Regulatory Guideline on The Rules and Procedures Regulating the Import and Medical Customs Release for Medical Products, Their Ingredients and Packaging materials Year 2026

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- Explanation of the rules and procedures governing the importation and Medical Customs Release process for pharmaceutical products, their raw materials, and packaging materials.

Scope of Application

- Importation and Medical Customs Release of pharmaceutical products (human pharmaceutical products / veterinary, herbal, complementary medical, biological, narcotic, cosmetic, disinfectant, and pesticide products), their pharmaceutical raw materials, and packaging materials.

Important Definitions

Annual Import Approval:
An import approval issued for raw materials and packaging materials used for pharmaceutical products registered with the Egyptian Drug Authority. It is not limited to a specific quantity, is valid for full and partial shipments, and remains valid for one year from the date of issuance.

Import Approval for Full and Partial Shipments:
An import approval issued for a single raw material, with no specified quantity limit, valid for full and partial shipments, and remaining valid for one year from the date of issuance.

Import Approval for Full Shipment – Unlimited Quantity:
An import approval issued for a single raw material, with no specified quantity limit, for full shipment only, and remaining valid for one year from the date of issuance.

Import Approval for Full Shipment – Specified Quantity:
An import approval issued for a single raw material/single pharmaceutical product, with a specified quantity, for full shipment only, and remaining valid for one year from the date of issuance.

Importation Plan:
An import approval issued for pharmaceutical products/raw materials in specified quantities, valid for either a fiscal year or a calendar year.

Import Approval for Individual and Entity Requests:
An import approval issued for unregistered pharmaceutical products requested by entities or individuals, with a specified quantity, and valid for full and partial shipments.

Sealed Customs Release letter:
A Medical Customs Release letter granted to allow the entry of the shipment into the country, pending final release by inspectors of the Central Administration of Inspection of Pharmaceutical Institution in accordance with the applicable rules and procedures.

Import authorization:
A permit issued for finished pharmaceutical products/imported-for-packaging products listed in the schedules annexed to the Egyptian Narcotics Law, as well as for narcotic substances, psychotropic substances, precursors, and certain chemicals, enabling the company to import such substances and products.

Withdrawal Permit:
A Medical Customs Release permitting the entry into the country of finished pharmaceutical products/imported-for-packaging products listed in the schedules annexed to the Egyptian Narcotics Law, as well as narcotic substances, psychotropic substances, precursors, and certain chemicals, pending their final release by inspectors of the Central Administration of Inspection of Pharmaceutical Institution in accordance with the applicable rules and procedures.

Export Permit:
A permit issued to exporting companies for products listed in the schedules annexed to the Egyptian Narcotics Law and registered with the Egyptian Drug Authority, their raw materials, and certain chemicals, allowing the company to export such substances and products in accordance with the applicable rules and procedures.

Non-Objection Letter:
A letter issued upon the request of the exporting company confirming that the substance is subject to regulatory control in the exporting country and is not listed in the schedules annexed to the Egyptian Narcotics Law.

Technical Inspection Letter:
A letter issued upon the request of the company for the prior review of the quality certificate (GMP/ISO) submitted before importing the pharmaceutical raw material or packaging material, in cases where obtaining a prior import approval/importation plan is not required.

Rules and Procedures Governing the Importation and Medical Customs Release of Medicinal Products (Human, Veterinary, Herbal, Complementary Medical, Biological, Narcotic, Cosmetic, Disinfectant, and Pesticide Products), Their Pharmaceutical Raw Materials, and Packaging Materials

1- Pharmaceutical Raw Materials for Human/Veterinary Herbal, Complementary Medical, and Biological Pharmaceutical Products, and Packaging Materials:

- **All companies and manufacturing facilities that own pharmaceutical products registered with the Egyptian Drug Authority are permitted to import and obtain Medical Customs Release the pharmaceutical raw materials/packaging materials used in the manufacture of such locally manufactured products (human pharmaceutical, veterinary, herbal, complementary medical, and biological products).**
- **Import approvals for pharmaceutical raw materials shall be issued to the following categories:**

1. Product owner companies
2. Pharmaceutical manufacturers
3. Pharmaceutical raw material importers (for the purpose of storage and direct supply to manufacturing facilities licensed by the Egyptian Drug Authority)

The procedures shall be as follows:

A- Product Owner Companies / Pharmaceutical Manufacturers:

Annual Import Approval for Active Pharmaceutical Ingredients (APIs):

- All companies and manufacturing facilities that own or manufacture pharmaceutical products registered with the Egyptian Drug Authority shall apply for an annual import approval for the active pharmaceutical ingredients used in the manufacture of such locally manufactured products.
- The company shall submit a consolidated statement of all active pharmaceutical ingredients required for import during the year for the manufacture of the company's products.
- All annual import approvals shall be issued without being restricted to specified quantities.
- The annual import approval shall be valid for full and partial shipments for a period of one year from the date of issuance, with applications permitted throughout the year without being restricted to the beginning of the fiscal year.
- Companies shall apply for an annual import approval for the following year at least four months prior to the expiry of the valid approval.

- The annual import approval shall be issued to the product owner company. In the case of contract manufacturing by a third party, the manufacturing company may obtain a separate annual import approval for each company for which it manufactures products, provided that an original authorization for importing raw materials and manufacturing the products is submitted, issued by the product owner company to the manufacturing facility applying for the approval.

Aligned with the Advance Cargo Information (ACI) system, companies and manufacturing facilities may, where required, obtain the following approvals:

1. A prior annual import approval valid for full and partial shipments for inactive raw materials and packaging materials used in the manufacture of the company's pharmaceutical products registered with the Egyptian Drug Authority, in the same manner as active pharmaceutical ingredients.

2. A prior import approval valid for full shipments of pharmaceutical raw materials and packaging materials for the following purposes:

- Conducting a **Pilot Batch** or for **Research and Development (R&D)** purposes for a pharmaceutical product under registration with the Egyptian Drug Authority.
- Evaluation of a new supplier for a pharmaceutical product registered with the Egyptian Drug Authority.

An exceptional import approval may be issued, valid for full shipment, for an active ingredient, inactive raw material, or packaging material in quantities sufficient to manufacture a production batch of a pharmaceutical product under registration or registered with the Authority, provided that the imported item remains under Medical Customs Release status and under the supervision of pharmaceutical inspection. Final release shall only be granted upon issuance of the final product registration notification, following review of the company's application and submission to the Head of the Central Administration for Pharmaceutical Policies and Market Access for approval on a case-by-case basis, in the following cases:

- Supporting the availability of the pharmaceutical product based on the Egyptian pharmaceutical market study and the market need for the product.
- Supporting competitiveness and investment in the Egyptian pharmaceutical market, based on the review and assessment of the reasons submitted by the company in light of the expected return and investment significance.

An import approval shall be issued for **primary raw materials** for licensed manufacturing facilities having a production line for pharmaceutical raw materials:

- An import approval shall be issued for each individual primary raw material, without quantity limitation, valid for full shipment only, and valid for one year from the date of issuance.

B- Pharmaceutical Raw Material Importers Registered with the Authority:

Import Approval for Full and Partial Shipments:

- An import approval shall be issued for each individual raw material, without quantity limitation, valid for full and partial shipments, and valid for one year from the date of issuance.

Import Approval for Full Shipment:

- An import approval shall be issued for each individual raw material, without quantity limitation, valid for full shipment only, and valid for one year from the date of issuance.
- In cases of importation for the purpose of supplying manufacturing facilities registered with the Egyptian Drug Authority for the manufacture of pharmaceutical products (human/veterinary), biological, herbal, and complementary medical products registered with or under registration with the Authority, the import approval shall be issued with a specified quantity.

Pharmaceutical raw material importers registered with the Egyptian Drug Authority are permitted to import pre-mixed active pharmaceutical ingredients and raw materials in specified quantities for full shipment only, for the purpose of direct supply to pharmaceutical manufacturing facilities for the manufacture of human, veterinary, biological, herbal, and complementary medical products registered with the Authority. Such materials shall not be stored.

Procedures for Issuing Import Approvals

A- Product Owner Companies / Pharmaceutical Manufacturers:

First: Procedures for Obtaining an Annual Import Approval for Active Pharmaceutical Ingredients Used in Human, Veterinary, Biological, Herbal, and Complementary Medical Products Registered with the Egyptian Drug Authority

- An annual import approval for active pharmaceutical ingredients shall be granted to licensed factories and companies that own or manufacture pharmaceutical products registered with the Egyptian Drug Authority. Such approval shall be valid for one year from the date of issuance and shall permit full and partial shipments.
- The annual import approval for active pharmaceutical ingredients shall be issued upon submission of the following:
  - An application for issuance of the annual import approval.
  - In the case of contract manufacturing, the original authorization issued by the product owner company authorizing the manufacturing facility to import raw materials and manufacture the products, specifying the names of the products and the active pharmaceutical ingredients for which the annual import approval is requested.
  - A consolidated list containing the details of the active pharmaceutical ingredients to be imported and the pharmaceutical products in which they are used.
  - Product registration documents.

- Quality certificates for the raw materials (GMP, ISO).
- An acknowledgement of documents authenticity

➢ Upon completion of the review, the company shall be issued an annual import approval together with a list of the approved active pharmaceutical ingredients, enabling their importation and placement under Sealed Customs Release.

Second: Procedures for Obtaining an Annual Import Approval for Inactive Pharmaceutical Raw Materials Used in Human, Veterinary, Biological, Herbal, and Complementary Medical Products Registered with the Egyptian Drug Authority (When Required)

➢ An annual import approval for inactive pharmaceutical raw materials shall be granted, where required, to factories and companies that own or manufacture human, veterinary, herbal, complementary medical, or biological pharmaceutical products registered and priced by the Egyptian Drug Authority. Such approval shall be valid for one year from the date of issuance and shall permit full and partial shipments.

➢ The annual import approval for inactive pharmaceutical raw materials shall be issued upon submission of the following:

- An application for issuance of the annual import approval.
- In the case of contract manufacturing, the original authorization issued by the product owner company authorizing the manufacturing facility to import raw materials and manufacture the products, specifying the names of the products and the inactive pharmaceutical raw materials for which the annual import approval is requested.
- A consolidated list of the inactive pharmaceutical raw materials to be imported and the pharmaceutical products in which they are used.
- A copy of the valid annual import approval issued for the active pharmaceutical ingredient used in the manufacture of the product for which the inactive raw materials are to be imported.
- The product composition statement approved by the competent General Administration under the Central Administration of Pharmaceutical Products, together with any decisions issued in respect of amendments to the approved composition statement.
- Quality certificates for the raw materials (ISO or GMP), provided that the company undertakes that the imported raw material is of pharmaceutical grade.
- An acknowledgement of documents authenticity

➢ Upon completion of the review, the company shall be issued an annual import approval together with a list of the approved inactive pharmaceutical raw materials, enabling their importation and placement under Sealed Customs Release.

Third: Procedures for Obtaining an Annual Import Approval for Packaging Materials Used in Human, Veterinary, Biological, Herbal, and Complementary Medical Products Registered with the Egyptian Drug Authority (When required)

- The annual import approval for packaging materials shall be issued upon submission of the following:
  - An application for issuance of the annual import approval.
  - In the case of contract manufacturing, the original authorization issued by the product owner company authorizing the manufacturing facility to import packaging materials and manufacture the products, specifying the names of the products and the packaging materials for which the annual import approval is requested.
  - A consolidated list of the packaging materials to be imported and the pharmaceutical products for which they are to be used.
  - A copy of the valid annual import approval issued for the active pharmaceutical ingredient used in the manufacture of the product for which the packaging materials are to be imported.
  - A copy of the product registration notification.
  - Where gelatin capsules are to be imported, a copy of the product composition statement approved by the General Administration of Registration.
  - Quality certificates for the packaging materials (ISO), provided that the company undertakes that the imported packaging materials are of pharmaceutical grade.
  - An acknowledgement of documents authenticity

- Upon completion of the review, the company shall be issued an annual import approval together with a list of the approved packaging materials, enabling their importation and placement under Sealed Customs Release.
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Fourth: Procedures for Obtaining a Prior Import Approval for Pharmaceutical Raw Materials/Packaging Materials for Products Under Registration for the Purpose of Producing a Pilot Batch, Research and Development (R&D), or Evaluating a New Supplier for a Product Registered with the Egyptian Drug Authority (When Required)

- The import approval shall be issued upon submission of the following:
  - An application for issuance of the import approval.
  - In the case of contract manufacturing, the original authorization issued by the product owner company authorizing the manufacturing facility to import the raw materials and manufacture the products, specifying the products and the raw materials or packaging materials for which the import approval is requested.

- In the case of contract manufacturing, the original valid purchase order, dated, signed, and stamped, issued by the manufacturing company, specifying the name and quantity of the raw material, the product name, and the registration number.
- Where pre-mixed or pre-processed raw materials are to be imported, a composition statement issued by the foreign manufacturer.
- Product registration documents enclosed with the application, or evidence that a registration application has been submitted in accordance with the applicable ministerial decisions, subject to compliance with their requirements.
- Quality certificates for the raw materials (ISO or GMP), provided that the company undertakes that the imported materials are of **pharmaceutical grade**.

➢ **Where the application is submitted to import raw materials for Research and Development (R&D) purposes or for the production of a Pilot Batch for a product under registration, the following shall also be submitted:**
- Calculations issued by the factory's Quality Control department indicating the quantities required to produce the pilot batch.
- The proposed formulation.
- In the case of contract manufacturing, a copy of the manufacturing agreement.

➢ **Where the application is submitted to import raw materials for the evaluation of a new supplier, the following shall also be submitted:**
- Calculations issued by the factory's Quality Control department indicating the quantities required for the evaluation studies.
- An acknowledgement of documents authenticity

➢ Upon completion of the review, the company shall be issued an import approval for the raw material or packaging material, enabling its importation and placement under Sealed Customs Release.

Fifth: Procedures for Obtaining an Import Approval for Primary Raw Materials for Manufacturing Facilities Licensed to Operate a Pharmaceutical Raw Material Production Line

- The company's application.
- Quality certificates for primary raw materials (ISO).
- A copy of the factory license indicating that it is licensed to operate a pharmaceutical raw material production line.
- A copy of the manufacturing process for the raw material, identifying the primary raw material used.
- A GMP certificate for the local manufacturing facility covering the relevant raw material.

B- Pharmaceutical Raw Material Importers Registered with the Authority

➢ **Procedures for Obtaining:**

1. **An import approval for pharmaceutical raw materials (active or inactive) for full and partial shipments, or for full shipment only, for storage purposes.**
2. **An import approval for pharmaceutical raw materials (active or inactive) for full shipment only, for the purpose of supplying manufacturing facilities registered with the Egyptian Drug Authority for the manufacture of human, veterinary, biological, herbal, and complementary medical pharmaceutical products that are registered with or under registration with the Authority.**

➢ The import approval shall be issued upon submission of the following:

- An application submitted on the company's letterhead, specifying whether the approval is requested for full shipment only or for full and partial shipments.
- Quality certificates for raw materials (GMP and ISO).
- A copy of the importer registration certificate issued by the Egyptian Drug Authority, indicating the name of the company supplying the raw material to be imported.
- A copy of the warehouse license issued by the Egyptian Drug Authority.
- Material Safety Data Sheet (MSDS) for the imported raw materials.

Procedures for Issuing a Sealed Medical Customs Release letter

- **Procedures for the Release of Pharmaceutical Raw Materials (Active/Inactive), Packaging Materials, Reference Standards, and Samples for Human, Veterinary, Biological, Herbal, and Complementary Medical Pharmaceutical Products Registered with, or Under Registration with, the Egyptian Drug Authority**
- A Sealed Medical Customs Release Letter for consignments submitted by companies that have obtained prior import approvals shall be issued within **one working day** upon submission of the following documents:
  - An application for Pharmaceutical Release.
  - The Invoice, matched against the import approval.
  - The bill of lading (shipping document).
  - An acknowledgement of documents authenticity
  - In the case of imports from a free zone, a Certificate of Origin.
  - Certificates of Analysis (CoAs) for the imported batches.
  - For raw materials subject to specific health requirements, the required health certificates.
  - Compliance with all conditions and requirements set out in the import approval.
  - The company shall receive a Sealed Medical Customs Release Letter covering the contents of the invoice, bearing the official seal of the Arab Republic of Egypt, provided that the consignment shall not be opened except by inspectors of the Central Administration of Inspection of Pharmaceutical Institution at the Egyptian Drug Authority .
  - The company shall also receive the invoice, duly endorsed by the Egyptian Drug Authority and bearing the official seal of the Arab Republic of Egypt, for the purpose of obtaining Sealed Medical Customs Release of the consignment from Customs.

- product applicants and pharmaceutical manufacturers may obtain a Sealed Medical Customs Release for incoming consignments without a prior import approval in the following cases:

Categories:

1. Inactive pharmaceutical raw materials and packaging materials used in the manufacture of pharmaceutical products registered with the Egyptian Drug Authority.
2. Raw materials and packaging materials imported for pharmaceutical products under registration for the purpose of producing a Pilot Batch or conducting Research and Development (R&D) activities.
3. Raw materials and packaging materials imported for the evaluation of a new supplier for a pharmaceutical product registered with the Egyptian Drug Authority.

4. Raw materials and packaging materials used in the manufacture of pharmaceutical products under the manufacture-for-export system.

➢ A Sealed Medical Customs Release Letter shall be issued for consignments submitted by the company within one working day upon submission of the following documents:

- An application for Pharmaceutical Release.
- The Invoice.
- The bill of lading (shipping document).
- An acknowledgement of documents authenticity
- In the case of imports from a free zone, a Certificate of Origin.
- Certificates of Analysis (CoAs) for the imported batches.
- For raw materials subject to specific health requirements, the required certificates shall be provided.
- In the case of pre-mixed and pre-processed raw materials, a composition statement issued by the foreign manufacturer.
- Product registration documents with attachments, or evidence of submission of the registration application in accordance with the applicable ministerial decisions, subject to compliance with their requirements.
- Quality certificates for the foreign manufacturing facility (GMP or ISO).

In the case of applications for importing raw materials for Research and Development (R&D) purposes or to produce a Pilot Batch for a product under registration:

- Factory calculations issued by the **Quality Control** department indicating the quantities required for producing the pilot batch.
- A copy of the proposed formulation.
- In the case of contract manufacturing, a copy of the manufacturing agreement.

In the case of applications for importing raw material samples for the evaluation of a new supplier:

- Factory calculations issued by the **Quality Control** department indicating the quantities required for the required studies.

In the case of applications for importing raw materials intended for the manufacture of pharmaceutical products under the manufacture-for-export system:

- An approval issued by the Export Support Department for the manufacture of the product for export purposes.
- In the absence of a GMP certificate for the raw material meeting the required specifications, importation shall be permitted based on a confirmation email sent from the official email address of the importing entity to the official email address of the

General Administration of Importation and Customs Releaseof Pharmaceutical Raw Materials, approving the importation of the raw material from the specified source.

- **A Sealed Medical Customs Release Letter may be obtained for samples of pharmaceutical raw materials and reference standards imported for analysis, testing, or presentation to companies, as follows:**

Samples of Imported Pharmaceutical Raw Materials and Reference Standards:

A Sealed Medical Customs Release Letter shall be issued for consignments submitted by the company within **one working day**, upon fulfillment of the following requirements:

1- Pharmaceutical Companies and Manufacturers "Permitted to import samples of pharmaceutical raw materials and reference standards"

- An application for Pharmaceutical Release.
- The Invoice.
- The bill of lading (shipping document).
- An acknowledgement of documents authenticity

2- Pharmaceutical Raw Material Importers "Permitted to import samples of pharmaceutical raw materials for presentation to companies and reference standards for analysis"

- An application for Pharmaceutical Release.
- The Invoice.
- The bill of lading (shipping document).
- A pharmaceutical raw material importer registration certificate indicating the company authorized as the source of import, in cases where reference standards are imported in commercial quantities for supply to pharmaceutical companies.
- An acknowledgement of documents authenticity

3- Bioequivalence Centers and Stability Centers Registered with the Egyptian Drug Authority "Permitted to import samples of pharmaceutical raw materials and reference standards"

- An application for Pharmaceutical Release.
- The Invoice.
- The bill of lading (shipping document).
- A license for the bioequivalence center or stability center issued by the Egyptian Drug Authority.
- An acknowledgement of documents authenticity

- Pharmaceutical manufacturers are also permitted to obtain a Sealed Medical Customs Release Letter for laboratory chemicals imported for analytical purposes or for preliminary manufacturing stages.

General Rules Applicable to Pharmaceutical Raw Materials and Packaging Materials:

- All decisions issued by the Egyptian Drug Authority and recommendations of the Pharmacovigilance Administration relating to pharmaceutical products and raw materials shall be complied with.
- All companies shall ensure that imported inactive raw materials and imported packaging materials are of pharmaceutical grade.
- The company shall ensure that the pharmacopoeia/specification of the raw material to be imported complies with the pharmacopoeia/specification stated in the approved composition statement, using the same edition or the latest edition. The use of flavoring agents, coloring agents, and fragrance materials with in-house specifications shall be permitted.
- A valid GMP certificate for the active pharmaceutical ingredient (API) shall be submitted, provided that the certificate is issued in the name of the manufacturing site producing the active pharmaceutical ingredient, issued by an accredited governmental health authority, and clearly indicates the name of the active pharmaceutical ingredient intended for import. An official link to the website of the health authority (official link) shall also be provided to verify the authenticity of the certificate. In cases where the health authority does not provide a link for certificate verification, the company shall submit a copy of the GMP certificate duly authenticated by the Chamber of Commerce and the Embassy in the country of origin.
- In the case of importing active pharmaceutical ingredients used in the manufacture of innovative pharmaceutical products from countries whose governmental authorities do not permit the inclusion of such ingredients in the GMP certificate issued for the foreign manufacturing site during the validity period of the patent, such ingredients may be imported without requiring their inclusion in the GMP certificate issued for the foreign manufacturing site. This is intended to support the national pharmaceutical industry and encourage companies to expedite the registration of new and innovative products. Such cases shall be subject to review of the company's application and submission, on a case-by-case basis, to the Head of the Central Administration for Pharmaceutical Policies and Market Access, after submitting the following documents:
  - A valid GMP certificate issued in the name of the foreign manufacturing site producing the active pharmaceutical ingredient, issued by an accredited governmental health authority, without requiring inclusion of the active pharmaceutical ingredient in the certificate.
  - A letter issued by the foreign manufacturer confirming that the raw material is manufactured on the same production line covered by the GMP certificate.

- A letter issued by the foreign manufacturer confirming that the raw material will be added to the GMP certificate upon expiry of the patent validity period for the active pharmaceutical ingredient.

➢ In the case of Extracts, Elements & Vitamins, Primary Raw Materials, Inactive Raw Materials, and Packaging Materials:

- A copy of an ISO certificate may be submitted according to the type of imported item, provided that it is valid, issued in the name of the manufacturer of the raw material/packaging material, accredited by the International Accreditation Forum (IAF), and that the certificate scope covers the imported raw material or packaging material. The company shall ensure that the imported raw material/packaging material is of pharmaceutical grade.
- In certain cases involving Extracts, Elements & Vitamins and some inactive raw materials, a copy of an SQF, IFS, or FSSC certificate may be submitted according to the type of imported item, provided that it is valid, issued in the name of the raw material manufacturer, accredited by the International Accreditation Forum (IAF), and that the certificate scope (Manufacturing) covers the imported raw material.

➢ The authenticity of all submitted certificates and the accreditation status of the issuing authorities shall be verified. In the event of any non-compliance, the importing company shall bear full responsibility, and the Egyptian Drug Authority shall bear no liability whatsoever.

➢ The following websites shall be reviewed to determine whether any warning has been issued against the foreign manufacturing site producing the raw material by any of the following authorities:

FDA Import Alert 66-40:
http://www.accessdata.fda.gov/cms_ia/importalert_189.html
Suspension or Withdrawal of EDQM:
https://extranet.edqm.eu/publications/Recherches_CEP.shtml
EUDRA <Statement of Non-Compliance>:
http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do

➢ Where a company intends to import from a foreign manufacturing site against which a warning has been issued by any of the three authorities referred to above:

- The company shall submit a GMP certificate issued to the foreign manufacturing site by a Stringent Health Authority (SHA) or another recognized reference regulatory authority, covering the relevant raw material, provided that the date of the certificate is later than the date of the warning. This requirement shall be fulfilled prior to importing or purchasing the raw material in order to safeguard the interests of companies and the health of Egyptian patients. The Egyptian Drug Authority shall not be liable for any losses resulting from failure to comply with these requirements.

- Where the raw material is imported through a broker or supplier, rather than directly from the manufacturer:
  - The original document evidencing the relationship between the foreign manufacturer and the supplier shall be submitted on the foreign manufacturer's letterhead, duly signed, stamped, containing complete details, and bearing a recent date. The document shall be authenticated by the Chamber of Commerce and the Embassy in the country of origin.

Or

  - An email shall be sent from the official email address of the foreign manufacturer, attaching a copy of the relationship document, to the official email address of the General Administration of Importation and Customs Releaseof Pharmaceutical Raw Materials.
- In the case of importing raw materials listed under the Explosives Schedule (e.g., H202 – Nitroglycerin), the company shall obtain an annual quantity-specific import approval for the raw material and shall first obtain approval from the Public Security Authority as a prerequisite for the issuance of a Sealed Medical Customs Release Letter.
- With respect to the following raw materials: Sulfuric Acid, Phenol, Toluene, Hexamine, Organic Peroxides, and Citric Acid, product owner companies and pharmaceutical manufacturers shall obtain a quantity-specific import approval/annual import approval. Pharmaceutical raw material importers may import these materials only pursuant to a purchase order issued by pharmaceutical manufacturing facilities registered with the Egyptian Drug Authority for the manufacture of human, veterinary, biological, or herbal pharmaceutical products that are registered with, or under registration with, the Authority.
- Certain raw materials require the submission of the necessary health certificates either prior to importation or at the time of Customs Pharmaceutical Release.

2-Imported Pharmaceutical Products (Finished & Bulk)
First: import plans and approvals for Imported pharmaceutical products registered at the Egyptian drug authority (human, herbal and Biological)

General Rules

- All companies registered in the **Pharmaceutical Importers Register** shall obtain **annual importation plans** for finished pharmaceutical products registered with the Egyptian Drug Authority.

For registered pharmaceutical products imported in **bulk** for local filling/packaging, importation shall be carried out either through the manufacturing facility authorized to package the product or through the product importer/applicant, provided that the required supply orders and authorizations are submitted at the time of obtaining the Sealed Customs Release.

- Annual importation plans shall be valid for one **fiscal year** and shall permit full and partial shipments.
- Companies shall comply with **Egyptian Drug Authority Chairman's Decree No. 39 of 2025**, which prohibits the importation of finished pharmaceutical and biological products, or products intended for local filling and packaging within the Arab Republic of Egypt, where the remaining shelf life is less than **two-thirds of the total shelf life** printed on the product packaging. The applicable shelf life for release and distribution purposes shall be calculated from the date of arrival of the shipment at the Egyptian ports. However, in emergency situations, such products may be imported and distributed notwithstanding the shelf-life requirement, provided that a detailed technical memorandum, supported by justifications and market studies, is prepared by the Central Administration for Pharmaceutical Policies and Market Access and approved by the Chairman of the Egyptian Drug Authority.
- The company shall submit its importation plan specifying the quantities expected to be imported on a **quarterly basis**, in a manner that ensures adequate coverage of market demand.
- Companies shall apply for the importation plan for the following year at least **three months** before the expiry of the current importation plan.
- **Importation plans for finished pharmaceutical products** shall be issued after the quantities requested by the company have been reviewed by the specialists of the General Administration of Importation and Customs Pharmaceutical Release. Such review shall be conducted in light of local market consumption during previous years, taking into consideration pharmaceutical market indicators and the economic factors affecting the market, with due regard to ensuring the availability of adequate quantities for the Egyptian market, projected market demand, the national strategy for localization of pharmaceutical manufacturing, the availability of therapeutic alternatives, and local market growth rates.

This assessment shall be carried out in coordination with the General Administration of Market Access and Business Continuity and the General Administration of Export Support and Investment Promotion.

Where a company applies for additional quantities for complementary importation plan, the request shall be evaluated on a case-by-case basis according to the market need for the pharmaceutical product, in coordination with the relevant departments of the Egyptian Drug Authority.

- Scientific offices shall be permitted to import free medical samples of registered pharmaceutical products for promotional purposes. Annual importation plans for such samples shall be issued, provided that the quantity does not exceed 10% of the total quantity specified in the importation plan for the product, or 25% in the case of pharmaceutical products registered for the first time.
- In the case of registered multi-dose vaccines, distribution shall be limited to tenders, procurement exercises, and hospitals.
- For importation plans relating to pharmaceutical products imported from free zones, the following documents shall be submitted at the time of obtaining the Sealed Customs Release: (Certificate of Analysis (CoA) for the finished product, Certificate of Analysis (CoA) for the imported raw material used in the manufacture of the product, Batch Record linking the imported raw material to the finished product, GMP certificate for the raw material manufacturing site).
- In the case of requesting the issuance of Conditional import approvals of Special packs from any product for various reasons after the end of the deadline or quantities specified by the technical committee for drug control, the update of imported quantities and the time period shall be approved by the head of the central Administration for pharmaceutical policies and market Access without a re-submission to the technical committee , Taking into consideration the standards of the drug market and the economic changes affecting it & Ensuring the availability of the product similars & alternatives required for the Egyptian market

These approvals shall be issued in accordance with the following conditions:

- It is allowed to issue these approvals for the product for a maximum of one year, provided that each approval is valid for total shipping, and then re-evaluate the actions taken by the company towards the localization of industry and local production.
- The total quantities of conditional shipments do not exceed the annual requirement rate for the product.
- The company's commitment to the requirements mentioned in the approval of the technical committee for the control of medicines.

-In the case of important and strategic products (Red label Products) that may suffer from a shortage or increased need according to the recommendation of the Department of drug availability & business Continuity at EDA, it is allowed to issue Conditional import approvals of Special packs for these products without the need to be presented to the technical committee for Drug Control, provided that they are imported according to the conditions and procedures for importing the pharmaceutical products as Special requests , after the presentation and approval of central Administration for pharmaceutical policies and market Access & this is relied on the requested site responsibility & MAH of the product , in order to ensure the availability & access of important and strategic products to the patients

A- The Procedures and Documents Required To Obtain An Import Plan For Registered Imported Pharmaceutical Products (Finished & Bulk):

1. The company's application.
2. A list of the pharmaceutical products included in the company's annual importation plan, identifying the manufacturing site for each product, the quantity requested for each product, and the required pack size, using the prescribed application form.
3. Product registration and pricing documents.
4. A valid Certificate of Pharmaceutical Product (CPP) issued in the country of origin.
5. The importation plan approval form for each product, approved by the Central Administration of Licensing, in the case of finished pharmaceutical products.
6. The company importers registry license stating the foreigner company contract and the product required to be, in the case of finished pharmaceutical products.
7. An acknowledgement of documents authenticity
8. In case of procuring for certain entities, procurement orders or purchasing orders and necessary delegations shall be submitted.

B- Procedures and documents required to obtain an import approval for imported pharmaceutical products(Finished & Bulk):

1. The company's application for the issuance of an import approval.
2. Product registration and pricing documents.
3. A valid Certificate of Pharmaceutical Product (CPP) issued in the country of origin.
4. A copy of the company's Importers register license showing the foreign company agreement and the pharmaceutical products requested for importation, in the case of finished pharmaceutical products.
5. In case of procuring for certain entities, procurement orders or purchasing orders and necessary delegations shall be submitted.
6. An acknowledgement of documents authenticity
7. The import approval shall be issued within a maximum of 48 hours.

Second: Import Approvals of Imported Finished Pharmaceutical Products as Special Requests (Human Pharmaceutical Products– Biological Products)

It is allowed to issue import approvals for pharmaceutical Products that are not registered at the Egyptian drug authority as special requests in case unavailability of similar products registered at the Authority and marketed locally, or if the available quantities are insufficient to cover the needs as per the statement of the department of drug availability & business Continuity at The Egyptian Drug Authority.

General Rules:

- -The import approval is with defined Quantity and valid for total and partial shipping.
- -The product shall be used inside the entity and under its responsibility and medical supervision without least liability on the Egyptian Drug Authority, The pharmaceutical product shall not be given to another entity with or without consideration and it shall not be used for any purpose other than the purpose to which the product is imported only after referring to the General Administration of importation and Customs medical release.
- -The supply of the imported quantities of the products to the requesting entity is followed up by the inspectors of the Central Administration for Inspection of Pharmaceutical Institution at The Egyptian Drug Authority.
- -In case of short age of some important and strategic pharmaceutical products, these product s shall be permitted to be imported through authorized distributors without prior specifying of the entities to which these products are imported, provided that the quantity decided by the department of drug availability & business continuity shall be constrained and under the discretion of the Egyptian Drug Authority while making a dispensing order and the procurement shall be followed by inspectors of the Central Administration of inspection of pharmaceutical institutions at EDA. This procedure shall be for one time until applying for registering the product.
- -In the case of non-reference applications for the import of products received as special requests from entities, the importing company/entity is obliged to conduct a pre – technical assessment at the central administration for Drug Control and provide the result of approved technical assessment when applying for import approval.
- -In the case of biological products applications (Reference / Non reference) for the import of products received as special requests from entities/Named Patient requests , the importing company/entity is obliged to conduct a pre –technical assessment at the Central administration of biological and innovative products and clinical studies and provide the result of approved technical assessment when applying for import approval.-In cases of submitting import applications for purchased pharmaceutical products to governmental entities subjected to the provisions of Law No. 151 of 2019,

the approval of the Egyptian unified purchasing authority for the import of the product is submitted.

- -In case of recent registered products which received a registration license, they are permitted to be imported under the same former import conditions for a period not exceeding six months as grace period until the fulfilling of the registration requirements, if they shall be formally imported as special requests.

Procedures:

A- Import approvals for Special Requests- Site Requests- (pharmaceutical products are registered and marketed in one of the reference countries or non-reference products marketed in one of the reference countries):

The import approval shall be valid for **six months** from the date of issuance.

Required Documents and Procedures for Obtaining an Import Approval

1. An import application.
2. A letter from the requesting entity stating its need for the pharmaceutical product that is not registered with the Egyptian Drug Authority, specifying the required quantity to treat patients for a period of six months.
3. A valid Certificate of Pharmaceutical Product (CPP), together with a certificate confirming that the product is registered in the country of origin and marketed in one of the Reference Countries, or evidence that the product is WHO Prequalified.
4. A copy of the Importers register license showing the foreign company, or an Agency Agreement or Authorization Letter.
5. The company shall undertake to notify the Egyptian Pharmacovigilance Center of the Egyptian Drug Authority of any adverse effects resulting from the use of the imported product.
6. For biological products, the importing company/entity shall conduct a technical evaluation through the Central Administration for Biological and Innovative Products and Clinical Studies and submit the results of the technical evaluation when applying for the import approval.

B- Import Approvals for Special Requests – Site Requests (pharmaceutical Products Neither Registered Nor Marketed in Any Reference Country):

-it is stipulated that the requesting entity / importing company cannot provide a similar product registered and marketed in one of the reference countries.

-The validity of the import approval is 3 months from the date of issue.

-The company is committed to submit the RMP (risk management plan) to the Egyptian pharmacovigilance Center at the Egyptian Drug Authority and the obliged to inform the pharmacovigilance center about any adverse effects that may result from the use of the product.

-The analyses of the imported Batches shall be fulfilled in the laboratories of the Egyptian Drug Authority, and the final release is carried out only after the issuance of the conformity.

Required Documents and Procedures for Obtaining an Import Approval

Import application Request.

2.letter from Applicant / Requested Entity concerning the need to the pharmaceutical product which is unregistered at the Egyptian Drug Authority with a quantity to be constrained for treating patients while the inability to provide similar from reference countries.

3.Certificate of the pharmaceutical product.

4.The importers register license showing the foreign company, or an Agency Agreement or Authorization Letter.

5.The result of the technical examination issued by the central administration of Drug Control/ Central administration of biological and innovative products and clinical studies

C- Import Approvals for Individual Requests (Products Registered and Marketed in a Reference Country):

The import approval shall be valid for **six months** from the date of issuance.

Required Documents and Procedures for Issuing Import Approval for Individual Requests

1. An import application.
2. A medical report approved by the treating physician, stating the patient's name, medical condition, prescribed dosage, and treatment period. The requested quantity shall not exceed that required for **six months of treatment**. The treating physician shall also provide an undertaking that the requested medicine will be used under his/her direct medical supervision and personal responsibility, without any liability whatsoever on the Egyptian Drug Authority , since the requested medicine is not registered or priced by the Egyptian Drug Authority.
3. A valid **Certificate of Pharmaceutical Product (CPP)** confirming that the product is registered and marketed in one of the **Reference Countries**.
4. A copy of the **Importers register license** showing the foreign company, or an **Agency Agreement** or **Authorization Letter**.
5. In the case of **biological products**, the importing company/entity shall conduct a technical evaluation through the **Central Administration for Biological and Innovative Products and Clinical Studies** and submit the results of the technical evaluation when applying for the import approval.

Third: Import Approvals for Pharmaceutical Products Imported as Donations or Grants

- Pharmaceutical and biological products imported as donations or grants may be imported in accordance with the regulations governing the acceptance of donations and grants, subject to compliance with the applicable technical requirements:
- Prime Minister's Decree No. 869 of 2010, as amended by Prime Minister's Decree No. 1818 of 2019, governing the controls and regulatory requirements applicable to donations, grants, and contributions, shall apply.

Required Documents and Procedures for Issuing an Import Approval for Pharmaceutical Products Imported as Donations or Grants

1. An import application.
2. Approval from the head of the receiving entity or the competent authority accepting the donation, in accordance with Prime Minister's Decree No. 1818 of 2019.
3. A Donation Letter issued by the donor.
4. A commitment from the entity to use the items listed on its responsibility and under its medical supervision without the slightest responsibility on the Egyptian drug authority, in the case of unregistered Products
5. A invoice and a Packing List identifying the imported items.
6. Certificates of Analysis (COAs) of the imported batch numbers.
7. Certificate of pharmaceutical product (CPP) or WHO Prequalified Medicines or FDA/EMA Approval or any quality certificates to the manufacturer such as GMP, in case it is not possible to submit a CPP.

   The validity of imported batches shouldn't be less than 6 months from date of issuing Sealed customs release letter.

Fourth: Sealed Medical Customs Release for Imported Pharmaceutical Products

A Sealed Medical Customs Release shall be granted for consignments submitted by the company within **one working day** upon submission of the following documents:

- An application for Sealed Customs Release.
- The invoice, complied with import approval/plan , with deducing the imported quantities accordingly.
- The bill of lading.
- Certificate of Origin.
- Packing List.
- Certificates of Analysis (COAs) for the imported batches.
- An acknowledgement of documents authenticity

- The company shall receive the **Sealed Medical Customs Release Letter**, the endorsed invoice bearing the official seal of the Arab Republic of Egypt, and the bill of lading, for the purpose of obtaining the Sealed Medical Customs Release of the shipment from Customs.
- The company shall also receive a Sealed Medical Customs Release **Letter** covering the contents of the invoice, provided that the consignment shall not be opened except by inspectors of the **Central Administration of Inspection of Pharmaceutical Institution at the Egyptian Drug Authority** .
- All conditions and requirements set forth in the relevant import approval shall be strictly complied with.
- A Sealed Medical Customs Release Letter may be issued directly for Demonstration Samples of pharmaceutical products that are either registered or under registration, provided that the scientific office submits an undertaking confirming that: the imported product contains no pharmacologically active substances; it will not be administered to patients; it is intended solely for promotional and patient education purposes; and it will not be marketed or distributed in the local market.
- Samples of pharmaceutical products imported for **analysis or research studies** on behalf of pharmaceutical companies, pharmaceutical manufacturers, and bioequivalence centers registered with the Egyptian Drug Authority may be released directly without prior import approval, provided that the purpose of importation is clearly stated and the required supporting documents are submitted.

Fifth: Procedures for the Release of Pharmaceutical Products Intended for Clinical Trials

A Sealed Medical Customs Release Letters shall be granted for consignments submitted by the company within **one working day** upon submission of the following documents:

- An application for Pharmaceutical Release, accompanied by the study protocol documentation, study sites, and the required quantities.
- An authorization issued by the research entity in favor of the applicant company.
- Approval from the Egyptian Drug Authority – Central Administration for Biological and Innovative Products and Clinical Trials authorizing the conduct of the clinical study.
- Approval of the submitted protocol by the Supreme Council for the Review of the Ethics of Clinical Medical Research, or approval of the study protocol by the relevant Research Ethics Committee.
- The invoice and the bill of lading.
- Packing List.
- Certificates of Analysis (COAs) for the imported product batches.
- An undertaking from the company/requesting entity confirming the authenticity of all submitted documents.

- The company shall receive a Sealed Medical Customs Release Letter covering the contents of the invoice, provided that the consignment shall not be opened except by inspectors of the Central Administration of Inspection of Pharmaceutical Institution at the Egyptian Drug Authority .

Procedures for Issuing Import Approvals and Sealed Medical Customs Release Letterss in Cases of Emergencies and Epidemics

General Conditions for Determining Pharmaceutical Products Eligible for Emergency Procedures:

- The issue of an emergency use license for the pharmaceutical product from the Egyptian Drug Authority.
- Inclusion of the drug in the treatment protocols for the emergency declared by the Egyptian Ministry of health with the unavailability of registered similar products & Substitutes of these drugs in quantities sufficient for the need of patients for a period to be determined by the administration of Drug Availability & Business Continuity at the Egyptian Drug Authority.

Procedures

- The import approval or the sealed customs release letter is issued within one working day from the submission of the file.
- The application for import approval and Customs medical release is submitted by the requesting entity / importing company in the form of a file or e-mail without being bound by the official submission methods, official working times or official working days, according to the degree of importance of the submitted application and are issued on the same day once applied, in cases of the pharmaceutical products that meet the conditions of emergencies and epidemics.
- The data of the imported Products is clarified by any of the following:

oImport application for the Product
oInvoice and packing list
oCertificates for imported Batches (COA - Batch release – Summary protocol).

- The import approval is issued according to the emergency use license issued for the product or based on the approval of the health authorities from the reference countries of the product, for example: (FDA – EMA – TGA, ..)or the World Health Organization (WHO), without the obligation to provide CPP while the company / entity has to submit the supply orders for the required quantity of the product to face the crisis.
- Compliance with the conditions set out in the import approval and the final release of the pharmaceutical products shall be monitored by inspectors of the **Central Administration of Inspection of Pharmaceutical Institution at the Egyptian Drug Authority** .
- The company/requesting entity shall notify the **Egyptian Pharmacovigilance Center** of any adverse effects resulting from the use of the pharmaceutical product and shall implement any additional risk management activities required for the product.
-

Rules and procedures for the import and release of Products and substances enrolled in the schedules enclosed in the Egyptian Anti-Narcotics Control Law

Scope:

- Importation of pharmaceutical products and substances listed on the schedules attached to the Egyptian anti-Narcotics Control Law, as well as other controlled substances, into the Arab Republic of Egypt.

General Rules for the Importation of Substances and Products Listed on the Schedules attached to the Egyptian anti-Narcotics Control Law:

- All companies and manufacturing facilities shall apply for an annual importation plan for the active pharmaceutical ingredients used in the manufacture of narcotic drugs registered with the Egyptian Drug Authority and owned by the company.
- All companies shall apply for an annual importation plan for their registered narcotic drugs, whether imported as finished or bulk products.
- Annual importation plans shall be quantity-specific, valid for one calendar year, and issued in accordance with the quantities allocated to Egypt under its international estimates for such substances.

First: Procedures for Issuing an Annual Import Approval/Importation Plan for Substances and Products Listed on the Schedules Attached to the Egyptian Anti-Narcotics Control Law:

- The same procedures applicable to the issuance of import approvals/annual import approvals for pharmaceutical raw materials, as well as the procedures governing import approvals and annual importation plans for registered finished pharmaceutical products and bulk imports, shall apply.

Second: Procedures for the Release of Substances and Products Listed on the Schedules Attached to the Egyptian Anti-Narcotics Control Law:

- An Import authorization shall be issued for substances and pharmaceutical products Listed on the Schedules Attached to the Egyptian Anti-Narcotics Control Law that have been granted an import approval or importation plan, upon submission of the following:
  - An application on the company's letterhead specifying the name of the raw material or pharmaceutical product and the required quantity.
  - The relevant import approval/importation plan.
  - A pro forma invoice.
  - A letter or email from the supplier specifying the supplier's full address.
  - An undertaking confirming the accuracy of the submitted information.
  - Where narcotic raw materials are imported for the purpose of producing a Pilot Batch, conducting Research and Development (R&D) activities for a pharmaceutical product under registration with the Egyptian Drug Authority, evaluating a new supplier for a

registered pharmaceutical product, or importing reference standards or samples, an Import authorization shall be issued without the need for a prior import approval.

- A Withdrawal Authorization shall be issued for raw materials, samples, and pharmaceutical products upon submission of the following:
  - An application on the company's letterhead specifying the name of the raw material or pharmaceutical product and the required quantity.
  - The Import authorization issued for the relevant raw material or pharmaceutical product.
  - The Invoice.
  - The bill of lading.
  - An acknowledgement of documents authenticity
  - Certificates of Analysis (CoAs) for the imported batches.
- The company shall receive the Withdrawal Authorization together with the invoice endorsed by the Egyptian Drug Authority and bearing the official seal of the Arab Republic of Egypt for the purpose of obtaining the Sealed Medical Customs Release of the shipment from Customs, provided that the consignment shall not be opened except by inspectors of the Central Administration of Inspection of Pharmaceutical Institution at the Egyptian Drug Authority .
- The inspectors of the Central Administration of Inspection of Pharmaceutical Institution at the Egyptian Drug Authority shall be notified of the consignments and quantities released to these companies in order to monitor such consignments and verify their delivery to the requesting entities.
- An Export Permit shall be issued as follows:

For pharmaceutical raw materials and pharmaceutical products:

The application shall be referred by the Export Department and accompanied by the following documents:

- An application on the company's letterhead.
- A invoice specifying the raw materials or pharmaceutical products to be exported.
- The registration documents for the pharmaceutical products. In the case of raw materials, approval from the competent authority of the importing country authorizing the export.
- An Import authorization issued by the competent authority of the importing country, where the exported pharmaceutical products are Listed on the Schedules Attached to the Egyptian Anti-Narcotics Control Law.

For chemicals:

- An application on the company's letterhead.
- The Industrial Register or Commercial Register.
- The Tax Card.

- The Invoice.
- An Import authorization issued by the competent authority of the importing country.

➢ **A Non-Objection Letter (NOL) shall be issued upon submission of the following**:

- An application on the company's letterhead specifying the name of the pharmaceutical product or raw material to be imported, the importing destination, and the required quantities.
- The Invoice.
- An email from the competent authority confirming that the pharmaceutical products or raw materials are subject to regulatory control in the exporting country.

note that all the above mentioned procedures are applied to acetone and potassium permanganate, except for the issue of the import plan from the Industrial Development Authority in the case of non-pharmaceutical industries.

Rules and Procedures For Import And Sealed Customs Medical Release Of Disinfectants, Pesticides And Cosmetics

1. Disinfectants

Scope:

Importation and release of registered disinfectants, in their finished form, and their raw materials, registered with the Egyptian Drug Authority.

- All companies shall apply for an annual import approval for the raw materials used in the manufacture of disinfectants registered with the Egyptian Drug Authority. Such approval shall be unlimited in quantity and valid for one year from the date of issuance. Companies shall apply for a new annual import approval at least three months before the expiry of the current approval.
- All companies shall apply for annual importation plans for finished products. The importation plan shall be valid for one fiscal year, and the company shall apply for a new plan at least three months before the expiry of the current plan.
- **Procedures:**

First: Procedures for Obtaining an Annual Import Approval/Importation Plan

- An application for the issuance of an annual import approval/importation plan.
- The product registration documents together with the required supporting documentation.
- Product certificates, as applicable to the product classification, such as ISO, CPP, Free Sale Certificate, CE, and GMP.
- A copy of the importing company's Importers Register certificate listing the product, in the case of finished products.
- An undertaking confirming the accuracy of the submitted information.

Second: Procedures for the Sealed Medical Customs Release of Disinfectants

- A Sealed Medical Customs Release Letters shall be granted for consignments submitted by the company within **one working day**, upon submission of the following documents:
  - An application for Pharmaceutical Release.
  - The Invoice.
  - The bill of lading.
  - An acknowledgement of documents authenticity
  - Packing List.
  - In the case of imports from a free zone, a Certificate of Origin and Certificates of Analysis (COAs) shall be submitted.
  - Where the imported raw materials are subject to specific health requirements, the required health certificates shall be provided.
  - All conditions and requirements set forth in the relevant importation plan/import approval shall be complied with.

- The company shall receive a Sealed Medical Customs Release Letter together with the invoice endorsed by the Egyptian Drug Authority and bearing the official seal of the Arab Republic of Egypt for the purpose of obtaining the Sealed Medical Customs Release of the shipment from Customs, provided that the consignment shall not be opened except by inspectors of the Central Administration of Inspection of Pharmaceutical Institution at the Egyptian Drug Authority .

2. Pesticides

First: rules and procedures for the import of household and public health pesticides & natural resources repellents (finished products):

Scope:

Importation and release of **finished Pesticides** and their raw materials registered with the Egyptian Drug Authority.

1- issuing import approvals for the total shipping of constrained quantities of household insecticides:

-Pesticide raw materials that are included in the manufacture of household Pesticides submitted for registration or re-registration for the purpose of conducting research and studies depending on the approval of the registration procedures.

-Finished Pesticides are under registration for the purpose of conducting research and studies depending on the approval of the registration procedures.

-Mosquito incense (natural repellent) registered at the Egyptian drug authority.

-The import approvals shall be issued after presentation to the Sub-Committee for the importation of pesticides.

2-issuing annual production plans for raw materials for the manufacture of household Pesticides:

-All manufacturers are obliged to apply for an annual production plan for their registered Pesticides raw materials.

-The company is committed to submit the plan with specifying the quantities expected to be imported during the year.

-The validity of the plan is a calendar year for total and partial shipping.

-The company is obliged to apply for an annual production plan for another calendar year with a period of not less than three months before the expiry of the valid plan.

-The production plan is issued after presentation to the subcommittee for the importation of pesticides.

3.issuing import approvals for public health pesticides:

-The import approval for pesticide raw materials is issued with constrained quantity valid for total shipping sufficient to produce the product with the quantity mentioned in the purchase orders after presentation to the subcommittee for the importation of pesticides at EDA.

4-issuing production plans for public health pesticide raw materials:
A semi-annual production plan (for a period of 6 months) is issued to manufacturers with evaluation at the end of the period and renewal of the issuance of the plan with compliance with the following conditions:
-Informing the Central Administration for Pharmaceutical Institution at the Egyptian drug authority, about the manufacturer periodic inspection and follow-up of the quantities of imported raw materials and the quantities of final Product manufactured and follow-up of their supply.
-Pledge to re-export any quantities remaining from the raw materials and the manufactured products which are expired and invalid for manufacturing or use as per the applicable rules and procedures.
-Submit a statement approved by the inspectors of Central Administration for Pharmaceutical Institution at the Egyptian drug authority , explaining the follow-up of actual supplies and follow-up of remaining quantities of raw materials and finished Products at the company.

- Quantities for Production Plan are guide calculated according to the following:

1.Actual imported quantities during the previous two years.
2.The current stock and disbursed quantities as per the statement of the Inspectors of Central Administration for Pharmaceutical Institution at the Egyptian drug authority.
3.The quantity permitted for import shall not exceed the production capacity as per the factory's industrial registry.
4.The presence of a minimum order at the supplier (depending on the situation)
5.The company submits preliminary purchase orders if it exists in the case of Public Health pesticides.

5-procedures for issuing an import approval for pesticides -natural resources repellents (finished Product):
The import approval is issued per an invoice & valid for total shipping for companies registered in the Register of importers of pesticides at the Egyptian drug authority after fulfilling the following requirements:
1.invoice
2.Copy of the registry of importers of pesticides at the Egyptian drug authority.
3.Valid registration documents
4.Quality certificate of the external manufacturer (ISO or Free Sale or GMP,....) Or any other quality certificate
5.Commitment letter from the external Manufacturer and the importing company to re-export the shipment in case it does not meet the specifications

6.Letter declaring the relationship between the manufacturer and the supplier.
The presentation is made to the subcommittee for importation of pesticides and their raw materials and the import approval is issued based on the approval of the committee.

Second: the procedures followed for the Sealed Customs release of household and public health pesticides:

The sealed customs medical release letter is granted within one working day.
The documents are submitted as follows:
-Request from the company
-The invoice and its conformity with the import approval/ plan .
-Bill of Lading
-Certificates of analysis for imported Batches
-Packing List
-In case of import from the Free Zone, A certificate of the country of origin and certificates of analysis are provided
-All the requirements contained in the import plan are complied with.
-The company shall receive a letter of sealed release for the contents of invoice provided that the contents covered by the invoice shall not be released except by the Inspectors of the Central Administration for Pharmaceutical Institution at the Egyptian drug authority.

3. Cosmetic Products

Scope:

*Importation and release of **cosmetic products**, their raw materials, and their packaging materials.

First: Procedures for Issuing Import Approvals for Cosmetic Products, Their Raw Materials, and Packaging Materials

First: Import Approval for Finished Cosmetic Products:

An import approval shall be issued per Invoice, valid for a full shipment only, to companies and agents of cosmetic products registered in the Cosmetic Importers Register of the Egyptian Drug Authority, upon submission of the following:

- An application on the company's letterhead.
- The Invoice.
- A copy of the approved product registration notifications, together with any amendments or variations thereto, in accordance with Ministerial Decree No. 151. For cosmetic products registered under the Notification System pursuant to Egyptian Drug Authority Chairman's Decree No. 122 of 2022, the product information shall be verified through the Notification System or by submitting the Notification License issued by the General Administration for Cosmetic Product Registration.

- A copy of the company's registration in the Cosmetic Importers Register maintained by the Egyptian Drug Authority.

Second: Import Approval for Cosmetic Raw Materials and Packaging Materials:

An import approval shall be issued per Invoice, valid for a full shipment only, for cosmetic raw materials and packaging materials intended for local companies and manufacturers that own cosmetic products. Import approvals shall also be issued for cosmetic raw materials imported by companies registered in the Cosmetic Raw Materials Importers Register of the Egyptian Drug Authority, upon submission of the following:

- An application on the company's letterhead.
- The Invoice.
- A copy of the approved product registration notifications, together with any amendments or variations thereto, in accordance with Ministerial Decree No. 151. For cosmetic products registered under the Notification System pursuant to Egyptian Drug Authority Chairman's Decree No. 122 of 2022, the product information shall be verified through the Notification System or by submitting the Notification License issued by the General Administration for Cosmetic Product Registration.
- A copy of the company's registration in the Cosmetic Raw Materials Importers Register maintained by the Egyptian Drug Authority, in the case of cosmetic raw material importers.
- A Material Safety Data Sheet (MSDS).
- A letter from the foreign manufacturer specifying the source of the raw material. Where the imported raw material is subject to specific health requirements, the required health certificates shall be submitted at the time of obtaining the Sealed Customs Release.
- In the case of colorants or pre-mixed and pre-prepared raw materials, a composition statement issued by the foreign manufacturer shall be submitted and matched against the approved formulation.
- Where the raw materials are intended for the manufacture of cosmetic products for export only, the manufacturer shall provide an undertaking confirming that the materials covered by the invoice will be used exclusively in the manufacture of products for export and will not be marketed in the local market.

Third: Whitelists for the Importation of imported Cosmetics & Raw Materials from Reference Country:

The White Lists are lists of companies engaged in the manufacture and importation of cosmetic products that comply with the applicable regulatory requirements and procedures and satisfy the criteria for inclusion, including Supporting local manufacturing, Compliance with the rules governing importation and Sealed Medical Customs Release procedures, Compliance with the applicable quality and product specification requirements.

Procedures:

- The company shall submit an application to be included on the White List.
- The company shall complete an electronic questionnaire containing a number of questions designed to assess the three criteria referred to above.
- The questionnaire shall be evaluated and reviewed by the General Administration for Importation and Customs Release, and, where necessary, an on-site inspection shall be conducted by the pharmaceutical inspection authority.
- Upon approval, the company shall be issued a White List Certificate, accompanied by an annex listing the finished reference cosmetic products covered by the certificate.
- Once a company has been approved for inclusion on the White List, it shall be permitted to import cosmetic raw materials, packaging materials, and finished cosmetic products without the need to obtain prior import approvals.
- The White List Certificate shall be valid for one year from the date of issuance. To maintain its status, the company shall reapply for inclusion, and its application shall be reassessed annually.
- Where a company commits a serious violation, it shall be temporarily suspended from the White List for a period of three months. The company may request amendments to the annex attached to its White List Certificate to add or remove cosmetic products and/or raw materials.

Procedures for the Sealed Medical Customs Release of Cosmetic Products, Cosmetic Raw Materials, and Packaging Materials

- A Sealed Medical Customs Release Letter shall be issued for imported consignments within one working day, upon submission of the following:
  - An application on the company's letterhead.
  - The Invoice, matched against the relevant import approval or the company's White List status.
  - The bill of lading.
  - An acknowledgement of documents authenticity
  - Packing List.
  - In the case of imports from a free zone, a Certificate of Origin and Certificates of Analysis (CoAs) shall be submitted.

- Where the imported raw materials are subject to specific health requirements, the required health certificates shall be provided.
- All conditions and requirements set out in the applicable import approval or White List shall be complied with.
- The company shall receive a Sealed Medical Customs Release Letter together with the invoice endorsed by the Egyptian Drug Authority and bearing the official seal of the Arab Republic of Egypt for the purpose of obtaining the Sealed Medical Customs Release of the shipment from Customs, provided that the consignment shall not be opened except by inspectors of the Central Administration of Inspection of Pharmaceutical Institution at the Egyptian Drug Authority .
- Where a tourism establishment imports finished cosmetic products, it shall be permitted to import such products on one occasion only. The establishment shall be granted a period of six months from the date of release to authorize a company registered with the Egyptian Drug Authority in the Cosmetic Importers Register to undertake the registration and importation of the product on its behalf.

Pharmaceutical Exemptions

1- Exemption from Value Added Tax (VAT):

*** The Procedures of implementing the provisions of the decision of the chairman of the Egyptian drug Authority No. 95 of 2022 regarding the exemption of pharmaceutical ingredients involved in the production of pharmaceutical Products**

First: Scope of Application:

This implementation mechanism shall apply to applications submitted by companies subject to the jurisdiction of the Egyptian Drug Authority in accordance with the provisions of Law No. (151) of 2019, whether such raw materials are used for production batches, research purposes, or experimental batches. Such applications shall be submitted pursuant to Item No. (55) of the "List of Goods and Services Exempt from Value Added Tax" annexed to the Value Added Tax Law promulgated by Law No. (67) Of 2016, as replaced by Law No. (3) Of 2022.

Second: General Rules:

- Pharmaceutical companies, pharmaceutical manufacturers, and importers of pharmaceutical raw materials (active/inactive) shall submit applications to the Egyptian Drug Authority for inclusion in the lists of materials exempt from Value Added Tax (VAT) pursuant to Item No. (55) of the "List of Goods and Services Exempt from Value Added Tax" annexed to the Value Added Tax Law promulgated by Law No. (67) Of 2016, as replaced by Law No. (3) Of 2022.The application shall specify the category of each material, whether it is: Active pharmaceutical ingredients (APIs), Inactive

pharmaceutical ingredients, Primary raw materials, Packaging materials, Pre-mixed and prepared pharmaceutical raw materials. The application shall be submitted using the forms prepared for this purpose, whether for imported materials or materials purchased from local suppliers.

- Pharmaceutical companies, pharmaceutical manufacturers, and pharmaceutical raw material importers (active/inactive) shall submit the original application, approved by the Chairman of the Company's Board of Directors, to the General Manager of the General Administration for Importation and Customs Release.

A. Imported Raw Materials and Packaging Materials:

1. For pharmaceutical companies and pharmaceutical manufacturers subject to the provisions of Law No.151 of 2019 on the Egyptian Drug Authority, a consolidated list of all required to be exempted and the company's annual valid import approval for both pharmaceutical raw materials (active /inactive),packaging supplies, and pre-mix materials must be submitted. In case of a request for exemption of imported primary raw materials, the valid import approval for the raw materials to be exempted must be submitted.
2. For importers of Pharmaceutical Raw Material, The importer shall submit: A consolidated list of all materials requested to be exempted, the valid import approval issued for each material.

B. Raw Materials and Packaging Materials Purchased from Local Suppliers:

The review is carried out according to the latest approved table of composition at the Egyptian Drug Authority database

*If the company wants to include new items to the Exempt List, It is necessary to apply for inclusion on an approved list in accordance with the same rules and procedures.

*All companies are committed to supply active/ inactive / pre-mix pharmaceutical raw materials, primary raw materials & packaging materials for manufacturers licensed from the Egyptian drug authority and for the manufacturing of pharmaceutical products registered at EDA.

Third: Procedures and Steps for Reviewing Applications:

- Companies shall submit the original application on company letterhead, bearing the company stamp, and signed by the Chairman of the Board of Directors, its legal representative, or an authorized delegate pursuant to an official authorization (signature authentication), requesting the inclusion of raw materials in the Value Added Tax exemption lists. The application shall be submitted to the office of the General Manager

of the General Administration of Importation and Customs Release, according to the forms prepared for this purpose, after payment of the prescribed service fee.

- The company shall upload a copy of the application through the electronic link: https://forms.gle/MChuDtL6ENkV4pzT7

Along with the documents specified above according to each individual case.

- The application shall be reviewed and lists of legally eligible items for exemption shall be prepared and submitted to the Chairman of the Egyptian Drug Authority.
- If a decision is issued by the Chairman of the Authority, an exemption eligibility letter shall be issued to the applicant by the General Manager of the General Administration of Importation and Customs Release.
- The letter shall be valid for one year from the date of issuance for the materials included in the lists attached to the Decision of the Chairman of the Authority.

2- Therapeutic Benefit Letter:

This is a letter issued for imported finished pharmaceutical products and bulk products to determine their therapeutic benefit, enabling the company to submit it to customs in order to exempt the product from the customs tariff item specified under Presidential Decree No. (69) Of 2015 and its amendments.

Required Documents for Issuing a Therapeutic Benefit Statement:

- Company application.
- Import approval/import plan.
- Approved package insert for medicines registered with the Egyptian Drug Authority, or the internal leaflet in cases of medicines not registered with the Egyptian Drug Authority.

3- Letter Determining the Annual Requirement of 96% Ethyl Alcohol:

- This letter is issued for pharmaceutical products registered and subject to mandatory pricing by the Egyptian Drug Authority.
- Please note that the Egyptian Drug Authority does not issue requirement determination letters for denatured alcohol.

Documents Required for Issuing the Annual Requirement Letter for 96% Ethyl Alcohol:

- Application submitted on company letterhead.
- Valid registration notification.
- Approved composition statement containing 96% alcohol.
- A statement showing the calculations of the required quantity of alcohol and the quantity used in manufacturing the pharmaceutical products signed and stamped by the Chairman of the Board of Directors of the company.

4- ACDIMA Companies Exemptions:

Pursuant to the Decision of the Prime Minister No. 709 of 1978 regarding exemptions from taxes and customs duties prescribed for the Arab Company for Pharmaceutical Industries and Medical Appliances (ACDIMA), Article (2) stipulates the following:
"Raw materials, production supplies, machinery, equipment, devices, spare parts, construction materials, tools and equipment, primary materials, chemicals, medicines, pharmaceutical preparations, and medical supplies imported by the company, its branches, agencies, and affiliated companies whose headquarters are located in the Arab Republic of Egypt shall be exempt from customs duties and taxes and all other taxes and fees."
Also, pursuant to the Decision of the Prime Minister No. 683 of 1982, which specified the exemption for the companies listed in the annex attached to the decision, as follows:

Egyptian International Pharmaceutical Industries Company (EIPICO)	Arab Pharmaceutical Glass Company
Arab Company for Pharmaceutical Raw Materials	Upper Egypt Pharmaceutical Industries Company (SEDICO)
Arab Company for Pharmaceutical Packaging	Arab Company for Medical Supplies
Arab Company for Gelatin Products	Arab Company for Hospital Equipment Manufacturing
Arab Company for Medicinal Plants (Mepaco)	Arab Company for Medical Foods

Article (2 (A)) of the Decision of the Prime Minister No. 683 of 1982 further stipulates:
"The items intended to be exempted pursuant to the provisions of this Decision shall be determined through lists approved by the Ministry of Health."
Accordingly, the Egyptian Drug Authority shall issue letters specifying the items and materials intended to be exempted for these companies, enabling them to submit such letters to the competent authorities.

Required Documents:

- Company application specifying the shipment details.
- Invoice.
- Bill of lading.
- Annual import plan/import approval.

The Rules and Procedures Followed for The Approval of Sealed Customs Medical Release of Pharmaceutical Shipments by EDA Representatives at Customs Ports

The sealed Customs release letter for imported shipments of pharmaceutical Products , raw materials and packaging Materials to the Arab Republic of Egypt, is reviewed and approved at ports and airports through EDA representatives at customs ports.

Procedures:

Requests for approval of the Sealed customs medical release made for shipments under the control of the Egyptian Drug Authority, which are presented to the EDA representatives at customs ports through a NAFEZA system, are reviewed during this process and the sealed customs release shall be approved after the importing company uploads the following documents on the customs declaration related to the shipment submitted through the NAFEZA system, electronically signed by the importer confirming the authenticity of the submitted documents:

1. Sealed Customs release letter
2. The invoice approved by the Egyptian Drug Authority attached to the release letter.

These documents shall be reviewed against the data included in the documents related to the customs declaration, namely:

1. Invoice.
2. Bill of Lading.
3. Customs review statement: a statement issued by the customs authorities describing and recording the quantity in terms of numbers and weights, apparently (item name-validity date-data recorded on the items), the status of imported shipments (the packaging)

If the above-mentioned documents are complete and compliant, the sealed customs release of the shipment shall be approved through the NAFEZA system. Accordingly, the shipment shall be released under bond from the customs port, provided that the contents of the shipment shall not be released finally except by inspectors of the Central Administration of inspection of Pharmaceutical Institutions at the Egyptian Drug Authority.

If the required documents are incomplete, comments shall be entered for the applicant through the NAFEZA system, specifying the type of document required to be added to the customs declaration.

<u>Procedures to Be Followed in Case of Differences in the Imported Shipment:</u>

1. Imported Quantities Received Short or in Excess:

- In case of shortages in the received quantities:
  The shipment shall be released directly by the representatives of the Egyptian Drug Authority at customs ports after notifying the competent department, in order to enable it to review and re-enter the data of the incoming shipments.
- In case of excess quantities received:
  The matter shall be resubmitted to the competent department at the Egyptian Drug Authority with a request for approval of the excess quantities received, accompanied by the customs inspection report specifying the quantities in detail.

2. Difference in Product Name and Expiry Date, or Missing Data or Different Data:
The matter shall be resubmitted to the competent department at the Egyptian Drug Authority, accompanied by an explanatory statement detailing the Differences found.

3. Damage to Products in Terms of Packaging and Packing of Incoming Shipments:
The representatives of the Egyptian Drug Authority at customs ports shall conduct an actual inspection of the shipment contents and prepare an inspection report describing: The nature, extent, and size of the damage or deterioration; and The extent of its impact on the incoming products. The matter shall then be resubmitted to the competent department at the Egyptian Drug Authority, accompanied by the inspection report.

- Medical Products Imported for Use in International, Regional, or Local Exhibitions Held in Egypt and Subject to the Supervision of the Egyptian Drug Authority but Not Registered with the Authority:

The medical customs release for such products shall be issued through the representatives of the Egyptian Drug Authority at customs ports, subject to the following conditions:

- The displayed products shall be used solely for exhibition purposes and shall not be circulated in the local market.
- Any unused products displayed shall be re-exported after the conclusion of the exhibition within a period not exceeding the validity period of the guaranteed letter submitted to customs. In case this period is exceeded, the customs rules and procedures applicable to abandoned goods shall apply.

Rules and Procedures for the Release of Imported Products for Personal Use:

The customs medical release of medical products subject to the provisions of the Egyptian Drug Authority Law No. 151 of 2019, whether registered or not registered at the authority for personal use, is allowed through the representatives of the Egyptian drug authority at customs ports.

First: pharmaceutical Products:

The customs release of an amount sufficient for the use of three months is allowed and in the case of medicines for chronic and incurable diseases, the customs release of an amount sufficient for the use of six months is allowed for personal use

Documents Required for Obtaining Medical Customs Release for Personal Use:

- Customs declaration or postal form.
- Invoice.
- Bill of lading.
- Original medical report or medical prescription indicating the dosage and the method of calculation.

Notes:

1. Products imported as health insurance medicines from abroad: A medical report issued by the foreign health insurance provider shall be submitted, provided that the imported medicines bear the following information: Patient's name; Insurance number; Name of the treatment/medicine.
2. Medicines imported for a patient enrolled in a clinical study abroad: The following shall be submitted: Clinical study protocol; Evidence that the patient is enrolled in an ongoing clinical study; Medical report indicating the duration of use.
3. Medicines imported as donations for AIDS patients registered in AIDS treatment programs abroad: A medical report issued by the treatment program shall be submitted, and release shall be permitted for the quantity specified in the medical report.
4. Medicines requiring specific storage conditions to maintain their safety: Storage conditions shall be verified by the representatives of the Egyptian Drug Authority at customs ports before granting final release.
5. Veterinary medicines: Release shall be permitted for quantities sufficient for the treatment of domestic animals.
6. Dietary Supplements imported in pharmaceutical dosage forms: Release shall be permitted for quantities sufficient for three months of use.

Products Not Permitted for Release:

1. Products listed under the Egyptian anti-Narcotics Control Law No. (182) of 1960 and its schedules.
2. Pesticides.
3. Products with misleading medical claims, including for example: Weight loss products; Detoxification pads; Body fat burning products; Products making sexual claims; other products with misleading medical uses.
4. Products containing extracts of blue-green algae (Spirulina).

A Therapeutic Benefit Statement Letter may be issued to exempt medicines used for the treatment of chronic or incurable diseases, imported for personal use, from the applicable customs tariff category.

- Samples imported for scientific research purposes under the supervision of governmental authorities and institutions.

Documents Required for Obtaining Medical Customs Release for Research Samples:

- Approval of the research entity for the scientific research, including details of the research and the required samples.
- Invoice.
- Bill of lading
-

- Cosmetic products imported for personal use shall be released as follows:

Cosmetic products such as: Make-up products; Creams and lotions; Personal care products; Wet wipes.

- Release shall be permitted for a quantity sufficient for personal use for a period not exceeding **three months**, based on the smallest available package size, except for the following items:

Product	Quantity
Hair straightening products and hair dyes	Quantity not exceeding six months of use according to the product catalogue or instructions for use
Gel nail polish	

General Rules:

- Cosmetic products classified under the following categories shall **not** be released for personal use:
  1. For Professional Use Only.
  2. Free Samples and Free of Charge Products.
  3. Tattoo ink, related materials, and needles for injection, according to the Material Safety Data Sheet (MSDS) or the Manufacturer's Catalogue.

Documents Required for Obtaining Medical Customs Release for Personal Use:

- Customs declaration or postal form.
- Invoice.
- Bill of lading.

List of customs ports covered by EDA Representatives	
1	Cairo International Airport
2	Alexandria Port
3	Burj Al Arab Airport
4	Dekheila Port
5	6th Of October Port
6	Damietta Port
7	Port Said Port (east)
8	Port Said port (west)
9	Abu Keer Port
10	Suez Free zone
11	Aladebya Port
12	Port Tawfik Port
13	Badr Port
14	Ain EL Sokhna Port
15	Obour port
16	Margham Port
17	10th of Ramadan Port
18	Sosdy port
19	6th Of October Dry Port (ODP)
20	Madinet Nasr Free Zone
21	Amiriya Free Zone
22	Badr Dry Port Suez
List of customs ports covered by EDA Representatives (NAFEZA remotely)	
1	Safaga Port
2	Ismailia Free Zone
3	Nuweiba Port

Final Instructions and Guidance

- All companies and importing entities shall refrain from shipping any consignments of pharmaceutical products, their raw materials, or packaging materials unless they have obtained a prior import approval from the Egyptian Drug Authority before shipment. Companies shall also comply with all conditions stated in the import approval at the time of shipment. This is to ensure the proper conduct and regularity of the importation and release procedures, and to safeguard the interests of companies and the health of Egyptian patients. The Authority shall not be responsible for any losses resulting from failure to comply with these instructions, and the company shall be subject to penalties for non-compliant shipments.
- Companies shall review and work on updating the registration data of their products in the Egyptian Drug Database, as well as their company data in the electronic Company Profile system, on a regular basis, in order to ensure accuracy and speed during data review and matching procedures and to avoid losses resulting from delays or failure to update the data.
- All requirements stipulated in the product registration notification, variation department decisions issued for the product, as well as Egyptian Drug Authority decisions related to raw materials or foreign manufacturing sites, shall be complied with.
- The return of shipments of raw materials or pharmaceutical products that have previously been exported abroad shall not be permitted.
- Importing companies shall ship consignments through the customs ports where representatives of the Egyptian Drug Authority are present, as indicated above. Importing companies shall bear full responsibility for the method of shipment, taking into consideration the nature and shipping conditions required for the imported product.

References

- Egyptian Drug Authority Chairman’s Decree No. 444 of 2023.

Application Links for The General Administration of Importation & Customs Release

Pharmaceutical Raw Materials	
Importation approvals for pharmaceutical Ingredients	https://forms.gle/7yAvHmrN5F6Yahmc6
Complementary Importation approvals for pharmaceutical Ingredients	https://forms.gle/uf8A6QR9QzGUcokn9
Importation approvals for Veterinary products	https://forms.gle/RJxySXFuV1e6y8r2A
Importation approvals for Gomhoria company (human -Vet. - Herbal)	https://forms.gle/P4UQmmLQrFkarEDYA
Importation Approvals for herbal pharmaceutical ingredients	https://forms.gle/xdQ8aefBrhhbSo8S6
Amendments for annual importation approval for pharmaceutical ingredients for human & Vet. Products	https://forms.gle/h9U1jZv6KrvYaPcR7
Requests for Sealed Customs Release of pharmaceutical ingredients	https://forms.gle/gkoVHbjuGpRJhwym7
Amendments Requests for Sealed Customs Release of pharmaceutical ingredients	https://forms.gle/r8LCa4TAeu8gZsNN8
Technical Assessment For pharmaceutical ingredients	https://forms.gle/Y3MUfq6V64etZX3D7
Annual importation Approvals for inactive pharmaceutical ingredients & packaging materials	https://forms.gle/P4sqRdL4b1iY96cr6
Setting an appointment to submit annual importation approval	https://forms.gle/7yAvHmrN5F6Yahmc6
Pharmaceutical Products	
Importation Approvals for imported finished/bulk pharmaceutical products & Free Medical Samples	https://docs.google.com/forms/d/e/1FAIpQLScHIC0WrHT3l8J1N8PeQ0L8Y3yhoOErp-aURdRMJltjO1_OOA/closedform
Importation approvals for special requests	https://forms.gle/vAEGxDSsq4H2zPfk9
Requests for Importation Plans of Imported Finished/ Bulk pharmaceutical products	https://forms.gle/YviqPEjVDGgTMjfa7

Sealed Customs Release of Pharmaceutical Products	https://docs.google.com/forms/d/e/1FAIpQLScw2l6UXvtyFygEQIyc8Ybq9wpYgiaepfOzqaJ1BP40cuDcMg/closedform
Complementary Requests of Sealed Customs Release of Pharmaceutical Products	https://docs.google.com/forms/d/e/1FAIpQLSdCyszhLbtRylTU8HzLSrx31amqdxMLtAmsVBVE3raG2L-9jw/viewform
Sealed Customs Release of Pharmaceutical Products (Special Requests)	https://docs.google.com/forms/d/e/1FAIpQLSfms2lqvxqL-VeC3yjIJpunWLaV3YEJHHyERUWMDNbF40WtzQ/closedform
Sealed Customs Release of Clinical Trials	https://docs.google.com/forms/d/e/1FAIpQLScXxGrs1fhCDIRx5f6nz0_P6Uyaawj8YfaPkkmN2E0nnOHTgA/closedform
Complementary Requests of Sealed Customs Release of Pharmaceutical Products (Special Requests) & Clinical trials	https://eur06.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdocs.google.com%2Fforms%2Fd%2Fe%2F1FAIpQLSc3SzF7n5fx-lIu71FlOyOXRxQwD2v7XWE9eHv3f5ljyohCXA%2Fviewform&data=05%7C02%7Cicr.followup%40edaegypt.gov.eg%7C8eb84a4edcd440a7aeca08def612d512%7C12a0763dad544ee7b7d1844ee14e87e5%7C0%7C0%7C639218757895470291%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=264krg46b6bbB7RNfH%2BXfDJZzaJVZCTP3LMB9lQu12Q%3D&reserved=0
Biological Products	
Importation Approvals for imported finished/bulk biological products	https://forms.gle/iTdJvKmdx5nXXsys9
Requests for Importation Plans of Imported Finished/ Bulk Biologicals products	https://eur06.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdocs.google.com%2Fforms%2Fd%2Fe%2F1FAIpQLSfOKnDn3MXvwD3X7zEAlXYb0s_dNhaf2ko5uki86tEow-tKcQ%2Fviewform&data=05%7C02%7Cicr.followup%40edaegypt.gov.eg%7C9375decd35924af11f3508def6b1e817%7C12a0763dad544ee7b7d1844ee14e87e5%7C0%7C0%7C639219441135624666%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=mzdu6ay6svjWEnI08bbICc2QeihP1JkY9FFDWmjIwR8%3D&reserved=0
Sealed Customs release for Biological Products & raw materials	https://eur06.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdocs.google.com%2Fforms%2Fd%2Fe%2F1FAIpQLScaAJCXd-OX-

	0sSzilrtqf8CZM_z_QOn4YHx-d81IPojw30Ig%2Fviewform&data=05%7C02%7Cicr.followup%40edaegypt.gov.eg%7Ccfdcc3ce4aa043b06a2a08def6b1dbc6%7C12a0763dad544ee7b7d1844ee14e87e5%7C0%7C0%7C639219440913556993%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=%2BbRMXT7hP7D0jHvu5nkRzb1sxED%2Bxjfb%2FQvnvl73uYw%3D&reserved=0
Complementary requests for Sealed customs release of Biological Products & their Ingredients	https://docs.google.com/forms/d/e/1FAIpQLSexE5AHpxzxUaOVAkdB5-n1Eb4yTPdB4QxyvW1dfdWcuHhXTQ/viewform

Narcotics	
Importation approvals & plans for Narcotics	https://eur06.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdocs.google.com%2Fforms%2Fd%2Fe%2F1FAIpQLSdeQnx8-vcip9875VxNBJXGQ3eA2lsGqF1SF9VGo62gfPYg_Q%2Fclosedform&data=05%7C02%7Cicr.followup%40edaegypt.gov.eg%7C7da3f36d0e3547c2468508def60fb319%7C12a0763dad544ee7b7d1844ee14e87e5%7C0%7C0%7C639218744498381380%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=nqqUEUPsZfDpg3xogJuN2Hkq28Hd7iyXYVAQ6t4EwzY%3D&reserved=0
Import Authorization	https://forms.gle/E29sBK4C4uffpDaX8
Withdrawal Authorization	https://forms.gle/vVy5z4MDyvVkzs5CA
Non objection letter	https://eur06.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdocs.google.com%2Fforms%2Fd%2Fe%2F1FAIpQLSexaPg5oc3z_8Whg-BavrXAZqgRNWPoOk6z3sivJnFEztEa7Q%2Fviewform&data=05%7C02%7Cicr.followup%40edaegypt.gov.eg%7C7da3f36d0e3547c246850

	8def60fb319%7C12a0763dad544ee7b7d1844ee14e87e5%7C0%7C0%7C638218744498356700%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=B3RI319EH6HYWoAcw7YArmxsCjzwIs7EdS%2FXFqs%2FNDc%3D&reserved=0
Cosmetics, disinfectants & pesticides	
Sealed Customs release for cosmetics	https://forms.gle/QK47bYp1GJUiyeSL8
Complementary Requests for Sealed Customs release for cosmetics	https://forms.gle/8GJx2XJ1V3iiB6dm8
Importation approvals for cosmetics	https://forms.gle/VSbeFFjSEjtQ9G9E9
Importation approvals or cosmetics raw materials	https://forms.gle/Ya5Lyoq5D5yqjjmM6
Complementary Requests for Cosmetics	https://forms.gle/iFe4TMQbUK4UDDP1A
Importation approvals for pesticides & disinfectants	https://forms.gle/nngL59KrzDfwhuT18
Sealed Customs release for pesticides & disinfectants	https://forms.gle/ghPt2k8jKcoiScDh7
Cosmetics White list	https://docs.google.com/forms/d/e/1FAIpQLSeZa9OcSV9tNJdBopTJHxTcP5cx6saKBe41IzN9Nno_FXoYhQ/viewform
Pharmaceutical Exemptions	
Exemptions List	https://forms.gle/MChuDtL6ENkV4pzT7
determination of the annual requirement of ethyl alcohol	https://forms.gle/FXb24K42DGiA95Gw6
Determination of customs code	https://forms.gle/m47Ru6bypXPdKHoQ7
ACDIMA Exemptions	https://docs.google.com/forms/d/e/1FAIpQLSd0o0t_dyQTz7C51oMUKsl0hb7D2ei2GQlTzzbx_Dv6vQnRzA/viewform
Complementary Requests	https://forms.gle/jhaZyc2LTEGud2dg6