

Organizational Guide for the Procedures of Licensing Scientific Offices 2024

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Introduction

Administration of licensing of scientific offices, stability and bioequivalence centers under, General Administration of Licensing of Scientific Offices, Medical Products Stores, Warehouses, Stability and Bioequivalence Centers are responsible for establishing rules and operational procedures related to the licensing of scientific offices. This enables the scientific office to conduct its activities, whether in matters of Marketing and promotion activities and related activities, or in the registration of medicinal pharmaceutical or biological products or medical devices, in its own name and on its own account, provided that such products or devices are imported.

Scope of Implementation

The operational procedures of the Administration of licensing of scientific offices, stability and bioequivalence centers under the Central Administration of Operations shall apply to the following:

1. Licensing of a new main scientific office
2. Renewal of the license of a main or branch scientific office for any of the reasons that necessitate renewal, as follows:
 - Change of the scientific office manager or the pharmacist in charge for the Samples store
 - Addition of a new Samples store, change of the premises of the licensed scientific office, or change of the premises of the Samples store.
 - Amendment of the Layout of the scientific office or the sample store.
 - Addition of companies on scientific office's license for marketing and promotion
 - Transfer of ownership / change of the scientific office name.
3. Licensing a new branch scientific office.
4. Issuance of a data certificate for the scientific office license.
5. Issuance of a replacement for a lost license of the main or branch scientific office.
6. Issuance of a replacement for a damaged license of the main or branch scientific office.
7. cancellation of the license of the main or branch scientific office.

Definitions

Scientific Office:

Any office that carries out marketing and promotion activities for pharmaceutical products, Medical devices, pharmaceutical chemicals, biological products, cosmetic products, and related products that provides Medical Union Syndicate members and others concerned with scientific information about the products, devices, and pharmaceuticals that are produced or used by the factories affiliate with such offices, through various media outlets, including delivering lectures, holding scientific seminars, assisting

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in scientific research, presenting films, distributing leaflets and free samples, and other media methods and means.

By a decree of the chairman of the Egyptian Drug Authority (EDA), a scientific office may be authorized to register pharmaceutical products, biological products, or medical devices in its own name and on its own account, provided that such products or devices are imported, and after payment of the prescribed service fee.

Types of Scientific Offices:

- 1. Scientific Office Affiliated with the Company Abroad:** A scientific office affiliated with a foreign company abroad, bearing the same name as the foreign company it is affiliated with, and conducting Marketing and promotion activities for the pharmaceutical products or medical devices of the foreign company it represents.
- 2. Scientific Office Affiliated with an Agent/Distributor:** A scientific office affiliated with a company that has a commercial register, bearing the same name as that company, and conducting Marketing and promotion activities for the pharmaceutical products or medical devices of the foreign companies with which Marketing and promotion contracts have been concluded.
- 3. Scientific Office Affiliated with a Local Company:** A scientific office affiliated with a local manufacturer or Toll manufacturer companies, bearing the same name as that company, and conducting Marketing and promotion activities for the pharmaceutical products or medical devices of the licensed local manufacturer or the Toll manufacturer companies.
- 4. Authorized Scientific Office:** A scientific office affiliated with a local company that has a commercial register and affiliated with a foreign company abroad, authorized by the foreign company to license the scientific office under the name of the local company to conduct Marketing and promotion activities for the pharmaceutical products or medical devices of the foreign company abroad, and bearing the same name as the local company.

Samples store:

A store for keeping free medical samples, located inside or outside the scientific office, with an area of not less than 25 m². The sample store of the scientific office shall be considered a Pharmaceutical Institution and shall be subject to the provisions of Law No. 127 of 1955 and its amendments, as well as the applicable executive regulations, in accordance with the definition stipulated in the Decree of the chairman of the Egyptian Drug Authority (EDA) No. 315 of 2021 regarding the regulation of scientific offices.

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Branch Scientific Office:

The licensed main scientific office shall have the right to license branch scientific offices affiliated with it across the Republic to carry out Marketing and promotion activities, with the appointment of a manager for each branch office. These branch offices shall be administratively and financially subordinate to the licensed Main scientific office

It should be noted that a branch scientific office may operate without a Samples store (reception area) or with a Samples store that meets all the requirements of a Samples store, with the appointment of a pharmacist in charge for each sample store.

Data Certificate:

A document containing all the data related to the latest license issued for the scientific office, issued upon the company's request for the purpose of submission to one of the administrative authorities.

Procedures

First: Procedures for Licensing a New Main Scientific Office

Required Documents for Licensing a New Scientific Office:

- The required documents (Group A, B, C, or D) shall be submitted according to the type of scientific office.
- The documents related to the scientific office manager and the Pharmacist in charge of sample store are standardized and shall be submitted for any type of scientific office.
- The application form for licensing a new scientific office shall be completed and signed by the legal representative of the scientific office before one of the inspectors of the Administration of licensing of scientific offices, stability and bioequivalence centers upon submission of the licensing file complete with all required documents.

First: Documents Related to the Scientific Office (According to Its Type):

A- Scientific Office Affiliated with the Agent/Distributor:

1. An application for establishing a scientific office submitted by the local company to the Egyptian Drug Authority, signed by the Chairman of the Board of Directors or his authorized representative as recorded in the commercial register (**Authenticated by a valid bank signature**)

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or signed before the General Legal Administration of the Egyptian Drug Authority. The application shall include all of the following data:

- The detailed address of the scientific office, indicating the building number, floor, and apartment.
- The detailed address of the sample store, indicating the building number, floor, and apartment.
- The name of the scientific office manager (of Egyptian nationality), the name of the syndicate to which he is affiliated, and the registration number therein.
- The name of the Pharmacist in charge of sample store.

It is required that the scientific office manager be a member of the Egyptian Medical Union Syndicate member, and that the Pharmacist in charge of sample store affiliated with the scientific office be a full-time pharmacist. It shall be permissible to combine both positions provided that:

- Both positions are held by a full-time pharmacist.
- The sample store is located within the premises of the scientific office.

2. A commitment on the company's letterhead addressed to the Egyptian Drug Authority to publish Approval decree of the chairman of the Egyptian Drug Authority (EDA) for licensing the scientific office in the Al-Waqā'i' al-Misriyya Gazette, with the company bearing all expenses related to the publication. **(Signature Authenticated by a valid bank signature)**
 3. Marketing and promotion contracts between the scientific office and the companies whose pharmaceutical products or medical devices are to be promoted **(the Marketing and promotion contracts shall be notarized by the Chamber of Commerce in the foreign country and subsequently authenticated by the Egyptian Embassy in the same country.)**
- **In the event of Marketing and promotion for a specified number of pharmaceutical products or medical devices:** the names and number of such pharmaceutical products or medical devices to be marketed shall be specified in the contract.
 - **In the event of Marketing and promotion for all pharmaceutical products or medical devices:** the phrase "all pharmaceutical products or medical devices of the company" shall be added to the contract.
4. A copy of the license for registration in the Importers Register (for the Egyptian agent/distributor), indicating the foreign companies for which advertising is required. **(Original for review).**
 5. An engineering Layout approved by a syndicate-registered engineer (one original and two copies) for the scientific office and the attached sample store, whether located inside or outside the premises of the scientific office, provided that it clearly indicates the name of the scientific office and the address in detail (to be stamped with the Engineers Syndicate seal after inspection), **indicating the following: -**
 - A horizontal plan showing the dimensions of the sample store to be licensed.
 - A vertical plan showing the height of the sample store to be licensed.

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6. A title deed for the premises (**a notarized lease or ownership contract from the Notary public, or a signature Authentication by a valid bank signature for both parties**), indicating the address in detail, as well as the property number, floor, and apartment, with specification of the type of activity (the purpose of using the premises) (original for review).
7. A copy of the commercial register of the company requesting the license for the scientific office. (original for review)
8. A commitment on the company's letterhead, signed by the manager of the scientific office, committing to retain a copy of the engineering Layout and the scientific office license, after issuance, inside the scientific office and the sample store.

■ In the case of licensing the scientific office with existing Registration licenses for the companies for which the scientific office will Market and promote:

A copy of the Registration licenses for the agent or distributor (at least one license) shall be submitted, and the activity may commence after the issuance of the scientific office license

■ In the case of licensing the scientific office without existing Registration licenses for the companies for which the scientific office will Market and promote:

- The scientific office shall submit a request to any of the relevant central administrations to obtain a registration permit, provided that the issued approval is submitted to the Administration of licensing of scientific offices, stability and bioequivalence centers
- A period of six months from the date of license issuance shall be granted to commence Marketing and promotion activities (by submitting the Marketing and promotion contract) and/or registration (by starting to submit registration-related requests to the relevant central administration).

The scientific office license may be canceled by a Decree of the Chairman of the Egyptian Drug Authority if the licensed activities are not commenced within this period, in accordance with the Egyptian Drug Authority Chairman's Decree No. 315 of 2021.

B- Scientific office affiliated with the Company Abroad:

1. A Authorized letter from the foreign company addressed to the Egyptian Drug Authority requesting the establishment of a scientific office, indicating the full address and authorizing one of the Medical Union Syndicate member to be appointed as the manager of the scientific office. **(The Authorization shall be done at the Chamber of Commerce in the foreign country, followed by authentication at the Egyptian Embassy in the same country)**
2. An application for establishing a scientific office addressed to the Egyptian Drug Authority, signed by the person authorized by the foreign company **(with signature Authenticated by a valid bank signature or signed before the Legal Administration at the Egyptian Drug Authority)**. The application shall include all of the following data:
 - The detailed address of the scientific office, indicating the building number, floor, and apartment.
 - The detailed address of the sample store, indicating the building number, floor, and apartment.

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- The name of the scientific office manager (of Egyptian nationality), the name of the syndicate to which he is affiliated, and the registration number therein.
- The name of the Pharmacist in charge of sample store.

It is required that the scientific office manager be a member of the Egyptian Medical Union Syndicate member, and that the Pharmacist in charge of sample store affiliated with the scientific office be a full-time pharmacist. It shall be permissible to combine both positions provided that:

- Both positions are held by a full-time pharmacist.
- The sample store is located within the premises of the scientific office.

3. A commitment on the company's letterhead addressed to the Egyptian Drug Authority to publish Approval decree of the chairman of the Egyptian Drug Authority (EDA) for licensing the scientific office in the Al-Waqā'i' al-Misriyya Gazette, with the company bearing all expenses related to the publication. **(Signature Authenticated by a valid bank signature)**
4. A copy of the license for registration in the Importers Register (for the Egyptian agent/distributor), indicating the foreign company abroad. (Original for review).
5. An engineering Layout approved by a syndicate-registered engineer (one original and two copies) for the scientific office and the attached sample store, whether located inside or outside the premises of the scientific office, provided that it clearly indicates the name of the scientific office and the address in detail (to be stamped with the Engineers Syndicate seal after inspection), **indicating the following:**
 - A horizontal plan showing the dimensions of the sample store to be licensed.
 - A vertical plan showing the height of the sample store to be licensed.
6. A title deed for the premises **(a notarized lease or ownership contract from the Notary public or a signature Authentication by a valid bank signature for both parties)**, indicating the address in detail, as well as the property number, floor, and apartment, with specification of the type of activity (the purpose of using the premises) (original for review).
7. A copy of the commercial register of the importer/distributor. (original for review)
8. A commitment on the company's letterhead, signed by the manager of the scientific office, committing to retain a copy of the engineering Layout and the scientific office license, after issuance, inside the scientific office and the sample store.

■ In the case of licensing the scientific office with existing Registration licenses for the companies for which the scientific office will Market and promote:

A copy of the Registration licenses for the agent or distributor (at least one license) shall be submitted, and the activity may commence after the issuance of the scientific office license

■ In the case of licensing the scientific office without existing Registration licenses for the companies for which the scientific office will Market and promote:

- The scientific office shall submit a request to any of the relevant central administrations to obtain a registration permit, provided that the issued approval is submitted to the Administration of licensing of scientific offices, stability and bioequivalence centers
- A period of six months from the date of license issuance shall be granted to commence Marketing and promotion activities (by submitting the Marketing and promotion contract) and/or registration (by starting to submit registration-related requests to the relevant central administration).

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The scientific office license may be canceled by a Decree of the Chairman of the Egyptian Drug Authority if the licensed activities are not commenced within this period, in accordance with the Egyptian Drug Authority Chairman's Decree No. 315 of 2021.

C- Scientific office affiliated with local companies:

1. An application for establishing a scientific office submitted by the local company to the Egyptian Drug Authority, signed by the Chairman of the Board of Directors or his authorized representative as recorded in the commercial register (**Authenticated by a valid bank signature**) or signed before the General Legal Administration of the Egyptian Drug Authority. The application shall include all of the following data:
 - The detailed address of the scientific office, indicating the building number, floor, and apartment.
 - The detailed address of the sample store, indicating the building number, floor, and apartment.
 - The name of the scientific office manager (of Egyptian nationality), the name of the syndicate to which he is affiliated, and the registration number therein.
 - The name of the Pharmacist in charge of sample store.

It is required that the scientific office manager be a member of the Egyptian Medical Union Syndicate member, and that the Pharmacist in charge of sample store affiliated with the scientific office be a full-time pharmacist. It shall be permissible to combine both positions provided that:

- Both positions are held by a full-time pharmacist.
- The sample store is located within the premises of the scientific office.

2. A commitment on the company's letterhead addressed to the Egyptian Drug Authority to publish Approval decree of the chairman of the Egyptian Drug Authority (EDA) for licensing the scientific office in the Al-Waqā'i' al-Misriyya Gazette, with the company bearing all expenses related to the publication.

(Signature Authenticated by a valid bank signature)

3. An engineering Layout approved by a syndicate-registered engineer (one original and two copies) for the scientific office and the attached sample store, whether located inside or outside the premises of the scientific office, provided that it clearly indicates the name of the scientific office and the address in detail (to be stamped with the Engineers Syndicate seal after inspection), **indicating the following:** -

- A horizontal plan showing the dimensions of the sample store to be licensed.
- A vertical plan showing the height of the sample store to be licensed.

4. A copy of the commercial register of the company (requesting the license for the scientific office). (original for review).

5. A title deed for the premises (**a notarized lease or ownership contract from the Notary or a signature Authentication by a valid bank signature for both parties**), indicating the address in detail, as well as the property number, floor, and apartment, with specification of the type of activity (the purpose of using the premises) (original for review).

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6.A commitment on the company's letterhead, signed by the manager of the scientific office, committing to retain a copy of the engineering Layout and the scientific office license, after issuance, inside the scientific office and the sample store.

7. A copy of the toll manufacturer or a copy of the local manufacturer's license of the company requesting the scientific office license (original for review).

Note: In the case of requesting the licensing of a local scientific office under Marketing and promotion contracts with other local companies, the following documents shall be submitted instead of document No. 7:

1. An Marketing and promotion contract between the company requesting the license and the company to be promoted (**notarized at the Notary public or a signature Authentication by a valid bank signature for both parties to the contract**) (original for review).
2. A copy of the commercial register of the company to be marketed and promoted (original for review).

■ In the case of licensing the scientific office with existing Registration licenses for the companies for which the scientific office will Market and promote:

A copy of the Registration licenses for the agent or distributor (at least one license) shall be submitted, and the activity may commence after the issuance of the scientific office license

■ In the case of licensing the scientific office without existing Registration licenses for the companies for which the scientific office will Market and promote:

- The scientific office shall submit a request to any of the relevant central administrations to obtain a registration permit, provided that the issued approval is submitted to the Administration of licensing of scientific offices, stability and bioequivalence centers.

- A period of six months from the date of license issuance shall be granted to commence Marketing and promotion activities (by submitting the Marketing and promotion contract) and/or registration (by starting to submit registration-related requests to the relevant central administration).

The scientific office license may be cancelled by a Decree of the Chairman of the Egyptian Drug Authority if the licensed activities are not commenced within this period, in accordance with the Egyptian Drug Authority Chairman's Decree No. 315 of 2021.

Note: In the case of Toll manufacturer companies (Toll Companies), the role of the scientific office is limited to promotion only, without performing registration activities.

D- Authorized Scientific Office:

1. Authorization from the foreign company to the local company (the authorized company) to license the scientific office in the name of the authorized company to conduct Marketing and promotion of the pharmaceutical products or medical devices belonging to the foreign company (**provided that the authorization is notarized at the Chamber of Commerce and then authenticated at the Egyptian Embassy in the same country**)

2. An application for establishing a scientific office submitted by the local company to the Egyptian Drug Authority, signed by the Chairman of the Board of Directors or his authorized representative as recorded in the commercial register (**Authenticated by a valid bank signature**) or signed before the General Legal Administration of the Egyptian Drug Authority. The application shall include all of the following data:

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- The detailed address of the scientific office, indicating the building number, floor, and apartment.
- The detailed address of the sample store, indicating the building number, floor, and apartment.
- The name of the scientific office manager (of Egyptian nationality), the name of the syndicate to which he is affiliated, and the registration number therein.
- The name of the Pharmacist in charge of sample store.

It is required that the scientific office manager be a member of the Egyptian Medical Union Syndicate member, and that the Pharmacist in charge of sample store affiliated with the scientific office be a full-time pharmacist. It shall be permissible to combine both positions provided that:

- Both positions are held by a full-time pharmacist.
- The sample store is located within the premises of the scientific office.

3. A commitment on the company's letterhead addressed to the Egyptian Drug Authority to publish Approval decree of the chairman of the Egyptian Drug Authority (EDA) for licensing the scientific office in the Al-Waqā'i' al-Misriyya Gazette, with the company bearing all expenses related to the publication.

(Signature Authenticated by a valid bank signature)

4. A copy of the importer's registration license for the Egyptian agent/distributor, indicating the foreign company (original for review).

5. An engineering Layout approved by a syndicate-registered engineer (one original and two copies) for the scientific office and the attached sample store, whether located inside or outside the premises of the scientific office, provided that it clearly indicates the name of the scientific office and the address in detail (to be stamped with the Engineers Syndicate seal after inspection), **indicating the following:** -

- A horizontal plan showing the dimensions of the sample store to be licensed.
- A vertical plan showing the height of the sample store to be licensed.

6. A copy of the commercial register of the company requesting the license (original for review).

7. A title deed for the premises **(a notarized lease or ownership contract from the Notary public or a signature Authentication by a valid bank signature for both parties)**, indicating the address in detail, as well as the property number, floor, and apartment, with specification of the type of activity (the purpose of using the premises) (original for review).

8. A commitment on the company's letterhead, signed by the manager of the scientific office, committing to retain a copy of the engineering Layout and the scientific office license, after issuance, inside the scientific office and the sample store.

■ In the case of licensing the scientific office with existing Registration licenses for the companies for which the scientific office will Market and promote:

A copy of the Registration licenses for the agent or distributor (at least one license) shall be submitted, and the activity may commence after the issuance of the scientific office license

■ In the case of licensing the scientific office without existing Registration licenses for the companies for which the scientific office will Market and promote:

- The scientific office shall submit a request to any of the relevant central administrations to obtain a registration permit, provided that the issued approval is submitted to the Administration of licensing of

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scientific offices, stability and bioequivalence centres.

- A period of six months from the date of license issuance shall be granted to commence Marketing and promotion activities (by submitting the Marketing and promotion contract) and/or registration (by starting to submit registration-related requests to the relevant central administration).

The scientific office license may be cancelled by a Decree of the Chairman of the Egyptian Drug Authority if the licensed activities are not commenced within this period, in accordance with the Egyptian Drug Authority Chairman's Decree No. 315 of 2021.

Note: -

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.

Second: Required Documents for the Scientific Office Manager (Egyptian Medical Union Syndicate member) and the Pharmacist in charge of sample store:

1. A copy of the National ID card (The original for review).
2. Original Criminal Record Certificate addressed to the Egyptian Drug Authority.
3. Original Certificate from the relevant Syndicate proving registration and membership.
4. For Pharmacists: A certificate of " Statement of assignment status " (Pharmacy manager certificate issued by the Certificates Department at the Central Administration of Operations - Egyptian Drug Authority.

For Non-Pharmacists: An official statement confirming non-employment in the government or the public sector (Social Insurance Printout).

5. A copy of the Professional practice license Issued by Ministry of Health and Population. (The original for review).

Note: The Scientific Office Manager shall be a member of the Egyptian Medical Union Syndicate member. The Pharmacist in charge of sample store affiliated with the Scientific Office shall be a full-time pharmacist. **The two positions may be combined provided that:**

- The incumbent is a full-time pharmacist.
- The samples store is located within the Scientific Office premises.

The Scientific Office licensing fee of fifty thousand Egyptian pounds (50,000 EGP), along with the publication fees in Al-Waqā'i' al-Misriyya Gazette, shall be paid prior to receiving the license, pursuant to Law No. 151 of 2019 and its Executive Regulations.

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Operational Procedures for Licensing a New Scientific Office:

1) Documents related to the Scientific Office license application shall be sent as a single PDF file to the email of the Administration of licensing of scientific offices, stability and bioequivalence centers:

License.scioff@edaegypt.gov.eg

Or via the electronic link of the Administration of licensing of scientific offices, stability and bioequivalence centers:

<https://forms.gle/2xVQUYRkSTrHEMuO6>

2) The submitted file shall be reviewed by the Administration:

- In the event of non-compliance or missing documents, an email shall be sent to the company to complete the requirements within **five (5) working days** from the date of receipt via the electronic link.

- In event that the required documents are complete, an email shall be sent to the company within **five (5) working days** from the date of receipt via the aforementioned link, requesting their attendance at the headquarters of the Administration of licensing of scientific offices, stability and bioequivalence centers to submit the application, provided that all original documents are presented for review, and to fill out the licensing application form by the legal representative or the manager of the scientific office in front of one of the Administration's pharmacists

3) A date for the site inspection shall be determined according to the inspection schedule, in coordination with the Administration 's inspectors. The company shall be notified of the scheduled date via telephone or official authenticated email. The prescribed service fees for conducting the inspection shall be paid.

4) The site inspection shall be conducted **within (30) days** from the date of submission of the licensing file by the pharmacists of the Scientific Offices, Stability and Bioequivalence Centers Licensing Administration. This is to verify the address of the Scientific Office and the sample store, ensure compliance with the submitted engineering layout for both facilities, confirm fulfillment of health requirements for the sample store, and draft the inspection report.

5) If the requirements are not met, an email shall be sent to the Scientific Office detailing the inspection remarks **within (3) working days** from the date of the inspection. (An official letter containing these remarks may also be dispatched), if any.

Note: If requirements and documents are incomplete, the Manager of the Scientific Office shall sign an undertaking to rectify the inspection remarks **within (30) days** from the inspection date. In the event of failure to fulfill the remarks and documents within this grace period, the application shall be archived.

6) Upon fulfillment the remarks, the company shall submit a request for a Fulfillment inspection. A date for the Fulfillment inspection shall be scheduled in accordance with the inspection timetable.

7) Once fulfillment of all remarks is verified, a memorandum shall be submitted to the Chairman of the Egyptian Drug Authority to issue a decree approving the license of the Scientific Office, pursuant to

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Article (3) of the Egyptian Drug Authority Chairman's Decree No. 315 of 2021 regarding the regulation of Scientific Offices.

8) Following the issuance of Approval decree of the chairman of the Egyptian Drug Authority (EDA) for licensing the scientific office, the authorized representative of the Scientific Office shall settle the licensing fees in accordance with the Egyptian Drug Authority Law No. 151 of 2019, as well as the fees for publishing the licensing decree in the Official Gazette (Al-Waqayi' al-Misriyya)

9) The license shall be drafted, including all data pertaining to the Scientific Office, and printed after a comprehensive review of all information **within (3) working days** from the completion of all required documentation.

10) The original Scientific Office license and a copy of the approved engineering layout shall be delivered to the company. A copy thereof shall be retained in the Scientific Office's specific file.

Upon delivery of the license, an authorized delegation letter authenticated by a by a valid bank signature shall be submitted.

Second: Procedures for Renewing a Scientific Office License

Required documents in case of changing the Manager of the Scientific Office (from among medical union syndicate member) or the Pharmacist in Charge of the sample store:

1 (A request on the company's official letterhead for changing the Scientific Office Manager or the Pharmacist in Charge of the sample store.

- Note: In case of changing the Scientific Office Manager, the Chairman of the Board or their legal representative as documented in the commercial register shall sign the request. The signature shall be authenticated by (a bank signature Verification) or signed before the General Administration of Legal Affairs at the Egyptian Drug Authority.

- In case of changing the Pharmacist in Charge of the sample store, the Scientific Office Manager or the Chairman of the Board shall sign the request. The signature shall also be (Signature verification by the bank or signed before the General Administration of Legal Affairs at the Egyptian Drug Authority.)

2. A copy of the National ID Card (The Original for review).

3. Original Criminal Record Certificate addressed to the Egyptian Drug Authority.

4. Original Syndicate Membership Certificate stating that the applicant is registered and in good standing.

5. For Pharmacists: A certificate indicating the Statement of assignment status issued by the Egyptian Drug Authority.

For Non-Pharmacists: A statement certifying that the applicant is not employed by the government or the public sector (Social Insurance Printout).

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6. A copy of the Professional practice license Issued by Ministry of Health and Population. (The Original for review).

7. In case of a branch of a foreign company, the following document is added:

- An authorization letter from the parent company abroad (**legalized by the Chamber of Commerce and the Egyptian Embassy in the parent company's country**) delegating one of the medical union syndicate member to be appointed as the Manager of the Scientific Office.

A service fee of 3,000 EGP shall be paid for changing the Scientific Office Manager or the Pharmacist in Charge of the sample store. This payment is pursuant to the Egyptian Drug Authority Chairman's Decree No. 316 of 2021 and shall be made upon submitting the request and documents.

Operational Procedures for Changing the Manager of Scientific Office and/ or Pharmacist in charge of sample store:

1- All required documents for the request of changing Manager of Scientific Office and/ or Pharmacist in charge of sample store shall be sent in a single PDF file to Administration of licensing of scientific offices, stability and bioequivalence centers:

License.scioff@edaegypt.gov.eg

Or via the electronic link of the Administration of licensing of scientific offices, stability and bioequivalence centers:

<https://forms.gle/2xVQUYRkSTrHEMuO6>

2- The submitted documents shall be reviewed. In the event of non-compliance or missing documents, an email shall be sent to the company to complete the requirements within five (5) working days from the date of receipt via the electronic link.

3- In the event that the required documents are completed, an email shall be sent to the company within five working days from the date of receiving the application via the aforementioned electronic link, to attend the headquarters of the Department of Scientific Office Licenses and Stability and Bioequivalence Centers to submit the application, provided that all original documents are presented for verification.

4- Upon receipt of the application, the Scientific Office file shall be reviewed. In the event of missing documents or expired documents—such as the title deed or registration notices—an email shall be sent to the company to complete the documentation within 5 working days from the date of application receipt.

5 -Following the completion of any missing documents, a site inspection date shall be determined (or waived) according to the following:

If less than one calendar year has elapsed since the date of the last inspection conducted for the Scientific Office and the samples store:

The licensing issuance procedures shall proceed as prescribed below without the need for a new inspection.

If more than one calendar year has elapsed since the date of the last inspection conducted for the Scientific Office and the samples store:

An inspection date shall be scheduled according to the inspection timetable in coordination with the Department's inspectors. The company shall be notified of the scheduled date via telephone or the

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official company-approved email. The prescribed service fee for the inspection shall be paid. An inspection shall be conducted to verify that the address and the layout of the Scientific Office and the samples store match the records and documents attached to the file.

6. If the requirements are not met, an email containing the inspection observations shall be sent to the Scientific Office within three (3) working days from the date of the inspection (an official letter of observations may be issued, if any).

Note: If the requirements and documents are not fulfilled, an acknowledgment shall be signed by the Director of the Scientific Office undertaking to fulfill the inspection observations within thirty (30) days from the inspection date. In the event of failure to fulfill the observations and documents within the said period, the application shall be archived.

7. Upon fulfillment of the observations, the company shall submit a request for a Fulfillment inspection, and a date shall be scheduled according to the inspection timetable.

8. Upon verification of the fulfillment of all observations and documents, the renewed Scientific Office license template shall be drafted, incorporating the new data, and printed (following review) within three (3) working days.

9. The original Scientific Office license shall be delivered to the company's representative, and a copy of the license shall be kept in the Scientific Office's file.

Required Documents for Receiving a Renewed Scientific Office License:

1. Original of the old license.

In case the original old license is lost, the following shall be submitted:

- A request on the company's letterhead for a lost replacement; the Chairman of the Board, their authorized representative as proven in the Commercial Register, or the Manager of the Scientific Office shall sign the request (Authenticated by a valid bank signature).
 - Payment of the prescribed service fees.
 - A Memorandum of Loss issued by the police department stating the name and address of the licensed facility.
2. A copy of the authorization (The original for review).
 3. A Commitment from the Manager of the Scientific Office to Retain the layout, the Scientific Office license, and the samples store license within the Scientific Office premises.

Required Documents for Adding a New Samples store, Changing the Licensed Scientific Office Headquarters, or Changing the Samples store Location:

1 -A request on the company's letterhead to change the licensed Scientific Office headquarters, change the samples store, or add a samples store, specifying the detailed address, building number, floor, and apartment number. The request shall be signed by the Chairman of the Board of Directors, his authorized as documented in the commercial register shall sign the request. The signature shall be (authenticated by a valid bank signature) or signed before the General Administration of Legal Affairs at the Egyptian Drug Authority.

2- **An approved layout** by a syndicate engineer (original and two copies) for the Scientific Office and its annexed samples store, whether located within or outside the Scientific Office headquarters. The

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drawing shall specify the name of the Scientific Office and the detailed address (to be stamped by the Engineers Syndicate after the inspection is conducted), including:

- A horizontal plan showing the dimensions of the samples store (in case of relocation of the samples store).
 - Vertical plan drawing (elevation) showing the height of the samples store (in case of relocation of the samples store).
3. A copy of the title deed for the premises (lease or ownership contract notarized by the notary public or Authenticated by a valid bank signature for both parties), specifying the detailed address (building number, floor, and apartment) and the type of activity (purpose of use) (The original for review).

The following service fees shall be paid pursuant to the decree of the Chairman of the Egyptian Drug Authority No. 316 of 2021, following the completion of the necessary inspections:

- Licensing an additional samples store for a main Scientific Office (10,000 EGP).
- Renewing the license of a main or branch Scientific Office for relocation (10,000 EGP).

Operating Procedures for Adding a New Samples store, Changing the Licensed Scientific Office Headquarters, or Changing the Samples store Location:

1. The documents related to the request for adding a new samples store, changing the licensed Scientific Office headquarters, or changing the samples store location shall be sent as a single PDF file to the email address of Administration of licensing of scientific offices, stability and bioequivalence centers

License.scioff@edaegypt.gov.eg

Or via the electronic link of the Administration of licensing of scientific offices, stability and bioequivalence centers:

<https://forms.gle/2xVQUYRkSTrHEMuO6>

2. The submitted documents shall be reviewed. In the event of non-compliance or missing documents, an email shall be sent to the company to complete the requirements within five (5) working days from the date of receipt via the electronic link.

3. Upon fulfillment of the required documents, an email shall be sent to the company within five (5) working days from the date of receipt via the aforementioned electronic link, requesting their attendance at the headquarters of the Administration of licensing of scientific offices, stability and bioequivalence centers to submit the application, provided that all original documents are presented for review.

4. Following the receipt of the application, the Scientific Office's file shall be reviewed. In case there are any deficiencies in the file or expired documents (such as the title deed or registration license), an email shall be sent to the company to complete the documents within five (5) working days from the date of receipt of the application.

5. An inspection date shall be scheduled according to the inspection timetable in coordination with the Department's inspectors. The company shall be notified of the scheduled date via telephone or the official company-approved email. The prescribed service fee for the inspection shall be paid.

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6. An inspection shall be conducted to verify that the address and the layout of the Scientific Office and the samples store match the records and documents attached to the file.

Notes: Inspections are conducted to verify the conformity of the layout and to confirm the address mentioned in the title deed for all the branch offices affiliated with the main scientific office, in preparation for renewing their licenses in the event of the relocation of the main scientific office.

7. If the requirements are not met, an email containing the inspection observations shall be sent to the Scientific Office within three (3) working days from the date of the inspection (an official letter of observations may be issued, if any).

Note: If the requirements and documents are not fulfilled, an acknowledgment shall be signed by the manager of the Scientific Office undertaking to fulfill the inspection observations within thirty (30) days from the inspection date. In the event of failure to fulfill the observations and documents within the said period, the application shall be archived.

8. Upon fulfillment of the observations, the company shall submit a request for a fulfillment inspection, and a date shall be scheduled according to the inspection timetable.

9. After verification of the fulfillment of all observations and documents, the renewed Scientific Office license template shall be drafted, incorporating the new data, and printed (following review) within three (3) working days.

10. The original Scientific Office license shall be delivered to the company's representative, and a copy of the license shall be kept in the Scientific Office's file.

Required Documents for Receiving a Renewed Scientific Office License:

1. Original of the old license.

In case the original old license is lost, the following shall be submitted:

- A request on the company's letterhead for a lost replacement; the Chairman of the Board, their authorized representative as proven in the Commercial Register, or the Manager of the Scientific Office shall sign the request (Signature verification by the bank).
 - Payment of the prescribed service fees.
 - A lost memorandum issued by the police department stating the name and address of the licensed facility.
2. A copy of the authorization (The original for review).
3. A commitment from the Manager of the Scientific Office to retain the layout, the Scientific Office license within the Scientific Office premises.

Required Documents in Case of Amendment of the layout of the Main Scientific Office, Branch or Samples store:

1 -A request on the company's letterhead to change the layout of the Main Scientific Office, Branch or Samples store. The request shall be signed by the Chairman of the Board of Directors, his authorized as documented in the commercial register shall sign the request. The signature shall be authenticated by (a

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bank signature Verification Authenticated by a valid bank signature) or signed before the General Administration of Legal Affairs at the Egyptian Drug Authority.

2- **An approved layout** by a syndicate engineer (original and two copies) for the Scientific Office and its annexed samples store, whether located within or outside the Scientific Office premises. The layout shall specify the name of the Scientific Office and the detailed address (to be stamped by the Engineers Syndicate after the inspection is conducted), **including:**

- Horizontal plan showing the dimensions of the samples store (In Case of Amendment of the layout of the Samples store).
- Vertical plan drawing (elevation) showing the height of the samples store (In Case of Amendment of the layout of the Samples store).
- **In a case of adding an apartment or a floor of the Scientific Office**, a copy of the title deed for the premises (lease or ownership contract notarized by notary public or authenticated by a bank signature verification for both parties), specifying the detailed address (building number, floor, and apartment) and the type of activity (purpose of use), of floor or apartment want to be add (The original for review).

The service fees (10.000EGP) shall be paid to amend the Engineering Drawing of the Main Scientific Office, Branch pursuant to the decree of the Chairman of the Egyptian Drug Authority No. 316 of 2021, following the completion of the necessary inspections:

Operating Procedures for Amending of the Engineering Drawing of the Main Scientific Office, Branch or Samples store:

1. The documents related to the request for Amending of the layout of the Main Scientific Office, Branch or Samples store, shall be sent as a single PDF file to the email address of Administration of licensing of scientific offices, stability and bioequivalence centers

License.scioff@edaegypt.gov.eg

Or via the electronic link of the Administration of licensing of scientific offices, stability and bioequivalence centers

<https://forms.gle/2xVQUYRkSTrHEMuO6>

2. The submitted documents shall be reviewed. In the event of non-compliance or missing documents, an email shall be sent to the company to complete the requirements within five (5) working days from the date of receipt via the electronic link.

3. Upon fulfillment of the required documents, an email shall be sent to the company within five (5) working days from the date of receipt via the aforementioned electronic link, requesting their attendance at the headquarters of the Administration of licensing of scientific offices, stability and bioequivalence centers to submit the application, provided that all original documents are presented for review.

4. Following the receipt of the application, the Scientific Office's file shall be reviewed. In case there are any deficiencies in the file or expired documents (such as the title deed or registration licenses), an

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email shall be sent to the company to complete the documents within five (5) working days from the date of receipt of the application.

5. An inspection date shall be scheduled according to the inspection timetable in coordination with the Department's inspectors. The company shall be notified of the scheduled date via telephone or the official company-approved email. The prescribed service fee for the inspection shall be paid.

6. An inspection shall be conducted to verify that the address and the layout of the Scientific Office and the samples store match the records and documents attached to the file.

7. If the requirements are not met, an email containing the inspection observations shall be sent to the Scientific Office within three (3) working days from the date of the inspection (an official letter of observations may be issued, if any).

Note: If the requirements and documents are not fulfilled, an acknowledgment shall be signed by the manager of the Scientific Office commitment to fulfill the inspection observations within thirty (30) days from the inspection date. In the event of failure to fulfill the observations and documents within the said period, the application shall be archived.

8. Upon fulfillment of the observations, the company shall submit a request for a fulfillment inspection, and a date shall be scheduled according to the inspection timetable.

9. After verification of the fulfillment of all observations and documents, the renewed Scientific Office license template shall be drafted, incorporating the new data, and printed (following review) within three (3) working days.

10. The original Scientific Office license shall be delivered to the company's representative, and a copy of the license shall be kept in the Scientific Office's file.

Required Documents for Receiving a Renewed Scientific Office License:

1. Original copy of the old license.

In case the original copy of the old license is lost, the following shall be submitted:

- A request on the company's letterhead for a lost replacement; the Chairman of the Board, their authorized representative as proven in the Commercial Register, or the Manager of the Scientific Office shall sign the request (Authenticated by a valid bank signature).
- Payment of the prescribed service fees.
- A lost memorandum issued by the police department stating the name and address of the licensed facility.

2. A copy of the authorization (The original for review).

3. A commitment from the Manager of the Scientific Office to maintain the layout, the Scientific Office license, within the Scientific Office premises and the samples store.

Required Documents for Adding Companies for marketing and promotion:

1. A request on the company's letterhead to add companies for marketing and promotion, signed by the Chairman of the Board, their authorized representative, as evidenced by the Commercial Register, or the manager of the Scientific Office. (Authenticated by a valid bank signature or signed before the General Department of Legal Affairs at the Egyptian Drug Authority).
2. Valid Registration licenses for the pharmaceutical products or medical devices for which marketing and promotion is required (at least one Registration license).

(The original for review)

In the event that the registration license has not yet been issued: The approval issued in the name of the Scientific Office by the relevant Central Administration authorizing the registration process shall be submitted (The original for review).

3. **The following documents shall be submitted according to the companies for which advertising is required:**

In the case of concluding an advertising contract between a licensed Scientific Office and a foreign company:

1. The Importers Register of the Egyptian agent/distributor, stating the companies for which marketing and promotion is required (The original for review).
2. **The marketing and promotion Contract** between the Scientific Office and the foreign company (authenticated by the Chamber of Commerce in the foreign country and then legalized by the Egyptian Embassy in the same country), or the Agency Agreement, explicitly stating the marketing and promotion article for the foreign company's products, accompanied by the Commercial Agents Register Card (Form S14). The contract shall be authenticated by the Chamber of Commerce in the foreign country and legalized by the Egyptian Embassy in the same country (The original for review).

In the case of concluding a marketing and promotion contract between a licensed Scientific Office and a local company:

1. A marketing and promotion Contract between the Scientific Office and the company for which marketing and promotion is required, (notarized by notary public, authenticated by a valid bank signature verification for both parties, or signed before the General Department of Legal Affairs at the Egyptian Drug Authority (The original for review).

In the case of concluding a marketing and promotion contract between a Scientific Office affiliated with a foreign company and a local company, the following document shall be added:

A Letter of Authorization from the foreign company authorizing the Scientific Office to advertise for the local company (authenticated by the Chamber of Commerce in the foreign country and legalized by the Egyptian Embassy in the same country) (The original for review).

Note:-

In the case of marketing and promotion for a specific number of pharmaceutical products or medical devices: The names and number of such products or devices shall be specified therein.

In the case of marketing and promotion for all pharmaceutical products or medical devices: The phrase "All pharmaceutical products or medical devices belonging to the company" shall be added thereto.

A service fee of 3,000 EGP shall be paid for each company to be added for marketing and promotion, pursuant to the decree of the Chairman of the Egyptian Drug Authority No. 316 of 2021, upon submitting the request and documents.

Operation Procedures for Adding an Advertising Company:

1. The documents related to the request for adding an advertising company shall be sent as a single PDF file to the email address of Administration of licensing of scientific offices, stability and bioequivalence centers

License.scioff@edaegypt.gov.eg

Or via the electronic link of the Administration of licensing of scientific offices, stability and bioequivalence centers

<https://forms.gle/2xVQUYRkSTrHEMuO6>

2. The submitted documents shall be reviewed. In the event of non-compliance or missing documents, an email shall be sent to the company to complete the requirements within five (5) working days from the date of receipt via the electronic link.

3. In event that the required documents are complete, an email shall be sent to the company within five (5) working days from the date of receipt via the aforementioned link, requesting their attendance at the headquarters of the Administration of licensing of scientific offices, stability and bioequivalence centers to submit the application, provided that all original documents are presented for review.

4. Following the receipt of the application, the Scientific Office's file shall be reviewed. In case of any deficiencies in the file or expired documents such as the title deed or registration licenses, an email shall be sent to the company to complete the documents within five (5) working days from the date of receipt of the application.

5. Upon fulfillment of the file deficiencies, a decision shall be made regarding the scheduling of an inspection as follows:

If less than one calendar year has elapsed since the date of the last inspection conducted for the Scientific Office and the samples store:

The licensing issuance procedures shall proceed as prescribed below without the need for a new inspection.

If more than one calendar year has elapsed since the date of the last inspection conducted for the Scientific Office and the samples store:

An inspection date shall be scheduled according to the inspection timetable in coordination with the Department's inspectors. The company shall be notified of the scheduled date via telephone or the official company-approved email. The prescribed service fee for the inspection shall be paid. An inspection shall be conducted to verify that the address of the Scientific Office and the samples store match the stated in the license and the title deed attached to the Scientific Office's file, as well as to ensure compliance with the approved layout attached to the file.

6. If the requirements are not met, an email containing the inspection observations shall be sent to the Scientific Office within three (3) working days from the date of the inspection (an official letter of observations may be sent, if any).

Note: If the requirements and documents are not fulfilled, a commitment shall be signed by the

manager of the Scientific Office committing to fulfill the inspection observations within thirty (30) days from the inspection date. In the event of failure to fulfill the observations and documents within the said period, the application shall be archived.

7. Upon fulfillment of the observations, the company shall submit a request for a fulfillment inspection, and a date shall be scheduled according to the inspection timetable.

8. Upon verification of the fulfillment of all observations and documents, the renewed Scientific Office license template shall be drafted, incorporating the new data, and printed (following review) within three (3) working days.

9. The original Scientific Office license shall be delivered to the company's representative, and a copy of the license shall be kept in the Scientific Office's file.

Documents Required Upon Receiving a Renewed Scientific Office License:

1. The original old license.

In event of loss of the original old license, the following shall be submitted:

- A request on the company's letterhead for the issuance of a replacement for the lost license, signed by the Chairman of the Board, their authorized representative as evidenced by the Commercial Register, or the manager of the Scientific Office (Authenticated by a valid bank signature).
- Payment of the prescribed service fee.
- A Memorandum of Loss issued by the police department detailing the loss, specifying the name of the licensed entity and the address.

2. A copy of the authorization (The original for review).

3. A Commitment from the manager of the Scientific Office to maintain the layout and the Scientific Office license within the premises of the Scientific Office and the samples store.

Documents Required in Case of Transfer of Ownership / Change of Scientific Office Name:

A) In the event of changing the name of the Scientific Office (Scientific Office affiliated with a local company, an agent, or an authorized office):

1. A request on the company's letterhead to change the Scientific Office name, signed by the Chairman of the Board or their authorized representative, as evidenced by the Commercial Register, (Authenticated by a valid bank signature or signed before the General Department of Legal Affairs at the Egyptian Drug Authority).

2. The Commercial Register of the company to which the Scientific Office is affiliated, reflecting the new name (The original for review).

3. A layout featuring the new name, certified by a syndicate engineer for the Scientific Office or the samples store, specifying the name of the Scientific Office, the samples store, and the detailed address. It shall be stamped by the Syndicate of Engineers after the inspection (original and two copies) and shall include:

- Horizontal plan showing the dimensions of the samples store to be licensed.
- Vertical plan showing the height of the samples store to be licensed.

4. A copy of the title deed for the premises under the new name (lease or ownership contract notarized by the notary public or Authenticated by a valid bank signature for both parties), specifying the type of activity (purpose of use) (The original for review).

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5. In the case of a Scientific Office affiliated with a local company, the following additional document is added: A copy of the factory license under the new name or a copy of the toll manufacturing card under the new name.

6. Regarding the status of Registration licenses:

- **If the products are registered in the name of the company or the agent: -**

Registration licenses under the new name shall be submitted prior to the issuance of the renewed Scientific Office license.

- **If the pharmaceutical products or medical devices are registered in the name of the Scientific Office:-**

A commitment to provide the registration licenses under the new name, or a letter from the Variations Department of the relevant Central Administration regarding the name change immediately upon issuance, shall be submitted after the issuance of the renewed Scientific Office license.

B) In the case of changing the Scientific Office name (affiliated with a foreign company):

1. A letter from the foreign company stating the change of the Scientific Office name (authenticated by the Chamber of Commerce in the foreign country and legalized by the Egyptian Embassy in the same country).

2. A request on the company's letterhead to change the Scientific Office name (Authenticated by a valid bank signature or signed before the General Department of Legal Affairs at the Egyptian Drug Authority).

3. A layout featuring the new name, certified by a syndicate engineer for the Scientific Office or the samples store, specifying the name, address, and stamped by the Syndicate of Engineers after the inspection (original and two copies), **including: -**

- Horizontal plan showing the lengths of the samples store to be licensed.

- Vertical plan showing the height of the samples store to be licensed.

4. A copy of the title deed or for the premises under the new name (lease or ownership contract notarized by the notary public or Authenticated by a valid bank signature for both parties), specifying the type of activity (purpose of use) (The original for review).

5. Regarding the status of Registration licenses:

- **If the products are registered in the name of the agent: -**

Registration licenses under the new name shall be submitted prior to the issuance of the renewed Scientific Office license.

- **If the pharmaceutical products or medical devices are registered in the name of the Scientific Office: -**

An undertaking to provide the registration licenses under the new name, or a letter from the Variations Department of the relevant Central Administration regarding the name change immediately upon issuance, shall be submitted after the issuance of the renewed Scientific Office license.

C) In the case of transfer of ownership to another company, the following document shall be added:

- A notarized waiver from the notary public in the case of a Scientific Office affiliated with a local company, an agent, or an authorized office.

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- An authenticated letter from abroad stating the transfer of company ownership (authenticated by the Chamber of Commerce in the foreign country and legalized by the Egyptian Embassy in the same country) in the case of a Scientific Office affiliated with a foreign company.

Operation Procedures for Ownership Transfer / Change of Scientific Office Name:

1. The documents related to the request for ownership transfer or name change shall be sent as a single PDF file to the email address of Administration of licensing of scientific offices, stability and bioequivalence centers

License.scioff@edaegypt.gov.eg

Or via the electronic link of Administration of licensing of scientific offices, stability and bioequivalence centers

<https://forms.gle/2xVQYRkSTrHEMuO6>.

2. The submitted documents shall be reviewed. In the event that any of the required documents are incomplete or outstanding, an email shall be sent to the company to complete the requirements within five (5) working days from the date of receipt of the application via the electronic link.

3. Upon fulfillment of the required documents, an email shall be sent to the company within five (5) working days from the date of receipt via the aforementioned electronic link, requesting their attendance at the headquarters of the Administration of licensing of scientific offices, stability and bioequivalence centers to submit the application, provided that all original documents are presented for review.

4. Following the receipt of the application, the Scientific Office's file shall be reviewed. In case there is any deficiencies in the file or expired documents (such as the title deed or registration licenses), an email shall be sent to the company to complete the documents within five (5) working days from the date of receipt of the application.

5. Upon fulfillment of the file deficiencies, a decision shall be made regarding the scheduling of an inspection as follows:

If less than one calendar year has elapsed since the date of the last inspection conducted for the Scientific Office and the samples store:

The licensing issuance procedures shall proceed as prescribed below without the need for a new inspection.

If more than one calendar year has elapsed since the date of the last inspection conducted for the Scientific Office and the samples store:

An inspection date shall be scheduled according to the inspection timetable in coordination with the Department's inspectors. The company shall be notified of the scheduled date via telephone or the official company-approved email. The prescribed service fee for the inspection shall be paid. An inspection shall be conducted to verify that the address and the layout of the Scientific Office and the samples store match the records and documents attached to the file.

6. If the requirements are not met, an email containing the inspection observations shall be sent to the Scientific Office within three (3) working days from the date of the inspection (an official letter of observations may be issued, if any).

Note: If the requirements and documents are not fulfilled, a commitment shall be signed by the manager of the Scientific Office committing to fulfill the inspection observations within thirty (30) days from the inspection date. In the event of failure to fulfill the observations and documents within

the said period, the application shall be archived.

7. Upon fulfillment of the observations, the company shall submit a request for a fulfillment inspection, and a date shall be scheduled according to the inspection timetable.
8. Upon verification of the fulfillment of all observations and documents, the renewed Scientific Office license template shall be drafted, incorporating the new data, and printed (following review) within three (3) working days.
9. The original Scientific Office license shall be delivered to the company's representative, and a copy of the license shall be kept in the Scientific Office's file.

Required Documents for Receiving a Renewed Scientific Office License:

1. The Original copy of the old license.

In case the original old license is lost, the following shall be submitted:

- A request on the company's letterhead for a lost replacement; the Chairman of the Board, their authorized representative as proven in the Commercial Register, or the Manager of the Scientific Office shall sign the request (Authenticated by a valid bank signature).
 - Payment of the prescribed service fees.
 - A Memorandum of Loss issued by the police department stating the name and address of the licensed facility.
2. A copy of the authorization (The original for review).
 3. A commitment from the Manager of the Scientific Office to maintain the layout, the Scientific Office license, and the samples store license within the Scientific Office premises.

Licensing of a Branch Scientific Office

Required Documents for Licensing a Branch Scientific Office (Reception Hall) without a Samples store or with a Samples store

1. A request on the company's letterhead for licensing a branch scientific office, specifying the detailed address (building number, floor, and apartment number). The request shall be signed by the Chairman of the Board, their authorized representative (as evidenced by the Commercial Register), or the manager of the Scientific Office (authenticated by a valid bank signature or signed before the General Department of Legal Affairs at the Egyptian Drug Authority).
2. A layout for the branch scientific office, specifying the office name and address, certified by a syndicate engineer, and stamped by the Syndicate of Engineers after the inspection (original and two copies), including:
 - Horizontal plan showing the lengths of the samples store to be licensed.
 - Vertical plan showing the height of the samples store to be licensed.
3. A copy of the title deed for the premises (lease or ownership contract notarized by the notary public or authenticated by a valid bank signature for both parties), specifying the detailed address (building number, floor, and apartment) and the type of activity (purpose of use) (The original for review).
4. Submission of documents pertaining to both the manager of the branch scientific office and the Pharmacist in charge of for samples store (in the event that a samples store is attached to the branch scientific office).

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Note:-

- The manager of the branch scientific office shall be a member of the Egyptian Medical Syndicate Union. The manager of the attached samples store shall be a full-time Pharmacist. It is permitted to combine both positions provided that the holder is a full-time Pharmacist and the samples store is located within the premises of the branch scientific office.
- A licensed Scientific Office may apply to the relevant department at the Authority to license branch scientific offices across the Republic, provided that a specific manager is appointed for each branch office.

The following service fees shall be paid pursuant to the decree of the Chairman of the Egyptian Drug Authority No. 316 of 2021, following the completion of the necessary inspections:

- Licensing a branch scientific office with an attached samples store (25,000 EGP)
- Licensing a branch scientific office without a samples store (Reception Hall) (15,000 EGP)

Procedures for Licensing a Branch Scientific Office

1. The documents required for the license request of a branch scientific office must be sent as one PDF file to the email of Administration of Licensing Scientific Offices and Stability and Bioequivalence Centers
License.scioff@edaegypt.gov.eg
Or via the electronic link of the Administration of licensing of scientific offices, stability and bioequivalence centers
<https://forms.gle/2xVQUYrKsTrHEmUo6>
2. The submitted documents shall be reviewed. In case any of the required documents are missing, an email will be sent to the company to complete the documents within 5 working days from the date of receiving the request through the electronic link.
3. If all required documents are complete, an email will be sent to the company within five working days from receiving the file through the previously mentioned electronic link, requesting them to attend the headquarter of the Administration of Licensing Scientific Offices and Stability and Bioequivalence Centers to submit the request along with all original documents for verification.
4. After receiving the request, the scientific office file will be reviewed. If there are missing documents or expired documents such as proof of premises possession or registration licenses, an email will be sent to the company to complete the documents within 5 working days from the request receipt date. An inspection date will then be scheduled according to the inspection timetable, in coordination with the department inspectors, and the company will be notified either by phone or via the officially approved company email, along with payment of the prescribed service fees for conducting the inspection.
5. An inspection of the subsidiary Scientific Office will be conducted by the department inspectors to verify that the address of the Scientific Office and/or sample storage area matches the attached proof of premises possession, as well as to verify compliance of the architectural layout of the new premises and ensure that the required health conditions are fulfilled.
6. If the requirements are not fulfilled, an email will be sent to the Scientific Office with the inspection remarks within 3 working days from the inspection date (an official letter may also be sent, if applicable).

Note: If the requirements and documents are not fulfilled, the manager of the Scientific Office must sign a commitment to fulfill the inspection remarks within 30 days from the inspection date. Failure to complete the requirements within this period shall result in the request being closed.

7. Once the remarks are fulfilled, the company shall submit a request for a fulfillment inspection to verify compliance, and an inspection date will be set according to the inspection schedule.
8. After confirming that all remarks have been fulfilled, and after payment of the required service fees and submission of a copy of the payment receipt, the subsidiary Scientific Office license form will be prepared and printed (after review) within 3 working days.
9. The company will then receive the original license of the Branch Scientific Office and a stamped and approved copy of the layout, while a copy will be kept in the Scientific Office's file.

Note: Upon receiving the license, an official authorization letter with authenticated by a valid bank signature must be presented.

Required Documents for Issuing a Replacement of a Lost License or layout

1. A request on the company's official letterhead requesting the issuance of a replacement license, signed by the Chairman of the Board of Directors or his authorized representative as stated in the Commercial Register, or by the Director of the Scientific Office manager, with the signature authenticated by a valid bank signature or signed in the presence of the General Legal Affairs Department at the Egyptian Drug Authority (EDA).
2. A Memorandum of Loss issued by the police department, stating the name of the lost document (license / layout), as well as the name and address of the licensed Scientific Office.

- **A service fee of 12,500 EGP shall be paid when issuing a replacement license for a branch Scientific Office that includes a sample store, in accordance with Egyptian Drug Authority Chairman's Decision No. 280 of 2021, upon submission of the request and required documents.**
- **A service fee of 7,500 EGP shall be paid when issuing a replacement license for a branch Scientific Office without a sample store (reception area only), in accordance with Egyptian Drug Authority Chairman's Decision No. 280 of 2021, upon submission of the request and required documents.**

Operation Procedures for Issuing a Replacement License/ layout

1. The inspector of the Administration of Licensing Scientific Offices, Stability and Bioequivalence Centers shall receive and review the request and the attached documents within 3 working days, and shall also review the company's file to inform them of any missing documents or to renew any expired documents. The company shall be notified of any deficiencies before issuing the replacement license.

2. The inspector of the Administration of Licensing Scientific Offices , Stability and Bioequivalence Centers shall prepare and print the replacement license with the same license number within 2 working days (after review and confirmation of payment of the prescribed service fees), and shall be certified by the Head of the Central Administration for Operations, or the layout replacement, if applicable, shall be approved within 2 working days by the department inspectors (in the event of obtaining a replacement of the layout).
3. One of the inspectors of the Scientific Offices Licensing Department shall make a photocopy of the original license and then hand over the original license to the Director of the Scientific Office manager or his authorized representative, while retaining the copy in the company's file, or hand over the approved layout (in the event of obtaining a replacement of layout).

Required Documents for Issuing a Damaged License Replacement

1. A request on the company's official letterhead requesting the issuance of a replacement for a damaged license, signed by the Chairman of the Board of Directors or his authorized representative as stated in the Commercial Register, or by the Scientific Office manager, with the signature (authenticated by a valid bank signature, or signed in the presence of the General Legal Affairs Department at the Egyptian Drug Authority (EDA)).
2. The original copy of the damaged license.
3. Proof of payment of the prescribed service fees.

Operation Procedures for Issuing a Replacement for a Damaged License:

1. The inspector of the Administration of Licensing Scientific Offices, Stability and Bioequivalence Centers shall receive and review the request and the attached documents within three working days, and shall also review the company's file to inform them of any missing documents or to renew any expired documents. The company shall be notified of any deficiencies before issuing the replacement license.
2. The inspector of the Administration of Licensing Scientific Offices, Stability and Bioequivalence Centers shall prepare and print the replacement license using the same license number within two working days (after review and verification of payment of the prescribed service fees), and it shall be approved by the Head of the Central Administration for Operations.
3. One of the inspectors of the Scientific Offices Licensing Department shall make a photocopy of the original license, then deliver the original license to the Scientific Office manager or his authorized representative, while retaining the copy in the company's file.

Certificate of Data

Required documents to issue a Certificate of Data:

1. A request on the company's letterhead to issue a Certificate of Data, stating the entity to which it will be submitted. The request must be signed by the Chairman of the Board of Directors or his authorized representative as recorded in the Commercial Register, or by the Scientific Office Manager, with the signature (authenticated by a valid bank signature, or signed in the presence of the General Legal Affairs Department at the Egyptian Drug Authority (EDA).
2. Payment of a service fee of 1,000 EGP in accordance with the decision of the Chairman of the Egyptian Drug Authority No. (280) of 2021, upon submission of the request and required documents.

Operation Procedures for Issuing a Certificate of Data:

1. A request to issue a Certificate of Data must be submitted, indicating the entity to which the certificate shall be addressed.
2. The prescribed service fee for issuing a Certificate of Data, amounting to 1,000 Egyptian Pounds, must be paid, and a copy of the payment receipt must be submitted along with the request.
3. The inspector of the Administration of Licensing Scientific Offices and Stability and Bioequivalence Centers shall receive and review the request within 3 working days.
4. The inspector of the Administration of Licensing Scientific Offices, Stability and Bioequivalence Centers shall prepare the Certificate of Data using the same information stated in the most recent license, print a copy within 2 working days, and have it approved by the Head of the Central Administration for Operations.
5. One of the inspectors of the Scientific Offices Licensing Administration shall deliver the original Certificate of Data to the Scientific Office Manager or an authorized representative, while a copy shall be kept in the company's file.

Suspension / Resumption of Activity

Required documents to suspend the activity upon the request of the Scientific Office / to resume the Scientific Office's activity:

1. A request on the company's letterhead to suspend the Scientific Office's activity / to resume the activity, signed by the Chairman of the Board of Directors or his authorized representative as recorded in the Commercial Register, or by the Scientific Office Manager, with the signature (authenticated by a valid bank signature, or signed in the presence of the General Legal Affairs Department at the Egyptian Drug Authority (EDA).

Note: In case of suspension of activity upon the request of the Scientific Office:

- The reason for suspension must be stated in the request, provided that it is acceptable to the competent administration.
- The suspension period must not exceed one full calendar year.
- The concerned departments must be officially notified of the suspension of activity.

Operation procedures for resuming activity upon the request of the Scientific Office:

1. The inspector of the Administration of Licensing Scientific Offices, Stability and Bioequivalence Centers shall receive and review the request within three working days and review the scientific office's file. In case there are any deficiencies in the file or if any documents have expired, such as the possession deed or registration license, an email shall be sent to the company to complete the required documents within 5 working days from the date of receiving the request, and the site inspection date shall then be scheduled according to the inspection timetable and in coordination with the administration's inspectors. The company shall be notified of the scheduled date either by phone or via its officially registered and approved email, along with payment of the prescribed service fee for conducting the inspection.
2. A site inspection shall be conducted to verify that the address of the scientific office and the sample store match the possession deed, as well as to verify that the engineering layout of the scientific office and the sample store corresponds with reality, and the inspection shall also ensure that the required health conditions are met, and an inspection report shall be prepared.
3. If the required conditions are not fulfilled, an email shall be sent to the scientific office with the inspection remarks within 3 working days from the date of the inspection (it is also possible to send an official letter with the notes, if applicable).
4. Once the notes have been fulfilled, the company shall submit a request for a fulfillment inspection to confirm compliance, and a date for this inspection shall be scheduled according to the inspection timetable.
5. After all notes have been addressed, the activities of the scientific office shall be resumed, and the Administration of Licensing Scientific Offices, Stability and Bioequivalence Centers shall notify the relevant departments of the resumption of activity.

Cancellation of the Scientific Office License

Required Documents for License Cancellation Upon Company Request:

1. A request signed by the Chairman of the Company's Board of Directors to cancel the scientific office license, with the signature (authenticated by a valid bank signature, or signed in the presence of the General Legal Affairs Department at the Egyptian Drug Authority (EDA)).

- For a scientific office affiliated with a foreign company, the following document is also required:

A notarized letter from the parent company abroad (**certified by the Chamber of Commerce, then authenticated by the Egyptian Embassy in the same country**), addressed to the Egyptian Drug Authority requesting **cancellation of the scientific office license**.

2. **If there are registered products or products under registration in the name of the scientific office: the status of these products must be clarified and documentation submitted confirming the appointment of a new authorized representative for registration.**
3. A Commitment on the company's letterhead addressed to the Egyptian Drug Authority committing to publish the decision to cancel the scientific office license in the Egyptian Official Gazette (Al-Waqa'i' al-Misriyya), with the company bearing all publication expenses. (Signature must be bank-authenticated)
4. Submission of the original scientific office license and the approved layout.

Operation Procedures for Cancelling a Scientific Office License:

A- In Case of License Cancellation Upon Company Request:

Procedures

1. The cancellation request shall be submitted at the headquarters of the Administration of Licensing Scientific Offices, Stability and Bioequivalence Centers, accompanied by the required documents.
2. An inspection appointment shall be scheduled to ensure that there are no free samples or promotional materials inside the scientific office or the sample store, and that the signage has been removed from the office and sample store. The prescribed service fee for conducting the inspection must be paid.
3. After inspection, and if it is proven that the scientific office is not carrying out its activity, a memorandum shall be submitted to the Chairman of the Egyptian Drug Authority to issue a cancellation decision.
4. After the cancellation decision is issued, the relevant departments at the Egyptian Drug Authority shall be notified of the cancellation of the scientific office license, and the company's authorized representative shall publish the decision in the Egyptian Gazette.

B. In the event that the license is cancelled based on inspection reports in accordance with any of the cancellation cases stated in the Chairman of the Egyptian Drug Authority's Decree No. 315 of 2021:

Procedures:

1. The matter shall be submitted in full to the Legal Advisor of the Egyptian Drug Authority, and after the legal opinion is issued, a memorandum shall be submitted to the Chairman of the Egyptian Drug Authority to issue the cancellation decision.
2. After the cancellation decision is issued, the relevant departments at the Egyptian Drug Authority shall be notified of the cancellation of the scientific office license.

Notes:

1. In the event that the main scientific office license is cancelled based on the company's request or based on inspection reports, the licenses of all affiliated branch scientific offices shall also be cancelled.
2. **Regarding the status of registration license registered in the name of the scientific office or products under registration:**
 - **If the scientific office license is cancelled at the company's request:** approval of the cancellation request shall not be granted unless a new registration representative is appointed in the event that there are registered or under-registration products.
 - **If the scientific office license is cancelled based on inspection reports:** registration license/ registration requests shall not be cancelled; however, registration / trading procedures shall be suspended while accounting the suspension period within the permitted trading timelines in accordance with the relevant ministerial decrees.

5. Cases of Cancellation of a Scientific Office License

Pursuant to Article (18) of the Chairman of the Egyptian Drug Authority's Decree No. 315 of 2021, the license of the scientific office may be cancelled by a decision of the Chairman of the Egyptian Drug Authority in the following cases:

1. If the license is not put into operation within six months from the date of its issuance.
2. If the office remains continuously closed for a period exceeding one calendar year.
3. If the office relocates from the address specified in the license to another location without prior approval from the competent authority.
4. If the office suspends its activities for six consecutive months without an acceptable justification submitted by the Scientific Office Manager to the competent authority.
5. If the office trades in, or offers for sale, samples of pharmaceutical products or medical devices that are designated for promotional purposes.
6. If the scientific office is devoid of any agencies, pharmaceutical products or medical devices that are registered and promoted through it.
7. If the office breaches the licensing requirements stipulated in Article (3) of the Decree thereof.

8. If the office breaches the requirements for storing samples stipulated in Article (4) of the Decree thereof.
9. If the office breaches the procedures for importing samples stipulated in Articles (6) and (7) of the Decree thereof.
10. If the office breaches the advertising and promotional requirements stipulated in Article (10) of the Decree thereof.
11. If the office fails to comply with the notification requirements for new products and medical devices as stipulated in Article (11) of the Decree thereof.
12. If the office fails to comply with the appointment requirements stipulated in Article (12) of the Decree thereof.
13. If the office, in bad faith, violates the applicable requirements for the registration of pharmaceutical, biological products or medical devices, resulting in the registration of any pharmaceutical, biological products or medical devices in the name of the scientific office contrary to the truth.
14. If the office violates the provisions of this Decree, Law No. 127 of 1955, Law No. 151 of 2019, other relevant laws, as well as the applicable regulations and decisions.

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

Note:

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

6. References

1. Law No. 127 of 1955 concerning the Practice of the Pharmacy Profession.
2. Law No. 151 of 2019 and its Executive Regulations regarding the establishment of the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management, and the Egyptian Drug Authority.
3. Decree of the Chairman of the Egyptian Drug Authority No. 315 of 2021 regarding the regulation of scientific offices.
4. Decree of the Chairman of the Egyptian Drug Authority No. 280 of 2021 regarding fees for certain services.
5. Decree of the Chairman of the Egyptian Drug Authority No. 316 of 2021 regarding fees for certain services.

6. The Organizational Guide for the Mechanisms, Procedures, and Rules for Implementing the Chairman of the Egyptian Drug Authority's Decree No. 343 of 2021 concerning "the registration procedures of biological products".
7. The Guidance Manual for Regulatory Procedures for Registration of Imported and Locally Manufactured Medical Devices Holding International Quality Certificates.
8. The Regulatory Manual for Registration of Locally Manufactured Medical Devices Not Holding International Quality Certificates.
9. The Regulatory Manual for the Procedures and Rules Governing Amendments to Medical Device Registration license.
10. The Regulatory Rules for the Registration and Circulation of Laboratory and Diagnostic Reagents.
11. Executive Procedures for Regulating the Registration / Re-Registration of Herbal Medicinal Products.
12. Procedures for Registration of Veterinary Products for the Year 2023.
13. The Regulatory Manual for Procedures for Re-Registration of Veterinary Medicinal Products in accordance with the Chairman of the Egyptian Drug Authority's Decree No. (434) of 2022.
14. The Regulatory Manual for Procedures for Registration of Imported Veterinary Medicinal Products from Reference Countries under the Fast Track Registration System (Track Fast).
15. The Regulatory and Guidance Manual and Rules for Registration of Disinfectants.
16. The Regulatory and Guidance Manual and Rules for Registration of Insecticides.
17. The Regulatory Manual for Decision No. 150-2022 – Fourth Edition.
18. The Regulatory Manual for the Unified Registration Decision No. 450 – Second Edition.
19. The Regulatory Manual for the Listing of Cosmetic Products.

7. Annexes

Health Requirements to be Met in the Samples Store:

1. The area of the sample's storage facility shall not be less than 25 m².
2. The ceiling height shall not be less than 260 cm.
3. The storage floor must be at the same level as the adjacent ground level. Exception may be made if adequate precautions are taken to prevent water leakage into the pharmaceutical institution, including installing a drainage system, provided that safe access to and from the storage facility is not compromised. In all cases, it is prohibited to establish a pharmaceutical facility in a basement or garage.
4. A permanent ventilation source must be provided (fans or air conditioning), ensuring that the temperature does not exceed 30°C and humidity does not exceed 65%.

5. An adequate number of temperature and humidity meters must be provided in all parts of the sample's store, with readings recorded at fixed intervals during working hours.
6. The flooring must be made of non-combustible material (such as ceramic, marble, or tiles).
7. Shelves or pallets must be non-wooden.
8. A fire extinguisher of a size appropriate to the area of the sample's store must be provided, with a capacity of not less than 6 kg.
9. A fixed sign must be placed at the entrance of the sample's store.
10. Fine mesh wire must be installed on all ventilation openings.
11. In the event that a water source exists inside the sample's store:
 - A separate source of clean water must be provided (from which water is taken directly through a tap installed above the sink inside the room, with a strainer). A sloped marble surface must be provided next to the sink, and ceramic tiles must cover the wall to a height of not less than 60 cm above the sink and strainer.
 - Drainage method: The sink drainage system must discharge into a separate gully trap, then into the public sewage system or the building's sewage line.
12. In the event that a restroom exists:
 - The restroom must be in a separate location and have a door that does not open directly onto areas used for storing medical preparations or medical devices.
 - A corridor must be built in front of the restroom, with a door for both the corridor and the restroom.
 - There must be a window opening to an external window or skylight, and the use of an exhaust fan is allowed.
 - The restroom walls must be covered with ceramic tiles.
 - The toilet must be connected to a dedicated inspection chamber that discharges into public sewage or the building's drainage system.
13. (In the case of licensing a local scientific office affiliated with a licensed factory), and a request has been submitted to license a sample store within the factory, and the sample store must have a separate entrance from the other factory storage areas, and there must be no direct connection between it and the factory storage areas.

Special guidelines for the scientific office:

1. The layout of the scientific office must match the actual layout and be certified by a registered engineer, stamped with the Engineers Syndicate seal after inspection. (Original and two copies)
2. A permanent sign bearing the name of the scientific office must be placed at its entrance.
3. There must be no connection between the activities of the scientific office and any other activities.