Notice to applicant

EG Human Pharmaceutical Module 1 Submission Guidance

Year 2026

Draft

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1 Introduction:

This notice to applicant is intended to provide guidance on the format of Module 1 of the human pharmaceutical products and indicates where the information should be located in the Module.

Module 1 (Administrative information), This module contains the specific EG-requirements for the administrative data (e.g. the application form, the proposed summary of product characteristics, labelling and package leaflet, etc.).

2 Scope:

This notice to applicant is applied for both local and imported Human Pharmaceutical Products that are submitting their applications for registration, re-registration or variation.

3 Module 1 Format:

Module 1:

- **1.0 Cover Letter**
- **1.2 Application Form**
  - **1.2.1 Application Form**
  - **1.2.2 Legal Documents**
    - 1.2.2.1 Letter of Attorney for Company Representative
    - 1.2.2.2 Manufacturing License and IDA License
    - 1.2.2.3 GMP Certificate(s) / Alternative Documents
    - 1.2.2.4 The Register of Trade
    - 1.2.2.5 Toll Manufacturer License
    - 1.2.2.6 Scientific Office License
    - 1.2.2.7 Importers Register License
    - 1.2.2.8 Store License
    - 1.2.2.9 Authorization Letter / Agency Agreement
    - 1.2.2.10 Manufacturing Agreement
    - 1.2.2.11 Packaging Agreement
    - 1.2.2.12 Storage Agreement
    - 1.2.2.13 Other Agreements
    - 1.2.2.14 Termination / Waiver
  - **1.2.3 EDA Approvals**
    - 1.2.3.1 Registration Request Approval
    - 1.2.3.3 Name Approval
    - 1.2.3.4 Registration License
    - 1.2.3.5 Preliminary Approval
    - 1.2.3.6 Non-Reference Approval
    - 1.2.3.8 Pricing Certificate
    - 1.2.3.9 Pharmacovigilance Approval
    - 1.2.3.10 Inspection Report

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1.2.3.11 Importation Approval for each API
1.2.3.12 CADC Report
1.2.3.13 Stability Study Approval
1.2.3.15 Module 3 Approval
1.2.3.16 Module 5 Approval
1.2.3.17 Pre-approved letters from EDA concerning the product
1.2.3.18 Variation Approvals
1.2.3.20 Registration License for the Solvent

1.2.4 Declarations

1.2.4.1 Declaration Letter stating the list of Registered & Under-Registration Products owned by the Toll Company
1.2.4.2 Declaration Letter from the License Holder specifying the API Manufacturers
1.2.4.3 Declaration letter from the license holder specifying approved pack in Egypt
1.2.4.4 Declaration Letter from the License Holder stating the Form of Bulk (Strips, Capsules, etc.)
1.2.4.5 Declaration Letter from the Manufacturer of the Active Substance to inform the Applicant in case of Modification of the manufacturing Process or Specifications
1.2.4.6 Declaration Letter from API Supplier
1.2.4.7 Declaration Letter for Site Addition
1.2.4.8 Declaration Letter Form LH stating all Variations & Justification for the Change
1.2.4.9 Other declarations requested by Egyptian Drug Authority
1.2.4.10 List of the Countries where the Product is registered & marketed

1.2.5 Reference Product Document / Compendial

1.2.5.1 The Reference Product Documents
1.2.5.4 The latest recent Pharmacopeia

1.2.6 Imported Products Documents

1.2.6.1 Certificate of Pharmaceutical Product (CPP)
1.2.6.2 List of Affiliates / Subsidiaries

1.2.7 Reliance Documents

1.2.7.1 Sameness Letter
1.2.7.2 Unredacted Assessment Report
1.2.7.3 RRA Variation Application with Annexes

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1.2.8 Composition Documents

1.2.8.1 Composition Certificate
1.2.8.2 Specifications
1.2.8.3 Any Composition Calculations
1.2.8.4 Pellets / Premix Composition and Certificates
1.2.8.5 Opadry / Coating Premix Composition
1.2.8.6 Capsule Shell Composition
1.2.8.7 Synonyms Evidence

1.2.9 Certificate of Analysis

1.2.10 Post Approval Changes Requirements

1.2.10.1 PAC Approval from the COO (Imported Products)
1.2.10.2 Summary of Change for Variation
1.2.10.3 Justification of the proposed Post Approval Change
1.2.10.4 Any additional Documents relevant to Variations

1.2.11 Proof of Payment

1.3 Product Information

1.3.1 SPC, Labelling and Package Leaflet
1.3.2 Mock-up

Responses to Questions
Additional Data

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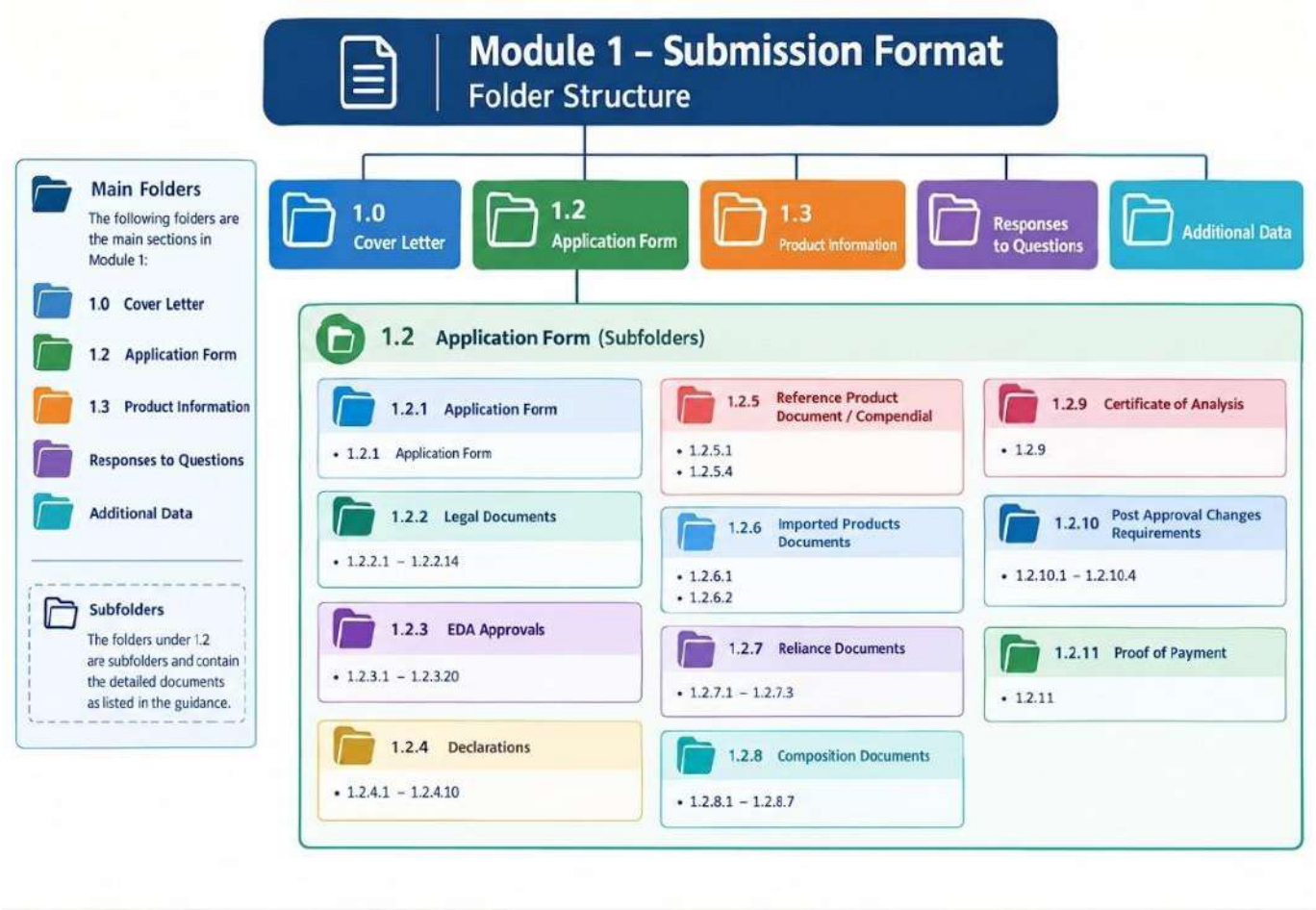


Figure (1): The diagram illustrates the hierarchy and folder structure required for **Module 1** submissions.

4 Document Mapping:

- All relevant documents are provided within the designated folders organized by regulatory activity (New, Renewal, variation).
- The Legal Documents folder is organized differently from the other document folders, with its contents categorized according to the registration type with the applicable legal documents identified under each category.

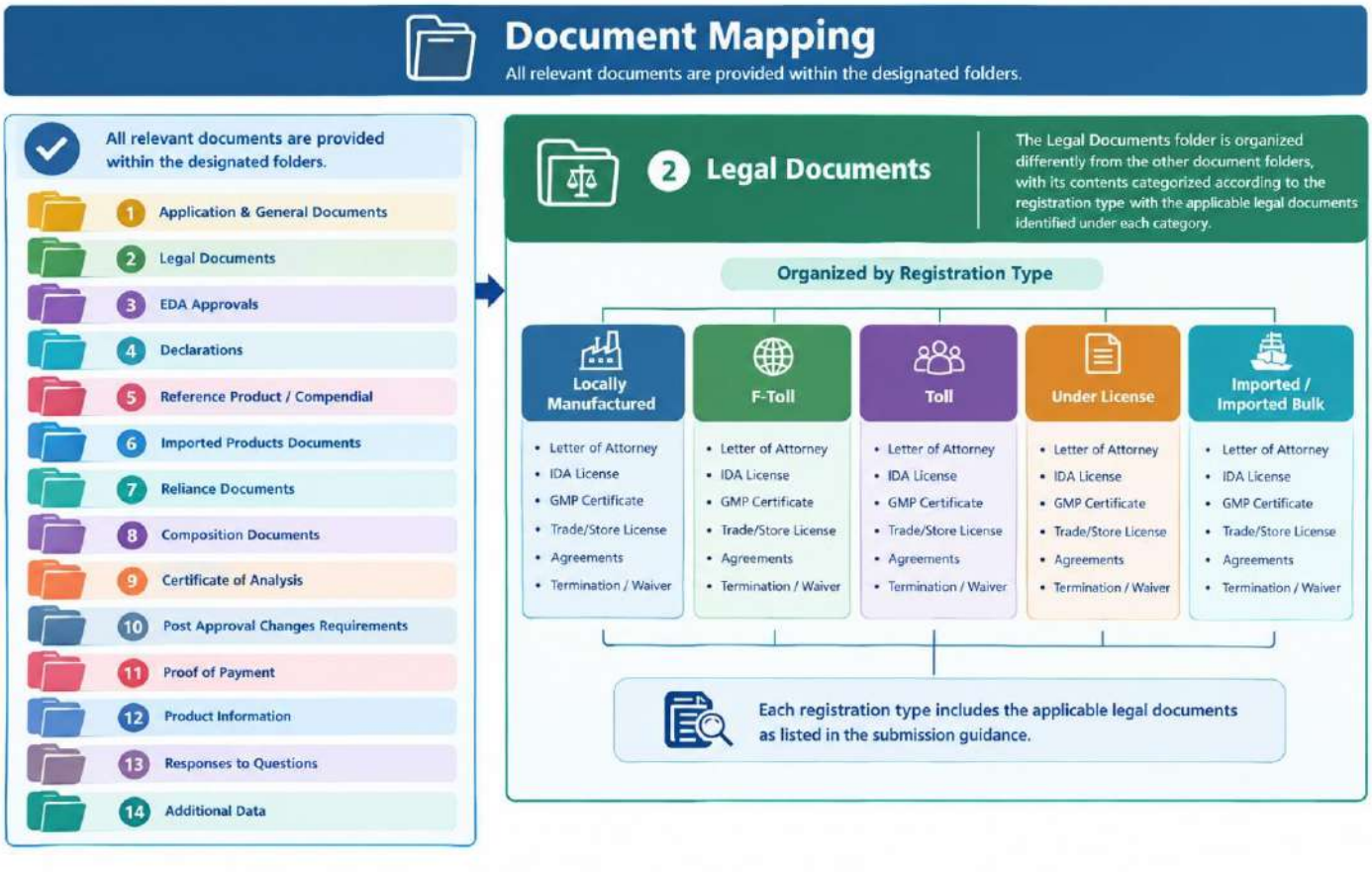


Figure (2): This diagram illustrates the document mapping framework for Module 1 submissions.

5 Module 1 Format Details:

1.0 Cover Letter

- **Cover Letter**
  - It is submitted on company letter head signed, stamped, and dated.
  - It includes:
    Introduction of the submission
    Clarification of Submission Type (e.g., new registration, variation, or renewal…..etc)
    Sequence number
    Point of Contact for regulatory correspondence

- **Tracking Table (Attached)**
  A table contains submissions history to track and summarize all changes, updates, and sequences that have been submitted throughout the lifecycle of the regulatory application.

- **Applicability:**
  The cover letter and tracking table are submitted for:
  - New registration
  - Variation
  - Re-registration Preliminary Approval
  - Renewal

1.2 Application form

1.2.1 Application Form

- The application form (attached) is submitted on company letterhead signed, stamped and dated.
- **Applicability:**
  The application form is submitted for:
  - New registration
  - Variation
  - Re-registration Preliminary Approval
  - Renewal

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Annexes of 1.2

1.2.2 Legal Documents

Legal Documents – Summary Table:

A concise table showing Registration Type + Legal Document + Section Number + Applicability.

Registration Type	Section No.	Legal Document	Applicability
Locally Manufactured Products	1.2.2.1	Letter of Attorney for Company Representative	New Registration Variation Re-Registration Preliminary Approval Renewal
	1.2.2.2	Manufacturing License and IDA License	New Registration Variation Renewal
	1.2.2.3	GMP Certificate(s) / Alternative Documents	New Registration Variation Renewal
	1.2.2.4	Register of Trade	New Registration Variation Renewal
	1.2.2.8	Store License	New registration Variation Renewal
	1.2.2.12	Storage Agreement	New registration Variation Renewal
	1.2.2.13	Other Agreements	Where applicable
	1.2.2.14	Termination Letter / Waiver Letter	Renewal Variation
F-Toll Products	1.2.2.1	Letter of Attorney for Company Representative	New Registration Variation Re-registration Preliminary Approval Renewal
	1.2.2.2	Manufacturing License and IDA License	New Registration Variation Renewal
	1.2.2.3	GMP Certificate(s) / Alternative Documents	New Registration Variation

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			Renewal
	1.2.2.4	Register of Trade	New Registration Variation Renewal
	1.2.2.10	Manufacturing Agreement	New Registration Variation Renewal
	1.2.2.12	Storage Agreement	New Registration Variation Renewal
	1.2.2.13	Other Agreements	Where applicable
	1.2.2.14	Termination Letter / Waiver Letter	Renewal Variation
Toll Products	1.2.2.1	Letter of Attorney for Company Representative	New Registration Variation Re-registration Preliminary Approval Renewal
	1.2.2.2	Manufacturing License and IDA License	New Registration Variation Renewal
	1.2.2.3	GMP Certificate(s) / Alternative Documents	New Registration Variation Renewal
	1.2.2.4	Register of Trade	New Registration Variation Renewal
	1.2.2.5	Toll Manufacturer License	New Registration Variation Renewal
	1.2.2.8	Store License	New Registration Variation Renewal
	1.2.2.10	Manufacturing Agreement	New Registration Variation Renewal
	1.2.2.12	Storage Agreement	New Registration Variation Renewal
	1.2.2.13	Other Agreements	Where applicable
	1.2.2.14	Termination Letter / Waiver Letter	Renewal Variation

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Under License Products	1.2.2.1	Letter of Attorney for Company Representative	New Registration Variation Re-registration Preliminary Approval Renewal
	1.2.2.2	Manufacturing License and IDA License	New Registration Variation Renewal
	1.2.2.3	GMP Certificate(s) / Alternative Documents	New Registration Variation Renewal
	1.2.2.4	Register of Trade	New Registration Variation Renewal
	1.2.2.6	Scientific Office License	New registration Variation Renewal
	1.2.2.8	Store License	New registration Variation Renewal
	1.2.2.9	Authorization Letter / Agency Agreement	New Registration Variation Renewal
	1.2.2.10	Manufacturing Agreement	New Registration Variation Renewal
	1.2.2.12	Storage Agreement	New Registration Variation Renewal
	1.2.2.13	Other Agreements	Where applicable
	1.2.2.14	Termination Letter /Waiver Letter	Renewal Variation
Imported / Imported Bulk Products	1.2.2.1	Letter of Attorney for Company Representative	New Registration Variation Re-registration Preliminary Approval Renewal
	1.2.2.2	Manufacturing License and IDA License	New Registration Variation Renewal
	1.2.2.3	GMP Certificate(s) / Alternative Documents	New Registration Variation Renewal
	1.2.2.4	Register of Trade	New Registration Variation

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			Renewal
	1.2.2.6	Scientific Office License	New registration Variation Renewal
	1.2.2.7	Importers Register License	New Registration Variation Renewal
	1.2.2.8	Store License	New Registration Variation Renewal
	1.2.2.9	Authorization Letter / Agency Agreement	New Registration Variation Renewal
	1.2.2.11	Packaging Agreement	New Registration Variation
	1.2.2.12	Storage Agreement	New Registration Renewal
	1.2.2.13	Other Agreements	Where applicable
	1.2.2.14	Termination Letter/ Waiver Letter	Renewal Variation

Detailed Legal Document Requirements

The detailed explanation of each document, organized according to registration type.

Locally Manufactured Products:

1.2.2.1 Letter of Attorney for Company representative

- A formal document in which a company grants authority to an individual to represent the company in dealings with Egyptian Drug Authority (EDA), or other legal entities.
- This letter authorizes the representative to sign, receive and submit regulatory documents on behalf of the company.
- The letter of Attorney must be valid (stating the validity date) and authenticated by a bank.
- **Applicability:**

  The Letter of Attorney is submitted for:
  - New registration
  - Variation
  - Re-registration Preliminary Approval
  - Renewal

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1.2.2.2 Manufacturing License and IDA License

- IDA License and/or EDA Data Certificate shall be provided.
- **Applicability:**

The Manufacturing License and IDA License are submitted for:

- New registration
- Variation
- Renewal

1.2.2.3 GMP certificate(s) / Alternative documents

- GMP of Manufacturer/s of Finished Product.
  - Valid GMP (Purpose of the GMP is for EDA Departments or company)
  - Production lines are specified.
- GMP of Manufacturer/s of API
- **Applicability:**

The GMP certificate(s) / Alternative documents are submitted for:

- New registration
- Variation
- Renewal

1.2.2.4 The Register of Trade

- Valid Register of Trade shall be provided.
- **Applicability:**

The Register of Trade is submitted for:

- New registration
- Variation (for License Holder only)
- Renewal

1.2.2.8 Store License

- A Store License shall be submitted in cases where the storage site differs from the factory.
- **Applicability:**

The store license is submitted for:

- New registration
- Variation
- Renewal

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1.2.2.12 Storage Agreement

- It is an agreement between the applicant/License Holder and the storage site.
- It must be valid.
- It must be authenticated by the bank and Legal department of EDA.
- **Applicability:**
  The Storage agreement is submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.13 Other Agreements

Any additional agreements in the dossier other than previously mentioned should be included here.

1.2.2.14 Termination / Waiver

Waiver Letter: a formal document in which one party voluntarily gives up a specific right, claim, or condition outlined in the agreement. This letter typically outlines the specific rights being waived, the reasons for the waiver, and any implications for the parties involved. It serves to confirm that the party giving up the right does so willingly and with full knowledge of the consequences.

- **It is submitted on:**
  In case of license holder transfer:
  It is submitted on Real Estate Registry at Ministry of Justice letterhead.
  In case of Manufacturing Site transfer:
  It is submitted on the old manufacturing site letterhead.
- **It includes:**
  Product Trade Name
  Product Strength
  Product Dosage Form
  Registration number
- **It is authenticated from**
  In case of license holder transfer:
  It must be authenticated from Real Estate Registry at Ministry of Justice and EDA legal Affairs.
  In case of Manufacturing Site transfer:
  It must be authenticated from Bank and EDA legal Affairs.
- **Applicability:**
  The Waiver letter is submitted for:
  - Renewal
  - Variation

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F- Toll Products:

1.2.2.1 Letter of Attorney for Company representative

- A formal document in which a company grants authority to an individual to represent the company in dealings with Egyptian Drug Authority (EDA), or other legal entities.
- This letter authorizes the representative to sign, receive and submit regulatory documents on behalf of the company.
- The letter of Attorney must be valid (stating the validity date) and authenticated by a bank.
- **Applicability:**

  The Letter of Attorney is submitted for:
  - New registration
  - Variation
  - Re-registration Preliminary Approval
  - Renewal

1.2.2.2 Manufacturing License and IDA License

- IDA License and/or EDA Data Certificate shall be provided for both parties (License Holder and Manufacturer).
- **Applicability:**

  The Manufacturing License and IDA License are submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.3 GMP certificate(s) / Alternative documents

- GMP of Manufacturer/s of Finished Product.
  - Valid GMP (Purpose of the GMP is for EDA Departments or company)
  - Production lines are specified.
- GMP of Manufacturer/s of API
- **Applicability:**

  The GMP certificate(s) / Alternative documents are submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.4 The Register of Trade

- Valid Register of Trade shall be provided for both parties (License Holder and Manufacturer).
- **Applicability:**

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The Register of trade is submitted for:

- New registration
- Variation (for License Holder only)
- Renewal

1.2.2.10 Manufacturing Agreement

- It is an agreement between the applicant/License Holder and the manufacturer outlining the terms, conditions and responsibilities for the production of pharmaceutical products.
- It has to be valid.
- It has to be authenticated by the bank and Legal department of EDA.
- The manufactured products should be specified in an annex to the agreement, including Trade Name, Dosage form, Strength.
- **Applicability:**

The Manufacturing agreement is submitted for:

- New registration
- Variation
- Renewal

1.2.2.12 Storage Agreement

- It is an agreement between the applicant/License Holder and the storage site.
- It must be valid.
- It must be authenticated by the bank and Legal department of EDA.
- **Applicability:**

The Storage agreement is submitted for:

- New registration
- Variation
- Renewal

1.2.2.13 Other Agreements

Any additional agreements in the dossier other than previously mentioned should be included here.

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1.2.2.14 Termination / Waiver

Waiver Letter: a formal document in which one party voluntarily gives up a specific right, claim, or condition outlined in the agreement. This letter typically outlines the specific rights being waived, the reasons for the waiver, and any implications for the parties involved. It serves to confirm that the party giving up the right does so willingly and with full knowledge of the consequences.

- **It is submitted on:**
  In case of license holder transfer:
  It is submitted on Real Estate Registry at Ministry of Justice letterhead.
  In case of Manufacturing Site transfer:
  It is submitted on the old manufacturing site letterhead.
- **It includes:**
  Product Trade Name
  Product Strength
  Product Dosage Form
  Registration number
- **It is authenticated from**
  In case of license holder transfer:
  It must be authenticated from Real Estate Registry at Ministry of Justice and EDA legal Affairs.
  In case of Manufacturing Site transfer:
  It must be authenticated from Bank and EDA legal Affairs.
- **Applicability:**
  The Waiver letter is submitted for:
  - Renewal
  - Variation

Toll Products:

1.2.2.1 Letter of Attorney for Company representative

- A formal document in which a company grants authority to an individual to represent the company in dealings with Egyptian Drug Authority (EDA), or other legal entities.
- This letter authorizes the representative to sign, receive and submit regulatory documents on behalf of the company.
- The letter of Attorney must be valid (stating the validity date) and authenticated by a bank.
- **Applicability:**
  The Letter of Attorney is submitted for:
  - New registration
  - Variation
  - Re-registration Preliminary Approval

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- Renewal

1.2.2.2 Manufacturing License and IDA License

- IDA License and/or EDA Data Certificate shall be provided.
- **Applicability:**

The Manufacturing License and IDA License are submitted for:

- New registration
- Variation
- Renewal

1.2.2.3 GMP certificate(s) / Alternative documents

- GMP of Manufacturer/s of Finished Product.
  - Valid GMP (Purpose of the GMP is for EDA Departments or company)
  - Production lines are specified.
- GMP of Manufacturer/s of API
- **Applicability:**

The GMP certificate(s) / Alternative documents are submitted for:

- New registration
- Variation
- Renewal

1.2.2.4 The Register of Trade

- Valid Register of Trade shall be provided for both parties (License Holder and Manufacturer).
- **Applicability:**

The Register of trade is submitted for:

- New registration
- Variation (for License Holder only)
- Renewal

1.2.2.5 Toll Manufacturer License

- The Toll Manufacturer License (Toll card) shall be valid and clearly specify the Factory and storage site
- **Applicability:**

The Toll manufacturer license is submitted for:

- New registration
- Variation
- Renewal

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1.2.2.8 Store License

- A Store License shall be submitted in cases where the storage site differs from the factory.
- **Applicability:**
  The store license is submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.10 Manufacturing Agreement

- It is an agreement between the applicant/License Holder and the manufacturer.
- It has to be valid.
- It has to be authenticated by the bank and Legal department of EDA.
- The manufactured products should be specified in an annex to the agreement, including Trade Name, Dosage form, Strength.
- **Applicability:**
  The Manufacturing agreement is submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.12 Storage Agreement

- It is an agreement between the applicant/License Holder and the storage site.
- It has to be valid.
- It must be authenticated by the bank and Legal department of EDA.
- **Applicability:**
  The Storage agreement is submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.13 Other Agreements

Any additional agreements in the dossier other than previously mentioned should be included here.

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1.2.2.14 Termination / Waiver

Waiver Letter: a formal document in which one party voluntarily gives up a specific right, claim, or condition outlined in the agreement. This letter typically outlines the specific rights being waived, the reasons for the waiver, and any implications for the parties involved. It serves to confirm that the party giving up the right does so willingly and with full knowledge of the consequences.

- **It is submitted on:**
  In case of license holder transfer:
  It is submitted on Real Estate Registry at Ministry of Justice letterhead.
  In case of Manufacturing Site transfer:
  It is submitted on the old manufacturing site letterhead.
- **It includes:**
  Product Trade Name
  Product Strength
  Product Dosage Form
  Registration number
- **It is authenticated from**
  In case of license holder transfer:
  It must be authenticated from Real Estate Registry at Ministry of Justice and EDA legal Affairs.
  In case of Manufacturing Site transfer:
  It must be authenticated from Bank and EDA legal Affairs.
- **Applicability:**
  The Waiver letter is submitted for:
  - Renewal
  - Variation

Under License Products:

1.2.2.1 Letter of Attorney for Company representative

- A formal document in which a company grants authority to an individual to represent the company in dealings with Egyptian Drug Authority (EDA), or other legal entities.
- This letter authorizes the representative to sign, receive and submit regulatory documents on behalf of the company.
- The letter of Attorney must be valid (stating the validity date) and authenticated by a bank.
- **Applicability:**
  The Letter of Attorney is submitted for:
  - New registration
  - Variation
  - Re-registration Preliminary Approval

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- Renewal

1.2.2.2 Manufacturing License and IDA License

- IDA License and/or EDA Data Certificate shall be provided.
- **Applicability:**

The Manufacturing License and IDA License are submitted for:

- New registration
- Variation
- Renewal

1.2.2.3 GMP certificate(s) / Alternative documents

- GMP of Manufacturer/s of Finished Product.
  - Valid GMP (Purpose of the GMP is for EDA Departments or company)
  - Production lines are specified.
- GMP of Manufacturer/s of API
- **Applicability:**

The GMP certificate(s) / Alternative documents are submitted for:

- New registration
- Variation
- Renewal

1.2.2.4 The Register of Trade

- Valid Register of Trade shall be provided for both parties (License Holder and Manufacturer).
- **Applicability:**

The Register of trade is submitted for:

- New registration
- Variation (for License Holder only)
- Renewal

1.2.2.6 Scientific Office License

- The Scientific Office License is submitted where the scientific office acts as the applicant.
- **Applicability:**

The scientific office license is submitted for:

- New registration
- Variation
- Renewal

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1.2.2.8 Store License

- A Store License shall be submitted in cases where the storage site differs from the factory.
- **Applicability:**
  The store license is submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.9 Authorization letter / Agency agreement

A legal agreement between the applicant and the license holder authorizing the applicant to act on behalf of the license holder in registration of pharmaceutical product clarifying its responsibilities for registration, all regulatory activities and signing contracts.

- It must be valid
- It must be submitted on the License Holder's letterhead.
- It must be legalized and authenticated by the Chamber of Commerce from the country of origin or a Notary Public, and the Egyptian consulate/embassy.
- It includes:
  - The Product's Trade Name, Dosage form and strength
  - Registration number
  - Name and address of the new applicant
- **Applicability:**
  The Authorization letter / Agency agreement is submitted for:
  - New Registration
  - Re-registration Preliminary Approval
  - Renewal
  - Variation

1.2.2.10 Manufacturing Agreement

- It is an agreement between the applicant/License Holder and the manufacturer.
- It has to be valid.
- It has to be authenticated by the bank and Legal department of EDA or legalized by the Chamber of Commerce and the Egyptian Embassy.
- The manufactured products should be specified in an annex to the agreement, including Trade Name, Dosage form, Strength.
- **Applicability:**
  The Manufacturing agreement is submitted for:
  - New registration
  - Variation
  - Renewal

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1.2.2.12 Storage Agreement

- It is an agreement between the applicant/License Holder and the storage site.
- It has to be valid.
- It must be authenticated by the bank, Legal department of EDA or legalized by the Chamber of Commerce and the Egyptian Embassy.
- **Applicability:**
  The Storage agreement is submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.13 Other Agreements

Any additional agreements in the dossier other than previously mentioned should be included here.

1.2.2.14 Termination / Waiver

Termination Letter: It is a formal document that notifies the parties involved of the decision to end or cancel the agreement before its intended completion. It outlines the reasons for termination, the effective date, and any other relevant terms or obligations related to the termination process.

- It must be submitted on the License Holder/Marketing Authorization Holder's letterhead in the case of Applicant Change.
- It includes:
  The Product Trade Name
  Registration number
  Reference to the manufacturing agreement date
- It must be authenticated from chamber of commerce from country of origin and the Egyptian consulate/embassy.
- **Applicability:**
  The Termination letter is submitted for:
  - Renewal
  - Variation

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Imported / Imported Bulk Products:

1.2.2.1 Letter of Attorney for Company representative

- A formal document in which a company grants authority to an individual to represent the company in dealings with Egyptian Drug Authority (EDA), or other legal entities.
- This letter authorizes the representative to sign, receive and submit regulatory documents on behalf of the company.
- The letter of Attorney must be valid (stating the validity date) and authenticated by a bank.
- **Applicability:**

  The Letter of Attorney is submitted for:
  - New registration
  - Variation
  - Re-registration Preliminary Approval
  - Renewal

1.2.2.2 Manufacturing License and IDA License

- IDA License and/or EDA Data Certificate shall be provided.
- **Applicability:**

  The Manufacturing License and IDA License are submitted for:
  - New registration (In case of Imported Bulk)
  - Variation (In case of Imported Bulk)
  - Renewal

1.2.2.3 GMP certificate(s) / Alternative documents

- GMP of Manufacturer/s of Finished Product.
  - Valid GMP
  - Production lines are specified.
- GMP of Packager (In case of imported bulk): Purpose of the GMP is for EDA Departments or company)
  - Valid GMP
  - Production lines are specified.
- GMP of Manufacturer/s of API
- **Applicability:**

  The GMP certificate(s) / Alternative documents are submitted for:
  - New registration
  - Variation
  - Renewal

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1.2.2.4 The Register of Trade

- Valid Register of Trade shall be provided.
- **Applicability:**
  The Register of trade is submitted for:
  - New registration
  - Variation (for License Holder only)
  - Renewal

1.2.2.6 Scientific Office License

- The Scientific Office License is submitted where the scientific office acts as the applicant.
- **Applicability:**
  The scientific office license is submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.7 Importers Register License

- The Importers Register License should be submitted where the importer acts as the applicant.
- **Applicability:**
  The Importer Register license is submitted for:
  - New registration
  - Variation
  - Renewal

1.2.2.8 Store License

- A Store License should be submitted.
- **Applicability:**
  The store license is submitted for:
  - New registration
    In case of Imported Bulk products: It is submitted where the storage site differs from the manufacturer.
    In case of Imported Finished Products: It is submitted where the storage site differs from that stated in the Importers Register License.
  - Variation
  - Renewal

Draft

1.2.2.9 Authorization letter / Agency agreement

A legal agreement between the applicant and the license holder authorizing the applicant to act on behalf of the license holder in registration of pharmaceutical product clarifying its responsibilities for registration, all regulatory activities and signing contracts.

- It must be valid
- It must be submitted on the License Holder's letterhead.
- It must be legalized and authenticated by the Chamber of Commerce from the country of origin or a Notary Public, and the Egyptian consulate/embassy.
- It includes:
  - The Product's Trade Name, Dosage form and strength
  - Registration number
  - Name and address of the new applicant
- **Applicability:**
  The Authorization letter / Agency agreement is submitted for:
  - New Registration
  - Re-registration Preliminary Approval
  - Renewal
  - Variation

1.2.2.11 Packaging Agreement

- It is an agreement between the applicant/License Holder/MAH and the packager.
- Authenticated by the bank and Legal department of EDA or legalized by the Chamber of Commerce and the Egyptian Embassy.
- It has to be valid.
- **Applicability:**
  The Authorization letter / Agency agreement is submitted for:
  - New Registration (In case of Imported Bulk products)
  - Variation (In case of Imported Bulk products)
  - Renewal (In case of Imported Bulk products)

1.2.2.12 Storage Agreement

- It is an agreement between the applicant/License Holder and the storage site.
- It must be valid.
- It must be authenticated by the bank and Legal department of EDA or legalized by the Chamber of Commerce and the Egyptian Embassy.
- **Applicability:**
  The Storage agreement is submitted for:
  - New registration
  - Renewal

Draft

1.2.2.13 Other Agreements

Any additional agreements in the dossier other than previously mentioned should be included here.

1.2.2.14 Termination / Waiver

Termination Letter: It is a formal document that notifies the parties involved of the decision to end or cancel the agreement before its intended completion. It outlines the reasons for termination, the effective date, and any other relevant terms or obligations related to the termination process.

- It must be submitted on the License Holder/Marketing Authorization Holder's letterhead in the case of Applicant Change.
- It includes:
  The Product Trade Name
  Registration number
  Reference to the manufacturing agreement date
- It must be authenticated from chamber of commerce from country of origin and the Egyptian consulate/embassy.
- **Applicability:**
  The Termination letter is submitted for:
  - Renewal
  - Variation

Draft

1.2.3 EDA Approvals

1.2.3.1 Registration Request Approval

- Approval allows the product to proceed in the registration process.
- **Applicability:**
  The Registration Request Approval is submitted for:
  - New Registration
  - Variation (In case of License Holder transfer for local products)

1.2.3.3 Name Approval

- Approval of the proposed product name must be obtained prior to proceeding with the registration process.
- **Applicability:**
  The Name Approval is submitted for:
  - New Registration
  - Variation (In case of change of Finished Product name after issuing registration license).

1.2.3.4 Registration License

- Approval granted by EDA that allows a product to be legally marketed.
- **Applicability:**
  The Registration License is submitted for:
  - Renewal
  - Re-Registration Preliminary Approval
  - Variation

1.2.3.5 Preliminary Approval

- An approval granted in the renewal process to proceed with fulfilling the renewal requirements and studies.
- **Applicability:**
  The Preliminary Approval is submitted for:
  - Renewal
  - Variation

Draft

1.2.3.6 Non-Reference Approval

- An Approval granted from Evaluation unit of scientific data and drug development for Human Pharmaceuticals to the product that does not have a scientific reference with the same API, same pharmaceutical form, concentration, or method of administration, in any reference country included in the list of reference countries approved by the Technical Committee of Drug Control after evaluating the scientific files of the product.
- **Applicability:**
  The Non-Reference Approval is submitted for:
  - New Registration
  - Renewal (Purpose of approval: re-registration process)

1.2.3.8 Pricing Certificate

- It is an official document that verifies the pricing details of the product.
- It must be valid.
- In case of expiration, evidence of submission of a pricing update request (e.g., screenshot) must be provided.
- In case of old pricing with no expiration, evidence of submission of a pricing update request (e.g., screenshot) must be provided.
- In case re-evaluation is required, the updated certificate must be submitted.
- **Applicability:**
  The Pricing Certificate is submitted for:
  - New Registration
  - Variation
  - Renewal

1.2.3.9 Pharmacovigilance Approval

- **Applicability:**
  The Pharmacovigilance Approval is submitted for:
  - New Registration
  - Variation
  - Renewal (Purpose of approval: re-registration process)

1.2.3.10 Inspection Report

- A Report that provides a detailed account of an inspection conducted by EDA's authorized inspector.
- **Applicability:**
  The Inspection Report is submitted for:
  - **New Registration**
    - Inspection Report for Pilot/Production Batch in case of Locally Manufactured Products

Draft

- Site Inspection Report is needed in case of imported products from non-reference countries and not marketed in reference countries.
- Inspection report for Bioequivalence study mentioning the name of Bioequivalence center.

- **Renewal**
  - Inspection Report for a Valid and Marketed Batch. (if not applicable, refer to Section 1.2.3.17: where the applicant should submit Exemptions from Decree 600).
  - Inspection report for Bioequivalence study mentioning the name of Bioequivalence center.
- **Variation**
  - In case of clarification of any variation
  - In case of Batch size (addition/change/Size of first production batch)
  - In case of Final approval (Report for Inspection sampling stating batch number and production dates / Evaluation of Process validation)

1.2.3.11 Importation approval for each API

- An approval issued by the Egyptian Drug Authority for each API, specifying the following information:
  - The company name.
  - The API supplier name.
  - The Trade name.
- **Applicability:**
  The Importation approval for each API is submitted for:
  - **New Registration**
    For Locally Manufactured Products: In case of Release Letter, an invoice should be submitted
  - **Renewal**
    In which case it is referred to as an Importation Plan. It must be the most recent version.
  - **Variation**
    In case of addition / clarification of API manufacturer:
    Importation approvals or production plans, Customs releases, invoices and supplier certificates, have the same batch numbers that were imported must be submitted.

1.2.3.12 CADC Report

- A certificate of analysis of a pharmaceutical product that is issued from Central Administration of Drug Control (CADC) and must be " confirm"
- **The certificate should include:**
  - Trade Name and Strength
  - Manufacturer and License Holder of Finished Pharmaceutical Product

Draft

- Manufacturer of Active Pharmaceutical Ingredient
- Batch Number and Batch Type
- Chemical, Physical and Microbiological Tests.

- **Applicability:**

The CADC Report is submitted for:

- **New Registration**
  - **For Imported Products:** Optional; however, it is mandatory in case of imported products from non-reference countries and not marketed in reference countries.

  - **For Locally Manufactured Products:** In case of production batches, the following shall be submitted: CADC certificate + CADC composition

- **Renewal**

  The following shall be submitted:

  CADC certificate + CADC composition+ Renewal certificate

  *In case the Renewal Certificate has not yet been issued, the Variation Referral for Analysis File Renewal must be submitted.

- **Variation**

  The following shall be submitted:

  CADC Certificate (issued by the Administration of Evaluation and Approval or by the Administration of Post-Approval Control)

  OR Detailed CADC Certificate (issued by the Administration of Post-Approval Control)

  + CADC Composition Certificate

  + Any relevant official letters or emails issued by CADC, where applicable

1.2.3.13 Stability Study Approval

- Approval for stability study that reflects the effect of temperature and humidity on the stability of drug substance or drug product in its final packaging material during the storage period to determine re-test period of an active pharmaceutical ingredient or shelf life of the finished pharmaceutical product and storage conditions.
- **Applicability:**

The Stability Study approval is submitted for:

- Renewal (Long Term stability study)
- Variation

Draft

1.2.3.15 Module 3 Approval

- Approval for Module 3 section in the Registration Dossier issued by Administration of Technical Affairs for Human Pharmaceuticals. It includes data on the drug substance, drug product, packaging, manufacturing sites, and quality control procedures.

- **Applicability:**
  The Module 3 approval is submitted for:
  - New Registration
  - Variation

1.2.3.16 Module 5 Approval

- Approval for Bioequivalence Study/Comparative In-Vitro Study in the Registration Dossier issued by Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals.
- The necessity for a bioequivalence (BE) study is determined based on the specific **dosage form** and in accordance with applicable published regulatory **guidelines**.

- **Bioequivalence / Comparative study approval should include:**
  - Trade Name and Strength
  - Manufacturer and License Holder of Finished Pharmaceutical Product
  - Manufacturer of Active Pharmaceutical Ingredient
  - Batch Number
  - Purpose of study
  - Composition

- **Applicability:**
  The Module 5 approval is submitted for:
  - **New Registration** (BE study decision letter is submitted for locally manufactured products)
  - **Renewal** (Purpose of study approval: re-registration or Exemption from the study)
  - **Variation**

Draft

1.2.3.17 Pre-approved letters from EDA concerning the product

- Approvals issued by EDA concerning the product or any relevant decision regarding the finished product or the active pharmaceutical ingredient or dosage form.
- **These approvals may be but not limited to:**
  - Technical committee decisions
  - Exemptions from Decree 600 in case Inspection Report for a Valid and Marketed Batch is not applicable.
  - Extension Approval
  - Approval to produce production batches instead of pilot batches
- **Applicability:**
  The pre-approved letters are submitted for:
  - New Registration
  - Renewal
  - Re-registration Preliminary Approval
  - Variation

1.2.3.18 Variation Approvals

- Post marketing variation approval / appeals for Administrative and/or quality post-authorization changes.
- Every variation is to be submitted in separate sub folder named with the variation type (e.g., Addition of Manufacturer of API, or composition change) in addition to all required studies arranged by date.
- **Applicability:**
  The Variation Approvals are submitted for:
  - Renewal
  - Re-registration Preliminary Approval
  - Variation

1.2.3.20 Registration license for the solvent

- The registration license of the solvents is required in case the dosage form needs a solvent and the solvent is attached with the product. The registration license of the solvent shall specify the pack of the attached solvent (**same solvent type and volume** as those supplied with the product).
- **Applicability:**
  The Registration license for the solvent is submitted for:
  - **New Registration**
  - **Renewal**
  - **Variation** (In case of solvent change / addition /clarification variation)

Draft

1.2.4 Declarations

1.2.4.1 Declaration letter stating the list of (Registered & Under-Registration) products

- A declaration letter stating the list of all registered and under-registration pharmaceutical products, including their active ingredients, owned by the toll company.
- It is submitted on the applicant letter head signed, stamped and dated.
- **Applicability:**
  The declaration is submitted for:
  - **New Registration** (For Toll Products)
  - **Variation** (In case of License Holder transfer to toll company stating all registered and under-registered pharmaceutical products with their active ingredients owned by the new owner company)

1.2.4.2 Declaration letter from the license holder specifying the API manufacturers

- A declaration letter from the license holder identifying the authorized API manufacturers, including their names and complete addresses, for each API
- It should be legalized by the chamber of commerce and the Egyptian embassy.
- **Applicability:**
  The declaration is submitted for:
  - **New Registration** (For Under License Products/Imported products)
  - **Renewal** (For Under License Products/Imported products)
  - **Variation**

1.2.4.3 Declaration letter from the license holder specifying approved pack in Egypt

- Detailed description of pack registered in Egypt.
- It should be legalized by the chamber of commerce and the Egyptian embassy.
- **Applicability:**
  The declaration is submitted for:
  - **New Registration** (For Under License Products/Imported products)
  - **Renewal** (For Under License Products/Imported products)
  - **Variation**

Draft

1.2.4.4 Declaration letter from the License Holder stating the form of bulk (strips, Capsules, etc……)

- In case of same entity or affiliate it might be on the License Holder letter head.
- It should be legalized by the chamber of commerce and the Egyptian embassy.
- **Applicability:**
  The declaration is submitted for:
  - **New Registration** (For Imported Bulk products)
  - **Renewal** (For Imported Bulk products)
  - **Variation** (For imported Bulk products)

1.2.4.5 Declaration Letter from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing Process or specifications

- It has to be Legalized by the chamber of commerce and the Egyptian embassy.
- **Applicability:**
  The declaration is submitted for:
  - Variation

1.2.4.6 Declaration Letter from API Supplier

- **Applicability:**
  The declaration is submitted for:
  - **Variation** (In case of clarifying Compaction or Mixture ratio or Polymorphism, …..etc)

1.2.4.7 Declaration Letter for Site Addition

- It is a letter stating that the company takes full legal responsibility for adding a new site without any responsibility on EDA, regarding the obligations and duties imposed under the manufacturing contract with the old factory (factories).
- It has to be authenticated by the Bank and legal department of EDA.
- **The declaration should include:**
  - The product trade name
  - Registration number
  - Name of old factories
- **Applicability:**
  The declaration is submitted for:
  Variation

Draft

1.2.4.8 Declaration letter from LH stating all variations & justification for the change

- **Applicability:**
  The declaration is submitted for:
  - **Variation**

1.2.4.9 Other declarations requested by Egyptian drug authority

- This section includes any additional declarations, confirmations, or official documents that are specifically required by the Egyptian Drug Authority (EDA) as part of the regulatory submission but are not covered under other predefined sections.
- **These declarations may be but not limited to:**

- Letter of access

- SmPC/ PIL declarations which may include:

a) In case of imported and innovator products with PIL only:
A Legalized letter from the country of origin clarifying that the attached leaflet (Patient information leaflet) with the specified Trade Name, generic name, concentration, version date and version number is marketed and registered in the country of origin and is to be translated to Arabic language as the patient information leaflet.

b) In case of non-English leaflets:
- A Legalized Letter from License Holder commit that the leaflet is translated according to authorized medical translation on their responsibility in accordance with the translation attached. (Signature & Stamp)

Or

- Legalized letter from the head office stating that the scientific office is responsible for the translation and the leaflet is translated medical translation through their scientific office, the medical translation submitted (2 languages: English and Non-English) should be signed and stamped by the scientific office.

In case the previous letters are not legalized:
A declaration letter from the scientific office declares that the letter is to be legalized within 6 months.

- **Applicability:**
  The other declarations are submitted for:
  - New Registration
  - Variation
  - Renewal
  - Re-registration Preliminary Approval

Draft

1.2.4.10 List of countries where the product is registered and marketed

- A Letter from License Holder stating the list of countries where the products is registered and marketed
- Authenticated by chamber of commerce and the Egyptian embassy.
- **Applicability:**
  The declaration is submitted for:
  - **New Registration** (For Under License Products and Imported Products)
  - **Variation** (For imported products)
  - **Renewal (**For Under License Products and Imported Products)

1.2.5 Reference product document/ compendial

1.2.5.1 The reference product document

The reference product should be identical to the submitted product in terms of the active ingredient, concentration, dosage form and route of administration.

It includes:

- **Recent on-line reference (**FDA, MHRA, EMA, ANSM, Swissmedic, TGA, Pmda, etc.) where the reference product should be registered and marketed.

OR

Latest Edition of BNF

- **The most updated SmPc & PIL of the reference product.**
- **Authorized Translation of the Reference** (In case of non-English reference)
- **Clear scanned strip/pack for the reference and test product**
- **Applicability:**
  The reference product document is submitted for:
  - New Registration
  - Variation
  - Re-registration Preliminary Approval
  - Renewal

1.2.5.4 The latest recent pharmacopeia

- The latest edition of pharmacopeia is submitted in case of **Pharmacopeial/compendial Finished Products**.
- **Applicability:**
  The latest pharmacopeia is submitted for:
  - New Registration
  - Variation
  - Re-registration Preliminary Approval
  - Renewal

Draft

1.2.6 Imported products Documents

1.2.6.1 Certificate of Pharmaceutical Product (CPP) / Electronic Certificate of Pharmaceutical Product (eCPP) issued by Competent Authorities in Country of Origin

- **The CPP should be:**
  - Valid
  - From the country of origin
  - Issued and authenticated by the competent authority
  - Signed and stamped by:
    - Chamber of Commerce or Notary Public or Foreign Affairs (If applicable)
    - Legalized by the Egyptian Embassy

    ***eCPP is exempted from legalization**
  - The Arab Republic of Egypt is mentioned as Importing Country
  - Date of issue is specified
  - Trade name of the Product is specified
  - Dosage form (s) and Strength (s) are specified.
  - License Holder (address, city, country) is specified
  - Product must be marketed in the COO for not less than one year (if not marketed, explain why marketing is lacking)
  - Product composition:
    - Active Ingredient(s) by its salt or hydrate form (if any) with its (their) quantity (ies) per unit dose is (are) specified
    - Inactive Ingredient(s) with its (their) quantity (ies) per unit dose is (are) specified (could be as attachment)
  - Capsule shell composition should be included in case of capsules.
  - If the Name of the product is different in Egypt, it must be noted (If not stated, a separate legalized declaration on the license holder letter head is required).
- **Applicability:**
  The CPP is submitted for:
  - **New Registration** (In case of Imported and Under license products)
  - **Variation** (In case of Imported and Under license products)
  - **Renewal** (In case of Imported and Under license products)

1.2.6.2 List of affiliates / Subsidiaries

- **Applicability:**
  The List of affiliates is submitted for:
  - **New Registration** (In case of Imported and Under license products)
  - **Variation**
  - **Renewal** (In case of Imported and Under license products)

Draft

1.2.7 Reliance Documents

1.2.7.1 Sameness Letter

- It is an authorized document issued by the License Holder to assure the same quality of the product and to provide transparency about any potential differences compared to the reference Stringent Regulatory Authority (SRAs).
- **Applicability:**
  The Sameness Letter is submitted for:
  - **New Registration** (For Imported Products)
  - **Variation** (For Imported Products)

1.2.7.2 Unredacted Assessment Report

- It is a complete version of assessment report of the SRA in which no information has been blacked out. It is a thorough report of the assessor's evidence-based findings, assessment, conclusions and rationale for reaching the final decision.
- **Applicability:**
  The Unredacted Assessment Report is submitted for:
  - **New Registration** (For Imported Products)
  - **Variation** (For Imported Products)

1.2.7.3 RRA Variation application with annexes

- Request for Regulatory Approval (RRA), The formal application submitted by the License Holder of the reference product to the relevant foreign regulatory authority to obtain regulatory approval for the product or for any proposed variation, in accordance with the regulatory requirements of the respective foreign country.
- Application and approval are required.
- **Applicability:**
  The RRA Variation application is submitted for:
  - Variation

Draft

1.2.8 Composition Documents

1.2.8.1 Composition Certificate

- The composition of the product should be submitted.
- **It should be submitted on**
  - The applicant head letter signed and stamped**.**
  - License holder or the manufacturer head letter and legalized if the composition is not attached in the CPP. **(For Imported and under license products).**
- **It should include**
  - Trade name of the Product.
  - Dosage form of the Product.
  - Active Ingredient(s), it's (their) hydrate(s) and salt form(s) with its (their) quantity (ies) per unit dose and its function.
  - Inactive Ingredient(s) with its (their) quantity (ies) per unit dose and grade and its function.
  - Active and Inactive ingredients should be separated in composition.
  - Any Overage.
  - Most recent specifications of each ingredient.
  - **Coated Tablets**:
    a) The core and coat composition are separated, and the weight of tablet should be mentioned.
    b) The Coating composition (e.g. Opadry coat) on the supplier's head letter should be included in section 1.2.8.5.
  - **Hard Gelatin capsules:**
    a) Write the body and cap. composition separated and mention the size of capsule.
    b) The Composition of the capsule shell on the supplier head letter should be included in section 1.2.8.6.
  - **Applicability:**
    The composition certificate is submitted for:
    - **New Registration (**identical to the inspection composition in case of Local New registration)
    - **Variation (**The old and new compositions are submitted)
    - **Renewal**

Draft

1.2.8.2 Specification

- Recent edition of specifications (pharmacopeias) and/or in-house specifications should be submitted.
- In-house specifications of all inactive ingredients should be submitted on the company letter head signed and stamped.
- **Applicability:**

The specification is submitted for:

- **New Registration**
- **Variation (**The old and new specifications are submitted)
- **Renewal**

1.2.8.3 Any Composition calculations

- The composition is provided in case needed along with the equivalence calculation on the applicant letter head signed and stamped, with reference for the molecular weight.
- **Applicability:**

The calculations are submitted for:

- **New Registration**
- **Variation (**Calculations of pellets/Premix and Calculation of approved limit in 1.2.8.4 (In case of presence of Methyl paraben and propyl paraben in oral liquid dosage forms 'suspension and syrup').
- **Renewal**

1.2.8.4 Pellets / Premix Composition and Certificates

- **Pellets**:
  Composition on supplier letter head should be attached and attach the calculation of pellets (weight /capsule) on company letter head
- **Premix:**
  Composition on supplier letter head should be attached.

- **Applicability:**

The Pellets / Premix Composition and Certificates is submitted for:

- New Registration
- Variation
- Renewal

Draft

1.2.8.5 Opadry / Coating Premix composition

- In case of coated tablets, the coating composition (e.g. Opadry coat) should be submitted on the supplier's head letter.
- **Applicability:**
  The Opadry / Coating Premix composition is submitted for:
  - New Registration
  - Variation
  - Renewal

1.2.8.6 Capsule shell composition

- In case of Hard Gelatin capsule, the composition of the capsule shell on the supplier head letter should be submitted.
- **Applicability:**
  The capsule shell composition is submitted for:
  - New Registration
  - Variation
  - Renewal

1.2.8.7 Synonyms Evidence

- Active Ingredient(s) and/or its salt must be identical to that in certificate of analysis of the supplier (if not: please submit the synonyms).
- **Applicability:**
  The Synonyms evidence is submitted for:
  - New Registration
  - Variation (In case of Change in name of the active substance or of an excipient)
  - Renewal

1.2.9 Certificate of Analysis

- It is submitted for Active Substance and Finished Pharmaceutical Product
- It should be signed and stamped
- The Manufacturing date, Expiry date and Batch number should be specified
- **Applicability:**
  The Certificate of Analysis is submitted for:
  - New Registration
  - Variation
  - Renewal

Draft

1.2.10 Post approval changes Requirements

1.2.10.1 PAC Approval from the COO (Imported Products).

- It is the approval of any changes made to a product or its associated documentation after it has already received Marketing Authorization License from reference regulatory authorities in the country where the product is originally manufactured.
- **Applicability:**
  The PAC approval from COO is submitted for:
  - **Variation** (In case of reliance evaluation routes for imported products)

1.2.10.2 Summary of change for variation

- It is a brief and clear overview of the changes made to a previously approved product or its documentation.
- It highlights key differences or updates to support regulatory assessment of the impact on safety, efficacy, and compliance.
- **Applicability:**
  The Summary of changes is submitted for:
  - **Variation** (In case of Full evaluation and Reliance evaluation routes for imported products)

1.2.10.3 Justification of the proposed Post approval Change

- It is the rationale provided by a company for changing a product after it has already been approved and marketed.
- It demonstrates that the proposed change does not affect the product's safety, efficacy, or compliance.
- **Applicability:**
  The justification of the proposed post approval change is submitted for:
  - **Variation**

1.2.10.4 Any additional documents relevant to Variations

- It may include List of machines, Manufacturing process flow chart, risk-based assessments, TSE/BSE supplier safety declaration, etc
- **Applicability:**
  The additional document relevant to variations are submitted for:
- **Variation)**In addition to reliance documents)

Draft

1.2.11 Proof of Payment

- Fees payment receipt in accordance with the relevant decree / case requirements.
- **Applicability:**
  The proof of payment is submitted for:
  - New Registration
  - Variation
  - Renewal

Note:

If any document requires legalization but cannot be legalized at the time of submission, the applicant must submit a declaration undertaking to complete the legalization process within six months.

1.3 Product Information

It contains comprehensive data and documentation related to the product's characteristics, packaging and labelling to support the marketing authorization application.

1.3.1 SPC, labelling and package leaflet

A) Approved leaflet is submitted

- Valid & Updated Leaflet with recent warnings if available.
- Manufacturer and excipients must be mentioned.

- **Applicability:**
  The Approved Leaflet is submitted for:
  - Renewal

B) Proposed Leaflet (English and Arabic in Word format (SmPC & PIL) is submitted and Pharmacology guidelines for warnings and exceptions should be checked.

- **Applicability:**
  The Proposed Leaflet is submitted for:
  - New Registration

Draft

1.3.2 Mock-up

A virtual full-sized model of human pharmaceutical products that haven't been produced yet showing how they will look. It also can be defined as layout or artwork.

A) Approved Mockup is submitted

- Different mockups are submitted for each manufacturer.
- **Applicability:**
  The Approved Mock-up is submitted for:
  Renewal

B) Proposed Mockup is submitted

- Colored stamped outer and inner layout (an editable PDF is preferable).
- Complete image of the original pack (For imported and under-license products).
- In case the submitted soft layout is accepted, the hard-colored stamped outer and inner layout must be provided to the unit administrator for signing and stamping by the unit.
- **Applicability:**
  The proposed mock-up is submitted for:
  New Registration

Responses to Questions

This section includes the written responses to a list of questions/ deficiency letters/inquiries from EDA. All supporting documents are submitted within the relevant folders and file structure, in alignment with the CTD format.

Additional Data

- The section 'Additional Data' should only be used for required information that is not currently included in the published EG M1 or EG eCTD M1 Specification.
- Also, this section can be used in eCTD for all procedures when an old version of a DTD is being used during an agreed transition period, to support inclusion of a newly defined section of EG eCTD M1 Specification.
- It is not intended to include already submitted documents. Any information/file which was already submitted in a previous sequence should not be submitted again. For already submitted documents, a reference/hyperlink/cross-link to the existing file should be created. This helps to avoid multiple lifecycles and repetitions of the files.

Annex (1)
Tracking Table

Product Name

Sequence Number	Submission Description	Submission Date
0006	Preliminary Approval	Dec-2023
0005	Variation (ex: Administrative Change – PAC N)	Jul-2023
0004	Responses to Letter of Comments	Oc-2022
0003	Variation (ex: Quality Change – PAC B)	Sep-2022
0002	Responses to Letter of Comments	May-2022
0001	Responses to Letter of Comments	Feb-2022
0000	New Marketing Authorization	May-2022

Draft

Annex (2)

Registration / Re-registration Application form

السيد الدكتور/ رئيس هيئة الدواء المصرية
تحية طيبة وبعد،،،،
نتقدم لسيادتكم بملف التسجيل للحصول على رخصة تسويق المستحضر الآتي:

Trade Name: English and Arabic		
Registration Request number /Registration number		
Active Ingredient(s) & Strength (s):		
Pharmaceutical dosage form:		
Route of administration:		
Physical Characters:		
Shelf Life:		
Storage Condition:		
Approved Price Pack:	Note: Kindly Specify No. of Units according to the Pricing Certificate & Packaging Material according to the Stability Approval.	
Price:		
Reference drug product (Note: According to bioequivalence approval)		
Name of reference product (RLD, RS,….:		
Name of MAH, Manufacturer and country of origin:		
Reference Link:		
Therapeutic Group: ATC Code:		
Approved Indication		
Applicant:		
Company Profile Username:		

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Marketing Authorization Holder/License Holder:	
Manufacturer:	
Manufacturer of Solvent/ Accessories (If Applicable):	

1505

Packager:	
Batch releaser:	
Storage Site & Address:	
Type of registration:	
Market status:	
EDA Chairman Decree:	
Batch Type	
Batch Number(s)	

1506

API information submitted as:	□ Prequalification □ CEP	□ DMF □ Full details in the PD
CEP number & issue date: *"If applicable"*		
API Name /Form/ Specs:		
Name of Manufacturer & country of origin + Address as in the manufacturer's GMP":		
Studies that had been performed on each manufacturer of API		

1507 Note: The above box can be repeated according to No. of APIs in Product

1508

Contact person:	
Telephone number:	
E-mail:	

1509

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وأتعهد أنا الموقع أدناه ..... رئيس مجلس إدارة)أو /العضو المنتدب/ المفوض بالإمضاء(شركة .....
بالآتي:

- بأن كافة البيانات المذكورة أعلاه صحيحة ودقيقة وكاملة.
- الالتزام بأحكام قانون حماية حقوق الملكية الفكرية رقم ٨٢ لسنة ٢٠٠٢ ولائحته التنفيذية دون أدنى مسؤولية على هيئة الدواء المصرية.
- الالتزام بطباعة اسم المصنع وعنوانه والشركة مالكة المستحضر (أو اسم الشركة مالكة الحق في التسويق للمستحضرات المستوردة بدلًا من الشركة مالكة المستحضر وذلك طبقاً لشهادة CPP المقدمة) وتاريخ الإنتاج وتاريخ انتهاء الصلاحية ورقم التشغيلة ورقم التسجيل والسعر على العبوة الخارجية وعدم إحداث أي تغيير في المستحضر إلا بعد الحصول على موافقة هيئة الدواء المصرية.
- إخطار هيئة الدواء المصرية بأسماء جميع الموزعين المعتمدين وبأي تغيير يطرأ على البيانات الخاصة بهم والتأكد من أن الموزع المعتمد يطبق قواعد التخزين والتوزيع الجيد (GSP&GDP) ومتابعتها من قبل الإدارة العامة للتفتيش على المصانع.
- عدم تغيير مصادر المادة الخام الفعالة إلا بعد موافقة الإدارة العامة لتسجيل المستحضرات البشرية، وإلا يلغى إخطار التسجيل.
- تحمل المسئولية الكاملة عن تخزين المواد الخام، وعن جميع مراحل تصنيع المستحضر، وعن مطابقة المستحضر للمواصفات الفنية وتخزين المنتج حتى تمام التوزيع وفى حالة التصنيع لدى الغير يشترط أن يكون المصنع مرخصاً وأن يلتزم بجميع الالتزامات الواردة بهذا القرار بقواعد التصنيع الجيد وما ورد بالقرار الوزاري ٥٣٩ لسنة ٢٠٠٧ بشأن اعتماد المدونة المصرية لأساليب التصنيع الجيد للمستحضرات الصيدلية.
- لا يتم نقل مكان التصنيع أو نقل الملكية إلا بعد موافقة الإدارة العامة لتسجيل المستحضرات البشرية، وإلا يلغى إخطار التسجيل.
- لا يتم نقل ملكية المستحضرات المحلية الابعد مرور ثلاث سنوات من التداول المحلي وموافقة الإدارة العامة لتسجيل المستحضرات البشرية،وإلا يلغى إخطار التسجيل(في حالة المستحضرات المقدمة طبقاً للقرار الوزاري /٤٢٥ ٢٠١٥ و قرار رئيس هيئة الدواء المصرية رقم ٤٥٠/٢٠٢٣ الحالة الأولى)
- لا يتم نقل ملكية المستحضرات المحلية الابعد مرور خمس سنوات من التداول المحلي وموافقة الإدارة العامة لتسجيل المستحضرات البشرية،وإلا يلغى إخطار التسجيل (في حالة المستحضرات المقدمة طبقاً للقرار الوزاري /٦٤٥ ٢٠١٨و قرار رئيس هيئة الدواء المصرية رقم ٤٥٠/٢٠٢٣ الحالة الثالثة)
- أن جميع البيانات المقدمة بملف التحليل بالإدارة المركزية للرقابة الدوائية للمستحضر مطابقة لما تم تقديمة بملف التسجيل بهيئة الدواء المصرية وأن

جميع المستندات والبيانات صحيحة وعلى مسئوليتي الخاصة.

- تقديم شهادة ال GMP وشهادة التحليل الخاصة بالمادة الخام، وذلك عند التقدم لإستيراد المادة الخام بهيئة الدواء المصرية.
- إبلاغ الإدارة العامة لليقظة الصيدلية عن أى آثار عكسية خطيرة يتم رصدها عن هذا المستحضرو تقديم تقرير Safety Periodic Report Update، متابعة مأمونية مستحضراتها وتنفيذ جميع أنشطة اليقظة الدوائية وذلك وفقاً للمهل المحددة والقواعد الواردة بأسس الممارسة الجيدة لليقظة الدوائية الصادرة والمفعلة من الإدارة.
- سوف يتم توزيع المستحضر عن طريق الشركات الآتية:
- تم إجراء دراسات إعادة التسجيل (تحليل بالإدارة المركزية للرقابة الدوائية / دراسة الثبات / دراسة التكافؤ الحيوى / معدل الذوبان) على تشغيلات إنتاجية باستخدام مصدر المادة الخام:.....
- تتعهد الشركة باستكمال الدراسات على تشغيلات إنتاجية باستخدام مصدر المادة الخام:.....
- تم عمل المتغيرات (Variations) الآتية / لم يتم عمل أى متغيرات (Variations) للمستحضر عن آخر إخطار تسجيل للمستحضر (لإعادة التسجيل) / موافقة طلب الاستعلام (للمستحضرات الجديدة) :

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Type of Variation	From	To	Status (Final /Conditioned)

ختم الشركة

رئيس مجلس الإدارة او المفوض إليه بالإمضاء

الاسم :

التوقيع :

التاريخ :

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Annex (3)

Variation Application Form of Post Marketed Human Products

Annex I: Product Information, Classification of Proposed Changes and General Amendments and Data	
1-Product Information	
Trade Name:	**Applicant:**
Dosage form:	**License Holder/MAH :**
Active substance(s):	**Manufacturer of Finished Pharmaceutical product:**
Concentration:	**Primary /Secondary Packager/Batch Releaser:**
Registration Decree:	**Manufacturer of solvent:**
Registration number:	**Storage Site:**
Type of License:	**Type of Marketing:**
2-Classification of the Submitted Variation According to Variation Guidelines	
-Mode of Submission: (Tick √) ○ Single PAC ○ Grouped PAC	
-Variation Evaluation Route: (Tick √) ○ Full Evaluation Route ○ Reliance Evaluation Route	
-Categorization of submission: (Tick √) ○ Appeal ○ Inquiry with assessment ○ Inquiry without assessment ○ Post Marketing Variation approval ○ Reliance route	
-Type of the request : (Tick √) ○ Administrative Change ○ Quality Change	

Variation changes (Tick the appropriate change required) Please Tick all the variations submitted in case of multiple variations	Change	Addition	Clarify
A) Composition & Specification Changes As:			
Name of active substance			
Name of an Excipient			
Imprints / Embossing / other marking			
Scoring			
Shape of pharmaceutical finished product			
Dimensions of pharmaceutical finished product			
Excipient			
Coating weight / weight of capsule shell			
Color of (coat / capsule shell, etc ….)			
Specification of Finished Pharmaceutical product			
Shelf life			
	Change	Addition	Clarify
Storage Conditions			
API form as salt equivalence and/or crystalline state			
Test procedure			
The particle size of API (state D90)			
Solvents			
Specification of Active ingredient			
Specification of Inactive ingredients			
Route of Administration			
Dosage Form			
B) Container Closure System Changes As:			
Primary packaging of finished pharmaceutical product			
Shape of container			
Pack size of finished pharmaceutical product			
Part of primary packaging material not in contact with the finished product formulation			
Supplier of packaging components / Devices			
Clarify the change concerning which type of packs: Local/Tender/Export/Hospital use			
C) Ownership / Manufacturing Changes As:			
Name of License holder			
Address of License holder			
Name of Manufacturer site			
Address of Manufacturer site			
Applicant for imported FPPs			

Modification of Registration License			
License Holder Transfer			
Marketing Authorization holder Transfer			
Marketing Authorization holder in **Egypt**			
Solvent Manufacturer			
Manufacture site			
Primary Packager			
Secondary Packager			
Storage Site			
Batch Releaser			
Batch size factor of 10 X			
Batch size over 10 X			
Change Registration Type			
Addition of Manufacturer for Export only			
In-Process Control			
Manufacturing process			
	Change	**Addition**	**Clarify**
D) API Manufacturer changes as:			
Name of API Manufacturer			
Address of API Manufacturer			
Deletion of API Manufacturer			
API Manufacturer (with DMF or Not)			
Manufacturing process of API			
Batch size of API			
In process tests during the manufacture of API			
Specification parameters &/or limits of API			
Test Procedures during the manufacture of API			
Primary packaging of API			
Retest period/storage period of API			
Storage condition of API			
CEP			
E) Miscellaneous			**Tick for required Issue**
Extensions			
Updating Analysis File			
Cancelling previous variation approvals			
Re-issuing Approvals			
Non-Reportable Requests: **(Please Describe the request)**			

3-kindly fulfill the following Amendments by Yes / NO	Yes	No
1- Is All documents & information submitted in the file are correct and on the responsibility of the applicant		
2- Is the submitted file contains all the approvals for the product that were not mentioned in the last released registration license		
3- Is the submitted file contains the latest issued registration license		
4- Is the submitted file contains Valid registration license **(In case of Invalidation Please submit registration renewal or validity extension)**		
5- Is the submitted file contains Valid Pricing license		
6- Is the submitted EDA lab composition and its certificate of analysis is the last composition analyzed by CADC Labs.		
7- Is the submitted file contains all approvals, variations, decisions & exemptions issued for the product from different EDA departments		
8- Is the submitted request fulfilling all conditions stated in guidelines		
9- Is the Manufacturing Site Registered Capable for production of the container closure system (In case of change /addition of pack)?		

4-Kindly state the following data:
1- In case of Any previous variations' approvals, variations, decisions & exemptions issued for the product from different EDA departments **(please arrange the with dates if available)**
1- 2-
2- Data of the last manufactured/imported production batch:
A- Batch No.: B- Production date: C- Expiry date: Is a Ministerial decree 600/2018 exemption approval **(If needed)** is Attached: **Yes / No**
3- If New Registration license is registered according to 425 or 645 **(In case of Batch Size)** (Please clarify if change is related to first three production batches manufactured or No) **Yes / No**
4- Status from submission to pharmacovigilance (In case of changing the applicant)
5- Payment receipt No: (Its Value according to Variation Request, must be directed to variation department and stamped with EDA Stamp with the Product Name, Concentration, Dosage Form, Type of variation.

6- Name & address of Manufacturers of API of product as stated in GMP Name & address of suppliers of API of product
7- Please Clarify the Following A- BCs Class of Active Substance: (Kindly attach Biopharmaceutics Classification System **Reference**) ☐ Class I ☐ Class II ☐ Class III ☐ Class IV B- The Product Is Innovator: ☐ Yes ☐ No

Annex II Technical Justification & Supportive Data

1- Summary of Change

(Please give detailed explanation for the proposed changes)

Current Approved Status	Proposed Status

2-Scientific Justification & Reason for Change

(In detailed description for the reason of change)

3-Impacted CTD Parts (s):

(According to the CTD relevant parts)
Tick (√)on the relevant module

○ Module 1 (Administrive /Labeling)	○ Module 3 (Quality /CMC)

4-Impacted CTD Parts (s):
(According to the CTD relevant parts)
Tick (√)on the relevant part

Module 3

- ○ 3.1 Table of Contents of Module
- ○ 3.2 Body of Data
- ○ 3.2.S DRUG SUBSTANCE
- ○ 3.2.S.1 General Information
- ○ 3.2.S.1.1 Nomenclature
- ○ 3.2.S.1.2 Structure
- ○ 3.2.S.1.3 General Properties
- ○ 3.2.S.2 Manufacture
- ○ 3.2.S.2.1 Manufacturer(s)
- ○ 3.2.S.2.2 Description of Manufacturing Process and Process Controls
- ○ 3.2.S.2.3 Control of materials
- ○ 3.2.S.2.4 Controls of critical steps and intermediates
- ○ 3.2.S.2.5 Process validation and/or evaluation
- ○ 3.2.S.2.6 Manufacturing process development
- ○ 3.2.S.3 Characterization
- ○ 3.2.S.3.1 Elucidation of structure and other characteristics
- ○ 3.2.S.3.2 Impurities
- ○ 3.2.S.4 Control of the API
- ○ 3.2.S.4.1 Specification
- ○ 3.2.S.4.2 Analytical procedures
- ○ 3.2.S.4.3 Validation of analytical procedures
- ○ 3.2.S.4.4 Batch analysis
- ○ 3.2.S.4.5 Justification of specification
- ○ 3.2.S.5 Reference standards or materials
- ○ 3.2.S.6 Container-closure system
- ○ 3.2.S.7 Stability

- ○ 3.2.P.2.2.1 Formulation development
- ○ 3.2.P.2.2.2 Overages
- ○ 3.2.P.2.2.3 Physicochemical and biological properties
- ○ 3.2.P.2.3 Manufacturing process development
- ○ 3.2.P.2.4 Container-closure system
- ○ 3.2.P.2.5 Microbiological attributes
- ○ 3.2.P.2.6 Compatibility
- ○ 3.2.P.3 Manufacture
- ○ 3.2.P.3.1 Manufacturer(s)
- ○ 3.2.P.3.2 Batch formula
- ○ 3.2.P.3.3 Description of manufacturing process and process controls
- ○ 3.2.P.3.4 Controls of critical steps and intermediates
- ○ 3.2.P.3.5 Process validation and/or evaluation
- ○ 3.2.P.4 Control of excipients
- ○ 3.2.P.4.1 Specifications
- ○ 3.2.P.4.2 Analytical procedures
- ○ 3.2.P.4.3 Validation of analytical procedures
- ○ 3.2.P.4.4 Justification of specifications
- ○ 3.2.P.4.5 Excipients of human or animal origin
- ○ 3.2.P.4.6 Novel excipients
- ○ 3.2.P.4 Control of FPP
- ○ 3.2.P.5.1 Specifications
- ○ 3.2.P.5.2 Analytical procedures
- ○ 3.2.P.5.3 Validation of analytical procedures
- ○ 3.2.P.5.4 Batch analyses
- ○ 3.2.P.5.5 Characterization of impurities
- ○ 3.2.P.5.6 Justification of specification(s)
- ○ 3.2.P.6 Reference standards or materials

○ 3.2.S.7.1 Stability summary and conclusions ○ 3.2.S.7.2 post-approval stability protocol and stability commitment ○ 3.2.P DRUG PRODUCT (OR FINISHED PHARMACEUTICAL PRODUCT (FPP)) ○ 3.2.P.1 Description and composition of the FPP ○ 3.2.P.2 Pharmaceutical Development ○ 3.2.P.2.1 Components of the FPP ○ 3.2.P.2.1.1 Active pharmaceutical ingredient ○ 3.2.P.2.1.2 Excipients ○ 3.2.P.2.2 Finished pharmaceutical product	○ 3.2.P.7 Container-closure system ○ 3.2.P.8 Stability ○ 3.2.P.8.1 Stability summary and conclusions ○ 3.2.P.8.2 post-approval stability protocol and stability commitment ○ 3.2.P.8.3 Stability data ○ 3.2.A APPENDICES ○ 3.2.A.1 Facilities and Equipment ○ 3.2.A.2 Adventitious Agents Safety Evaluation ○ 3.2.A.3 Excipient

Module 1
(Write the parts will be affected)

5-Risk Assessment For the Change

A-Supportive Documents for Post Marketing Variation Approval & Inquiry with Assessment Submissions

1-Supportive documents for DMF

- Comparison between the specifications of current suppliers, and proposed suppliers according to the monograph, as follows:

Specifications according to the monograph	Current Suppliers COA Specification Limits	Specification (S4.1) of Current Suppliers in case it is supported by DMF	Proposed Suppliers COA Specification Limits	Specification (S4.1) of Proposed Suppliers	Justification for any change

- Submit the following DMF sections as **a PDF (in a separated folder)**
  - Manufacturer S.2.1

- Organic impurities & residual solvents (S.3.2)
- Specifications of API S.4.1
- Batch analysis S.4.4
- Container closure system S.6
- Stability Specification S.7.1 & S.7.2
- GMP with License
- Letter of Access and Statement of Commitment

N.B.

Comparison should be made for specification values, not the result value

2-In Case of Change of API Specification and Finished product Specification submitted for Inquiry with assessment

In case of Finished product specification

Old Finished product Specifications	New Finished product Specifications	Justification for any differences

Note: Mention all tests, please specify the applicable reference or standard, indicating whether the test is based on an in-house method or a pharmacopeial reference.

In Case of API Specification

Specification limit of COA of old supplier(s)	Specification limit of COA of old supplier(s)	Tests mentioned in monograph

Note: Mention all tests, please specify the applicable reference or standard, indicating whether the test is based on an in-house method or a pharmacopeial reference.

-In Case of any differences please Justify :

3- In Case of Submission of a Post-Marketing Variation Approval: - Submit Required Supporting Studies & Comparison			
***The submission shall include the following documents:**	**Yes**	**No**	**No. of Batches**
1-Batch Analysis Data: [No.of batches - Result:(e.g. Conform/Non-conform)]			
2-Stability Data: [type of study (6 months Accelerated & Long-term) ,Result: (e.g.. Pass) & Date of Approval.]			
3-Comparative dissolution study / bioequivalence. Result: conform.]			
4-Process Validation Report: [3 consecutive batches successfully produced – type of Batches (pilot or production)]			

***Comparison**

Appoved Finished Product Specification 3.2.P.5.1	CADAC Specification	Stability Approval Specification	Stability data 3.2.P.8.3	Justification for any Changes

Note: Mention all tests, please specify the applicable reference or standard, indicating whether the test is based on an in-house method or a pharmacopoeial reference.

-In Case of any differences please Justify :

B-For Submissions of Inquiry without assessment

	Yes	No
If the submitted request **will affect the approved specifications of the finished product?**		

***Note: Please Attach The cover letter mentioned in (Annex II Declarations template 5 Signed and Stamped)**

C-For Appeal Submissions

***Full Description of the appeal**

***Applicant Justification**

***Supportive Documents/Studies**

D- For Reliance Submissions

The submission shall include the following documents:

	Yes	No
1.Valid Certificate of Pharmaceutical Product. (CPP)		
2. Updated relevant sections of CTD dossier. (However, the non-sequential order of versions of the Common Technical Document (CTD) makes the reliance evaluation unreliable as the company must submit the updated version contains all sequential updates)		
3. Verification of Sameness. (Sameness Letter signed and stamped on		
4. Unredacted Assessment report and/or Q&A (otherwise justified).		
5. Proof of Approval from at least one reference regulatory authority.		
6. Application submitted to the SRA (A linking between the application and the approval from the Reference Authority must be declared (unless otherwise justified)		

***Please Identify the Climatic Zone on which the stability study in country of origin was approved.**

*The submission shall include the following documents:	Yes	No	No. of Batches	Result
1-Batch Analysis Data:				
2-Stability Data: [type of study (6 months Accelerated & Long-term) & Date of Approval.]				
3-Comparative dissolution study / bioequivalence.				
4-Process Validation Report: { type of Batches (pilot or production)}				

I hereby declare that all information and accompanying supporting data provided in this application and dossier are accurate, authentic, and complete. The proposed variation complies with all regulatory and quality standards.

-Signature by the Authorized Person: **-Official Title:** **-Date:**	**-Company Stamp**

Annex II: Declarations
(In case of License holder Transfer -Addition of Manufacturing Site -Inquiry Without Assessment/Fullfilling Studies)
*Note: All declarations (of the request) shall be submitted attached with the application

Template 1

السيد / رئيس الإدارة المركزية للمستحضرات الصيدلية
الإدارة العامة لتسجيل المستحضرات البشرية
إدارة المتغيرات للمستحضرات البشرية

تحية طيبة وبعد،،،،

ص المستحضر الآتي:

Trade Name:		
Dosage Form:		
Active Ingredients / Strength:		
Registration No.:		
Applicant Company:		
License Holder / MAH:		
Manufacturer / Packager:		
License Validity:	○ Valid ○ In-valid	Re-Reg 296/2009 Re-Reg 425/2015 Re-Reg 150/2022
Current status:		
Proposed status:		

أتعهد أنا ..... رئيس مجلس إدارة شركة .....(المالك القديم للمستحضر) ..... بأن المستحضر ليس له تركيزات أخرى من نفس الشكل الصيدلي أو أشكال صيدلية أخرى مسجلة أو تحت التسجيل مملوكة للشركة.

و تفضلوا بقبول وافر الإحترام والتقدير،،،،

رئيس مجلس ادارة الشركة **ختم الشركة**

Template 2

السيد / رئيس الإدارة المركزية للمستحضرات الصيدلية
الإدارة العامة لتسجيل المستحضرات البشرية
إدارة المتغيرات للمستحضرات البشرية

تحية طيبة وبعد،،،،

بخصوص المستحضر الآتي:

Trade Name:		
Dosage Form:		
Active Ingredients / Strength:		
Registration No.:		
Applicant Company:		
License Holder / MAH:		
Manufacturer / Packager:		
License Validity:	○ Valid ○ In-valid	Re-Reg 296/2009 Re-Reg 425/2015 Re-Reg 150/2022
Current status:		
Proposed status:		

أتعهد أنا ..... رئيس مجلس إدارة شركة .....(المالك الجديد للمستحضر) ..... بأن المستحضر ليس له تركيزات أخرى من نفس الشكل الصيدلي أو أشكال صيدلية أخرى مسجلة أو تحت التسجيل مملوكة للشركة.

و تفضلوا بقبول وافر الإحترام والتقدير،،،،

رئيس مجلس ادارة الشركة **ختم الشركة**

Template ٣

السيد / رئيس الإدارة المركزية للمستحضرات الصيدلية
الإدارة العامة لتسجيل المستحضرات البشرية
إدارة المتغيرات للمستحضرات البشرية

تحية طيبة وبعد،،،،

أتعهد أنا ..... رئيس مجلس إدارة شركة ..... بأن المستحضرات المملوكة للشركة هم كالآتي:

Registered Product				Under-Registration Products			
	Trade Name / Dosage Form	API / Strength	Reg. Decree		Trade Name / Dosage Form	API / Strength	Reg. Decree

و تفضلوا بقبول وافر الإحترام والتقدير،،،،

رئيس مجلس ادارة الشركة **ختم الشركة**

Template ٤

السيد / رئيس الإدارة المركزية للمستحضرات الصيدلية
الإدارة العامة لتسجيل المستحضرات البشرية
إدارة المتغيرات للمستحضرات البشرية

تحية طيبة وبعد،،،،

بخصوص المستحضر الآتي:

Trade Name:		
Dosage Form:		
Active Ingredients / Strength:		
Registration No.:		
Applicant Company:		
License Holder / MAH:		
Manufacturer / Packager:		
License Validity:	○ Valid ○ In-valid	Re-Reg 296/2009 Re-Reg 425/2015 Re-Reg 150/2022
Current status:		
Proposed status:		

أتعهد أنا ..... رئيس مجلس إدارة شركة ..... بتحمل كافة المسؤولية القانونية لإضافة مكان التصنيع .....(اسم المصنع الجديد/المصانع الجديدة) ..... دون أدنى مسؤولية على هيئة الدواء المصرية تجاه عقود التصنيع المبرمة بين شركة .....(اسم المالك للمستحضر) ..... وشركة .....(اسم المصنع القديم/المصانع القديمة) .....

وتفضلوا بقبول وافر الإحترام والتقدير،،،،

رئيس مجلس ادارة الشركة **ختم الشركة**

Template 5

الإدارة العامة لتسجيل المستحضرات البشرية
إدارة المتغيرات للمستحضرات البشرية

تحية طيبة وبعد،،،،

بخصوص المستحضر الآتي:

Trade Name:		
Dosage Form:		
Active Ingredients / Strength:		
Registration No.:		
Applicant Company:		
License Holder / MAH:		
Manufacturer / Packager:		
License Validity:	○ Valid ○ In-valid	Re-Reg 296/2009 Re-Reg 425/2015 Re-Reg 150/2022

Current Status	Proposed Status	Justification for the change

*اتعهد انا شركة..... بان الطلب المقدم لادارة المتغيرات inquiry without assessment وبان التغيير المذكور اعلاه سوف (يؤثر /لا يؤثر) علي المواصفات النهائية للمستحضر وان الشركة سوف تقوم بالتغيير علي مسؤليتها

و تفضلوا بقبول وافر الإحترام والتقدير،،،،

رئيس مجلس ادارة الشركة

ختم الشركة

Template 6

السيد / رئيس الإدارة المركزية للمستحضرات الصيدلية
الإدارة العامة لتسجيل المستحضرات البشرية
إدارة المتغيرات للمستحضرات البشرية

تحية طيبة وبعد،،،،

بخصوص المستحضر الآتي:

Trade Name:		
Dosage Form:		
Active Ingredients / Strength:		
Registration No.:		
Applicant Company:		
License Holder / MAH:		
Manufacturer / Packager:		
License Validity:	○ Valid ○ In-valid	Re-Reg 296/2009 Re-Reg 425/2015 Re-Reg 150/2022
Current status:		
Proposed status:		

أتعهد أنا شركة ..... باستكمال دراسة الثبات طويلة المدي على التشغيلة الانتاجية الاولي (.....) وفي حالة حدوث اي تغييرفي مواصفات المستحضر النهائية وله تاثير سلبي علي جودة وفاعلية المستحضر نتعهد بابلاغ ادارة المتغيرات بهذا التغيير.

وتفضلوا بقبول وافر الإحترام والتقدير،

رئيس مجلس ادارة الشركة **ختم الشركة**

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History Table

Summary of Changes	Issue date	Version No.
New Issue		1

Draft