# Regulatory guideline for mechanisms and rules of implementing the decree of Egyptian Drug Authority's Chairman No. (343) of 2021

## 2025

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## 1. Introduction

This regulatory guide aims to establish the implementation mechanisms for the various pathways available for biologics registration, including the normal track, fast track, reliance, and re-registration, by identifying the requirements, processes, and key considerations for each pathway.

Biologics registration pathways are subject to Egyptian Drug Authority (EDA) chairman decree No. 343/2021, in addition to detailed regulatory guidelines for each pathway.

**This guide should be read in conjunction with the following regulatory guidelines:**

"Guideline for content file of biological products for registration & reregistration file Code: EDREX.GL.Bioinn.004"

"Procedures for Registration of Biological products through Reliance pathways. Code: EDREX.GL.Bioinn.002"

**In addition to the following notice to applicants:**

"Rules for registering biological products under the fast track registration pathway. Code: EDREX.NP.Bioinn.007"

"Mechanisms for registering a second brand. Code: EDREX.NP.Bioinn.008

## 2. Scope

This guide outlines the pathways available at the EDA for registering biological products intended for human use. It covers all registration pathways and applies for locally manufactured as well as imported biological products submitted for registration within the Arab Republic of Egypt.

## 3. Abbreviation

| | |
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| **BioInn** | Central Administration of Biological and Innovative Products and Clinical Studies |
| **COO** | Country Of Origin |
| **CPP** | Certificate of Pharmaceutical Product |
| **CTD** | Common Technical Document |
| **EDA** | Egyptian Drug Authority |
| **GMP** | Good Manufacturing Practice |
| **ICH** | International Council for Harmonization |
| **SMF** | Site Master File |
| **SmPC** | Summary of product characteristics |

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| **WDs** | Working days |
| **WHO** | World health organization |

## 4. Definitions

**Biological products:** Products containing one or more active ingredient produced or derived from a biological source, including but not limited to human vaccines, serum, blood and plasma products and derivatives, also products manufactured using biotechnology and the like, as well as, any products or substances that may be created based on science update and/or international standard and reference.

**Imported products:** Biological products imported from abroad, fully manufactured or manufactured abroad and subsequently subjected to secondary packaged in factories within the Arab Republic of Egypt.

**Locally manufactured products:** Biological products manufactured within the Arab Republic of Egypt or products imported in bulk and manufactured and/or primary packaged within the Arab Republic of Egypt.

**Reliance:** The act whereby the NRA in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

## 5. Main topic

### 5.1 . Registration procedures:

#### 5.1.1. Main criteria:

These criteria are set to determine the most appropriate pathway for the registration of a biological product, based on the extent to which it meets the requirements of each pathway as shown in **Annex 1**

#### 5.1.2. Registration steps:

Registration steps are carried out according to the following steps for the different registration pathways. **Annex 2** summarize the main steps of each pathway.

## Inquiry steps

1. The applicant for registration is obligated to submit an inquiry about the product through the automated inquiry system at EDA website for this purpose on the EDA's website, accompanied by the required documents (**Annex 3**).

2. The applicant shall be informed with the status of the application within **10 WDs** from the date of receipt of the application for the normal track, and within **5 WDs** for those submitted under reliance pathway.
3. The applicant should complete the inquiry with the requested documents/ data within **20 WDs** from the date of notification; otherwise, the inquiry shall be cancelled.
4. The application for names is submitted through the electronic program designated for this purpose on the EDA's website, in conjunction with the inquiry.
5. Upon approval of the inquiry and fulfilling the required basic requirements, the applicant may submit a request to be shifted to the fast track pathway, with the payment of the applied service consideration.
6. The applicant must submit a separate inquiry for each concentration, pharmaceutical form, or volume of the product.
   **Note:** A pre-submission meeting may be held with the applicant in some cases based on the evaluation of the registration administration, including, but not limited to:
   - Discuss the optimal pathway for the product, including but not limited to genetic cell, and advanced technology products.
   - Discuss the documents required for each registration pathway.
   - Discuss the guidelines for registering biological products.

## Exemption steps

There are some cases in which certain approvals must be obtained before the submitted inquiry is approved, as follows:

- Imported biological products submitted for registration that are not markted in any of the reference countries approved by the Technical Committee for Drug Control and are not prequalified by the World Health Organization (WHO).
- Imported biological products that do not have a scientific reference.

1. The exemption file (**Annex 4**), along with the vigilance file, must be submitted to the scientific file examination unit within **20 WDs** from the date of notification through the inquiry program; failure to do so will result in cancellation of the inquiry.
2. The preliminary evaluation of the exemption file and pharmacovigilance file will be completed within **15 WDs** from the submission of the product.
3. If any additional requirements are requested, the company must provide them within **60 WDs**; otherwise, the application will be deemed cancelled.

4. The file will be evaluated within **60 WDs** upon acceptance of the complete file and subsequently presented to the Specialized Scientific Committee for Biological Products, after receiving the report issued from the General Administration of Pharmacovigilance. The committee resolution will then be issued to either approve or reject the application.
5. For imported biological products that are neither marketed in any of the reference countries approved by the technical committee for Drug Control nor prequalified by the WHO, the site master file must be submitted to the Central Administration of inspection on pharmaceutical institutions following approval of the exemption by the specialized scientific committee. The manufacturing facility shall then undergo inspection.
6. For imported biological products lacking a scientific reference, and the specialized scientific committee resolution was approval, the product should be submitted to the Technical Committee for Drug Control, which will issue the final decision on the recommendation - either approval or rejection - prior to granting approval for the inquiry.

## Pricing

After the approval of inquiry, the following steps must be followed:

1. The required documents for pricing must be submitted to the central administration of drug policies and market support within **30 WDs** of the inquiry approval date; otherwise, the inquiry approval shall be cancelled.
2. Pricing of biological products under the normal track is determined within a maximum of **60 WDs** from the date of receipt of the complete pricing file.
3. Pricing of biological products under the fast track and the reliance track is determined within a maximum of **30 WDs** from the date of receipt of the complete pricing file.

## Inspection

1. The central administration of inspection on pharmaceutical institute conducts inspections of all relevant manufacturing sites, including active ingredient facilities, bulk production facilities, and finished product facilities, following the evaluating of the site master file. The inspection results are then communicated to the central administration of biological and innovative products and clinical studies.
2. In the case of locally manufactured products, and in some cases, the central administration of inspection on pharmaceutical institutions is contacted to assess the readiness of the local facility/production line before obtaining inquiry approval.

3. Good Manufacturing Practice (GMP) certified facilities by a reference regulatory authority or accredited by the WHO are exempt from the inspection visit.
4. Plasma collection centers that are neither accredited by any of the reference countries approved by the technical committee for drug control, nor possess a GMP certificate from a reference country, nor accredited by international authorities such as (Plasma Protein Therapeutics Association/International Quality Plasma Program), shall be subject to inspection by the central administration of inspection on pharmaceutical institutions.
5. After registration, the product is placed under a risk-based inspection plan.

## Stability

In the case of local products, the stability study protocol shall be submitted for review and approval by the Stability Unit within a maximum period of **30 WDs** prior to the starting of the stability study and submission of the registration file

## Submitting registration file

1. The ICH guideline M4 on the Common Technical Document (CTD) is applied in preparing the registration file, which is then submitted to the Biologicals Registration administration.
2. The registration file for the normal track must be submitted no later than **two years** from the product pricing date for local and within **60 WDs** from the product pricing date for imported products. Otherwise, the registration application shall be deemed cancelled.
3. If the file is submitted in the reliance track or through the fast track, the registration file may be submitted in parallel with the pricing file.

**Screening:**

1. The submitted registration file will undergo a primary screening to ensure that it meets the technical evaluation requirements. This screening will be conducted within **20 WDs** for the normal and fast tracks, within **5 WDs** for the first level of the reliance track, and within **10 WDs** for the second level of the reliance track, at the relevant central administrations (the central administration of biological and innovative products and clinical studies, the central administration of inspection on pharmaceutical institutions, and the central administration of pharmaceutical care).
2. The applicant will be notified of the application status, including whether it fulfills the specified requirements.
3. The applicant must complete the requirements within **60 WDs**.

**Technical evaluation:**

1. The technical evaluation is conducted upon receipt of the file by the relevant administrations (the central administration of biological, innovative products, and clinical studies, the central administration of inspection on pharmaceutical institutions, and the central administration of pharmaceutical care).
2. The file shall be evaluated in line with WHO standards, as well as ICH standards and their updates (**Annex 5**).
3. The applicant will be notified of the required queries/ supplementary documents (if any) within **70 WDs** for the normal track, **45 WDs** for the fast track, **10 WDs** for the level 1 reliance track, and **15 WDs** for the level 2 reliance track.
4. The applicant must complete these inquiries/additions within **60 WDs**, renewable once.
5. The initial review of the submitted information is conducted within **5 WDs** for the normal track, the fast track, and the level 2 reliance track, and **within 2 WDs** for the level 1 reliance track, to ensure its completeness before completing the evaluation process.
6. The technical evaluation shall be completed within **10 WDs** for the normal track, the fast track, and the second level of the reliance track, and **within 8 WDs** for the first level of the reliance track.
7. The applicant will be notified of any additional queries/ supplementary documents (if any) which must be addressed within **60 WDs**.
8. If the applicant fails to complete the required requirements/inquiries, the registration application shall be cancelled.
9. The registration file evaluation will be completed after all requirements have been completed and inquiries have been clarified within **35 WDs** for the normal track, **30 WDs** for the fast track, and **10 WDs** for the second level of reliance.
10. All previous steps shall be completed within **120 WDs** for the normal track and within **90 WDs** for the fast track. For reliance tracks, all steps shall be completed within **20 WDs** for the first level and **40 WDs** for the second level of reliance.

## Analysis for registration

1. The central administration of biological and innovative products and clinical studies will notify the central administration of inspectoin on pharmaceutical institutions of the number of samples required for analysis within **20 WDs** of receiving the registration file for the normal and fast track, and within **8 WDs** for the reliance pathway.
2. The applicant must submit the analysis requirements and samples from a single batch of the finished product within **60 WDs** from the date of issuance of the letter specifying the number of samples. This period may be renewed only once.

3. If multiple manufacturing facilities are involved in producing the raw material, bulk, finished product, or solvent, and these facilities were evaluated within the product's registration file during registration along with the analysis of a single finished product batch, the marketing authorization license shall require that analysis also be performed at the other facilities listed in the marketing authorization license, in line with the EDA's release policy.
4. For products that fall within the reliance level 1, a conditional marketing authorization license shall be issued mentioning that the analysis shall be performed on the first incoming batch after registration.

## Submission to the technical committee

1. The product will be presented to the Technical Committee for Drug Control within **20 WDs** for the normal track, within **10 WDs** for the fast track, and within **5 WDs** for the reliance track, from the date of receipt of all required approvals from the relevant stakeholders responsible for evaluating the registration file. A final decision will then be issued on whether to approve or reject the product's registration.
2. In case of approval, the product shall be granted a marketing authorization license valid for five years.
3. In case of rejection of the product's registration, the applicant shall be notified in a letter stating the reason for the rejection.
4. The applicant has the right to request that the product be reconsidered by the Technical Committee for drug control in the case of registration rejection. The applicant may also appeal the final decision within 60 WDs from the date of its issuance, through a substantiated request submitted to the Grievances Committee established in accordance with the Law on the Establishment of the EDA, supported by the documents and information the applicant wishes to rely upon in the appeal process.

### 5.2. Re-registration Procedures:

All biological products are re-registered every five years based on a request submitted by the applicant to the biological registration administration at the central administration of Biologicals, innovative products, and clinical studies, including the required documents for re-registration. This request must be submitted within the final year of the product marketing authorization license's validity, in accordance with the following procedures:

1. Primary screening of the updated registration file is conducted within **15 WDs.**
2. The updated registration file for the product, along with a list of changes made to the product, is reviewed within **40 WDs**.

3. If any requirements exist, the product owner must meet them within **60 WDs,** and this period is renewable only once.
4. Failure to meet these requirements will result in the product being referred to the Head of the central administration of biologics, innovative products, and clinical studies for further action.
5. The product is exempt from referral to the specialized scientific committee for biologics, except for products that were previously registered without being presented to this committee.
6. The product is exempt from re-evaluating its stability study if the stability study was evaluated during the product's registration.
7. The inspection file is evaluated according to the inspection plan based on risk assessment.
8. The product's leaflets and outer pack / layout shall be evaluated.
9. Pharmacovigilance documents are evaluated by the relevant administrations.

**Note:** The validity of the product marketing authorization license may be extended after its invalidation date in emergency situations without a request from the applicant, after presentation to the head of the central administration of biological and innovative products and clinical studies.

## Obligations

The applicant is obligated to:

1. Submit a pledge acknowledging their commitment to the provisions of Intellectual Property Protection Law No. 82 of 2002 and that they take full responsibility if a violation of the aforementioned law is proven. The central administration of biological and innovative products and clinical studies has the right to suspend or cancel the registration based on the recommendation of the Technical Committee for drug control.
2. Write the name of the manufacturer and the company that owns the product, the production date, expiration date, batch number, barcode, registration number, and price on the outer pack / layout, and print the name of the manufacturer, production date, expiration date, and batch number on the inner label.
3. No changes to the product shall be made without consulting the central administration of biologic, innovative products, and clinical studies, and submitting a file detailing any post approval changes (PACs) made to the product for evaluation in accordance with the applicable rules (Guideline on the Regulation of Post-Approval Changes to Registered Biotherapeutic Products in Egypt code: EDREX.GL.Bioinn.008). These changes shall be approved by the biologics registration administration.

4. If a plasma derivative is used as an excipient in a biological product, the applicant must provide evidence that the supplier is committed to notifying them of any information related to the safety and efficacy of the substance, whether concerning plasma derivatives are registered or not in the Arab Republic of Egypt.
5. Products that have received a marketing authorization license in accordance with this decision shall be made available in the market within one and a half years from the date of marketing authorization license.
6. A pledge that all information provided in the product's registration file is correct and that the applicant is fully responsible for it.
7. Acknowledge full responsibility for the storage of raw materials, all stages of product manufacturing, and compliance with technical specifications until full distribution, in accordance with the EDA's applicable rules for good distribution and storage.
8. In case of toll manufacturing, the manufacturer must be licensed by the EDA and comply with all obligations in this decision and with good manufacturing practices.
9. Notify EDA of the names of all authorized distributors and any changes to their data, ensuring that the authorized distributor adheres to good storage and distribution practices.
10. Update the applicant's company profile information on the EDA's dedicated website.

## General rules

1. A facility inspection shall be conducted in case two consecutive non-conformities are detected for the registered product, based on a letter from the central administration of biologicals, innovative products, and clinical studies.
2. Biological products along with its registration numbers are announced on the EDA website no later than the tenth day of the month following the marketing authorization license. Public Assessment Reports (PARs) are published on the Egyptian Drug Authority's website within **15 WDs** of the marketing authorization license date. Any interested party has the right to object to any of the products announced for registration within two months of the notification date.
3. The applicant may submit an application to register a second brand for reference product, in accordance with applicable regulations.
4. Marketing authorization license issued according to Minister of Health Decision No. 297 of 2009 remain valid until their invalidation and re-registration is applied according to EDA chairman decree No. 343 of 2021.

## 6. References

- Egyptian Drug Authority Chairman Decision No. 343 of 2021 issuing rules for registering biological products.
- ICH M4 Organization of the common technical document for the registration of pharmaceutical for human use (M4)

## 7. Annexes

**Annex I**: Key criteria for biologics registration pathways

**Annex II**: Detailed table of regulatory pathways for biologics registration

**Annex III**: Documents required for the inquiry

**Annex IV**: Documents required for the exemption file

**Annex V**: Ministerial decrees and scientific references for file evaluation

## Annex I: Key criteria for biologics registration track pathways

| Registration track pathways | Main criteria |
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| Normal track | To register a product under this pathway, the product submitted for registration must be a biological product, whether locally manufactured or imported<br><br>**Requirements for imported products:**<br><br>-It must be marketed in the country of origin Some vaccines included in the routine immunization schedule of the central administration of preventive affairs of the ministry of health and population are exempt from this requirement<br><br>-The product must be marketed in at least one of the reference countries approved by the Technical Committee for Drug Control or prequalified by the WHO. If it is neither marketed in any of the approved reference countries nor prequalified by the WHO, the exemption procedures outlined above shall apply prior to the approval of the inquiry. |
| Fast track | The fast track registration system prioritizes registration for biological products that meet this system, based on public health priorities<br><br>-Mandatory vaccines included in the Expanded Program on Immunization, school-age vaccinations, traveler vaccinations, and emergency vaccines<br><br>-Products intended for the treatment of serious epidemic diseases with no comparable alternatives<br><br>-Products classified as an orphan drug<br><br>-Products with a shortage in local supply or that meet unique therapeutic uses |
| Reliance | -The submitted product is registered and distributed in a reference country in accordance with reliance rule. |

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| | -The submitted CTD to the EDA must be identical to the version approved by the reference regulatory authorities<br><br>-The submitted product has not been rejected by any of the reference regulatory authorities for reasons related to the product's safety or efficacy<br><br>-If there are any potential differences between the CTD submitted to the EDA and that submitted to the reference regulatory authorities, these changes must be justified for evaluation on a case-by-case basis.<br><br>-In the case of Level 1, a detailed assessment report and/or questions and answers issued by the reference regulatory authorities must be submitted. |

## Annex II: Detailed table of regulatory pathways for biologics registration

| Tracks / Stage | Normal track | | | Fast track | | | Reliance | | Re-registration | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Local | Imported | | Local | Imported | | Level 1 | Level 2 | Local | Imported |
| | | reference | Non reference | | reference | Non reference | | | | |
| **Inquiry steps** | The applicant will be informed with the status of the submitted inquiry within **10 WDs** | | It is presented to the specialized scientific committee & inspection of the site before obtaining approval for the inquiry | The applicant will be informed with the status of the submitted inquiry within **10 WDS** | | It is presented to the specialized scientific committee & inspection of the site before obtaining approval for the inquiry | The applicant will be informed with the status of the submitted inquiry within **5 WDs** | | X | |

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| | | | The applicant for registration may, after obtaining approval for the inquiry and fulfilling the required main requirements, submit a request to move to the fast track with payment of the prescribed service consideration | | | |
| **Pricing** | It shall be submitted within **30 WDs** from the date of approval of the inquiry; otherwise, the approval of the inquiry shall be considered cancelled. | | | | | X |
| | Biological products will be priced within a maximum period of **60 WDs** from the date of receipt of the complete pricing file | | | Biological products will be priced within a maximum period of **30 WDs** from the date of receipt of the complete pricing file | | Biological products will be priced within a maximum period of **30 WDs** from the date of receipt of the complete pricing file |
| **Scientific Committee** | It is presented to the specialized scientific committee as part of the registration steps | It is presented to the specialized scientific committee as part of the registration steps | It is presented to the specialized scientific committee before obtaining approval for the inquiry | It is presented to the specialized scientific committee as part of the registration steps | It is presented to the scientific committee before obtaining approval for the inquiry | It is presented to the scientific committee as part of the registration steps | The product is exempt from registration except in the case of products that were previously registered without being presented to this committee |

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| **Procedures followed** | **The file will not be submitted until pricing approval is obtained** | | | **The file is submitted in parallel with the pricing file** | | | **The file is submitted in parallel with the pricing file** | X |
| **Inspection** | Inspections are conducted at all relevant manufacturing sites, including active ingredient plants, block production plants, and finished product plants, following site master file evaluation, in accordance with a risk-based inspection plan | Factories that are accredited by one of the reference regulatory/control authorities or prequalified from the WHO are exempt from the inspection visit | Inspections are conducted at all relevant manufacturing sites, including active ingredient plants, block production plants, and finished product plants, following site master file evaluation, in accordance with a risk-based inspection plan | Inspections are conducted at all relevant manufacturing sites, including active ingredient plants, block production plants, and finished product plants, following site master file evaluation, in accordance with a risk-based inspection plan | Factories that are accredited by one of the reference regulatory /control authorities or prequalified from the WHO are exempt from the inspection visit | The site master file is submitted for evaluation after obtaining the approval of the scientific committee for the exception, and then the factory is inspected | Factories that are accredited by one of the reference regulatory/control authorities or prequalified from the WHO are exempt from the inspection visit | The inspection file is evaluated according to the inspection plan based on risk assessment |

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| **Stability Protocol Review** | The stability protocol shall be submitted for review and approval by the stability unit within a maximum period of **30 WDs** before the start of the stability study and submission of the registration file. | X | X | The stability protocol shall be submitted for review and approval by the stability unit within a maximum period of **30 WDs** before the start of the stability study and submission of the registration file. | X | X | X |
| **Submitting the registration file** | It must be submitted within **two years** at most from the date of pricing the product, otherwise the registration | It must be submitted within **60 WDs** from the pricing date, otherwise the registration request will be considered cancelled | | The file is submitted in parallel with the pricing file | | The file is submitted in parallel with the pricing file | An application submitted by the product owner to the Registration administration within the last year from the |

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| | application will be considered cancelled | | | | date of notification of the product registration. |
| **Primary screening of the file** | within **20 WDs** | | within **20 WDs** | within **5 WDs** | within **10 WDs** | within **15 WDs** |
| **Registration file evaluation** | -The applicant will be evaluated and notified of any comments within **70 WDs**<br><br>-The applicant will complete these comments/requirements and respond to the initial letter within **60 WDs**, renewable once<br><br>-The company will conduct an initial review of the submitted requirements within **5 WDs** for the main track to ensure they are complete before completing the evaluation process<br><br>-The technical evaluation process will be completed within **10 WDs**<br><br>-The applicant will be notified of any additional requirements/inquiries (if any) and will complete them within **60 WDs**<br><br>-If the applicant fails to complete the required requirements or inquiries, the registration application will be considered cancelled<br><br>-The registration file evaluation will be completed after all requirements have been completed and inquiries have been clarified within **35 WDs**. | | -The applicant will be evaluated and notified of any comments **within 45 WDs**-<br><br>-The applicant will complete these comments/requirements, and a response to the initial letter will be made within **60 WDs**, renewable once.<br><br>-The company will conduct an initial review of the submitted requirements within **5 WDs** to ensure they are complete before completing the evaluation process.<br><br>-The technical evaluation process will be completed within **10 WDs**<br><br>The applicant will be notified of any additional requirements/inquiries (if any) and will complete them **within 60 WDs**<br><br>If the applicant fails to complete the required requirements or inquiries, the registration application will be considered cancelled | -The applicant will be evaluated and notified of any comments within **10 WDs**.<br><br>-The applicant will complete these comments/additions and respond to the initial letter within **60 WDs,** renewable once<br><br>The company will conduct an initial review of the submitted | -The applicant will be evaluated and notified of any comments within **15 WDs**<br><br>-The applicant will complete these comments/requirements, and the initial response will be within **60 WDs**, renewable once<br><br>-The company will conduct an | The registration file, along with the list of changes made to the product, will be reviewed within **40 WDs** . These notes/additions will be completed within **60 WDs** and will be renewed once |

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| | | The registration file evaluation will be completed after all requirements have been met and inquiries have been clarified within **30 WDs** | additions within **2 WDs** to ensure they are complete before completing the evaluation process<br><br>The technical evaluation process will be completed within **8 WDs** | initial review of the submitted requirements within **5 WDs** to ensure they are complete before completing the evaluation process<br><br>-The technical evaluation process will be completed within **10 WDs**<br><br>-The applicant will be notified of any additional requirements/inquiries (if any) and will complete them within **60 WDs** | |

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| **Registration file evaluation**<br><br>**(continued)** | | | | -If the applicant fails to complete the required requirements or inquiries, the registration application will be considered cancelled<br><br>-The registration file evaluation will be completed after all requirements have been met and inquiries have been clarified within **10 WDs** | |
| **Analysis procedures** | -The central administration of inspection on pharmaceutical institutions will be notified of the number of samples required for analysis within **20 WDs** | | Analysis can be done before the first shipment | Analysis is done at the pre- | X |

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| | -The company must submit the analysis requirements and samples from a single batch of the finished product within **60 WDs** from the date of issuance of the letter specifying the number of samples. This period may be renewed only once | | is released to the market | registration stage | |
| | | | The central administration of inspection on pharmaceutical institutions will be notified of the number of samples required for analysis within **8 WDs**<br><br>The company must submit the analysis requirements and samples from a single batch of the finished product within **60 WDs** from the date of issuance of the letter specifying the number of samples. This period may be renewed only once. | | |
| **Time frame** | All the above steps will be completed within **120 WDs** | All the above steps will be completed within **90 WDs** | All the above steps will be completed within **20 WDs** | All the above steps will be completed within **40 WDs** | All the above steps will be completed within **40 WDs** |
| **Technical Committee** | The product shall be presented to the Technical Committee for Drug Control within **20 WDs** | The product shall be presented to the Technical Committee for Drug Control within **10 WDs** | The product shall be presented to the Technical Committee for Drug Control within **5 WDs** | | The product shall be presented to the Technical Committee |

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| | | | | for Drug Control within **20 WDs** |
| **License of product registration** | • In case of rejection, the applicant will be notified<br>• In case of approval, the product will be granted a marketing authorization license valid for five years | | | |

## Annex III: Documents required for the inquiry

- Service consideration for the inquiry of biological products.
- A copy of the scientific reference for the original product, provided it is from an internationally accredited source (such as reference official sites of countries defined by technical committee, Vidal, USP, Rote Liste, Compendium Suisse, PDR).

**For imported products, the aforementioned documents must be submitted in addition to the following**:

- Certificate of pharmaceutical products (CPP) according to the WHO recommended format, authenticated by the Chamber of Commerce or its equivalent in the country of origin and legalized by the Egyptian embassy abroad. eCPP certificates are exempt from legalization, if their validity can be verified on the website of the regulatory/supervisory authority that issued the certificate
- Contracts or letters of authorization from the marketing license holder must be submitted, detailing all the data and steps authorized by the applicant, authenticated by the Chamber of Commerce or its equivalent in the country of origin and legalized by the Egyptian embassy abroad
- The CTD sections detailing the facilities responsible for the active ingredient and finished product are provided.

**For locally manufactured products, or for importing the active ingredient or bulk from abroad to be manufactured, filled and packaged locally, the following documents must be submitted**

- GMP certificate for the active ingredient/bulk manufacturer
- Local facility license. In some cases, documents such as risk assessment, cleaning validation, and process flowchart are required to assess the facility's ability to manufacture the submitted products
- Contracts concluded between the bulk-producing company and the applicant, authenticated by the Chamber of Commerce or its equivalent in the country of origin and legalized by the Egyptian embassy abroad. These documents must also clearly state all the steps and powers delegated to the applicant, as well as the manufacturing and details of the finished product.
- For toll manufactured products: Submit contracts concluded between the company and the local manufacturer, certified by a legal advisor, detailing all product details. Submit a commercial registry detailing the toll manufacturing activity.
-A letter detailing all of the company's registered and under-registration products must also be submitted. The inquiry must be submitted using the company
-The naming request must be attached to the designated program on company letter head, and a pledge from the company approving the name chosen from the attached list

## Annex IV: Documents required for the exemption file

1. Covering letter on applicant letter head signed and stamped for file submission for Exemption
2. Payment receipt (according to last update of fees decree)
3. Authorization letter for the person responsible for communication on behalf of applicant during the procedure and this letter should be certified as truly signed
4. CPP of the product
5. SmPC of the product
6. List of the countries where the product is registered & marketed including trade name in each country & marketing status, should be notarized from the chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad
7. Suggested price (signed and stamped on company letter head)
8. Scientific reference of the imported biological products neither WHO prequalified nor marketed in one of the reference countries
9. Source & manufacture of the biological active ingredients.
10. Composition Certificate ( Signed & Stamped by the license holder)
11. Pack Presentation and pack size (s) of the Product is (are) specified
12. Product proposed leaflet (reference insert in case of biosimilar)
13. Module 2, Module 4 and Module 5
14. Plasma master file, PMF approval from health authority & viral inactivation, certificate of release from Health Authority, certificate of analysis (plasma derived product as active or excipient)

**Annex V**: Ministerial decrees and scientific references for file evaluation

**First**: **Ministerial decrees**

- Egyptian pharmacy law (127/1955)
- Egyptian Drug Authority establishing decree (151/2019)
- Prime minister decree at (777/2020)
- EDA Chairman Decree (343/2021)
- EDA Chairman Decree no. 38/2022 regarding amendment of article no. 4 of EDA Chairman Decree no. 343/2021.

**Second: scientific references**

- WHO summary of product characteristics (SmPC) template
- WHO patient information leaflet (PIL) template
- Stability ICH Guidelines (Q1A - Q1E)
- Validation of analytical procedure: text and methodology (Q2).
- Impurities ICH Guidelines (Q3C – Q3D)
- Quality of Biotechnological products (Q5A-Q5E).
- Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (Q6B)
- ICH Guidelines (Q7-Q11)
- ICH Guidelines (Q13-Q14)
- The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions (E1)
- Clinical safety data management: definitions and standards for expedited reporting (E2A).
- Post-approval safety data management: definitions and standards for expedited reporting (E2D).
- ICH Guidelines ( E3-E11)
- ICH Guidelines (E14-E19)
- MedDRA-Medical Dictionary for Regulatory Activities (M1).
- Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (M3)
- Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (M7)
- Drug Interaction Studies (M12)
- ICH Guidelines (S1-S12)
- All relevant WHO guidelines related to biological products