Decree No. 429 of 1976 on Regulating Scientific Offices in the Affairs of Advertising for Drugs and Medical Devices.

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Ministry of Health

Decree No. 429 of 1976

on Regulating Scientific Offices in the Affairs of Advertising for Drugs and Medical Devices(*)

Minister of Health

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;

Law No. (113) of 1972 on Reorganizing Importation, Manufacturing, and Trading of Drugs, Medical and Chemical Devices;

Decree of the President of the Arab Republic of Egypt No. (545) of 1976 defining some areas of competence of the Ministry of Health;

Decree of the Minister of Health No. (449) of 1969 on Regulating Scientific Offices Working on Advertising Affairs for Drugs and Medical Devices;

has decided:

Article 1 - In the implementation of this DECREE provisions, a scientific office is any office that practices advertising activities for drugs, medical products and devices, and pharmaceutical chemicals, 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.

Article 2 - Pursuant to the provisions of Law No. (127) of 1955 and the Ministerial Resolution No. (85) of 1976 regulating the import of drugs and pharmaceutical products, a license to establish a scientific office shall only be

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granted to pharmaceutical agents who have obtained the required license from the General Administration of Pharmaceutical Affairs. A person applying for a license to establish a scientific office must be a member of one of the medical professions' associations.

In case the producing company has no appointed agent, the said company may establish a scientific office in accordance with the applicable law and rules.

Article 3 – Except for the scientific offices existing at the time this decree is issued, no scientific office shall be established unless it obtains a license issued by a decree from the Minister of Health. The following are the requirements of obtaining a license:

(a) A license application must be filled in the appropriate form and be submitted to the General Administration of Pharmaceutical Affairs.

(b) The General Administration of Pharmaceutical Affairs shall verify the fulfillment of the conditions prescribed under the Law on Pharmacy Profession Practice and other and the Ministerial Resolutions issued for its implementation, as regards registering, storing and distributing the product samples.

Article 4 - 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 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 General Administration of Pharmaceutical Affairs to record the movement of samples in the entries of received, issued and remained items.

(c) A monthly statistical statement on the movement of samples shall be submitted to the General Administration of Pharmaceutical Affairs.

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

Article 5 - Samples of medical products 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.

Article 6 – A scientific office shall obtain a permission from the General Administration of Pharmaceutical Affairs to import each and every drug sample consignment. Upon granting such a permission, the General Administration of Pharmaceutical Affairs shall conform to the applicable rules and systems. The word 'samples' shall mean all items imported to advertise for drugs.

Article 7 – Customs clearance of a consignment of drugs imported to a scientific office may not be granted except in the presence of a representative of the General Administration of Pharmaceutical Affairs. 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 General Administration of Pharmaceutical Affairs 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 8 - The Ministry of Health 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 Ministry of Health. 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 Administration storehouses.

Article 9 - The aforementioned committee shall convene whenever necessary at the headquarter of General Administration of Pharmaceutical Affairs. Apart from its above-mentioned role, this committee shall be concerned with developing a system for storing the Ministry share 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 10 - 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 its products only in medical fields or periodicals specialized in the activity branch practiced by the office.

(c) Obtaining the prior consent as regards the form of its advertisement from the General Administration of Pharmaceutical Affairs at the Ministry of Health.

Article 11 – A scientific office shall notify the General Administration of Pharmaceutical Affairs every six months with a statement identifying the new drugs and products produced by the companies to which the office is affiliated and reporting on research conducted on these products.

The General Administration of Pharmaceutical Affairs shall notify these offices of the procedures and resolutions it takes regarding these drugs and products. A scientific office shall also periodically notify the General Administration every three months at most of dormant items, stored items, registered items, and items that have ceased to be imported.

Article 12 - 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. Those who have occupied these positions before the implementation of this decree are exempted from this condition.

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 General Administration of Pharmaceutical Affairs shall be notified when a technical employee is appointed in a scientific office.

Article 13 - 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 14 – 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 15 – In its work, a scientific office may not appoint, hire, or second an employee from government or public business sector, even temporarily.

Article 16 – The General Administration of Pharmaceutical Affairs shall have the right to supervise scientific offices to ensure that this DECREE is implemented and shall have the right to conduct a technical inspection of the medical samples' storehouses affiliated to scientific offices and of their records. It shall have the right to ensure that the provisions prescribed in laws and ministerial resolutions are implemented in accordance with the rules stated in the Law on Pharmacy Profession Practice and its and its enforcing ministerial regulations.

Article 17 – A license issued to a scientific office may be withdrawn upon a decree from the Minister of Health if the scientific office is proven to be in violation of the provisions of this decree or the provisions of other laws and regulations. An act of violation is proven as a result of an investigation conducted by the General Administration of Pharmaceutical Affairs and attended by a representative of the office or a representative of the association of scientific offices.

Article 18 - Ministerial Resolution No. 449 of 1969 shall be null and void.

Article 19 - 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.

Written on Rajab 22, 1396 (July 20, 1976)