executive regulation;**

**Law No. (121) of 1982 on Regulating Importers' Register and its Executive regulation;**

**Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019 and its Executive Regulation;**

**Decree of the Minister of Health No. (429) of 1976 on Regulating Scientific Offices of Advertising Affairs for Drugs and Medical Devices; and**

**Having considered the interest of work;**

**has decided:**

**(Article One)**

**In the implementation of this DECREE provisions, a Scientific Office is any office that practices advertising activities for medical products and devices , medical chemicals, biological products, cosmetic products, and related products, and fulfills the requirements of such publicity, including providing members of medical professions' associations and other concerned persons with scientific information related to products, Devices and drugs produced or used by the factories to which these offices are affiliated through various media means such as conducting lectures,**



holding scientific symposia, supporting scientific research, screening movies, distributing leaflets and free samples, and other media methods and means..

By a decree of the president of the Egyptian Drug Authority, a scientific office shall be granted a license to register pharmaceutical or biological products or medical devices in its name and for itself, provided that such products or devices shall be imported and the stated charge of the service shall be paid.

(Article Two)

Pursuant to the provisions of the above-mentioned Law No. (151) of 2019 and the resolutions regulating importing medical products and devices, a license to establish a scientific office shall only be granted to companies producing medical products or devices and any other related products, be they local or foreign, or to authorized and delegated commercial agents of such companies that have obtained the required license from the competent administration of the Egyptian Drug Authority. In all cases, a person applying for a license to establish a scientific office must be a member of one of the medical professions' associations.

(Article Three)

A scientific office may not be established unless it obtains a license issued by a decree from the chairman of the Board of Directors of the Egyptian Drug Authority. The following are the requirements of obtaining a license:

(a) A license application shall be filled in the appropriate form and be submitted to the competent administration of the Egyptian Drug Authority. A license application shall include the essential information of the scientific office, including but is not limited to:

- 1- Address of the scientific office to be licensed.
- 2- Name of the company that produces the medical products and devices or a statement of a valid and certified trade agency.
- 3- Specifying the targeted activities of establishing the scientific office.
- 4- Attestation by the legal representative of the office that he has perused all laws and regulations pertinent to advertising and promoting medical products and devices, and that he shall abide by their provisions.

(b) The competent administration of the Egyptian Drug Authority shall verify the fulfillment of the conditions prescribed under the Law on Pharmacy Profession



Practice and other resolutions issued for its implementation, as regards registering, storing and distributing the product samples. The competent administration shall also verify the availability of all technical and health standards of the storehouse of the samples, in terms of the requirements of good storage in accordance with the applicable laws and resolutions regulating these affairs, with the exception of the condition of area.

(Article Four)

Each and every scientific office shall establish a storehouse for keeping drug samples in the appropriate technical ways. A sample storehouse in a scientific office shall be deemed a pharmaceutical institution governed by the provisions of Law No. (127) of 1955 and its amending laws and resolutions.

A sample storehouse may be located inside or outside the premises of the scientific office, provided that the area of the storehouse shall 25 m<sup>2</sup> at least.

A scientific office shall abide by observing the following:

(a) Storing samples shall be in accordance with the appropriate technical standards prescribed in the Law on Pharmacy Profession Practice and its implementing regulations.

(b) Bookkeeping a sample register whose pages shall be numbered and stamped with the seal of the competent administration of the Egyptian Drug Authority to record the movement of samples in the entries of received, issued and remained items.

(c) Submitting a monthly statistical statement on the movement of samples to the competent administration of the Egyptian Drug Authority.

(d) Dispensing free medical samples shall be only for the eligible persons who are authorized by Law to receive free medical samples.

(Article Five)

Samples of medical products and devices brought by a scientific office to be used for advertising purposes shall be stamped on their inside and outside parts by a hard-to-remove seal to state that these samples are free and are not authorized for sales.



The seal may be replaced with a water mark or any other device legalized by the competent Administration of the Egyptian Drug Authority.

(Article Six)

A scientific office shall obtain a permission from the competent administration of the Egyptian Drug Authority to import each and every drug sample consignment. Upon granting such a permission, the administration shall conform to the applicable rules and systems. The word 'samples' shall mean all items imported to advertise for the medical products and devices.

(Article Seven)

Customs clearance of a consignment of medical products and devices imported to a scientific office may not be granted except in the presence of a representative of the competent administration of the Egyptian Drug Authority. The samples shall be stamped with the customs' seal when they are delivered to him. The receiving scientific office shall undertake that it shall not use the samples of this consignment until the competent administration unseals these samples and duly conducts its inspection to ensure that these samples are useable enough to meet the standards of the applicable laws and rules.

(Article Eight)

The Egyptian Drug Authority may take a percentage of the medical samples allocated for advertising affairs. Such percentage shall be specified by a committee which is formed by a decree from the chairman of the Board of Directors of the Egyptian Drug Authority. Such percentage may not exceed (25%) of the imported free sample quantity; it shall be distributed freely for the purposes stated by the committee and it shall be stored in the Authority storehouses.

(Article Nine)

The aforementioned committee shall convene whenever necessary at the headquarter of the Egyptian Drug Authority. Apart from its above-mentioned role, this committee shall be concerned with developing a system for storing the authority's allocation of these samples, specifying the ways of distributing these samples and defining the bodies that shall receive these samples to ensure that they are used for their intended purposes.



(Article Ten)

A scientific office shall adhere to the applicable rules and regulations of the competent administration of the Egyptian Drug Authority concerning the material used in the activities of publicity, education, awareness, and providing members of medical professions' associations and other concerned persons with scientific information, movies, leaflets and other advertising substances through the various means of media.

A scientific office prohibited to do any of the following:

- a) Advertising for items that have not been registered at the Ministry of Health in accordance with the provisions of the Law on Pharmacy Profession Practice or advertising for items whose importation is prohibited.
- b) Advertising for items of companies that are not incorporated in the Scientific Office License, or keeping samples of these companies' products in the sample storehouse.
- c) Advertising for its products only in medical fields or specialized periodicals in a way that suits the nature of the products being advertised.
- d) Advertising for its products only after obtaining a prior consent of advertising from the competent administration of the Egyptian Drug Authority.

(Article Eleven)

A scientific office shall notify the competent administration of the Egyptian Drug Authority every six months with a statement identifying the new products and devices produced by the companies to which the office is affiliated and reporting on research conducted on these products.

A scientific office shall also periodically notify the said competent administration every three months at most of dormant items, stored items, registered items, and the items that have ceased to be imported.

The said competent administration shall notify scientific offices of the procedures and resolutions it adopts regarding these drugs and products.

(Article Twelve)

A person appointed to a job in a scientific office shall fulfill the following conditions:



- a) The applicant must be a national of The Arab Republic of Egypt.
- b) The applicant must be of good conduct and must have a good reputation.
- c) The applicant must be technically and highly qualified at the branch of the office activities if he is to be appointed to the position of the Director of the Scientific Office or to the technical positions therein.

The Director of the Scientific Office must be a member to the union of medical professions' associations. The manager of the storehouse affiliated to the scientific office must be a full-time pharmacist.

Both positions may be combined and held by one person, provided that the person occupying both positions shall be a full-time pharmacist, and the storehouse location is inside the premises of the scientific office.

- d) The applicant must never have been convicted of a criminal offence or sentenced to imprisonment for an offence prejudicial to honor or integrity, unless he has been officially rehabilitated.

The competent administration of the Egyptian Drug Authority shall be notified when a technical employee is appointed in a scientific office.

**(Article Thirteen)**

A scientific office shall be administratively and financially affiliated to the only agent that has the license if there is an agent available; otherwise the scientific office shall be affiliated to the produced company.

**(Article Fourteen)**

A license may be given to establish a special joint office for a number of companies or factories. In such a case, the license must identify the names of these joint companies which share the office along with the amount of expenses that each company or factory bears in the office.

**(Article Fifteen)**

A licensed scientific office may apply to the competent administration of the Egyptian Drug Authority to license some other branch offices affiliated to the scientific office throughout the Republic, provided that every branch office shall have their own managers.



A branch office may include an annex storehouse of medical samples, provided that this storehouse shall fulfil all the conditions pertinent to the storehouse of medical samples, and that a pharmacist shall be appointed to be responsible for each storehouse of medical samples.

A branch office may be established without a storehouse of medical samples (a reception hall) provided that this branch office shall be administratively and financially affiliated to a licensed main scientific office.

(Article Sixteen)

In its work, a scientific office may not appoint, hire, or second an employee from government or public business sector, even temporarily.

(Article Seventeen)

The Egyptian Drug Authority shall have the right to supervise scientific offices to ensure that this DECREE is implemented and shall have the right to technically inspect storehouses of medical samples affiliated to scientific offices and their records. It shall have the right to ensure that the provisions prescribed in laws and resolutions are implemented in accordance with the rules stated in the Law on Pharmacy Profession Practice and the Law on Establishing Egyptian Drug Authority and their executive resolutions.

(Article Eighteen)

A license of a scientific office may be cancelled upon a decree from the chairman of the Board of Directors of the Egyptian Drug Authority in the following cases:

- 1- If a scientific office does not make use of the license within six months from the date of its issuance.
- 2- If a scientific office closes for a period more than one Gregorian calendar year.
- 3- If the headquarter of the licensed office is moved from its premises stated in the license to another place without the prior consent of the competent administration.
- 4- If a scientific office suspends its activities for a continuous period of six months without a valid permission submitted by the director of the scientific office to the competent administration.



- 5- If a scientific office is engaged in trading in the free samples of the medical products or devices allocated for advertising or in offering these samples for sale.
- 6- If a scientific office is devoid of any firms to represent or any registered pharmaceutical products or devices to advertise.
- 7- If a scientific office fails to fulfill the license requirements, as provided for in Article Three of this DECREE.
- 8- If a scientific office fails to fulfill the conditions of storing samples, as provided for in Article Four of this DECREE.
- 9- If a scientific office fails to fulfill the procedures of importing samples, as provided for in Article Six and Article Seven of this DECREE.
- 10- If a scientific office fails to fulfill the advertising and promotion conditions, as provided for in Article Ten of this DECREE.
- 11- If a scientific office fails to notify of the new products and devices, as provided for in Article Eleven of this DECREE.
- 12- If a scientific office fails to conform to the conditions of appointment, as provided for in Article Twelve of this DECREE.
- 13- If a scientific office maliciously violates the applicable conditions of registering pharmaceutical products, biological products or medical devices, in a way that resulted in a wrongful registration of a pharmaceutical product, a biological product or a piece of medical devices in the name of the scientific office, which is contrary to the truth.
- 14- If a scientific office breaches the provisions of this DECREE, the provisions of Law No. (127) of 1955, Law No. (151) of 2019 or any other relevant laws, or applicable regulations or resolutions.

Cancellation shall be mandatory if a scientific office fails to redress the balance of its situations within six months at most and in case an offence is repeated.

(Article Nineteen)

The legal representative of a scientific office may file a grievance against the decrees and resolutions of the Authority to the ad hoc committee of grievance within sixty days of their issuing date in accordance with the proper procedures and fees specified in the Executive Regulation of Law No. (151) of 2019, issued by Prime Minister's Decision No. (777) of 2020.

(Article Twenty)



Scientific Offices shall redress the balance of their situations within six months from the date of the issuance of this DECREE and they shall notify the competent administration of the Egyptian Drug Authority of their new situation.

(Article Twenty-one)

Any provision that contradicts the provisions of this DECREE shall be null and void.

(Article Twenty-two)

This DECREE shall be published in *Al-Waqa'i' al-Misriyya* 'Egyptian Chronicles, the Supplement of the Official Gazette' and shall enter into force as of its publication date.

President of Egyptian Drug Authority

Prof. Tamer Mohamed Essam

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