

# **Regulatory Guideline for the Requirements and Procedures of Medical Products Store Licenses and the Health Conditions to be implemented, pursuant to the Decree of the Chairman of the Egyptian Drug Authority No. (725) of 2024**

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**1. Introduction:**

The Administration of Medical Products Stores and Warehouses licensing, under the General Administration of Licensing of Scientific Offices, Medical Products Stores, Warehouses, Stability and Bioequivalence Centers, is responsible for establishing the system and procedures related to Medical Products Store licenses. This includes Medical Products Stores involved in the storage and distribution of drugs, medical products, and medical supplies under the jurisdiction of the Egyptian Drug Authority, with the goal of delivering safe and effective medication to Egyptian patients.

**2. Scope:**

The work procedures shall be applied to all the relevant branches of the Egyptian Drug Authority, as well as the Administration of Medical Products Stores and Warehouses licensing at the Central Administration of Operations at the main headquarters of the Egyptian Drug Authority, regarding the following:

- Licensing a New Medical Products Store.
- Updating a Medical Products Store License for any reason that necessitates an update.
- Renewing a Medical Products Store License to renew its validity period.
- Licensing a Accessory Store related to a Medical Products Store.
- Canceling a Medical Products Store License.

**3. Definitions:**

- **Medical Products Store License Holder:**

The person submitting the license application, whether the Medical Products Store is registered under an individual's name or a company, whose name appears on the license as the Medical Products Store owner.

- **Authorized Agent for the Medical Products Store License:**

The person delegated by the licensed company to legally represent it regarding the Medical Products Store license. Their personal documents are submitted with the Medical Products Store licensing file.

- **Representative of the Medical Products Store License Holder:**

The person who represents the license holder to follow up the licensing procedures, based on a signature verification by the bank or a notarized power of attorney.

- **Medical Products Store Layout:**

The layout of the Medical Products Store, signed and stamped by a syndicated engineer, showing the dimensions, area, internal layout, and the location of the property.

#### IV. Main subject:

##### **First: Licensing a new Medical Products Store**

##### 1- Documents Required for Licensing a Medical Products Store:

##### 1.1 Essential documents in accordance with the Law of Pharmacy profession Practice no. 127 year 1955:

- 1.1.1 An application form for licensing a Medical Products Store (the form is fulfilled at the relevant branch of the Egyptian Drug Authority in the governorate where the location to be licensed as a Medical Products Store is situated, duly completed and signed by the license applicant or authorized representative).
- 1.1.2 A copy of the National ID card of the license applicant or the authorized representative to whom the Medical Products Store license shall be issued. In case the application is submitted in the name of a company, a valid National ID card must be provided.
- 1.1.3 An original official extract of the birth certificate of the license applicant or the authorized representative to whom the Medical Products Store license shall be issued. In case the application is for licensing a Medical Products Store in the name of a company.
- 1.1.4 An original valid criminal record (No Recorded Criminal Verdicts) for the license applicant or the authorized representative to whom the Medical Products Store license shall be issued. In case of applying for a Medical Products Store license in the name of a company, it shall be addressed to the Egyptian Drug Authority.
- 1.1.5 Three (3) copies of the layouts of the store to be licensed, drawn to a scale of 1:50, signed and stamped by a syndicated engineer (to ensure conformity with the actual site during inspection of the Medical Products Store, then approved by the Inspection Committee and stamped by the Egyptian Drug Authority) provided that all of the following items are clearly indicated on a single layout sheet.
  - Horizontal layout illustrating the dimensions of the site intended to be licensed.
  - Vertical layout illustrating the height of the site intended to be licensed.
  - Sketch layout illustrating the boundaries specific to the store intended to be licensed.
  - Facade of the site intended to be licensed.
  - Data table illustrating the license holder's name, license type, site address.
  - the shop boundaries as indicated on the layout.

- A table showing lengths, height, and ventilation openings.
- 1.1.6 A postal receipt in the license holder's name (receipt proving payment of the review fee) with an amount of Five Egyptian Pound, addressed to the Egyptian Drug Authority.

## **1.2 Documents to be completed during the licensing procedures and prior to the issuance of the license**

1.2.1 A true copy of the original of the title deed for the store intended to be licensed whether (a lease contract or ownership contract) in the name of the license holder, and must be valid and notarized at (the Real Estate Authority, or by court judgment). The lease term must not be less than five years. (The original document must be presented for review).

1.2.2 An original document from the electricity company confirming the existence of an independent electricity meter within only the store intended to be licensed. The document must clearly state the meter number and the address of the store.

Alternatively, if the store do not have an electricity meter, a certificate from the relevant electricity company confirming that electricity has been permanently and independently connected until a meter is installed, along with an explanation for the delay in the meter installation from the electricity company.

1.2.3 An original document from the water company confirming the existence of a private and independent connection from the public water supply serving the store intended to be licensed as Medical Products Store, (in the event that a bathroom is available within the store intended to be licensed as a Medical Products Store).

It should be noted that the electricity and water utilities must be independent for each Medical Products Store separately. The electricity meter number located inside the Medical Products Store must be recorded in the licensing inspection report, and the documents related to these utilities must be submitted separately for each Medical Products Store.

1.2.4 Documents confirming the availability of civil defense and safety measures issued by the competent Civil Protection Department.

1.2.5 Legal documents related to the location of the store intended to be licensed:

1.2.5.1 **In the event that the Medical Products Store intended to be licensed falls under the jurisdiction of district authority:** a letter must be obtained from the competent district authority

or from the entity responsible for issuing building licenses governing the Medical Products Store address, stating the status of the store intended to be licensed in terms of the following:

- Whether it is a commercial premise and not a residential apartment, basement, or garage.
- Whether a demolition or removal order has been issued for the property, and whether the building has been issued a construction license.
- A statement from the district authority confirming that there are no obstacles preventing the continuation of the licensing procedures for the store the subject of application, with reconciliation documents attached in the event of any violations related to the store.
- A statement confirming that the address of the Medical Products Store intended to be licensed is geographically located within a city and not within a village, as licensing Medical Products Stores in villages is not permitted.

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- In the event that the Medical Products Store intended to be licensed falls under the jurisdiction of the New Urban Communities Authority, the Authority shall be contacted to provide its opinion regarding approval or disapproval of licensing the requested activity as a Medical Products Store, as well as to confirm that the store intended to be licensed is not a garage, basement, residential apartment, or administrative unit. In the event of non-approval, the file submitted for licensing the Medical Products Store shall be cancelled, and the applicant shall be notified by registered mail with acknowledgment of receipt.

Note: (The district authority, the New Urban Communities Authority, or the entity responsible for issuing building permits shall be contacted by the relevant branch of Egyptian Drug Authority in the governorate where the site intended to be licensed is located, after receiving the licensing file and registering it in the records).

- 1.2.5.2 A certificate issued by the General Directorate of Certificates and Licensing Follow -up - Central Administration of Operations - Egyptian Drug Authority, registering the responsible pharmacist as the Medical Products Store manager before issuing the Medical Products Store license.
- 1.2.5.3 A declaration of the license applicant's approval to appoint the pharmacist in charge of the Medical Products Store upon issuance of the license. If the license holder is a company, the declaration must have a signature verification by the bank.
- 1.2.5.4 A copy of the valid National ID of the pharmacist in charge of the Medical Products Store, a copy of the syndicate membership card, and a copy of the pharmacy practice license.
- 1.2.6 In the case where a company is applying for a Medical Products Store license, the following documents must be submitted:
- 1.2.6.1 A true copy of the original of the company's current and valid commercial register (The original document must be presented for review). The company's trade name must not include the phrase "pharmacy management" or the name of a governorate. The company's administrative headquarters must have an address different from the address of the store intended to be licensed as a Medical Products Store. The company's activity must include the trade and distribution of medicines.

Note: The company holding the license is obligated, when making an amendment to the commercial register regarding the trade name, trademark, or type of company, to notify the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is located within 3 months from the date of the amendment, so that the necessary procedures can be taken regarding the amendment of the license. In the event that the branch is not notified of the amendment, the necessary legal procedures will be taken.

- 1.2.6.2 A true copy of the original of the company's current and valid tax card (The original document must be presented for review).
- 1.2.6.3 A true copy of the original of the title deed whether (a lease contract or ownership contract) in the name of the company for the store to be licensed as Medical Products Store, provided that it must be valid and notarized at the Real Estate Authority (The original document must be presented for review). The lease

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term must not be less than five years.

- 1.2.6.4 Authorization from the Chairman of the Board of Directors of the company or the manager of the company that submitted the license application (pursuant to the administrative powers in the Commercial Register) to specify the name of the person authorized to issue the Medical Products Store license in his name, provided that the authorization have a signature verification by the bank.

**(Note: No authorization is required if the person authorized to issue the license in his name is the chairman of the company's board of directors or its manager, and is the sole representative and manager of the company, in accordance with the powers of the administration in the commercial register).**

- 1.2.7 Application signed by the license applicant requested that the Medical Products Store distribution area be specified for the governorates, provided that the distribution area of the new Medical Products Store, when the license is issued, is only the licensed governorate where the Medical Products Store is located, until the activity is carried out and the competent inspection Administration confirms that there are no violations. He may submit a request to update the license data by increasing the distribution area of the Medical Products Store outside the licensed governorate after obtaining the GSDP certificate and pursuant to the procedures explained in the section on updating the license data in the regulatory guideline.
- 1.2.8 The license applicants are required to submit the following documents regarding the Medical Products Store's vehicles:
- 1.2.8.1 A true copy of the original of the vehicle transport license – used for transporting pharmaceutical products – owned by the Medical Products Store owner, provided it is valid. (The original document must be presented for review).
- 1.2.8.2 If the transport vehicle used to transport pharmaceutical products is not owned by the Medical Products Store owner, a lease contract signed by the vehicle license holder must be submitted. The contract must be valid for the duration of the license, notarized at the Real Estate Authority, and renewed upon expiry. A copy of the renewed contract must be submitted to be kept in the file.
- 1.2.8.3 In all cases, the owners of Medical Products Store licenses must notify the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is located about the new transport vehicles belonging to the Medical Products Store for inspection and verification of their suitability, provided that the approved licensing inspection report is kept in the Medical Products Store license file.
- 1.2.9 The prescribed fees for licensing a Medical Products Store, estimated at 20,000 EGP (Twenty Thousand Egyptian Pounds) in accordance with Law No. (151) of 2019 and its executive regulations, must be paid before receiving the license.

- The new Medical Products Store

license is issued with a validity period of five years from the date of issuance, and an application for renewal must be submitted during the last six months of the last year of the license term.

- If the Medical Products Store License validity period ends and the license holder does not submit a request to renew the license before its validity period ends, the Medical Products Store license holder retains his legal position in renewing the license with all its components, provided that trading from the Medical Products Store is stopped until the license is renewed in compliance with the requirements of the World Health Organization, i.e. the Medical Products Store is administratively closed.

## **2- Procedures for Licensing a Medical Products Store:**

2.1 The Medical Products Store license application is written by the license holder or their representative on the form prepared for this purpose at the relevant branch of the Egyptian Drug Authority in the governorate where the site intended to be licensed as a Medical Products Store is located.

2.2 The Medical Products Store license application is sent by registered mail with acknowledgment of receipt requested to the relevant branch of the Egyptian Drug Authority in the governorate where the site intended to be licensed as a Medical Products Store is located.

2.3 If the essential documents for the license are complete, the date for the first inspection will be set within 30 days from the date of receiving the file, pursuant to the inspection schedule, and the license applicant will be notified by registered mail with acknowledgment of receipt requested.

2.4 If the essential documents stipulated by the Law of Pharmacy profession Practice no. 127 year 1955 are not fullfiled (the documents specified from No. 1.1 to No. 1.6, the documents required for a Medical Products Store license), the file is cancelled and the license applicant is notified by registered letter with return receipt requested that the application has been cancelled and the reason for keeping it is determined by the relevant branch of the authority.

2.5 The district or the entity responsible for issuing Building licenses or the New Urban Communities Authority to which the site to be licensed as a Medical Products Store belongs (through the relevant branch of the authority) should be contacted to provide a statement on the following:

- The store is classified as a commercial institution and not (administrative, residential apartment, basement, or garage) and are not subject to state property.
- Whether the store is located in a slum area or not, or whether a demolition order has been issued against it or not.
- Whether the store has a Building license or not.
- There are no obstacles that impede the progress of the licensing procedures for the store, subject of the application, with the attachment of reconciliation forms if any exist, and the place to be licensed is a Medical Products Store located geographically within a city and not within a village

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(in the event that the place belongs to one of the districts).

- Expressing an opinion on whether to approve or reject the license for the requested activity (a Medical Products Store activity), and that the place to be licensed is not a basement, garage, residential activity, or administrative activity, and that the place to be licensed is a Medical Products Store located geographically within a city and not within a village (in the event that the place belongs to the New Urban Communities Authority). In the event of non-approval, the file submitted for the Medical Products Store license will be cancelled at the responsibility of the license applicant.

2.6 The initial inspection of the store to be licensed is carried out by the relevant branch of the Egyptian Drug Authority, as well as an inspection of the vehicles belonging to the Medical Products Store, in the presence of the applicant for the license or his representative. If it is found that the requirements that must be fulfilled by the Medical Products Stores attached to Decree No. (725) of 2024 are not met, the following shall be done:

2.6.1 The applicant is granted an initial timeframe of four months to fulfill the requirements. The applicant must then submit an application to the relevant branch of the Egyptian Drug Authority in the governorate where the site to be licensed as a Medical Products Store is located, in order to schedule the second inspection.

2.6.2 If the required conditions are fulfilled before the end of the first timeframe for addressing the observations, and the second inspection proves that the required conditions and documents have been met, the file is sent to the Administration of Medical Products Stores and Warehouses licensing in the Central Administration of Operations at the main headquarters of the Egyptian Drug Authority to review the file and issue the license.

2.6.3 If the requirements are not fulfilled within the first timeframe, the applicant is granted a second timeframe of half the first timeframe, which is two months, to complete the requirements. At the end of this second timeframe, the final inspection will be carried out, or at the request of the license holder before the end of the timeframe. If it is found that the requirements are not met, the license application will be cancelled and the applicant will be notified by registered mail with acknowledgment of receipt by the relevant branch of Egyptian Drug Authority.

2.7 After fulfilling the requirements and submitting the necessary documents, the licensing file, including all documents submitted by the applicant, licensing inspection reports of the location to be licensed, a certified and stamped vehicle licensing inspection report, and other documents required for licensing, is sent from the relevant branch of

the Egyptian Drug Authority in the governorate where the location to be licensed as a Medical Products Store is located to the Administration of Medical Products Stores and Warehouses licensing at the Central Administration of Operations for review. The following steps are taken:

2.7.1 If the required documents for licensing are not met, the relevant branch of the Egyptian Drug Authority in the governorate where the site to be licensed as a Medical Products Store is located will be contacted to complete them within a timeframe of 90 days from the date of the final inspection that proved compliance with the requirements that must be fulfilled for Medical Products Stores attached to

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Decree No. (725) of 2024.

2.7.2 After fulfilling the requirements and submitting the necessary documents within the allotted timeframe for licensing, the license is issued.

2.7.3 If the documents are not completed within the timeframe granted for licensing, the file will be cancelled by the branch of the Egyptian Drug Authority responsible in the governorate where the site to be licensed as a Medical Products Store is located.

- The license holder or his representative shall pay the fees in accordance with Law No. (151) of 2019 and its executive regulations before receiving the license.

**3- Cases of cancelling Medical Products Stores license files:**

Medical Products Store licensing files are cancelled in all the following cases, taking into account that the license applicant is notified of the file being kept by registered mail with acknowledgment of receipt by the relevant branch of the Egyptian Drug Authority:

3.1 Sending the license file without any of the essential licensing documents being completed (documents from 1.1 to 1.6). The criminal record of the license applicant or the person authorized to issue the license in his name is not valid if the license application is in the name of a company or if it is not addressed to the Egyptian Drug Authority, when examining the file after it has arrived at the relevant branch of the Egyptian Drug Authority by mail and after making a report of opening the envelope of documents.

3.2 A statement was received from the relevant district indicating that the place is a place with administrative activity, a basement, a residential activity, a garage, or that the property has not been issued a building license and no reconciliation has been carried out regarding it, or the district refused the license, in the event that the shop to be licensed belongs to one of the districts.

3.3 The Urban Communities Authority does not approve the activity of a Medical Products Store, or the place is an administrative activity, basement, garage, residential activity, or other activity other than a Medical Products Store (in the event that the shop to be licensed belongs to a city authority of the Urban Communities Authority).

3.4 If the property for which a Medical Products Store license is required is geographically located within a village and not within a city.

3.5 Failure to fulfill requirements for proper storage or the required documents within the timeframe granted for the license.

3.6 If the initial inspection committee finds that the address of the site for which a license is sought is different from the address that was established in the license application.

3.7 If the initial inspection committee finds that the place to be licensed is not clearly defined by three walls, a roof, and a door for entering the store .

**Second: Updating a Medical Products Stores license**

Medical Products Stores are required to submit a Good Storage and Distribution Practices (GSDP)

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certificate when applying to update their store license for any of the purposes listed in the organizational manual. This procedure will be mandatory starting from 01.01.2026.

1- Documents required to update a Medical Products Store license

**1.1 Transfer of ownership of a licensed Medical Products Store by:**

- 1.1.1 An application submitted by the person or company wishing to transfer ownership of the Medical Products Store license to it. If the request is to transfer the Medical Products Store license to a company, the application shall be signed by the chairman of the board of directors of the company or the manager of the company wishing to transfer the license to it, in accordance with the powers specified in the commercial register and should have a signature verification by the bank. The application should be addressed to the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is located, and the application should include the Medical Products Store license details in full (the name of the Medical Products Store pursuant to the license, the license number, and the Medical Products Store address).
- 1.1.2 The original waiver form of the license, documented by the Real Estate Registry in accordance with a ratification report and written by the owner of the Medical Products Store license to the person or company to whom the ownership of the license is to be transferred, or the certified statement of the original sale contract, documented by the real estate registration and documentation authority in accordance with a attestation minute that includes the transfer of the Medical Products Store license, provided that the name of the Medical Products Store, the license number and the address of the Medical Products Store are proven by the transfer of the license or by the sale contract in the real estate registration and documentation authority.

**Note:**

- **If the Medical Products Store whose ownership is to be transferred has a licensed Accessory Store, a waiver of the storage facility license must be submitted, documented by the Real Estate Registry, in accordance with a certified statement that includes all the required information.**
  - **If a change of the Medical Products Store's trade name is requested upon transfer of ownership, the applicant for the transfer of ownership must provide a statement of the new trade name of the Medical Products Store upon transfer of ownership. However, if the same trade name of the Medical Products Store is retained, the transfer of the license must include a transfer of the trade name of the Medical Products Store, provided that the Medical Products Store is licensed in the name of a person and not in the name of a company.**
- 1.1.3 Personal documents of the new license holder or the person authorized to issue the Medical Products Store license in his name in the event of a request to transfer ownership of a Medical Products Store license in the name of a company (a copy of the valid national identity card - a valid criminal record certificate (certificate of no prior convictions) addressed to the Egyptian Drug Authority - an official extract of the birth certificate).

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- 1.1.4 A true copy of the original of the title deed (lease contract or ownership contract) from the owner of the store where the Medical Products Store is located and the applicant for transferring ownership of the license, provided that it is valid and authenticated (real estate registry or Court Judgment) (bring the original for review).
- 1.1.5 Approval from the applicant for transfer of ownership and the pharmacist manager to continue working after the transfer of ownership if the pharmacist manager continues after the transfer of ownership. However, in the event of a change in the pharmacist manager, the original certificate of registration of a new pharmacist manager issued by the General Directorate of Certificates and Licensing Follow -up of the Egyptian Drug Authority must be submitted with the approval of the applicant for transfer of ownership for his appointment.
- 1.1.6 A copy of the valid national ID card of the pharmacist manager responsible for the Medical Products Store and a copy of his/ her syndicate membership card.
- 1.1.7 A valid and up-to-date commercial registration and tax card for the company, in the event that the company is the owner of the Medical Products Store license that will be transferred.
- 1.1.8 If the ownership of the Medical Products Store license is transferred to the company and not to an individual, the following documents must be submitted:
  - 1.1.8.1 A true copy of the original of the valid and up-to-date commercial registration and tax card of the company to which the Medical Products Store license is to be transferred (bring the original for review). It should be noted that the company's administrative headquarters must have a different address than the Medical Products Store address, and the company's activity must include the trade and distribution of medicines. The company's trade name must not include the phrase (pharmacy management) or the name and name of a governorate.
  - 1.1.8.2 A certified bank signature authorization from the Chairman of the Board of Directors of the company or the company manager (pursuant to the powers in the commercial register) to indicate the name of the authorized person from the company for the issuance of the license in his name when transferring ownership of the Medical Products Store license to it.
  - 1.1.8.3 Copies of the licenses for the Medical Products Store's vehicles that will be used to transport medicines, which have been inspected by the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, and photos of the lease contracts authenticated by the Real Estate Registry and valid in the event that the vehicles are not owned by the owner of the new Medical Products Store license.
  - 1.1.8.4 A request addressed to the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, submitted by the company requesting the transfer of ownership, to define the Medical Products Store's distribution scope. The distribution scope at the time of license issuance will be limited to the licensed governorate only in which the medical products store is licensed, until the activity commences under the company's name to which the medical products store license is transferred and the competent inspection administration verifies the absence of violations. The company may submit a request to update the license data to expand the Medical Products Store's distribution scope beyond the licensed governorate after obtaining a GSDP certificate, in accordance

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with the procedures outlined in the "Updating License Data" section of the regulatory guideline, for the purpose of increasing the Medical Products Store's distribution scope.

- 1.1.8.5 Original Medical Products Store license belonging to the license holder.
- 1.1.8.6 Receipt for payment for the service of requesting transfer of ownership of a Medical Products Store, pursuant to the Decree of the Chairman of the Egyptian Drug Authority No. 280 of 2021.

**1.2 Transferring ownership of a licensed Medical Products Store to the heirs of the license holder (in the case of Medical Products Stores licensed in the names of individuals and not companies), the following documents must be submitted:**

- 1.2.1 A request signed by the heirs of the license holder or their agent (by virtue of an official power of attorney authenticated by the Real Estate Registry) addressed to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, to transfer ownership of the Medical Products Store to the legal heirs, provided that the request includes the complete Medical Products Store license data (the name of the Medical Products Store pursuant to the license - the license number - the Medical Products Store address).
- 1.2.2 A copy of the national identity card for all heirs of the owner of the Medical Products Store license - or the original official extract of birth certificates for minor heirs who have not obtained national identity cards.
- 1.2.3 A true copy of the original of the legal inheritance certificate (with the original to be presented for review).
- 1.2.4 Original official extract of the license holder's death certificate.
- 1.2.5 Original Medical Products Store license belonging to the license holder.
- 1.2.6 If there are minor children, their guardianship documents must be submitted.
- 1.2.7 A true copy of the original of a valid title deed (lease or ownership contract) for the licensed store used as a Medical Products Store, provided that it is valid and authenticated (real estate registry or Court Judgment), and that the lease term is not less than five years (bring the original for review).
- 1.2.8 Copies of the licenses for the Medical Products Store's vehicles that will be used to transport medicines, which have been inspected by the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, and photos of the lease contracts authenticated by the Real Estate Registry and valid between the owner of the vehicle and the heirs or their agent.
- 1.2.9 A statement from the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, regarding the full details of the current pharmacist manager responsible for the Medical Products Store, in the event that the pharmacist manager continues after the transfer of ownership, with the approval of the applicant for the transfer of ownership and the pharmacist manager to continue working after the transfer of ownership. In the event of a change of the pharmacist manager, the original certificate of registration of a new pharmacist manager issued by the General Directorate of Certificates and Licensing Follow -up of the Egyptian Drug Authority must be submitted, with the approval of the applicant for the transfer of ownership for his appointment.
- 1.2.10 A copy of the valid national ID of the pharmacist manager responsible for the Medical Products Store, a copy of the syndicate membership card, and a copy of the pharmacy practice license.

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- 1.2.11 A request addressed to the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, submitted by the legal heirs of the owners of the ownership transfer request or their authorized representative (by virtue of an official power of attorney notarized by the Real Estate Registry), to determine the Medical Products Store's distribution scope. The distribution scope, at the time of license issuance, shall be limited to the licensed governorate only, until the activity commences in the name of the legal heirs of the owners of the ownership transfer request and the competent inspection administration verifies the absence of violations. They may submit a request to update the license data to expand the Medical Products Store's distribution scope beyond the licensed governorate after obtaining the GSDP certificate, in accordance with the procedures outlined in the "Updating License Data" section of the organizational regulatory guideline, for the purpose of increasing the Medical Products Store's distribution scope.
- 1.2.12 Receipt of payment for the service of requesting transfer of ownership of a Medical Products Store, in accordance with the Decree of the Chairman of the Egyptian Drug Authority No. 280 of 2021.
- 1.3 Changing the person authorized to issue the Medical Products Store license in his name (in the case that the owner of the Medical Products Store license is a company):
- 1.3.1 A request signed by the Chairman of the Board of Directors of the company or the manager of the company holding the Medical Products Store license, in accordance with the powers specified in the commercial register, addressed to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, in order to change the authorized person to whom the Medical Products Store license is issued in his name, provided that the request includes the full license data and the data of the new authorized person (and the request should have a signature verification by the bank).
- 1.3.2 A true copy of the original of a valid and up-to-date commercial registration certificate for the company. (Bring the original copy for verification).
- 1.3.3 A true copy of the original of the company's valid and up-to-date tax card. (Bring the original for verification).
- 1.3.4 Personal documents of the new authorized representative (a copy of the valid national identity card - a valid criminal record certificate (certificate of no prior convictions) addressed to the Egyptian Drug Authority - an official extract of the birth certificate)
- 1.3.5 Copies of the Medical Products Store's vehicle licenses that will be used to transport medicines and which have been inspected by the Egyptian Drug Authority, and photos of the lease contracts authenticated by the Real Estate Registry and valid in the event that the vehicles are not owned by the Medical Products Store license holder.
- 1.3.6 A true copy of the original of the title deed (lease or ownership contract) for the store where the Medical Products Store is located, provided that the assignment of the warehouse license and in the name of the Medical Products Store license holder (with the original to be presented for review).

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- 1.3.7 A copy of the valid national ID of the pharmacist manager responsible for the Medical Products Store, a copy of the syndicate membership card, and a copy of the pharmacy practice license.
- 1.3.8 A copy of the Good Storage and Distribution Practices (GSDP) certificate issued by the Egyptian Drug Authority for the Medical Products Store (bring the original for verification).
- 1.3.9 Original Medical Products Store license belonging to the license holder.

**1.4 Replacement for a lost license for a licensed Medical Products Store:**

- 1.4.1 A request addressed to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, from the Medical Products Store license holder, to issue a replacement license (if the Medical Products Store license holder is a company, the request must be signed by the company's chairman of the board or the company manager holding the Medical Products Store license, pursuant to the powers specified in the commercial register) and has a signature verification by the bank. The request must include all the Medical Products Store license details, including the license number, Medical Products Store name, and address.
- 1.4.2 The original memorandum of loss issued by the police department of the Medical Products Store license was prepared by the license holder or his representative.
- 1.4.3 A declaration and undertaking from the license holder to hand over the original license that was lost if it is found after the issuance of a replacement license, and to bear full legal responsibility in the event of dealing with it.

1.4.4 A true copy of the original of the title deed (lease or ownership contract) for the store where the Medical Products Store is located, provided that the Contract is valid and notarized and in the name of the Medical Products Store license holder (with the original to be presented for review).

1.4.5 A true copy of the original of the company's valid and up-to-date commercial registration and tax card (the original must be presented for verification) if the Medical Products Store is licensed in the company's name.

1.4.6 A recent copy of the national ID card of the license holder or their authorized representative (if the Medical Products Store is licensed in a company's name).

1.4.7 copies of the notarized and valid Medical Products Store lease agreements, if the vehicles are not owned by the Medical Products Store license holder, and copies of the vehicle registration documents for the Medical Products Store vehicles that will be used to transport medications, which have been inspected by the Egyptian Drug Authority and are licensed to the Medical Products Store.

1.4.8 A copy of the Medical Products Store pharmacist manager's valid national ID card, a copy of his/her syndicate membership card, and a copy of his/ her pharmacy practice license.

1.4.9 A copy of the Good Storage and Distribution Practices (GSDP) certificate issued by the Egyptian Drug Authority for the Medical Products Store (the original must be presented for verification).

1.4.10 Receipt of payment for the service of requesting a replacement for a lost Medical Products Store license, in accordance with the Decree of the Chairman of the Egyptian Drug Authority No. 280 of 2021.

**1.5 Replacement of a Licensed Medical Products Store's damaged License:**

1.5.1 A request addressed to the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, from the Medical

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Products Store license holder, for issuing a replacement of a Licensed Medical Products Store's damaged License, (if the Medical Products Store license holder is a company, the request must be signed by the company's chairman of the board or the company manager holding the Medical Products Store license, pursuant to the powers specified in the commercial register) and has a signature verification by the bank. The request must include all the Medical Products Store license details, including the license number, Medical Products Store name, and address.

1.5.2 The original damaged license.

1.5.3 A true copy of the original of the company's valid and up-to-date commercial registration and tax card (the original must be presented for verification) if the Medical Products Store is licensed in the company's name

1.5.4 A true copy of the original of a valid and up-to-date tax card for the company (the original must be presented for verification), if the Medical Products Store is licensed in the company's name.

1.5.5 A copy of valid and new national ID card of the license holder or their authorized representative (if the Medical Products Store is licensed in the company's name).

1.5.6 copies of the notarized and valid Medical Products Store lease agreements, if the vehicles are not owned by the Medical Products Store license holder, and copies of the vehicle registration documents for the Medical Products Store vehicles that will be used to transport medications, which have been inspected by the Egyptian Drug Authority and are licensed to the Medical Products Store

1.5.7 A true copy of the original certified deed (lease or ownership contract) for the store where the Medical Products Store is located, as long as the contract is legal and signed by the person who holds the Medical Products Store license (the original must be shown for verification).

1.5.8 A copy of the valid national ID card of the pharmacist in charge of the Medical Products Store, a copy of his/ her syndicate membership card, and a copy of his/ her pharmacy practice license.

1.5.9 A copy of the Good Storage and Distribution Practices (GSDP) certificate issued by the Egyptian Drug Authority for the Medical Products Store (the original must be presented for verification).

**1.6 Modification of the Layout for a licensed Medical Products Store**

1.6.1 A request addressed to the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, from the Medical Products Store license holder, (in the event of a company, the request must be signed by the company's chairman of the board or manager, in accordance with the powers granted in the commercial register and has a signature verification by the bank. The request shall specify the type of modification required in detail and provide complete information about the Medical Products Store license, including the license number, name, and address of the Medical Products Store.

1.6.2 The required modification to the layout mustn't conflict with the conditions for proper storage and distribution or reduce the storage area to less than the area permitted for the storage license, in accordance with the Decrees in force at the time of licensing.

1.6.3 Three copies of the modified Medical Products Store's layout, signed and stamped by a

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syndicated engineer.

1.6.4 A true copy of the original certified deed (lease or ownership contract) for the store where the Medical Products Store is located, as long as the contract is legal and signed by the person who holds the Medical Products Store license (the original must be shown for verification). If the Medical Products Store's layout are modified to include additional space, the contract must clearly specify the new area and number of floors.

1.6.5 A letter from the relevant district or city authority to which the Medical Products Store's address belongs, confirming the requested modification. If the modification requires a permit from the district or city authority, and if the Medical Products Store space is being added, the relevant authority must be contacted to verify that the requested space is for a commercial property and not a residential apartment, basement, garage, located in slums, or subject to a demolition order. (the relevant branch of the Egyptian Drug Authority will contact the district or city authority after receiving the renewal request.)

1.6.6 A statement from the water company confirming that a separate and independent connection from the public water supply has been made in case the layout are modified to include a bathroom.

1.6.7 A true copy of the original of the company's valid and up-to-date commercial registration and tax card (the original must be presented for verification) if the Medical Products Store is licensed in the company's name

1.6.8 A true copy of the original of a valid and up-to-date tax card for the company (the original must be presented for verification), if the Medical Products Store is licensed in the company's name.

1.6.9 A copy of valid and new national ID card of the license holder or their authorized representative (if the Medical Products Store is licensed in the company's name).

1.6.10 copies of the notarized and valid Medical Products Store lease agreements, if the vehicles are not owned by the Medical Products Store license holder, and copies of the vehicle registration documents for the Medical Products Store vehicles that will be used to transport medications, which have been inspected by the Egyptian Drug Authority and are licensed to the Medical Products Store.

1.6.11 A copy of the Medical Products Store pharmacist manager's valid national ID card, a copy of his/ her syndicate membership card, and a copy of his/ her pharmacy practice license.

1.6.12 A copy of the Good Storage and Distribution Practices (GSDP) certificate issued by the Egyptian Drug Authority for the Medical Products Store (the original must be presented for verification).

1.6.13 An original Medical Products Store license belonging to the license holder.

**1.7 Changing the Trade Name of the Medical Products Store:**

1.7.1 A request addressed to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, from the Medical Products Store license holder, to issue a replacement license having the new name (if the Medical Products Store license holder is a company, the request must be signed by the company's chairman of the board or the company manager holding the Medical Products Store license, pursuant to the powers specified in the commercial register) having signature verification by the bank. The new trade name must also be registered in the company's commercial register. The request must include all the Medical Products Store license details, including the

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license number, Medical Products Store name, and address.

1.7.2 A true copy of the original of a valid and up-to-date commercial registration certificate for the company. (Bring the original copy for verification).

1.7.3 A true copy of the original of a valid and up-to-date tax card for the company (bring the original for verification) if the Medical Products Store is licensed in a company's name.

1.7.4 A recent copy of the national ID card of the license holder or their authorized representative (if the Medical Products Store is licensed in a company's name).

1.7.5 Copies of the Medical Products Store's vehicle licenses that will be used to transport medicines and which have been inspected by the Egyptian Drug Authority, and photos of the lease contracts authenticated by the Real Estate Registry and valid in the event that the vehicles are not owned by the Medical Products Store license holder.

1.7.6 A true copy of the original certified title deed (lease or ownership contract) for the store where the Medical Products Store is located, provided that the Contract is valid and notarized and in the name of the Medical Products Store license holder (with the original to be presented for review).

1.7.7 A copy of the valid national ID of the pharmacist manager responsible for the Medical Products Store, a copy of the syndicate membership card, and a copy of the pharmacy practice license.

1.7.8 A copy of the Good Storage and Distribution Practices (GSDP) certificate issued by the Egyptian Drug Authority for the Medical Products Store (bring the original for verification).

1.7.9 Original Medical Products Store license belonging to the license holder.

1.7.10 Receipt for payment for the service of requesting changing the Trade Name of a Medical Products Store, pursuant to the Decree of the Chairman of the Egyptian Drug Authority No. 280 of 2021.

### **1.8 Change in Distribution scope across Governorates**

1.8.1 A request addressed to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, from the Medical Products Store license holder, to issue an updated for the license (if the Medical Products Store license holder is a company, the request must be signed by the company's chairman of the board or the company manager holding the Medical Products Store license, pursuant to the powers specified in the commercial register) having signature verification by the bank To determine the governorates to be distributed in. The request must include all the Medical Products Store license details, including the license number, Medical Products Store name, and address.

1.8.2 A true copy of the original of a valid and up-to-date commercial registration certificate for the company. (Bring the original copy for verification).

1.8.3A true copy of the original of the company's valid and up-to-date tax card. (Bring the original for verification).

1.8.4 A recent copy of the national ID card of the license holder or their authorized representative (if the Medical Products Store is licensed in a company's name).

1.8.5 Original Medical Products Store license belonging to the license holder.

1.8.6 Copies of the Medical Products Store's vehicle licenses that will be used to transport medicines and which have been inspected by the Egyptian

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Drug Authority, and photos of the lease contracts authenticated by the Real Estate Registry and valid in the event that the vehicles are not owned by the Medical Products Store license holder. It shall be in accordance with the applicable regulatory evidence in this regard, with the implementation of all technical conditions relating to the storage facilities of the Medical Products Store and in accordance with the requirements stipulated therein.

1.8.7 A copy of the Good Storage and Distribution Practices (GSDP) certificate issued by the Egyptian Drug Authority for the Medical Products Store (bring the original for verification).

1.8.8A copy of the valid national ID of the pharmacist manager responsible for the Medical Products Store, a copy of the syndicate membership card, and a copy of the pharmacy practice license.

1.8.9 A true copy of the original certified title deed (lease or ownership contract) for the store where the Medical Products Store is located, provided that the Contract is valid and notarized and in the name of the Medical Products Store license holder (with the original to be presented for review).

**Notification: If the Medical Products Store breaks any laws or rules and the inspection Administration of the relevant branch of the Egyptian Drug Authority records this violation within the year before the request is sent in, the request will be cancelled and the Medical Products Store will have to follow the distribution scope set out in the license, after being reviewed by the General Administration for Market Control.**

**1.9 Change of pharmacist manager in charge of Medical Products Store:**

1.9.1 A request addressed to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, from the Medical Products Store license holder, to issue a an updated for the license (if the Medical Products Store license holder is a company, the request must be signed by the company's chairman of the board or the company manager holding the Medical Products Store license, pursuant to the powers specified in the commercial register) and the details of the new pharmacist manager (full name, national ID number, professional license number, syndicate registration number, and appointment date), along with the details of the previous pharmacist manager (full name and clearance date).

1.9.2 Original Medical Products Store license belonging to the license holder.

1.9.3 A true copy of the original of a valid and up-to-date commercial registration certificate for the company. (Bring the original copy for verification).

1.9.4 A true copy of the original of the company's valid and up-to-date tax card. (Bring the original for verification).

1.9.5 A recent copy of the national ID card of the license holder or their authorized representative (if the Medical Products Store is licensed in a company's name).

1.9.6 Copies of the Medical Products Store's vehicle licenses that will be used to transport medicines and which have been inspected by the Egyptian Drug Authority, and photos of the lease contracts authenticated by the Real Estate Registry and valid in the event that the vehicles are not owned by the Medical Products Store license holder.

1.9.7 A true copy of the original certified title deed (lease or ownership contract) for the store where the Medical Products Store is located, provided that the contract is valid and notarized and in the name of the Medical Products Store license holder

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(with the original to be presented for review).

1.9.8 Obtaining a certificate from the General Directorate of Certificates and Licensing Follow -up - Central Administration of Operations - Egyptian Drug Authority to register the responsible pharmacist as the Medical Products Store manager.

1.9.9 A formally signed and authenticated declaration from the license holder approving the appointment of the pharmacist responsible for the Medical Products Store. If the license holder is a company, the declaration must be signed on its behalf and has a signature verification by the bank.

1.9.10 A valid copy of the national ID card of the pharmacist responsible for the Medical Products Store, a copy of his/ her syndicate membership card, and a copy of his/ her pharmacy practice license.

**2- Procedures for updating a Medical Products Store license**

2.1 The license holder, or an authorized representative, shall submit a request to update the Medical Products Store license to the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, clearly indicating the reason for the updating and enclosing all required documents, after payment of the service fee prescribed under the relevant ministerial decrees.

2.2. The submitted request and all attached documents, as well as the licensed Medical Products Store file held by the relevant branch of the Egyptian Drug Authority, shall be received and examined. The license holder shall be notified of any required additional documents.

2.3 In the case of requests to update the Medical Products Store ownership or modify the Medical Products Store's layout, an inspection of the Medical Products Store will be conducted to verify the availability of all the requirements stipulated for Medical Products Stores attached to Decree No. (725) of 2024 and the conformity of the layout to reality. This inspection will be carried out by the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, as well as an inspection of the Medical Products Store's vehicles. If the requirements remain unmet, the Medical Products Store will be given an initial timeframe of 60 days from the inspection date to comply. If the requirements are still not fulfilled within this timeframe, a second timeframe of 30 days, equivalent to half of the initial timeframe, will be provided.

2.4 After fulfilling the requirements, the Medical Products Store license update file will be sent from the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed to the Administration of Medical Products Stores and Warehouses licensing at the central Administration of Operations at the Egyptian Drug Authority headquarters. This file should contain the following details:

2.4.1 All documents required for the update

2.4.2 licensing inspection reports and inspection reports with complete data, and vehicle licensing inspection report approved and stamped by the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed.

2.4.3 Original Medical Products Store license belonging to the license holder and the license of the Egyptian Drug Authority branch.

2.4.4 A statement from the relevant branch of the Egyptian Drug Authority confirming that the Medical Products Store has not committed any violations during the previous calendar year. (In case of a request

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to increase the Medical Products Store's Distribution scope).

2.4.5 A statement from the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed regarding the current pharmaceutical manager responsible for the Medical Products Store.

2.5 The update file is reviewed, and all necessary procedures are taken to ensure compliance with all requirements by the relevant branch of the Egyptian Drug Authority.

- After fulfilling all the requirements and the required documents, the updated Medical Products Store license is issued
- In the event that the required documents are not fulfilled, the application will be cancelled by the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, and the license holder will be notified of the filing. The license holder may receive the original license from the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed.

**Third: Renewal of the validity period of Medical Products Store license**

**Medical Products Stores are obligated to submit a Good Storage and Distribution Practices (GSDP) Certificate when applying to renew the validity period of Medical Products Store license. This procedure shall be applied starting from 01.01.2026.**

- The Medical Products Store license is valid for five (5) years from the date of issuance. The license holder must submit an application for renewing the license within six (6) months before the license validity period ends.
- In the case of the Medical Products Store License validity period ends and the license holder does not submit a renewal application before the validity period ends, the license holder retains of his legal right to renew the license with all its associated rights. However, distribution from the Medical Products Store will be suspended until the license is renewed, in accordance with the requirements of the World Health Organization. In other words, the Medical Products Store will be administratively closed.
- The five (5) year validity period of the license does not conflict with the application of the provisions of Article No. 14 of the Law of Pharmacy profession Practice no. 127 year 1955, which related to the cancellation of pharmaceutical institutions.
- In the case of the license was issued as a temporary license due to the failure to submit the final reconciliation documents upon licensing, the license holder is obligated to submit the final reconciliation document with the renewal application of the license validity period. If the reconciliation is not completed, the necessary procedures will be taken, and the license will not be renewed.

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**1- Documents required to renew the validity period of the Medical Products Store license:-**

- 1.1 An application submitted to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, in the case of the Medical Products Store license holder is a company, the application must be signed by the company's chairman of the board or the company manager holding the Medical Products Store license, pursuant to the powers specified in the commercial register, and has a signature verification by the bank, for the renewal of the Medical Products Store license. Provided that the application must include all the data of the Medical Products Store license, including the license number, Medical Products Store name, and address.
- 1.2 A copy of the Good Storage and Distribution Practices (GSDP) Certificate issued by the Egyptian Drug Authority for the Medical Products Store (bring the original for review)
- 1.3 A true copy of the original of a valid and update commercial register of the company (bring the original for review) (if the Medical Products Store is licensed in the name of the company).
- 1.4 A true copy of the original of a valid and update tax card of the company (bring the original for review) (if the Medical Products Store is licensed in the name of the company)
- 1.5 A copy of the valid National ID Card of the license holder or the person authorized to issue the license in his name, in the case of licensing the Medical Products Store in the name of the company.
- 1.6 A copies of the Medical Products Store vehicles licenses that will be used to transport the medicines, which have been inspected by the Egyptian Drug Authority, and copies of the notarized and valid lease contracts in case the vehicles are not owned by the Medical Products Store license holder.
- 1.7 A copy of the valid National ID of the pharmacist manager responsible for the Medical Products Store, a copy of the Syndicate Membership Card, and a copy of the Pharmacy Practice License.
- 1.8 A true copy of the original certified title deed (Lease or Ownership Contract) for the store where the Medical Products Store is located, provided that the contract is valid and notarized, and in the name of the owner of the Medical Products Store license, and that the lease term is not less than five (5) years. (Bring the original for review).
- 1.9 A copy of the original of the Medical Products Store license of the license holder.

**2- Procedures for renewing the validity period of a Medical Products Store license:-**

- 2.1 The license holder or his representative shall submit an application to renew the validity period of the Medical Products Store license, attaching the necessary documents, and submitted to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed.
- 2.2 The submitted application and all attached documents are received and reviewed, as well as the file of the licensed Medical Products Store existing with the relevant branch of the Egyptian Drug Authority, and the license holder shall be notified of the required documents, if any.
- 2.3 After completing all documents, the Medical Products Store license renewal file is sent from the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed to the Administration of Medical Products Stores and Warehouses licensing at the Central

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Administration of Operations at the main office of the Egyptian Drug Authority, and the file must include the following:-

2.3.1 All required documents for renewal.

2.3.2 Complete inspection reports, approved and stamped by the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed.

2.3.3 The original of the Medical Products Store license of the license holder and the license of the Egyptian Drug Authority branch.

2.3.4 A statement from the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed regarding the current pharmacist in charge of the Medical Products Store.

2.4 The renewal file is reviewed by the Administration of Medical Products Stores and Warehouses licensing, and all necessary procedures are taken to ensure compliance with the requirements by the relevant branch of the Egyptian Drug Authority.

2.5 After fulfilling the requirements and submitting the required documents, the renewed Medical Products Store license is issued. The license is valid for five years from the date of issuance, and the license holder must submit a renewal application within six months before the validity period ends.

2.6 If the required documents are not fullfiled, the application is cancelled by the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, and the license holder is notified of the filing.

2.7 The license holder may receive the original license from the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed.

**Fourth: Licensing a Accessory Store related to a Medical Products Store**

**1- Documents required for licensing an Accessory Store related to a Medical Products Store:**

1.1 An application from the license holder submitted to the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, requesting a license for a Accessory Store related to a Medical Products Store. The application must include all details of the Medical Products Store license and the address of the Accessory Store to be licensed.

1.2 A postal order with the amount of three (3) Egyptian pounds made payable to the Egyptian Drug Authority.

1.3 Three copies of the layout of the store to be licensed as a Accessory Store, at a scale of 1:50, showing all the following points on a single sheet of paper, to be signed and stamped by a syndicated engineer.

1.3.1 Vertical layout of the site.

1.3.2 Horizontal layout of the site.

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- 1.3.3 A sketch showing the location of the store to be licensed as a Accessory Store.
- 1.3.4 Facade of the site intended to be licensed.
- 1.3.5 Indicating the borders of the store on the layout
- 1.3.6 Table showing lengths - height - ventilation openings.
- 1.3.7 Data table of the place to be licensed (name of the Accessory Store related to the main Medical Products Store - address of the shop to be licensed as a Accessory Store).
- 1.4 A true copy of the original certified title deed for the store to be licensed as a Accessory Store (lease or ownership contract) from the store owner to the main Medical Products Store license holder, provided that it shall be valid and notarized by the (Real Estate Registry or a Court Judgment), and the lease term is not less than five (5) years. (Bring the original for review).
- 1.5 An original document from the electricity company stating the existence of a separate electricity meter within only the store to be licensed. The document must clearly state the meter number and the address of the store. Alternatively, an original document from the electricity company stating that electricity has been permanently and independently connected until the meter is installed, along with an explanation from the electricity company for the meter not being installed.
- 1.6 A declaration from the main Medical Products Store license holder stating that they will not sell from the Accessory Store related to a Medical Products Store to the public or any other pharmaceutical institution, and that they will not store any pharmaceutical products belonging to another pharmaceutical institution.
- 1.7 The relevant district office to which the address of the location to be licensed as a Accessory Store belongs is addressed by the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed. This is after receiving the Accessory Store license application to ascertain the status of the location: whether it is a commercial shop and not a residential building, basement, garage, or subject to a demolition order, and whether the property has a building license or not, and whether the location is within a city and not within a village.
- If the site falls under the jurisdiction of the New Urban Communities Authority, they shall be addressed with it to obtain their opinion on whether or not to approve the license for the requested activity, and also to confirm that the store for which a license is requested are not a garage, basement, residential, or administrative use.
- 1.8 The fee for the service of licensing a Accessory Store related to the main Medical Products Store is paid pursuant to Egyptian Drug Authority Resolution No. 272 of 2021, before receiving the license.

**2- Documents required to update the Medical Products Store license when licensing a Accessory Store related to the Medical Products Store:**

- 2.1 A copy of the National ID Card of the license holder, or the authorized person to issue the license in his name if the license is in the name of a company.
- 2.2 The original Medical Products Store license of the license holder.

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2.3 A copy of the Good Storage and Distribution Practices (GSDP) Certificate issued by the Egyptian Drug Authority for the Medical Products Store (Bring the original for review).

2.4 A true copy of the original of a valid and update commercial register of the company (Bring the original for review) (if the Medical Products Store is licensed in the name of the company).

2.5 A true copy of the original of a valid and update tax card of the company (Bring the original for review) (if the Medical Products Store is licensed in the name of the company).

2.6 A copies of the Medical Products Store vehicles licenses that will be used to transport the medicines, which have been inspected by the branch of the Egyptian Drug Authority in the governorate in which the Medical Products Store is licenses, and copies of the notarized and valid lease contracts in case the vehicles are not owned by the Medical Products Store license holder.

2.7 A copy of the valid National ID Number of the pharmacist manager responsible for the Medical Products Store, a copy of the Syndicate Membership Card, and a copy of the Pharmacy Practice License.

2.8 A true copy of the original of the title deed (Lease or Ownership Contract) for the store where the Medical Products Store is located, provided that the contract is valid and notarized, and in the name of the owner of the Medical Products Store license (Bring the original for review).

**Notes regarding the licensing of a Accessory Store related to the Medical Products Store:**

- The Medical Products Store is licensed to have only one Accessory Store.
- An accessory store is licensed within the same district related to the main Medical Products Store.
- An accessory store is licensed if the main Medical Products Store is open, operating, and stocked with pharmaceutical products, and this is proven by an inspection report of the main Medical Products Store.
- Distribution is not carried out through the accessory store. The purpose of the accessory store is solely to meet the main Medical products store's need for storing goods exceeding the original institution's storage capacity. Storing pharmaceutical products for other pharmaceutical institutions or selling to the public is prohibited.
- There should be no toilet inside the storage area.
- An accessory store related to a Medical Products Store is not licensed within villages.
- If the license of the main Medical Products Store is cancelled, the license of the accessory store will be cancelled as well.
- The accessory store license for the Medical Products Store is issued for the same duration as the Medical Products Store license itself.

**3- Procedures for licensing a accessory store related to the Medical Products Store**

3.1 The license holder or their representative shall submit a formal application for a license for a accessory store related to the main Medical Products Store, attaching the necessary documents and the original Medical Products Store license

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belonging to the license holder, to the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed.

3.2 The submitted application and all accompanying documents are examined, as well as the file of the licensed Medical Products Store kept at the branch. The license holder is notified of any required documents.

3.3 The district or the New Urban Communities Authority to which the site to be licensed as a accessory store belongs is contacted to provide information on the following:

3.3.1 The status of the store , in terms of whether it is a commercial store and not an administrative, residential, basement, or garage premises, and is not subject to state property.

3.3.2 Regarding whether or not a demolition order has been issued for the property, and to ensure that the site belongs to a city and not a village.

3.3.3 Regarding whether the property has a Building license (if the location falls under a district), and providing an opinion on whether to approve or reject the requested activity license (if the location falls under the jurisdiction of the New Urban Communities Authority). If approval is not granted, the file submitted for the accessory store license will be cancelled at the applicant's responsibility.

3.4 The initial inspection of the store to be licensed as a accessory store is conducted to ensure compliance with the prescribed health requirements within 30 days (thirty days from the date of receipt of the accessory store license file by the relevant branch of the Egyptian Drug Authority in the governorate where the accessory store is licensed).

3.5 The main Medical Products Store is inspected to ensure that:

3.5.1 Availability of health requirements and conformity of layouts

3.5.2 Its accumulation with pharmaceutical products requires a accessory store license, and the vehicles belonging to the Medical Products Store are also inspected.

3.6 If the inspection proves that the health requirements are met, the Medical Products Store license renewal file is sent to the Administration of Medical Products Stores and Warehouses licensing in the Central Administration of Operations for review.

3.7 If the inspection proves that the health requirements are not met, the license holder shall be granted a timeframe of 8 months (eight months) from the date of the inspection to fulfil the requirements required for licensing the accessory store. If the health requirements are not met, he shall be granted a second timeframe estimated at (four months). In the event that the prescribed health requirements are not met, the application for licensing the accessory store shall be cancelled and the license holder shall be notified.

3.8 After fulfilling the health requirements and submitting the required documents, the update file is sent from the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, to the Administration of Medical Products Stores and Warehouses licensing at the Central Administration of Operations. The file should include the following:-

3.8.1 All documents required to update the original Medical Products Store license and to license the

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accessory store.

3.8.2 licensing inspection reports and inspection reports with complete data and vehicle licensing inspection reports approved and stamped by the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed.

3.8.3 Original main Medical Products Store license belonging to the license holder, and the branch license of the Egyptian Drug Authority.

3.8.4 A statement from the relevant Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed regarding the current pharmacist in charge of the Medical Products Store.

3.9 The accessory store license file and main Medical Products Store update are reviewed by the Administration of Medical Products Stores and Warehouses licensing, and all necessary procedures are taken to ensure compliance with requirements by the relevant branch of the Egyptian Drug Authority as follows:

3.9.1 If the health requirements and required documents are fulfilled within the given timeframe, the updated Medical Products Store license and the new accessory store license are issued.

3.9.2 If the documents are not met, the application is cancelled by the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, and the license holder is notified of the filing.

3.10 The license holder or their representative pays the service fee for licensing an accessory store related to the Medical Products Store, in accordance with the Egyptian Drug Authority Chairman's Decree No. 272 of 2021, upon receiving the license at the Administration of Medical Products Stores and Warehouses licensing at the Egyptian Drug Authority headquarters.

#### **4- Updating an accessory store license related to a licensed Medical Products Store:**

##### **4.1 Required documents for amending the layout of the accessory store related to the main Medical Products Store:**

4.1.1 An application addressed to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, from the Medical Products Store license holder. If the Medical Products Store license holder is a company, the application must be signed by the chairman of the board of directors or the company manager holding the Medical Products Store license, pursuant to the powers specified in the commercial register and has a signature verification by the bank. The application must specify the type of modification required to the layout of the storage area belonging to the Medical Products Store, and must include complete data for the Medical Products Store license and storage area, including the license number, Medical Products Store name, and address.

4.1.2 Three copies of the layout of the storage area after modification, signed and stamped by a syndicated engineer.

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- 4.1.3 A true copy of original of a valid and notarized title deed for the area to be added to the accessory store (if adding area is requested) (bring the original for review).
- 4.1.4 A letter from the relevant district or city authority to which the storage location's address belongs, stating the required modification if the modification requires obtaining a license from the district or city authority. In the case of adding space, the district is contacted to verify whether the space to be added is a commercial space and not a residential activity, basement, garage, or for which a demolition or removal order has been issued (the district or city authority is contacted by the relevant branch of the Egyptian Drug Authority after receiving the renewal request).
- 4.1.5 A true copy of the original of a valid and update commercial register of the company (bring the original for review), if the Medical Products Store is licensed in the name of a company.
- 4.1.6 A true copy of the original of a valid and update tax card of the company (bring the original for review), if the Medical Products Store is licensed in the name of a company.
- 4.1.7 A recent copy of the national ID card of the license holder (if the Medical Products Store is licensed in the name of a person) or the person authorized to issue the license in his name (if the Medical Products Store is licensed in the name of a company).
- 4.1.8 A copies of the Medical Products Store vehicles licenses that will be used to transport the medicines, which have been inspected by the branch of the Egyptian Drug Authority in the governorate in which the Medical Products Store is licenses, and copies of the notarized and valid lease contracts in case the vehicles are not owned by the Medical Products Store license holder.
- 4.1.9 A true copy of the original of the title deed (Lease or Ownership Contract) for the store where the Medical Products Store is located, provided that the contract is valid and notarized, and in the name of the owner of the Medical Products Store license (Bring the original for review).
- 4.1.10 The original Medical Products Store and accessory store license of the license holder.

**4.2 Required Documents in Case of Cancellation of a accessory store related to a Licensed Medical Products Store upon the Request of the License Holder**

- 4.2.1 A request addressed to the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, from the Medical Products Store license holder, to cancel a accessory store related to the Medical Products Store. If the Medical Products Store license holder is a company, the request must be signed by the Chairman of the Board of Directors of the company or the company manager holding the Medical Products Store license, pursuant to the powers specified in the Commercial Register and has a signature verification by the bank.
- 4.2.2 A true copy of the original of a valid and update commercial register of the company (bring the original for review), if the Medical Products Store is licensed in the name of a company.
- 4.2.3 A true copy of the original of a valid and update tax card of the company (bring the original for review), if the Medical Products Store is licensed in the name of a company.
- 4.2.4 A recent copy of the national ID card of the license holder (if the Medical Products Store is licensed in the name of another person) or the person

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authorized to issue the license in his name (if the Medical Products Store is licensed in the name of a company).

4.2.5 A copies of the Medical Products Store vehicles licenses that will be used to transport the medicines, which have been inspected by the branch of the Egyptian Drug Authority in the governorate in which the Medical Products Store is licenses, and copies of the notarized and valid lease contracts in case the vehicles are not owned by the Medical Products Store license holder.

4.2.6 The original Medical Products Store license of the license holder and original accessory store license.

**4.3 Procedures for updating the accessory store license related to a Medical Products Store:**

4.3.1 The license holder or their representative shall submit an application to update the accessory store license, stating the purpose of the update and attaching all necessary documents, to the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, after paying the service fee stipulated in the applicable ministerial decrees.

4.3.2 The submitted application and all enclosed documents received, as well as the licensed Medical Products Store file held by the relevant branch of the Egyptian Drug Authority, shall be examined. The license holder shall be notified of any additional required documents.

4.3.3 An inspection of the accessory store shall be conducted by the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed, if the layouts of the accessory store have been modified, to verify compliance with all storage and proper distribution requirements and to ensure the layouts match the actual situation.

4.3.4 If the requirements are not met, the license holder shall be granted an initial timeframe of 60 days (Sixty Days) from the date of the inspection to fulfill the requirements. If the requirements are not fulfilled within the first timeframe, a second timeframe of 30 days (Thirty Days) shall be granted, half the first timeframe

4.3.5 After fulfilling the requirements, the file for updating the accessory store license for the Medical Products Store is sent from the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed to the Administration of Medical Products Stores and Warehouses licensing at the Central Administration of Operations. The file must include the following:

4.3.5.1 All documents required for the update.

4.3.5.2 Licensing inspection report and inspection reports with complete data, and vehicle inspection reports approved and stamped by the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed.

4.3.5.3 The original Medical Products Store and accessory store license of the license holder and the licenses of the Egyptian Drug Authority branch.

4.3.5.4 A statement from the Egyptian Drug Authority branch in the governorate where the Medical Products Store is licensed regarding the current pharmacist manager responsible for the Medical Products Store.

4.3.6 The update file is reviewed, and all necessary procedures are taken to ensure compliance with the requirements by the relevant branch of the Egyptian Drug Authority. If all requirements and required documents are met, the updated accessory store license is issued.

4.3.7 If the documents are not fullfiled, the application will be cancelled by the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed, and the license holder will be notified of the filing.

4.3.8 The license holder can receive the original updated licenses either at the head office of the Administration of Medical Products Stores and Warehouses licensing at the Egyptian Drug Authority's head office or at the head office of the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed.

- The five-year validity period of the license does not conflict with the application of the provisions of Article No. 14 of the Law of Pharmacy profession Practice no. 127 year 1955 concerning the cancellation of pharmaceutical institutions.

### **Fifth: Cancelling the Medical Products Store License**

-The five-year validity period of the license does not conflict with the application of the provisions of Article 14 of the Law on the Practice of the Pharmacy Profession No. 127 of 1955, concerning cases of cancellation of pharmaceutical establishments.

#### **1- In the event of cancellation the license upon the request of the license holder:**

##### **1.1 Required Documents:-**

1.1.1 Application to cancel a Medical Products Store license submitted by the license holder personally or by their authorized representative (if the power of attorney permits this action), or submitted by the Chairman of the Board of Directors or the company manager according to the powers stated in the Commercial Register – if the Medical Products Store license is issued in the name of a company. The application must have signature verification by the bank and submitted to the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed.

1.1.2 The original Medical Products Store license of the owner.

1.1.3 A true copy of the original of a valid and update Commercial Register and Tax Card of the company (Bring the original for review), if the Medical Products Store is licensed in the name of a company.

##### **1.2 Procedures**

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1.2.1 The license holder submits the cancellation request to the relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed. An inspection is conducted by the branch of the Egyptian Drug Authority to ensure the Medical Products Store is free of pharmaceutical products and the sign is removed from the Medical Products Store gate.

1.2.2 The complete cancellation file is sent to the Administration of Medical Products Stores and Warehouses licensing at the Central Administration of Operations at the Egyptian Drug Authority headquarters for review and issuance of a Decree of cancellation the Medical Products Store license if the documents are complete.

1.2.3 The relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed is contacted to notify them of the Decree of cancellation and to notify the owner by registered mail with acknowledgment of receipt.

**2. Cancellation of the License Upon Approved Inspection Reports.**

**2.1 The license shall be cancelled upon approved inspection reports that prove any of the following:-**

2.1.1 If the licenses have not been operated within six (6) months of their issuance date.

2.1.2 If the pharmaceutical institution has been continuously closed for a period exceeding one calendar year.

2.1.3 If the pharmaceutical institution has been relocated, unless the relocation was due to demolition or fire.

**2.2 Procedures:**

2.2.1 The branch of the Egyptian Drug Authority in the governorate where the Medical Products Store to be cancelled is licensed shall send the complete cancellation file to the Administration of Medical Products Stores and Warehouses licensing at the Central Administration of Operations for review.

- In the event that the required documents are not fullfiled, all necessary procedures shall be taken to ensure compliance by the relevant branch of the Egyptian Drug Authority.

2.2.2 The entire matter shall be presented to the Legal Administration of the Egyptian Drug Authority by the Administration of Medical Products Stores and Warehouses licensing at the Central Administration of Operations. If the Legal Administration deems it permissible to cancel the Medical Products Store license, a Decree of cancellation shall be issued.

2.2.3 The relevant branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is licensed will be addressed to notify the holder license (with a registered letter with acknowledgement of receipt ) that a decree of cancellation is issued.

**V. References**

- i. Law of Pharmacy profession Practice no. 127 year 1955.
- ii. Egyptian Drug Authority Law No. 151 of 2019 and its Executive Regulations.
- iii. Decree of the chairman of the Egyptian Drug Authority No. (725) of 2024, regarding the conditions and procedures for licensing Medical Products Stores and the health requirements that must be met.
- iv. Decree of the chairman of the Egyptian Drug Authority No. 271 of 2021 regarding the requirements that must be fulfilled for licensing Medical Products Stores belong to pharmaceutical institutions.
- v. Decree of the chairman of the Egyptian Drug Authority No. 272 of 2021, regarding services fees related to licensing Medical Products Stores belong to pharmaceutical institutions.
- vi. Decree of the chairman of the Egyptian Drug Authority No. 280 of 2021, regarding fees for certain services provided by the Central Administration of Operations.
- vii. Decree of the chairman of the Egyptian Drug Authority No. 121 of 2022, regarding the approval of the World Health Organization's guidelines on Good Storage and Distribution Practices and their updates as Egyptian Rules for Good Storage and Distribution Practices.
- viii. WHO TRS 1025 annex 7 for good storage and distribution practices.

## **VI. Annex**

### **Requirements to be fulfilled at the Medical Products Store**

1. Must comply with the **Good Storage and Distribution Practices (GSDP)** requirements outlined in the regulatory guideline issued by the Egyptian Drug Authority and published on its official website, as well as all regulatory guideline according to the WHO Code and Other International Organizations, and any subsequent updates.
2. Must comply with all technical specifications approved by the Central Administration of Operations for the full implementation of the Drug Tracking System, and any subsequent updates.
3. The Medical Products Store is a commercial shop. It must not have a direct connection to a private residence, a shop used for another industry, or any access points connecting to any of these. The store to be licensed must not be a garage, basement, or a place licensed for residential or administrative use.
4. The Medical Products Store area must not be less than 500 square meters (commercial) storage space. The required storage space may be divided into two interconnected floors with a single, independent entrance. The Medical Products Store must be separate from any other activity, and its entrance must be separate from

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any private residence, a shop used for another industry, or any access points connecting to any of these.

5. When licensing the Medical Products Store, the total area is calculated without deducting any columns or encumbrances within the scope of the place.
6. The floor of the shop must be at the same level as the adjacent ground. An exception is made if sufficient measures are taken to prevent water seepage into the Medical Products Store, including the installation of a drainage network before the Medical Products Store entrance, provided that this does not impede the safe entry and exit of those using the Medical Products Store. In all cases, a license may not be issued for a basement, garage, or a place licensed for residential or administrative use.
7. The net height between the Medical Products Store floor and the underside of the ceiling must not be less than 2.6 m in all parts of the Medical Products Store.
8. The place must be constructed of modern, non-combustible building materials that comply with Egyptian standard requirements. If the building is a metal truss, it must be thermally insulated and painted with easily cleanable materials that prevent bacterial growth. A certificate from a certified consulting engineer must be provided, specifying the type of thermal insulation and confirming that it is made of non-combustible materials.
9. Walls must be covered with easily cleanable, non-combustible materials to prevent bacterial growth, regardless of the materials used.
10. Floors must be made of non-combustible materials, smooth, welded joints, and easy to clean.
11. Without prejudice to obtaining the approvals of the Competent Civil Protection Department before issuing the license, a suitable number of functional fire extinguishers must be provided, with a minimum capacity of 6 kg, or a fire suppression system.
12. Medicines must be placed on metal stands—or stands made of non-combustible materials that prevent bacterial growth—with a height of 45 cm from the ground. It is strictly forbidden to place anything under these stands. Stored preparations must be at least 20 cm away from the wall and at least 60 cm away from the ceiling.
13. A licensed electricity meter and a recent electricity bill, or a certificate issued by the competent electricity company if the company does not have an electricity meter, confirming a continuous and permanent electricity supply to the store until a permanent meter is installed for the store to be licensed, must be provided.
14. If the license holder requests a bathroom, the following must be provided:
  - It must be located in a separate area and have a door that does not open directly onto the storage areas for the pharmaceutical preparations.
  - A corridor in front of the bathroom is required.
  - A door for both the bathroom and the corridor is required.
  - A bathroom window overlooking a skylight or street is required. A fine-mesh screen must be

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provided on the window, and an extractor fan may be used.

- The bathroom walls must be tiled with ceramics.
- A separate water supply must be provided.

**Drainage Method:**

- The sink drains into a drainage room, which drains into the public sewer or building sewer.
- The toilet drains into the store sewer room, which drains into the public sewer or building sewer.
- The drainage room and store sewer room must be outside the Medical Products Store.
- No tank, inspection chamber, or drainage room may be located under the floor of the facility. Drainage pipes, siphons, or toilet elbows may not be located within it. Drainage pipes may pass under the floor of the facility in emergency situations approved by the competent health authority, in which case all safety measures must be taken.
- Medical Products Stores may be exempted from the requirements regarding the water supply and drainage method, provided that there are no toilets inside them.

**15- If the license holder requests an attic**

- Well-built.
- The walls are high enough to allow passage for an average person.
- It has its own good ventilation.
- Its edge is surrounded by a fixed and secure barrier at least 70 cm high.
- The wall below it is at least 2 meters high, and its area does not exceed 1/3 of the Medical Products Store area.
- It is provided with a fixed and secure staircase.
- The attic area is not included in the total Medical Products Store area.
- A toilet is not permitted in the attic.

16. Maintaining the temperature and humidity levels stipulated by the specifications for medicines and preparations, by providing a constant and suitable ventilation source (fans or air conditioners) in all parts of the Medical Products Store, provided that the temperature inside the Medical Products Store does not exceed 30 degrees Celsius and the humidity does not exceed 65% throughout the year. Ventilation openings such as windows and doors are not included in the calculation.

17. Providing an appropriate number of thermometers and humidity meters in each storage room, with the necessity of recording readings at fixed intervals during working hours

18. Provide a cold room or a sufficient number of refrigerators for storing medicines within the Medical Products Store that require storage temperatures ranging from 2 to 8 degrees Celsius, with a thermometer placed inside the refrigerators or cold room and readings recorded regularly.

19. Provide wire netting with narrow openings on all windows in the Medical Products Store.

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20. Provide a permanent sign on the Medical Products Store facade showing the Medical Products Store name in Arabic, according to the name on the issued license.

21. It is necessary to have an effective method for eliminating rodents and insects without using poisons, with a certificate from a specialized company and a map showing the locations of traps.

22. All medicines stored in the Medical Products Store shall be clearly identified with the following information: (Batch/Lot Number – Date of Manufacture – Expiry Date).

23. A separate and clearly designated area shall be allocated for expired pharmaceutical products, away from other pharmaceutical products in use, until such products are disposed of or returned to the manufacturing company pursuant to approved documents, with due coordination with the competent administrations of the Egyptian Drug Authority. A sign shall be placed on such area bearing a clear statement reading: (*Expired Pharmaceutical Products – Not for Use*).

24. Internet access shall be made available, and a dedicated computer software program shall be used to record all data pertaining to the medicines handled, including sales and purchase invoices, as well as supplier and customer information. All records and data related to the Medical Products Store shall be maintained in such a manner that any information can be retrieved upon request. Furthermore, Invoices and documents evidencing incoming and outgoing medicines shall be archived for a minimum period of five (5) years.

25. Medical Products Stores shall be obligated, when obtaining or selling medicines, to procure pharmaceutical products exclusively from factories licensed by the Egyptian Drug Authority, registered importers listed in the Egyptian Drug Authority's records, or Medical Products Stores holding a Good Storage and Distribution Practices (GSDP) certificate. This shall be done pursuant to storage and distribution contracts duly authenticated by the Legal Affairs Administration of the Egyptian Drug Authority. A copy of such contracts shall be kept at the Medical Products Store premises. It is strictly prohibited to store any medicines or pharmaceutical products that are not covered by a distribution contract.

26. Medical Products Stores shall be obligated, upon entering into storage contracts with factories licensed by the Egyptian Drug Authority, registered importers listed in the Egyptian Drug Authority's records, or third-party manufacturing companies, to submit the following documents to the competent branch of the Egyptian Drug Authority:

- Contracts authenticated by the Legal Affairs Administration of the Egyptian Drug Authority.
- A copy of the third-party manufacturing registration indicating the storage locations, in case of contracting with a third-party manufacturing company.
- An importers' registry license, in case of contracting with importing companies registered with the Egyptian Drug Authority.

27. Pharmaceutical waste shall be disposed of in a safe and proper manner that poses no hazard to the environment or threat to public health.

28. In the case of licensing Medical Products Stores related with companies, the licensed company shall— upon making any amendment to the commercial register regarding the trade name, brand name, or legal form of the company— notify the branch of the Egyptian Drug Authority in the governorate where the Medical Products Store is located within

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three (3) months from the date of amendment, in order to enable the necessary procedures to be taken with respect to the license.

Failure to notify the branch of such amendments will result in the necessary legal actions being taken.

29. Technical specifications for vehicles used for the transport of medicines belonging to the storehouse:

Medical Products Stores shall be obligated to transport pharmaceutical products via a transport vehicle—as defined under the Traffic Law promulgated by Law No. 66 of 1973 and amended by Law No. 17 of 2024—provided that the vehicle meets the following requirements:

29.1 A lined box insulated with two layers separated by an insulating material.

29.2 A refrigeration unit, with due consideration to maintaining temperature and humidity in accordance with the storage conditions stated on the pharmaceutical product packaging during transportation.

29.3. A temperature measuring device with a notification to record readings regularly.

29.4 General cleanliness.

29.5 Proper arrangement and organization of packages to reduce the risk of product damage during transportation.

29.6 The number of vehicles shall be determined according to the geographic scope of the Medical Products Store distribution across governorates, as follows:

- If the distribution scope is within the same governorate where the Medical Products Store is located, at least one (1) properly equipped vehicle shall be provided.
- If the distribution scope extends outside the governorate where the Medical Products Store is located and includes a number of neighboring governorates, at least two (2) properly equipped vehicles shall be provided.
- If the distribution scope extends outside the governorate where the Medical Products Store is located and includes a number of border or remote governorates, at least three (3) properly equipped vehicles shall be provided, one of which shall be equipped with a refrigerator.

**Requirements to be fulfilled at the Accessory Store related to the Medical Products Store**

The Accessory Store shall be a commercial property and shall not have any direct connection to private residential units, or property used for another industry, or outlets connected to any such activities. In all cases, the store to be licensed shall not be a garage, basement, or an apartment licensed for residential or administrative use.

1. The area of the Accessory Store related with a Medical Products Store shall not be less than 25 m<sup>2</sup> (twenty-five square meters) and shall not exceed 500 m<sup>2</sup> (five hundred square meters).
2. The floor level of the Accessory Store shall not be below ground level. An exception may be made where adequate measures are taken to prevent water leakage into the Accessory Store, including the installation of a drainage network before the entrance, provided that this does not obstruct the entry and exit of personnel. In all cases, licensing a Accessory Store in a basement is not permitted.
3. The store shall be constructed of modern, non-combustible building materials compliant with Egyptian standard specifications, and the ceiling

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- height shall not be less than 260 cm in all parts of the store to be licensed.
4. Walls shall be covered with easy-to-clean materials that prevent bacterial growth.
  5. Flooring shall be made of non-combustible material, with sealed joints, and shall be easy to clean.
  6. An adequate number of fire extinguishers shall be provided, provided that the capacity of each extinguisher is not less than 6 kg.
  7. Shelves/pallets shall be metallic or made of non-combustible materials.
  8. An independent electricity meter for the store to be licensed shall be provided; or an original document from the Electricity Company stating that the electrical current has been permanently and independently connected shall be brought until the meter is installed, with clarification of the reason for not installing the meter.
  9. In the event the license holder requests the installation of a attic floor, it shall meet the following requirements:
    - Structurally sturdy.
    - Wall height sufficient to allow the passage of an average person.
    - Independently and adequately ventilated.
    - Its edge shall be surrounded by a fixed and secured barrier with a height of not less than 70 cm.
    - The wall height beneath it shall not be less than 2 meters, and the attic floor area shall not exceed one-third (1/3) of the Medical Products Store area.
    - A fixed and secured staircase shall be allocated thereto.
    - The area of the attic is not included within the total area of the Medical Products Store.
  10. A permanent ventilation source (fans or air-conditioning units) shall be provided so that the temperature inside the Medical Products Store does not exceed 30°C and the humidity does not exceed 65%, throughout the year.
  11. An appropriate number of temperature and humidity gauges shall be provided in all parts of the Medical Products Store, with readings recorded at fixed intervals during working hours.
  12. Wire netting with narrow openings shall be installed on all ventilation openings within the Accessory Store.
  13. A fixed sign on the facade of the Accessory store shall be placed, with " Accessory store related to a Medical Products Store" written on it in a clear Arabic font, and the name of the Medical Products Store written according to the license. Additionally, the phrase "No sales are conducted through it" shall be added.
  14. A refrigerator or cold room shall be provided where pharmaceutical products requiring special temperature storage conditions are present, with readings recorded regularly through calibrated external gauges.
  15. A separate place shall be designated for expired pharmaceutical products, with placing an identification sign on it.

### **Application process for storing unregistered dietary supplements from Egyptian Drug Authority**

**First:** The manufacturing company/producer, being the owner of the product registered and licensed by the National Food Safety Authority, shall submit a request for storage and circulation in Medical Products Stores licensed by the Egyptian Drug Authority to the National Food Safety Authority via the designated email address, after completion of manufacturing and analysis procedures by the National Food Safety Authority and receipt of compliant analysis results.

**Second: The manufacturing/owning company shall attach the following to the request referred to in Clause "First":**

1. A special food storage request form.
2. Product licensing certificate and approved annexes (composition statement and all licensed product sizes).
3. Annexes relating to any amendments made to the product, if any.
4. Analysis certificate issued by the National Food Safety Authority, stating approval for the circulation of the product (an analysis certificate shall be submitted for each manufacturing facility where the product is manufactured).
5. High-quality actual photographs of the product packaging after production from all sides (6 sides).
6. A payment receipt at an amount of EGP 1,000 as a service fee (stating the purpose of the request).

**Third: The competent official shall receive the request, review its attachments, and send the product data and attachments to the General Administration for Market Surveillance at the Egyptian Drug Authority.**

**Fourth: The General Administration for Market Surveillance at the Egyptian Drug Authority shall respond to the request within a maximum period of two (2) working days, whether by approval, rejection, or request for completion of documents.**

**Fifth: The competent official at the National Food Safety Authority shall follow up the process by sending the approval indicating the permissibility of storage in Medical Products Stores licensed by the Egyptian Drug Authority and circulation of the product through pharmaceutical institutions to the product owner.**

#### **Notes:**

1. Approval shall be issued in accordance with the license and approved documents submitted by the company. In the event that a specific size/package is not submitted, it shall not be included in the approval and its storage shall not be permitted.
2. The product owner shall be obligated to submit analysis certificates for the first batch produced at any factory approved by the National Food Safety Authority, as well as high-quality actual photographs of the product packaging after production from all sides.
3. If the product has obtained an annex for the addition of one or more manufacturing facilities, the

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- approval shall include all factories where manufacturing took place.
4. Failure to submit or complete the full required documents in full shall be the responsibility of the company/matrix manufacturer owning the product (Special Food), and only the data submitted by the applicant and approved by the National Food Safety Authority shall be deemed valid.