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

Year 2025

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1. Introduction

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

Biological product 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 & re-registration file Code: EDREX.GL.Bioinn.004"

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

"Guideline for Registration of Biosimilar Products in Egypt Code: EDREX.GL.Bioinn.005"

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 registration of 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

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
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 fully 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** .

Inquiry Request steps

1. The applicant is obligated to submit an inquiry request through the automated inquiry system at EDA website for this purpose, 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 request 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 request.
5. after issuance of the inquiry request the applicant can submit a request to be shifted to the fast-track pathway, with the payment of the applied service consideration.
6. The applicant shall 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 for the submitted request from the applicant, including, but not limited to:
   - Discuss the proper 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 registration of biological products.

Exemption steps

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

- Imported biological products submitted for registration that are not marketed 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 according to (**Annex 4**), along with the vigilance file, should be submitted to the scientific file examination unit within **20 WDs** from the date of notification through the inquiry program; otherwise, the inquiry request shall be cancelled.
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 shall provide them within **60 WDs**; otherwise, the application shall be 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 recommendation 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 that are approved by the technical committee for Drug Control nor prequalified by the WHO, the site master file shall be submitted to the Central Administration of inspection on pharmaceutical institutions following the approval of the exemption file by the specialized scientific committee. To preform onsite inspection for the manufacturing site
6. For imported biological products lacking a scientific reference, and after having the specialized scientific committee recommendation for 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 request, the following steps shall be followed:

1. The required documents for pricing shall be submitted to the central administration of drug policies and market support within **30 WDs** of the inquiry request 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 onsite 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 request approval.
3. Good Manufacturing Practice (GMP) certified facilities by a reference regulatory authority or accredited by the WHO are exempted from the onsite inspection visit.
4. Plasma collection centers that are neither accredited by any of the reference countries that are 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 subjected to onsite 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 Applicant may submit the stability study protocol for review and approval by the stability unit within a maximum period of **30 WDs** from the date of submission of the protocol prior to the starting of the stability study and submission of the registration file

Submitting registration file

the registration file shall be prepared according to ICH guideline M4 on the Common Technical Document (CTD), to be submitted to the biological Product registration administration.

1. The registration file for the normal track shall be submitted not later than **two years** from the product pricing date for locally manufactured products and within **60 WDs** from the product pricing date for imported products. Otherwise, the registration application shall be cancelled.
2. 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 step.

Preliminary validation:

1. The submitted registration file will undergo a preliminary validation to ensure that the CTD file is complete and it meets the technical evaluation requirements. This preliminary validation will be conducted within **20 WDs** for the normal and fast track, 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 or not.
3. The applicant shall complete the requirements within **60 WDs**.
4. After submission of the requirements if the required documents are incomplete the applicant shall complete the requirements within another **60 WDs** otherwise the registration application shall be cancelled.

Technical evaluation:

1. The technical evaluation is conducted upon receipt of the complete CTD 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 shall complete these inquiries/ supplementary documents within **60 WDs**, renewed once.
5. The initial review of the submitted inquiries/ supplementary documents 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 shall be addressed within **60 WDs**.
8. If the applicant fails to complete the required requirements/inquiries for the second round, 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 applicant and the central administration of inspection on pharmaceutical institutions of the number of samples required for analysis within **20 WDs** of receiving the CTD registration file for the normal and fast track, and within **8 WDs** for the reliance pathway.
2. The applicant shall 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 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 has to be performed for the other facilities listed in the marketing authorization license, in line with the EDA's Lot release policy.

4. For products that fall within the reliance level 1, a conditional marketing authorization license can 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 to be resubmitted by the Technical Committee for drug control in 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 products registration administration at the central administration of Biological, innovative products and clinical studies, including the required documents for re-registration. This request shall be submitted within the final year of the product marketing authorization license's validity, in accordance with the following procedures:

1. Primary preliminary validation of the updated CTD file is conducted within **15 WDs.**
2. The technical evaluation is conducted upon receipt of the updated CTD file, along with the list of post approval changes made to the product, and the applicant will be notified of any inquiries/additions (if any) **within 30 WDs.**
3. The applicant shall complete these inquiries/ supplementary documents within **60 WDs**, renewable once only
4. The submitted inquiries/ supplementary documents response will be reviewed within **10 WDs**.
5. Failure to meet these inquiries/ supplementary documents in the specified time will result in the product being referred to the Head of the central administration of biologics, innovative products, and clinical studies for further action.
6. All previous steps shall be completed within **40 WDs**.

7. The product is exempt from referral to the specialized scientific committee for biological products, except for products that were previously registered without being presented to this committee.
8. The product is exempt from re-evaluating its stability study if the stability study was evaluated during the product's registration.
9. The inspection file is evaluated according to the inspection plan based on risk assessment.
10. The product's leaflets and outer pack / layout will be evaluated.
11. Pharmacovigilance documents will be evaluated by the relevant administrations.

Note: Without an applicant's request, the product marketing authorization license's validity can be extended after its invalidation date in emergency cases.

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 biological, 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 biological registration administration.
4. If a plasma derivative is used as an excipient in a biological product, the applicant shall provide evidence that the supplier is committed to notify 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 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 shall 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 onsite inspection shall be conducted in case two consecutive non-conformities issued through lot release administration process for a registered biological product, based on a letter from the central administration of biological, innovative products, and clinical studies to central administration of inspection on pharmaceutical institutions
2. Biological products along with its registration numbers are announced on the EDA website not 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 apply to register a second brand product 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 biological product registration pathways

Annex II: Detailed table of regulatory pathways for biological product registration

Annex III: Documents required for the inquiry request

Annex IV: Documents required for the exemption file

Annex V: Ministerial decrees and scientific references for file evaluation

Annex I: Key criteria for biological product registration track pathways:

Registration track pathways	**Main criteria**
Normal track	To register a product under this pathway, the product submitted for registration shall be a biological product, whether locally manufactured or imported **Requirements for imported products:** - It shall be marketed in the country of origin knowing that some vaccines included in the routine immunization schedule of the central administration of preventive affairs of the ministry of health and population are exempted from this requirement - The product shall be marketed in at least one of the reference countries approved by the Technical Committee for Drug Control or prequalified by WHO. If it is neither marketed in any of the approved reference countries nor prequalified by 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 - Mandatory vaccines included in the Expanded Program on Immunization, school-age vaccinations, traveler vaccinations, and emergency vaccines - Products intended for the treatment of serious epidemic diseases with no comparable alternatives - Products classified as an orphan drug - 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. -The submitted CTD to the EDA shall be identical to the version approved by the reference regulatory authorities -The submitted product has not been rejected by any of the reference regulatory authorities for reasons related to the product's safety or efficacy -If there are any potential differences between the CTD submitted to the EDA and that submitted to the reference regulatory authorities, these changes shall be justified for evaluation on a case-by-case basis. -In the case of Level 1, a detailed assessment report and/or questions and answers issued by the reference regulatory authorities shall 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	
				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
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 on all relevant manufacturing sites, including active ingredient plants, block production plants, and finished product plants, following site master file evaluation, in	Factories that are accredited by one of the reference regulatory authorities or prequalified from the WHO are exempt from	Inspections are conducted on all relevant manufacturing sites, including active ingredient plants, block production plants, and finished product plants, following site master file evaluation, in	Inspections are conducted on all relevant manufacturing sites, including active ingredien	Factories that are accredited by one of the reference regulatory authorities or prequalif	The site master file is submitted for evaluation after obtaining the approval of the scientific committee for the exception, and then the	Factories that are accredited by one of the reference regulatory 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

	accordance with a risk-based inspection plan	the inspection visit	accordance with a risk-based inspection plan	t plants, block production plants, and finished product plants, following site master file evaluation, in accordance with a risk-based inspection plan	ied from the WHO are exempt from the inspection visit	factory is inspected		

Stability Protocol Review	The stability protocol shall be submitted for review and approval by the stability unit within period of **30 WDs** as a maximum 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 shall be submitted by maximum **two years** from the date	It shall be submitted within **60 WDs** from the pricing date, otherwise the		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

	of pricing the product, otherwise the registration application will be considered cancelled	registration request will be considered cancelled				Registration administration within the last year from the 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** -The applicant will complete these comments/requirements and respond to the initial letter within **60 WDs**, renewable once -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 -The technical evaluation process will be completed within **10 WDs** -The applicant will be notified of any additional requirements/inquiries (if any) and will complete them within **60 WDs** -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 45 WDs**- -The applicant will complete these comments/requirements, and a response to the initial letter will be made within **60 WDs**, renewable once. -The company will conduct an initial review of the submitted requirements within **5 WDs** to ensure they are complete before completing the evaluation process. -The technical evaluation process will be completed within **10 WDs** The applicant will be notified of any additional requirements/inquiries (if any) and will complete them **within 60 WDs**	-The applicant will be evaluated and notified of any comments within **10 WDs**. -The applicant will complete these comments/additions and respond to the initial letter within **60 WDs,** renewable once The company will conduct	-The applicant will be evaluated and notified of any comments within **15 WDs** -The applicant will complete these comments/requirements, and the initial response will be within **60 WDs**, renewable once	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

	-The registration file evaluation will be completed after all requirements have been completed and inquiries have been clarified within **35 WDs**.	If the applicant fails to complete the required requirements or inquiries, the registration application will be considered cancelled The registration file evaluation will be completed after all requirements have been met and inquiries have been clarified within **30 WDs**	an initial review of the submitted additions within **2 WDs** to ensure they are complete before completing the evaluation process The technical evaluation process will be completed within **8 WDs**	-The company will conduct an initial review of the submitted requirements within **5 WDs** to ensure they are complete before completing the evaluation process -The technical evaluation process will be completed within **10 WDs** -The applicant will be notified of any additional requirements/inquiries (if any) and will complete	

Registration file evaluation **(continued)**				them within **60 WDs** -If the applicant fails to complete the required requirements or inquiries, the registration application will be considered cancelled -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** -The company shall 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		Analysis can be done before the first shipment is released to the market	Analysis is done at the pre-registration stage	X
			The central administration of inspection on pharmaceutical institutions will be notified of the number of samples required for analysis within **8 WDs** The company shall 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 from the date of receiving of the complete file	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 for Drug Control within **20 WDs**
License of product registration	• In case of rejection, the applicant will be notified • In case of approval, the product will be granted a marketing authorization license valid for five years			

Annex III: Documents required for the inquiry request:

- 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 shall 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/license holder shall 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 products imported from non- reference country, GMP and manufacturer license for the manufacturer.

For locally manufactured products, Whether the active ingredient or bulk from abroad **to be manufactured, filled and packaged locally, the following documents shall 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 shall 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 shall also be submitted. The inquiry shall be submitted using the company

-The naming request shall 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