2 Al-Waqa'i' Al-Masriya – Issue No. 155 (Supplement A), dated 12 July 2021

Egyptian Drug Authority
Decision No. (315) of 2021
Regarding the Regulation of Scientific Offices

The Chairman of the Egyptian Drug Authority,

Having reviewed:

- Law No. (127) of 1955 concerning the Practice of the Pharmacy Profession, and the amending laws thereof;

- Law No. (212) of 1960 concerning the regulation of the trade and distribution of drugs, chemicals, medical supplies, and pharmaceutical chemicals, and the amending laws thereof;

- Law No. (113) of 1962 concerning the reorganization of the importation, manufacture, and trade of drugs, medical supplies, and pharmaceutical chemicals;

- Law No. (120) of 1982 regulating commercial agency and brokerage activities, and its Executive Regulations;

- Law No. (121) of 1982 regulating the Importers' Register, and its Executive Regulations;

- The Law establishing the Egyptian Drug Authority promulgated by Law No. (151) of 2019, and its Executive Regulations;

- Minister of Health Decree No. (429) of 1976 regulating scientific offices for pharmaceutical and medical supplies promotion;

- And in the interest of proper workflow;

Resolved as Follows:

(Article 1)

For the purposes of applying the provisions of this Decision, a scientific office shall mean any office that carries out marketing and promotional activities for pharmaceutical products, medical devices, pharmaceutical chemicals, biological products, cosmetics, and related products. Such promotion includes providing members of medical professional syndicates and other concerned parties with scientific information on the products, devices, and medicines produced or used by the factories affiliated with such offices, through various media, including delivering lectures, holding scientific seminars, assisting in scientific research, screening films, distributing brochures and free samples, and other media methods and tools.

By virtue of a Decree of the Chairman of the Egyptian Drug Authority, a scientific office may be authorized to register pharmaceutical, biological products, or medical devices in its own name and for its own account, provided that such products or supplies are imported, and after payment of the prescribed service fee.

(Article 2)

A license to establish a scientific office shall be granted only to companies producing pharmaceutical products, medical devices, or related products, whether local or foreign, or to commercial agents duly accredited and authorized by such companies, and licensed accordingly by the competent administration of the Egyptian Drug Authority in application of the provisions

of Law No. (151) of 2019 referred to above and the regulatory decisions governing the importation of pharmaceutical products and medical devices. In all cases, it shall be a condition for granting a license to establish a scientific office that the licensee be a member of one of the medical professional syndicates.

(Article 3)

No scientific office may be established except after obtaining a license issued by a Decree of the Chairman of the Board of Directors of the Egyptian Drug Authority. The following conditions shall be met for granting such license:

(a) Submission of a license request to the competent administration of the Egyptian Drug Authority on the form prepared for this purpose, provided that the request includes the basic data of the scientific office, including:

1. The address of the scientific office to be licensed;

2. The name of the company producing the pharmaceutical products or medical devices, or proof of a valid and accredited commercial agency;

3. Specification of the intended activities for establishing the scientific office;

4. A declaration by the legal representative of the office confirming that they have reviewed all laws and regulations governing promotion and advertising of pharmaceutical products and medical devices, and undertaking to comply with their provisions.

(b) Verification by the competent administration of the Egyptian Drug Authority that the conditions stipulated in the Law regulating the Practice of the Pharmacy Profession and the decisions issued in implementation thereof are met, with regard to registration, storage, and distribution of samples, as well as verification that all health and technical requirements for the sample store are fulfilled in accordance with the applicable laws and regulatory decisions governing such regard, with the exception of the area requirement.

(Article 4)

A sample store shall be established in each scientific office for the proper technical storage of drug samples. The sample store of the scientific office shall be deemed a pharmaceutical institution subject to the provisions of Law No. (127) of 1955 and the amending laws and decisions thereof. The free medical sample store may be located within or outside the premises of the scientific office, provided that the storage area shall not be less than 25 square meters.

Scientific offices shall be obliged to comply with the following:

(a) Store samples in accordance with the technical principles stipulated in the Law regulating the Practice of the Pharmacy Profession and the decisions issued in implementation thereof.

(b) Maintain a sample register with numbered pages stamped with the seal of the competent administration of the Egyptian Drug Authority to record the movement of samples by registering incoming, outgoing, and remaining balances.

(c) Submit a monthly statistical statement to the competent administration of the Egyptian Drug Authority regarding the movement of such samples.

(d) Not to dispense free medical samples except to persons legally permitted to receive them.

(Article 5)

Samples of pharmaceutical products and medical devices imported by the scientific office for use in its promotional activities shall be sealed internally and externally with a seal that is not easily removable, stating that such samples are free of charge and not authorized for sale.

The seal may be replaced with a watermark or any other means approved by the competent administration of the Egyptian Drug Authority.

(Article 6)

The scientific office shall obtain permission from the competent administration of the Egyptian Drug Authority to import each consignment of drug samples. In granting such permission, the administration shall observe the applicable rules and systems.

For the purposes of this Article, the term samples shall mean all items imported for the promotion of pharmaceutical products and medical devices.

(Article 7)

Customs release of consignments of samples of pharmaceutical products and medical devices received to a scientific office shall not be effective except in the presence of a representative of the competent administration of the Egyptian Drug Authority. Upon delivery, the consignment shall be sealed with the customs seal, and a committment shall be obtained not to use the samples contained in the consignment until the competent administration removes the seals and carries out the required inspection to verify their suitability for use in accordance with the applicable laws and regulations.

(Article 8)

The Egyptian Drug Authority may obtain a percentage of the medical samples intended for promotional purposes, to be determined by a committee formed by a decision of the Chairman of the Board of Directors of the Authority, provided that such percentage shall not exceed (25%) of the imported quantity. This percentage shall be distributed free of charge for purposes determined by the committee and shall be stored in the Authority's warehouses.

(Article 9)

The aforementioned committee shall convene at the Egyptian Drug Authority whenever necessary and shall, in addition to the foregoing, be responsible for establishing the system for storing the Authority's share of such samples, determining the method of their distribution, and specifying the entities to which such samples shall be distributed, in order to ensure their use for the purposes for which they are allocated.

(Article 10)

The scientific office shall comply with the rules and systems applied by the competent administration of the Egyptian Drug Authority regarding materials used in promotional, educational, and awareness activities, and in providing members of medical professional syndicates and other concerned parties with scientific information, films, brochures, and all other promotional materials, through various media channels.

It shall be prohibited for scientific offices to engage in the following:

(a) Promotion for products that have not been registered with the Egyptian Drug Authority in accordance with the provisions of the Law regulating the Practice of the Pharmacy Profession, or whose importation is prohibited.

(b) Promotion for products belonging to companies not listed in the license of the scientific office, or the presence of samples thereof in the sample store.

(c) Advertising for their products except in medical or specialized fields commensurate with the nature of the advertised products.

(d) Advertising for their products without obtaining prior approval for the advertisement from the competent administration of the Egyptian Drug Authority.

(Article 11)

Scientific offices shall notify the competent department at the Egyptian Drug Authority every six months with the new products and devices statement produced by the companies affiliated with these offices and conducted researches. In addition to inform them, regularly every three months at most, of stagnant items, available items in warehouses, registered items, and suspended import items.

The competent department shall inform such offices of the procedures and decisions it takes regarding these medicines and products.

(Article 12)

Those appointed to scientific offices must fulfill the following:

A. Shall be a citizen of the Arab Republic of Egypt.

B. Shall be good conduct and reputation.

C. Shall be high technical qualified in the office activity field, if the appointment is for the position of Office Manager or technical positions therein.

The Scientific Office Manager shall be a member of one of the Medical Union Syndicates, and the Manager of the sample store affiliated to the scientific office be a full-time pharmacist.

Combining the two positions is permitted provided that the occupant shall be a full-time pharmacist and that the sample store located within the headquarters of the scientific office.

D. To not have been previously convicted of a criminal penalty or a crime involving a breach of honor or trust, unless they have been rehabilitated.

The competent department at the Egyptian Drug Authority shall be notified upon appointing any technical workers in scientific offices.

(Article 13)

Scientific offices shall be administratively and financially subordinate to the sole agent licensed for such purpose, or to the manufacturing company in the absence of an agent.

(Article 14)

Licensing may be granted for the establishment of a joint private office for multiple companies or factories. The license shall specify the names of the participating companies within the office and the determine the proportionate share of expenses to be incurred by each entity.

(Article 15)

The licensed scientific office may submit a request to the competent department of the Authority for licensing a branch of scientific offices nationwide, provided that appointing a manager for each branch. Furthermore, the scientific office branch may be annexed with a medical sample store , provided that it complies with all medical sample stores requirements, in addition to appointing pharmacist in charge for each sample store. A scientific office branch may be established as reception halls without samples store; provided that such branches shall remain administratively and financially subordinate to the original licensed scientific office.

(Article 16)

Scientific offices shall not appoint, second, or seek the assistance of employees of the Government or the Public Business Sector, even in a temporary or incidental capacity.

(Article 17)

The Egyptian Drug Authority shall have the power of oversight over scientific offices to verify the implementation of this Decree in addition to have the right to conduct technical inspections of sample stores affiliated to Scientific offices, audit records, and verify compliance with laws and decrees, pursuant to the Law of Pharmacy Profession Practicing and the Law Establishing the Egyptian Drug Authority, and their respective executive regulations.

(Article 18)

The license of the scientific office may be revoked by a resolution from the Chairman of the Board of Directors of the Egyptian Drug Authority in the following instances:

1.Failure to commence operations within six months from the date of lisense issuance.
2.Continuous closure of the scientific office for a period exceeding one calendar year.
3.Relocation of the office from the site designated in the license to another location without prior written consent from the competent department.
4.If the office suspended its activity for six consecutive months without an accepted valid justification submitted to the competent department by the Scientific Office Manager.
5.If the office engages in the trade of medicinal samples or medical supplies intended for promotion or offering them for sale.
6.If the office became devoid of any agencies or registered pharmaceutical products or medical devices for which it conducts promotional activities.
7.If the office violates the licensing conditions stipulated in Article (3) hereof.
8.If the office violates the sample storage conditions stipulated in Article (4) hereof.
9.If the office violates the sample importation procedures stipulated in Articles (6) and (7) hereof.
10.If the office violates the promotion and advertising requirements stipulated in Article (10) hereof.
11.If the office Fails to comply with the notification requirements for new pharmaceutical products and medical devices as set forth in Article (11) hereof.
12.If the office Fails to comply with the appointment requirements stipulated in Article (12) hereof.
13.If the office violates, in bad faith, the registration conditions for pharmaceutical or biological products or medical devices , leading to the registration of any such products in the name of the scientific office contrary to the facts.
14.If the office violates the provisions hereof, the provisions of Law No. 127 of 1955, Law No. 151 of 2019, other relevant laws, or the executive regulations and decisions in force.

Revocation shall be mandatory in the event of failure to regularize the status within a maximum period of six months, and in the event of recidivism.

(Article 19)

The legal representative of the office may appeal against the Authority's decisions before the Competent Grievance Committee within sixty days from its issuance date, pursuant to the procedures and fees specified in the Executive Regulations of Law No. 151 of 2019, issued by Prime Minister Decree No. 777 of 2020.

(Article 20)

Existing scientific offices shall regularize its status within six months from the date of issuance hereof and notify the competent department at the Egyptian Drug Authority.

(Article 21)

Any provision contrary to the provisions hereof this Decree shall be repealed.

(Article 22)

This Decree shall be published in Al-Waqa'i' al-Misriyya (The Egyptian Gazette) and shall come into force as of the date of its publication.

Chairman of Egyptian drug Authority

Prof /Tamer Mohamed Essam

Issued on: 7/7/2021

(Article 11)

Scientific offices shall notify the competent department at the Egyptian Drug Authority every six months with the new products and devices statement produced by the companies affiliated with these offices and conducted researches. In addition to inform them, regularly every three months at most, of stagnant items, available items in warehouses, registered items, and suspended import items.

The competent department shall inform such offices of the procedures and decisions it takes regarding these medicines and products.

(Article Five)

The Egyptian Drug Authority is responsible for inspection of the research institutions and relevant entities which the clinical medical research being conducted for verifying the compliance with the good clinical practice. The Egyptian Drug Authority has the right, for achieving that, to check, examine and revise all research-related documents; records and installations and collect the necessary evidences to guarantee applying law provisions and regulated rules.

(Article Six)

In cases of public health emergencies' internationally or domestically or in cases of epidemics spread, the Egyptian Drug Authority has the right to take exceptional procedures and measures other than that the rules of assessing the clinical studies which are in the jurisdiction of the authority to guarantee the quick availability of relevant products and medical devices for the public benefits.

(Article Seven)

The Egyptian Drug Authority has the right to rely on rules, reports and data of stringent regulatory authorities in accordance with that determined by the Technical Committee for Drug Control pursuant to the international standards, in order to adopt a decision concerning assessing and approving a clinical medical research submitted for carrying it out within the Arab Republic of Egypt. The relying on decision of aforementioned bodies will neither diminish the Egyptian Drug Authority's independency nor its responsibility for the issued decision by it.

(Article Eight)

The chairman of the Central Administration of Biological and Innovative Products and Clinical Trials shall issue a guideline for good regulatory oversight of clinical trials within five days of the date of approving this decree.

President

Egyptian Drug Authority

Prof /Tamer Mohamed Essam

Issued on 21/2/2022