



Guidelines on Veterinary Pharmaceuticals Variations

Year 2026

Code:EDREX:GL.CAPP.037

Version No: 2

Issue Date: 17/9/2026

Table of Contents

Content	Page
1. Background	3
1.1. Objective	3
1.2. Scope	3
2. Definitions	3
3. Procedures	4
3.1. Overview on handling variation requests	4
3.2. Variation evaluation route	5
4. General consideration	6
4.1. Post Market changes for Specification & Composition variation	6
4.1.1 Administrative Changes Concerning Specifications & Composition Variation	6
4.1.2. Quality Changes Concerning Specifications & Composition Variation	6
4.2. Post Market Changes for manufacturers of API for veterinary pharmaceuticals	17
4.2.1. Administrative Changes concerning manufacturer of the API	17
4.2.2 Quality Changes Concerning manufacturer of the API	17
4.3. Post Market Changes Concerning Ownership / Manufacturer of Finished Product	20
4.3.1. Administrative Changes concerning Ownership / Manufacturer of finished product	20
4.3.2. Quality Changes Concerning Ownership / Manufacturer	28
4.3.3. Change Type of Registration	33
5. Annexes	41
6. Templates	45
7. Variation Flow Chart	52
8. References	53
9. History of Change	54

1. Background:

This guidance document is intended to provide supportive information on how to present an application to implement a variation to a veterinary medicinal product.

Changes to the details of the product in order to accommodate technical and scientific progress, or to improve or introduce additional safeguards for the registered veterinary product are referred to as variations.

Requirements for the different types of variations are set out in this guidance in order to facilitate the submission of appropriate documentation by applicants and their assessment by EDA and to ensure that variations to the veterinary medicinal product do not result in health concerns.

*This guidance supersedes the guidance published in 2024.

1.1 Objective:

These guidelines are intended to:

- Assist applicants with the classification of changes made to the registered veterinary medicines
- Provide guidance on the technical and other general data requirements to support changes made to the registered veterinary medicines

1.2 Scope:

This guidance document is applicable to veterinary pharmaceuticals variations.

2. Definitions:

Variations: Administrative &/or post-authorization changes that take place on the post marketed finished pharmaceutical product or active pharmaceutical ingredients.

Submission Guidance: List of Required documents used by companies to fulfill the submitted variation requests.

Final approval: Letter stating that EDA approved the change submitted by the applicant company after fulfilling the required studies.

Finished Pharmaceutical Product (FPP): The dosage form in the final immediate packaging intended for marketing.

Active substance: Any substance or mixture of substances having pharmacological activity intended to be used in manufacture of FPP.

Excipient: Any substance or compound other than active substance and packaging materials that intended to be used in manufacture of FPP.

Container closure system: The sum of packaging components that together contain and protect pharmaceutical product, including primary and secondary packaging components.

Production Batch: A batch of FPP manufactured at production scale by using production equipment in a production facility.

Marketing Authorization: is the Pharmaceutical Product Registration License.

EDA's approved Reference Countries List: List of reference Countries according to the most updated decisions of the technical committee of drug control.

3. Procedures

3.1 Overview on handling variation requests:

These guidelines include specific examples of changes. However, it should be noted that a change not covered by these guidelines, should be evaluated through a risk-based assessment.

It remains the responsibility of the applicant to submit relevant documentation to justify that the change will not have a negative impact on the quality, safety and efficacy of the product. In addition, the applicant is responsible to notify the Variation Administration in EDA in case of any unfavorable out of specification that has negative impact on the quality of the finished pharmaceutical products.

The applicant will apply the variation request according to the submission guidance.

For All variations when accelerated stability study is required, the applicant should place the first production-scale batch of the Finished Product produced with the new variation into the long-term stability program. A commitment is given that this long-term stability study will be finalized and that data will be provided immediately to the Variation Administration if outside specifications or potentially outside specification at the end of the approved shelf life (with proposed action).



3.2 Variation Evaluation Routes

3.2.1 Full Evaluation Route:

Full evaluation will apply to variations subject to EDA full review and assessment prior to change. The procedure starts from the date of submission of a valid payment receipt and variation request. Then, the application will undergo initial review and technical evaluation by the concerned unit of variation. For Further consultation, the variation request may be subjected to variation evaluation committee (VEC) or to technical committee for drug control (TCDC) or both. By the end of the technical evaluation period, the variation administration will determine its decision on the variation request and inform the applicant about the acceptance or rejection of the variation

3.2.2 Reliance Evaluation Route:

For imported finished product that has been approved by at least one reference regulatory authority (SRA), the variation administration will implement regulatory reliance for assessment of variations that were already approved by other reference countries (SRAs–Annex II).

Reliance on other SRAs involves leveraging the assessments and evaluations conducted by trusted regulatory agencies instead of duplicating the entire evaluation process. However, EDA remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.

The application should be identical to that approved by the SRA in terms of dosage form, strength and formulation (as applicable) and the applicant should therefore confirm and attest that the information (variation dossier) submitted to the EDA is the same as that submitted to reference SRA along with a copy of the reference SRA decision or other document confirming the final decision of the reference SRA. A linking between the application and the approval from the Reference Authority must be declared (unless otherwise justified)

When submitting proof of the SRA final decision, EDA acknowledges the different evaluation criteria, variation categorization and approval process between each individual SRA as well as the difference between the SRA and the EDA procedures.

4. General Consideration

4.1 Post Market Changes for Specifications & Composition Variation

4.1.1 Administrative Changes Concerning Specifications & Composition Variation

	Requirements	
	CADC	Stability
4.1.1.1 Change in name of active substance or of an excipient		

Condition to be fulfilled

The substance shall remain the same

4.1.2 Quality Changes Concerning Specifications & Composition Variation

4.1.2.1 Description and composition

4.1.2.1.1 Change in the composition (excipients) of the finished pharmaceutical product		Requirements	
		CADC	Stability
a) Changes in components of the flavoring or coloring system			
1	Addition, deletion or replacement	A*	6M**
2	Increase or reduction		6M**
b) Other (excipients)			
1	Replacement of a single excipient with a comparable excipient with the same functional characteristics and same quantity at a similar level.	A*	6M**
2	Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the medicinal product	A*	6M**
3	Clarification /Change of excipients functions for non-functional excipients		
4.1.2.1.2 Changing / Clarifying Active/In active Ingredient Specification			
1	Change from one pharmacopeia to another pharmacopeial specification.	N***	

2	Change from pharmacopeial specification to in-house specification. (If change is within pharmacopeial limits)	A*	6 M**
3	Change from pharmacopeial specification to in-house specification. (If there is no change within pharmacopeial limits)		
4	Change from in-house specification to pharmacopeial specification.	N***	
5	Clarifying specification for active ingredient (if API specs: in house)	A*	6 M**
6	Clarifying specification for active ingredient (if API specs: pharmacopeial specs)	N***	
7	Addition of Another Pharmacopeial Specification for active /in actives.		
8	Clarification /Change of excipients Specifications.		
4.1.2.1.3 Changing / Clarifying salt equivalence and crystalline state			
1	Change in salt equivalence and crystalline state (e.g., hydrate, solvate, Polymorph...)	A*	6M**
2	Clarification of salt equivalence and crystalline state (e.g., hydrate, solvate, Polymorph...)		
4.1.2.1.4 Change in particle size for water Insoluble or sparingly soluble API (particle size must be stated in suppliers COA by D90 or mesh size)		A*	6M**
4.1.2.1.5 Introduction or change in the overage that is used for the active substance			

Requirements guidance:

- * Batch Analysis for first production batch at CADC labs.
- ** Result of stability testing generated on first production batch with a minimum of 6 months accelerated testing.
- ***Notification.

Submission guidance:

1-Common Administrative Documents: Refer to Annex III

(Should be submitted with all variations in addition to Relevant Documents According to the Variation Type)

2-Relevant Documents According to Composition & Specification variation type:

Change in name of active substance or of an excipient
Required documents
1-Old composition "signed and stamped".
2-New composition "signed and stamped".
3-Comparison table between old and new composition
4-Pharmacopeial monograph for active ingredient or reference for the name of inactive ingredient.

Change in the composition (excipients) of the finished pharmaceutical product/ Elimination, Reduction or Addition of an overage
Required documents
1-Old composition "signed and stamped".
2-New composition "signed and stamped".
3-Comparison table between old and new composition "signed and stamped".
4-Scientific justification & Reference and write in composition the cause of Addition (e.g., for Manufacturing loss) (In case of Addition of an overage).

Change / Clarification of Active/ Inactive Ingredient Specification
Required documents
1-Old composition "signed and stamped".
2-New composition "signed and stamped".
3-Comparison table between old and new composition "signed and stamped".
4-Pharmacopeia Monograph (Last Edition)
5-Comparison between Old & New Finished Pharmaceutical Product Specification signed and stamped.
6-Import plans or approvals, Customs releases, invoices and supplier certificates, have the same batch numbers that were imported for three consecutive years. (In case of clarifying Specifications of Active Ingredient)
Clarification/Change of salt equivalence and/or crystalline state (E.g., hydrate, solvate, polymorph)
Required documents
1-Old composition "signed and stamped".
2-New composition "signed and stamped".
3-Comparison table between old and new composition. "Signed and stamped".
4-Scientific Reference for Molecular weight of base and salt. (e.g., Pharmacopeia).
5-Calculations of salt equivalence on company paper signed and stamped.
6-In case of clarification: a report from Central Administration of Inspection on Pharmaceutical Institutions stating the form of used materials including batch record and any previous studies on the same batch.
7-In case of clarification: Import plans or approvals, Customs releases, invoices and supplier certificates, have the same batch numbers that were imported for three years.
Clarification /Change in particle size for water Insoluble or sparingly soluble API (Particle size must be stated in suppliers COA by D90 or mesh size)
Required documents
1-Old composition "signed and stamped".
2-New composition "signed and stamped" (State Range of D90 in New Composition).
3-Comparison table between old and new composition "signed and stamped".
4-C.O. A of all suppliers for active ingredient stated D 90 or mesh size

5-A report from Central Administration of Inspection on Pharmaceutical Institutions stating the Range of D90 of used materials (In case of Clarifying Particle Size)

6-Import plans or approvals, Customs releases, invoices and supplier certificates, have the same batch numbers that were imported for three years (In case of Clarifying Particle Size).

4.1.2.2 Control of finished pharmaceutical product

4.1.2.2.1 Change in the specification parameters and/or limits of the finished pharmaceutical product		Requirements	
		CADC	Stability
a	Tightening of specification limits		
<u>Condition to be fulfilled</u> 1. The test procedure shall remain the same, or changes in the test procedure shall be minor 2. The change should be within the range of currently approved limits.			
b	Deletion of a non-significant specification parameter (e.g., deletion of an obsolete parameter such as odor and taste or identification test for a coloring or flavoring material)		
<u>Condition to be fulfilled</u> 1. The change shall not relate to an unexpected event during manufacture. 2. The change shall not concern a critical parameter or have the potential to affect the identity, strength, quality, purity, potency or physical characteristics of the finished product			
c	Addition of a new specification parameter to the specification with its corresponding test method	A*	
d	Widening of specification limits “the change is not the result of unexpected events arising during manufacture”	A*	6M**
e	Change the Pharmacopeial product from Pharmacopeial product to Non pharmacopeial one	A*	6M**

4.1.2.2.2 Change in the shelf life or storage conditions of the finished pharmaceutical product		Requirements	
		CADC	Stability
a	Extension of the shelf life of the finished pharmaceutical product As packaged for sale (supported by real time data) After first opening (supported by real time data) After dilution or reconstitution (supported by real time data)		Approval from Stability Administration for proposed Change.
b	Change in storage conditions of the finished pharmaceutical product or the diluted/reconstituted product		Approval from Stability Administration for proposed Change
<u>Condition to be fulfilled</u> -Approval from Stability Administration for proposed change.			
c	Reduction of the shelf life of the finished product as packaged for sale, after first opening or after dilution or reconstitution		
<u>Condition to be fulfilled</u> The change shall not be the result of unexpected events arising during manufacture or because of stability concerns.			

Requirements guidance:

* Batch Analysis for first production batch at CADC labs.

** Result of stability testing generated on first production batch with a minimum of 6 months accelerated testing.

***Notification

Submission guidance:

1 -Common Administrative Documents: Refer to Annex III

(Should be submitted with all variations in addition to Relevant Documents According to the Variation Type)

2-Relevant Documents According to Composition & Specification Variation type:

(Control of finished pharmaceutical product)

Change in the specification parameters and/or limits of the finished pharmaceutical product
Required documents
1- Old finished pharmaceutical product specifications "signed and stamped"
2- New finished pharmaceutical product specifications "signed and stamped"
3- Comparison table between old and new finished pharmaceutical product specifications
4- Scientific justification & Reference for the requested change
5-Pharmacopeia Monograph
6- Scientific Reference for Finished Pharmaceutical Product PH (In Case of Change PH Range)
Change in the shelf life or storage conditions of the Finished Pharmaceutical product
<u>Reduction of the shelf life</u>
Required documents
1- Scientific Justification for this Reduction
2-Any Stability studies or documents for new shelf life clarifying the need of reduction of shelf life must be submitted
3- In case of imported or under license files: declaration letter from LH/MAH in COO signed and stamped, stating reasons of reduction.
Change in the shelf life or storage conditions of the Finished Pharmaceutical product
<u>Extension of the shelf life</u>
Required documents
Stability study approval
Change in the storage conditions of the Finished Pharmaceutical product or the diluted/reconstituted product
Required documents
Stability study approval

4.1.2.3 Change in Physical Character of Finished Product:		Requirements	
		CADC	Stability
a	Change in range of color without any qualitative or quantitative change in excipients or active ingredients (To be as the stated color in CADC COA)	N	
b	Change in range of color without any qualitative or quantitative change in excipients or active ingredients (The Color Range differs from what is stated in CADC COA)	A*	**6M if needed
<u>Condition to be fulfilled</u> -The change shall not affect the delivery, use or safety of the finished product. -The finished product release and shelf-life specifications shall not have been changed except for appearance.			
c	Change in scoring /break lines not intended to divide the FPP into equal doses		
d	Change in scoring /break lines intended to divide into equal doses	A*	

Requirements guidance:

* Batch Analysis for first production batch at CADC labs.

** Result of stability testing generated on first production batch with a minimum of 6 months accelerated testing.

Submission guidance:

1-Common Administrative Documents: Refer to Annex III

(Should be submitted with all variations in addition to Relevant Documents According to the Variation Type)

2-Relevant Documents According to Composition & Specification Variation type:

(Change in Physical Character of Finished Product)

Change in color of finished product
Required documents
1- Sample (IF needed)
2- Old & new certificate of analysis
3- Pharmacopeia monograph & certificate of analysis of supplier of active ingredient (In case of change in range of color without any qualitative or quantitative change in composition)
4- Scientific Justification for color change with scientific reference
5- Manufacturing process flow chart (In case of the change in physical character is due to change in manufacturing process).

Change in scoring configuration
Required documents
1-Old composition "signed and stamped". (If needed)
2-New composition "signed and stamped". (If needed)
3- Safety data sheet for Ink including composition of ink (In case of change or addition of imprints)
4- Reference for scoring (In case of change of scoring/break lines on tablets).

4.1.2.4 Change in Container closure system			
4.1.2 4.1 Change in primary packaging of the finished pharmaceutical product		Requirements	
		CADC	Stability
a)	Qualitative and quantitative packaging (composition within the same packaging type)		
	1. Sterile medicinal products / Semi-solid and non-sterile liquid pharmaceutical forms	A*	6M**
	2. Solid pharmaceutical forms		6M**
<u>Condition to be fulfilled</u>			
The change only concerns the same packaging container type			
b)	Change to a new type of packaging container such as glass to plastic or addition of a new container	A*	6M**
4.1.2.4.2 Change in any part of the primary packaging material not in contact with the finished product formulation (such as change of color due to different plastic used for flip-off caps, color code rings on ampoules or change of needle shield			
<u>Condition to be fulfilled</u>			
The change shall not concern a part of the packaging material that affects the delivery, use, safety or stability of the finished product			
4.1.2.4.3 Change in shape or dimensions of the container or closure (immediate packaging)			
1. Non sterile finished product			
<u>Condition to be fulfilled</u>			
-The change shall not concern a part of the packaging material, which affects the delivery, use, safety or stability of the finished product.			
-The change shall not concern the qualitative or quantitative composition of the container.			
2. Sterile finished product		A*	6M**

4.1.2.4.4 Change in pack size of the finished product			
a)	Change in pack size (number of units e.g., tablets, ampoules, etc. in a pack)		
<u>Condition to be fulfilled</u>			
The primary packaging material shall remain the same			
b)	Change in the fill weight/fill volume of non-sterile multi-dose medicinal products		6M**
C)	Change in the fill weight/fill volume of sterile multi dose medicinal products	A*	6M**

Requirements guidance:

* Batch Analysis for first production batch at CADC labs.

** Result of stability testing generated on first production batch with a minimum of 6 months accelerated testing.

Submission guidance:

1-Common Administrative Documents: Refer to Annex III

(Should be submitted with all variations in addition to Relevant Documents According to the Variation Type)

2-Relevant Documents According to Composition & Specification Variation type:

(Change in Container closure system)

Change in Container closure system
Required documents
1-Cover letter clarifying full detailed description for type of old / new pack its capacity and liner
2-Sample "If needed"
3-Factory license with suitable production line "in case of change to a new type of container or addition of a new container"

4.2 Post Market Changes for Manufacturers of the API for veterinary pharmaceuticals		
4.2.1 Administrative Changes concerning Manufacturer of the API		
	Requirements	
	CADC	Stability
4.2.1.1 Change in Name and/ or Address of Manufacturer of the API		
Condition to be fulfilled		
-The manufacturing site and all manufacturing operations must remain the same.		
4.2.1.2 Deletion of manufacturing sites for an API		
Condition to be fulfilled		
-There shall at least remain one site/manufacturer, as previously authorized performing the same function as the one(s) concerned by the deletion.		

4.2.2 Quality Changes concerning API		
	Requirements	
	CADC	Stability
4.2.2.1 Addition of a new manufacture for an API	A*	6 M**

Requirements guidance:

*Analysis of the first production batch of Finished Pharmaceutical product manufactured from the API manufacturer at CADC labs.

**Results of stability testing generated with a minimum of 6 months Accelerated testing, and to be released -to the market by Central Administration of Inspection on Pharmaceutical Institutions after evaluating the results of a minimum of 3 months of the first production batch of Finished Pharmaceutical product manufactured with the new API manufacturer.

Submission guidance:

1-Common Administrative Documents: Refer to Annex III

(Should be submitted with all variations in addition to Relevant Documents According to the Variation Type)

2- Relevant Documents According to variation type of API for veterinary pharmaceuticals:

Change in the name and/or address of a manufacturer of an API	
1	Recent API Manufacturer certificate with the new name as the same address mentioned in old name certificate, submit one of the following: ▪ GMP. ▪ ISO 9001 – 2015 (for Minerals, Vitamins and Extracts only). ▪ CPP. ▪ Written confirmation letter. In case of new name certificate is not including API: Complete & recent API manufacturer license (or CPP) with the same new name certificate address & mentioning the API(s) name.
2	API Manufacturer certificate with the old name as the same address mentioned in new name certificate, submit one of the following: ▪ GMP. ▪ ISO 9001 – 2015 (for Minerals, Vitamins and Extracts only). ▪ CPP. ▪ Written confirmation letter.
3	In case of local API(s) manufacturer(s), Submit one of the following: For current & required to be added manufacturer(s), submit one of the following: ▪ API Manufacturer License issued from Egyptian Drug Authority mentioning the API production line. ▪ Data Certificate with API Manufacturer name issued from Egyptian Drug Authority mentioning the API production line.
4	In case of the new name GMP is not issued yet: Declaration letter from the authority which is responsible for the manufacturer inspection declares the name change without changing the manufacturing site (location).
5	API variation Notification Form (template 2)

Deletion of manufacturing sites for an API	
1	For Current API manufacturer(s), Submit one of the following: ▪ GMP. ▪ ISO 9001 – 2015 (for Minerals, Vitamins and Extracts only). ▪ CPP. ▪ Written confirmation letter.
2	For Current local API manufacturer(s), Submit one of the following: ▪ API Manufacturer License issued from Egyptian Drug Authority mentioning the API production line. ▪ Data Certificate with API Manufacturer name issued from Egyptian Drug Authority mentioning the API production line.
3	API variation Notification Form (template 2)

Addition of a new manufacturer for an API	
1	For API manufacturer(s) to be added, Submit one of the following: ▪ GMP. ▪ ISO 9001 – 2015 (for Minerals, Vitamins and Extracts only). ▪ CPP. ▪ Written confirmation letter. <u>N.B.:</u> the submitted certificate is required to be complete, recent, mentioning the API(s) manufacturer name & its address & the API(s) name(s). <u>N.B.:</u> if the submitted certificate does not mention the API(s) name: Submit a complete, recent API(s) manufacturer license (or CPP) with the same address of GMP certificate & mentioning the API(s) name.
2	In case of <u>local</u> API(s) manufacturer(s), Submit one of the following: ▪ API Manufacturer License issued from Egyptian Drug Authority mentioning the API production line. ▪ Data Certificate with API Manufacturer name issued from Egyptian Drug Authority mentioning the API production line.
3	API(s) manufacturer(s) CoA(s), it should fulfill the following: ▪ With the same specification of the API in the product registration license composition. ▪ Matching with API monograph in all tests and specification limits ranges. ▪ Mentioning the expiry date or re-test date.
4	In case of the submitted CoA on manufacturer letterhead Different from the API manufacturer: Relationship Declaration Letter between the two manufacturers is required.
5	Updated Pharmacopeia Monograph for API(s).
6	API variation Notification Form (template 2)

4.3 Post Market Changes Concerning Ownership /Manufacturer of Finished Product		
4.3.1 Administrative Changes concerning Ownership /Manufacturer of finished product		
	Requirements	
	CADC	Stability
4.3.1.1 Change in Name and/or Address of License Holder or Marketing Authorization Holder		
<u>Condition to be fulfilled</u> -Product License Holder and/or Marketing Authorization Holder shall remain the same legal entity.		
4.3.1.2 Change in Name and/or Address of Manufacturing sites (including bulk manufacturer, packager & batch releaser)		
<u>Conditions to be fulfilled</u> -The physical location of the manufacturing site and all manufacturing operations must remain the same		
4.3.1.3 Change in Applicant (Imported FPP)		
<u>Conditions to be fulfilled</u> -The applicant shall be authorized for registration.		
4.3.1.4 Modification of registration license		
<u>Conditions to be fulfilled</u> -Approval of EDA relevant department (s) on related modification.		
4.3.1.5 License Holder or Marketing Authorization Holder transfer		

Conditions to be fulfilled

- The new FPP LH/MAH is a different legal entity.
- If there is another product registered or under registration with the same name in the old company, either one of the products' names should be changed.
- If the product is a line extension to a product registered or under registration owned by the new company, the names should be unified.

4.3.1.6 Addition/Change of FPP Marketing Authorization Holder in Egypt (Imported, UL & Bulk FPP)

Conditions to be fulfilled:

- FPP MAH in Egypt must comply with all FPP specifications, composition and all manufacturing operations as mentioned in the FPP CPP from NRA in the country of origin.

4.3.1.7 Change/addition Supplier of solvent for a FPP (Local & UL FPP)

Conditions to be fulfilled

- Solvent from new supplier must be registered.
- Shelf life of solvent from new supplier must comply with shelf life of the FPP.
- Pack of solvent from new supplier must comply with previously approved pack.

4.3.1.8 Deletion of manufacturing/packaging site for a FPP

Conditions to be fulfilled

- There shall at least remain one site/manufacturer, as previously authorized performing the same function as the one(s) concerned by the deletion.

Submission guidance

1-Common Administrative Documents: Refer to Annex III

(Should be submitted with all variations in addition to Relevant Documents According to the Variation Type)

2- Relevant Documents According to Ownership & Manufacturer variation type:

Change in Name / Address of License Holder/Marketing Authorization Holder (Local FPP)	
1	Declaration Letter With list of all products affected by this name change. *Signed & stamped.

2	Declaration Letter The proposed company trade name in English *Signed & stamped.
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Change in Name / Address of License Holder/Marketing Authorization Holder (Imported, UL & Bulk FPP)	
1	Declaration Letter From LH/MAH Stating that it's the same legal entity with no change in LH/MAH, product specifications, quality, composition, manufacturing site & process. Authenticated from Chamber of commerce & Egyptian consulate/embassy
2	Official document from a relevant official body In case of changing address Justifying the change in address

Change in Name / Address of Manufacturing sites (Local FPP)	
1	Declaration Letter With list of all products affected by this name change. *Signed & stamped.
2	Declaration Letter The proposed company trade name in English *Signed & stamped.

Change in Name / Address of Manufacturing sites (Imported, UL & Bulk FPP)	
1	No Change Declaration Letter From LH Stating that there's no change in the physical location of the manufacturing site, manufacturing process, quality & composition of the product. Authenticated from Chamber of commerce & Egyptian consulate/embassy
2	Certificate of Good Manufacturing Practice (GMP) For the Site with the new name/address Valid Authenticated from Chamber of commerce & Egyptian consulate/embassy
3	Certificate of Good Manufacturing Practice (GMP) For the Site with the old name/address Authenticated from chamber of commerce & Egyptian consulate/embassy

4	Official document from a relevant official body In case of changing address Justifying the change in address
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Change in Applicant for Registration (Imported, UL & Bulk FPP)	
1	In Case of Imported finished Pharmaceutical Product if the applicant is either Scientific Office or Company the following documents to be submitted: * Scientific Office: a) Authorization letter for the scientific office to register finished Imported veterinary Pharmaceutical Products” issued by inquiry requests unit for veterinary pharmaceuticals. b) Declarations Letter Clarifying the Company's profile Code signed & stamped * Company: - Last updated importer record.
2	Termination letter From License Holder The Product trade Name & Reg. no. is mentioned Name & address of old Applicant mentioned Authenticated from chamber of commerce from country of origin & the Egyptian consulate /embassy + Original Arabic translation from a certified translation center Waiver From Old Applicant The product trade name & reg. no. is mentioned Authenticated from bank
3	Authorization Letter From License Holder The Product trade name & Reg. no. is mentioned Name & address of new applicant mentioned Clarifying its responsibilities for registration, all regulatory activities & signing contracts. Authenticated from chamber of commerce from country of origin & the Egyptian consulate/embassy + Original Arabic translation from a certified translation center. OR Agency Agreement between License Holder and new Applicant The Product trade name & reg. no. is mentioned Name & address of new applicant mentioned (as written in its commercial register)

	Clarifying its responsibilities for registration & all regulatory activities. Authenticated from chamber of commerce from country of origin & the Egyptian consulate/embassy + Original Arabic translation from a certified translation center
4	Manufacturing contract For UL FPP, between new applicant & manufacturer. Authenticated from Chamber of Commerce, Egyptian Consulate/Embassy and Bank
5	Attached Annex Mentioning the product name & reg. no.

Modification of Registration License	
1	EDA Approval Of the required change to be updated in the registration license issued from relevant EDA department

License Holder Transfer (Local FPP)	
1	Cover letter on new License Holder letterhead clarifying the proposed change Authenticated from Bank
2	Ownership Waiver From old LH to new LH Authenticated from Real Estate Registry at Ministry of Justice Product trade name, strength, dosage form & reg.no. is mentioned.
3	Manufacturing contract Between LH & manufacturing site, valid & Authenticated from Bank.
4	Attached Annex of the contract The product trade name & reg. no. is mentioned. Authenticated from Bank.
5	Composition declaration on new LH letterhead. Identical to the one attached with the registration license or to the latest finally approved composition Signed & stamped
6	Declaration Letter: (Template 3) From old LH, declaring all registered & under registration veterinary products containing the same active ingredient, Signed & stamped.

7	Declaration Letter: (Template 3) From new LH, declaring all registered & under registration veterinary products containing the same active ingredient, Signed & stamped
8	Declaration Letter: (Template 4) From new LH Stating all owned registered & under-registrations veterinary products (In case of Toll -under construction companies) Signed & stamped.
9	Declaration Letter No change in composition, specifications, manufacturing process, or container/closure system of the FPP, signed & stamped.

License Holder/ Marketing Authorization Holder Transfer (Imported, UL & Bulk FPP)	
1	Declaration Letter From new LH/MAH Stating the ownership transfer Ensuring that there is <u>NO CHANGE</u> in product composition, specification, manufacturing process and container/closure system. The product trade Name & Reg. no. is mentioned. Authenticated from Chamber of commerce & Egyptian consulate/embassy + Original Arabic translation from a certified translation center.
2	Authorization Letter From new LH/MAH in Egypt to the current applicant. The product trade name & reg. no. is mentioned Name & address of applicant mentioned Clarifying its responsibilities for registration & all regulatory activities Authenticated from chamber of commerce & the Egyptian consulate/embassy
3	Manufacturing contract For UL FPP Between new LH/MAH & manufacturer. Authenticated from Chamber of Commerce, Egyptian Consulate/Embassy and Bank <u>If the contract is between the applicant & manufacturer:</u> A letter from LH/MAH authorizing the applicant to sign contracts

4	Packaging contract For Bulk FPP Between new LH/MAH & packager. Authenticated from Chamber of Commerce, Egyptian Consulate/Embassy, and Bank <u>If the contract is between the applicant & packager: A letter from LH/MAH authorizing the applicant to sign contracts</u>
5	Attached Annex Mentioning the product name & reg. no. Authenticated from Bank .

Addition/Change of Marketing Authorization Holder in Egypt (Imported, Under License & Bulk FPP)	
1	Declaration Letter From LH in Country of origin. Product name, reg.no. mentioned Appointing the New MAH in Egypt clarifying its full responsibilities including but not limited to the right to sell the product in Egypt Authenticated from Chamber of commerce & Egyptian consulate/embassy
2	Applicant Authorization Letter From New MAH in Egypt Product name, reg. no. mentioned Name & address of applicant mentioned matching with Commercial Register <u>Clarifying its responsibilities for registration & all regulatory activities</u> Authenticated from chamber of commerce & the Egyptian consulate/embassy
3	NO CHANGE Declaration Letter From New MAH in Egypt Ensuring that there is <u>NO CHANGE</u> in product composition, specification, manufacturing process and container/closure system. Authenticated from chamber of commerce & the Egyptian consulate/embassy

Change/addition Supplier of solvent for a FPP (Local & Under License FPP)	
1	EDA valid registration license of solvent If invalid: Approval for registration renewal
2	Last Updated Commercial Register of manufacturer of solvent
3	Latest New Manufacturing site license of manufacturer of solvent
4	Letter of Variation For UL Products From product LH in Country of Origin Stating the required variation authenticated from chamber of commerce, Egyptian embassy/consulate or notary.

Deletion of manufacturing/packaging site for a FPP	
1	Cover letter on the license holder's (LH) official letterhead clearly describing the proposed change, authenticated by the bank.
2	Waiver From the current manufacturing/packaging site: Mentioning the product name and registration number. Confirming approval for the transfer of manufacturing and/or packaging of the product to the new manufacturing/packaging site. Authenticated by the bank. OR Termination letter issued by the license holder to the current manufacturing/packaging site, signed and stamped, with proof of delivery.
3	Declaration letter confirming that there are no changes to the product composition, specifications, manufacturing process, or container closure system. Signed and stamped.

4.3.2. Quality Changes Concerning Ownership /Manufacturer variation				
4.3.2.1 Change in the manufacturing site for part or all of the manufacturing process of the FPP		Requirements		
		CADC	Stability	Process validation
a)	Addition or replacement of a site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging for local FPP	- Please Refer to Updated Regulations of Addition / Change of manufacturing site published on 4/3/2026		
	Addition or replacement of a site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging for imported FPP	*A	**6M	*** process validation
Condition to be fulfilled -The proposed site appropriately authorized (To perform the specified operation for the concerned FPP) -No change in FPP container closure system. -Manufacturing at the new site shall be in a compliance with cGMP.				
b)	Addition or replacement of primary packaging site (Local).	- Please Refer to Updated Regulations of Addition / Change of manufacturing site published on 4/3/2026		
	Addition or replacement of primary packaging site (Imported).	*A	**6M	*** process validation
Condition to be fulfilled -The proposed site appropriately authorized (To perform the specified operation for the concerned FPP) -No change in FPP container closure system. -Manufacturing at the new site shall be in a compliance with cGMP. -The change does not concern sterile FPP.				
c)	Addition or replacement of secondary packaging site (non-functional)			
Conditions to be fulfilled -The proposed site appropriately authorized (To perform the specified operation for the concerned FPP) -No change in FPP container closure system. -Manufacturing at the new site shall be in a compliance with cGMP.				

d)	Addition or replacement of batch release / batch control site			
e)	Addition or replacement of Storage site			
<u>Conditions to be fulfilled</u> -The proposed site appropriately authorized (To perform the specified operation for the concerned FPP)				

Requirements guidance:

*Analysis of the first imported shipment manufactured/packed at the proposed site at CADC labs (Administration of post approval control) (if the analysis is carried out before by the evaluation and approval administration) or analysis of the first imported shipment by the evaluation and approval administration, in case of the analysis is never carried out by the evaluation and approval administration before and the conformity report is a condition for release.

**Submit an accelerated stability study (6 months) on three consecutive production batches of the product manufactured/packed at the proposed site. The first imported shipment from the proposed site shall not be released until the accelerated stability study has been submitted.

***Submit process validation for three consecutive production batches of the product manufactured/packed at the proposed site; to be followed up by the Central Administration of Inspection on Pharmaceutical Institutions.

Submission guidance:

1-Common Administrative Documents: Refer to Annex III

(Should be submitted with all variations in addition to Relevant Documents According to the Variation Type)

2- Relevant Documents According to Ownership & Manufacturer Variation type:

- Replacement of a Manufacturing/Packaging site (Local & Under License FPP)	
1	Cover letter on License holder's official letterhead clarifying the proposed change Authenticated from bank
2	Manufacturing/Packaging contract Between LH/applicant & new manufacturer/packager, Valid Authenticated from bank. In case of a foreign party signing the contract: Authentication from chamber of commerce, Egyptian embassy/consulate or notary

3	Attached annex of the contract The product trade name & reg.no. is mentioned & authenticated from bank.
4	Latest new manufacturing site license: Production line &/or area needed for manufacturing the product is present.
5	Last updated commercial register Of the new manufacturing site
6	If the site was previously temporarily added: Copy of the previous approval Copies of all studies & analysis approvals done for this site.
7	Waiver From old manufacturing/packaging site Mentioning the product name & reg. no. Stating his approval of transferring manufacturing/packaging of the product to a new manufacturing site Authenticated from bank
8	<u>OR</u> Termination letter From LH to old manufacturing/packaging site signed & stamped with proof of delivery.
9	Declaration Letter NO change in composition, specifications, manufacturing process, or container/closure system of the FPP. *Signed & stamped.
10	Letter of Variation For UL Products From product LH in COO Stating the required variation Authenticated from chamber of commerce, Egyptian embassy/consulate or notary

- Addition of a Manufacturing/Packaging site (Local FPP)	
1	Cover letter on License holder's official letterhead clarifying the proposed change Authenticated from bank
2	Manufacturing/Packaging contract Between LH/applicant & new Manufacturer/Packager, valid & authenticated from bank In case of a foreign party signing the contract: Authentication from chamber of commerce, Egyptian embassy/consulate or Notary
3	Attached annex of the contract The product trade name & reg. no. is mentioned. Authenticated from bank.
4	Latest new manufacturing site license: Production line &/or area needed for manufacturing the product is present.
5	Last updated commercial register Of the new manufacturing site
6	If the site was previously temporarily added: Copy of the previous approval Copies of all studies & analysis approvals done for this site.
7	Declaration Letter From old manufacturing/packaging site. The product trade name & reg. no. is mentioned. Stating his approval of adding a new manufacturing site. Authenticated from bank.
8	<u>OR</u> Declaration Letter (Template 5) From the LH The product trade name & reg. no. is mentioned. Stating: "The company takes the full responsibility for adding a new site without any responsibility on EDA, regarding to the obligations and duties imposed under the manufacturing contract with the old factory (factories)". Name of old factories is mentioned". Authenticated from bank.
9	Letter of Variation For UL Products From product LH in COO Stating the required variation Authenticated from chamber of commerce, Egyptian embassy/consulate or notary

- Replacement or addition of a Storage Site	
1	Cover letter on License holder's official letterhead clarifying the proposed change Authenticated from bank
2	Storage contract: Between LH & storage site, valid & authenticated from bank.
3	Storage site License

- Replacement or addition of a Manufacturing/Packaging/Batch Releasing Site (Imported, Under License & Bulk FPP)	
1	Letter of Variation From product LH in country of origin Product name, reg.no. mentioned Stating the required variation Authenticated from chamber of commerce, Egyptian embassy/consulate or notary.
2	Certificate of Good Manufacturing Practice (GMP) For new site Valid Authenticated from chamber of commerce & Egyptian consulate/embassy
3	If the New Site is located in a non-reference country: CPP from Reference country: Valid Product registered & marketed Where the proposed site is mentioned (For MFG/1ry packaging site) Authenticated by the Health Authority in COO, Chamber of commerce & Egyptian consulate

4.3.3 Change type of Registration				
4.3.3.1 change from Imported Finished to:		Requirements		
		CADC	Stability	
a)	Bulk (for primary packaging in Egypt)	*A	**6M	*** process validation
Conditions to be fulfilled -The proposed site appropriately authorized to perform the specified operation for the concerned FPP. -The change does not concern sterile FPP.				
b)	Bulk (for secondary packaging in Egypt)			
Conditions to be fulfilled - The proposed site appropriately authorized to perform the specified operation for the concerned FPP.				
C)	Under license	*A	**6M	*** process validation
Conditions to be fulfilled -The proposed site appropriately authorized to manufacture product concerned.				
d)	Local	*A	**6M	*** process validation
Conditions to be fulfilled -The proposed site appropriately authorized to manufacture product concerned. - The physical and chemical specifications must remain the same as the imported products				

Requirements guidance:

*Batch analysis of the first three consecutive production batches produced /packed at the new site at CADC labs (Administration of post approval control) (if the analysis is carried out before by the evaluation and approval administration) or analysis of the first batch by the evaluation and approval administration , the second and third batches by the post approval control administration, in case of the analysis is never carried out by the evaluation and approval administration before , the conformity report is a condition for release.

** Accelerated stability study for 6 Months on three consecutive batches produced/packed at the new site

***Process validation for the first three consecutive production batches of the product manufactured/packed at the new site; to be followed up by the Central Administration of Inspection on Pharmaceutical Institutions.

guidance:

1-Common Administrative Documents: Refer to Annex III

(Should be submitted with all variations in addition to Relevant Documents According to the Variation Type)

2- Relevant documents according to change type of Registration variation:

- Change Reg. Type from Imported Finished to Imported Bulk	
1	Letter of Variation From LH/MAH Stating the change in packaging site(s) of the product and justification for these changes The product trade name & reg. no. is mentioned Authenticated by the health authority in COO, chamber of commerce & Egyptian consulate/embassy
2	Packaging contract Between LH/applicant & new packager. A letter from LH/MAH authorizing the applicant to sign contracts Authenticated from bank. Authentication form chamber of commerce, Egyptian embassy/consulate or notary is needed in case that the LH/MAH signing the contract.
3	Attached Annex of the contract The product trade name & reg. no. is mentioned. Authenticated from bank.
4	Latest New Packaging site license Production line &/or area needed for manufacturing the product is present

5	Last updated commercial register Of the new packaging site
6	Storage contract Between LH/Applicant & Storage site. Valid. Authenticated from bank. Authentication form chamber of commerce, Egyptian embassy/consulate or notary is needed in case that the LH/MAH signing the contract.
- Change Reg. Type from Imported Finished to Under License	
1	Letter of Variation From LH/MAH Stating the change in MFG site(s) of the product and <u>justification</u> for these changes The product trade name & reg. no. is mentioned Authenticated by chamber of commerce & Egyptian consulate/embassy
2	Manufacturing contract: Between LH/Applicant & new manufacturer/packager. A letter from LH/MAH authorizing the applicant to sign contracts Authenticated from bank. Authentication form chamber of commerce, Egyptian embassy/consulate or notary is needed in case that the LH/MAH is signing the contract.
3	Attached Annex of the contract The product trade name & reg. no. is mentioned. Authenticated from bank.
4	Latest new manufacturer site license: Production line &/or area needed for manufacturing the product is present.
5	Last updated commercial register (New Manufacturer)
6	Storage contract Between LH/Applicant & Storage site. Valid. Authenticated from bank. Authentication form chamber of commerce, Egyptian embassy/consulate or notary is needed in case that the LH/MAH signing the contract.
7	Submission of API supplier addition request. Refer to API supplier addition checklist

- Change Reg. Type from Imported Finished to Local	
1	Letter of Variation From LH/MAH Stating the transfer of ownership of the product with clarification of the consequential changes and justification for this change The product trade name & reg. no. is mentioned Authenticated by the chamber of commerce & Egyptian consulate/embassy
2	In case of Toll Manufacturing: Manufacturing contract: Between new LH & new manufacturer/packager. Authenticated from bank.
3	Attached Annex of the contract The product trade name & reg. no. is mentioned. Authenticated from bank.
4	Latest new manufacturing site license Production line &/or area needed for manufacturing the product is present.
5	Last updated commercial register (New Manufacturer)
6	Storage contract: Between new LH & Storage site. Valid. Authenticated from bank.
7	Storage Site License
8	3 Copies Composition declaration: On new LH paper signed & stamped Identical to the one attached with the registration license or to the latest finally approved composition
9	Submission of API supplier addition request. Refer to API supplier addition checklist

4.3.3.2 Change from Under License to:		Requirements		
a)	Imported finished	CADC	Stability	
		A*	6M**	
<u>Conditions to be fulfilled</u> - Satisfactory inspection in the last three years by an inspection service of a country where an operational Good Manufacturing Practice (GMP) exists. -The proposed site appropriately authorized to manufacture product concerned.				
b)	Bulk (for primary packaging in Egypt)	A*	6M**	*** process validation
<u>Conditions to be fulfilled</u> - Satisfactory inspection in the last three years by an inspection service of a country where an Operational Good Manufacturing Practice (GMP) exists. -The proposed site appropriately authorized to manufacture product concerned. -The change does not concern Sterile FPP.				
c)	Bulk (for secondary packaging in Egypt)	A*	6M**	
<u>Conditions to be fulfilled</u> - Satisfactory inspection in the last three years by an inspection service of a country where an operational Good Manufacturing Practice (GMP) exists. -The proposed site appropriately authorized to manufacture product concerned.				
d)	Local (at the same manufacturing site)	CADC Notification	Ongoing stability study on production batches submitted upon request	
<u>Conditions to be fulfilled</u> - The physical and chemical specifications must remain the same as the imported product.				

e)	Local (transfer to different manufacturing site)	A*	6M**	*** process validation
Conditions to be fulfilled -The proposed site appropriately authorized to manufacture product concerned. - The physical and chemical specifications must remain the same as the imported product.				

Requirements guidance:

*Batch analysis of the first three consecutive production batches produced /packed at the new site at CADC labs (Administration of post approval control) (if the analysis is carried out before by the evaluation and approval administration) or analysis of the first batch by the evaluation and approval administration , the second and third batches by the post approval control administration, in case of the analysis is never carried out by the evaluation and approval administration before , the conformity report is a condition for release.

** Accelerated stability study for 6 Months on three consecutive batches produced/packed at the new site

***Process validation for the first three consecutive production batches of the product manufactured/packed at the new site; to be followed up by the Central Administration of Inspection on Pharmaceutical Institutions.

Submission guidance:

1-Common Administrative Documents: Refer to Annex III

(Should be submitted with all variations in addition to Relevant Documents According to the Variation Type)

2-Relevant documents according to change type of Registration variation

Change Reg. Type from UL to Imported Finished	
1	Letter of Variation From LH/MAH Stating the change in MFG site(s) of the product and justification for these changes. The product trade name & reg. no. is mentioned Authenticated, by chamber of commerce & Egyptian consulate/embassy
2	Certificate of Good Manufacturing Practice (GMP) For new MFG/Packaging site, Valid & authenticated from chamber of commerce & Egyptian consulate/embassy

3	Manufacturing Waiver From old manufacturer, the product trade name & reg. no. is mentioned Authenticated from bank.
Change Reg. Type from UL to Imported Bulk	
1	Letter of Variation From LH/MAH Stating the change in MFG site(s) of the product and justification for these changes. The product trade name & reg. no. is mentioned Authenticated by, chamber of commerce & Egyptian consulate/embassy
2	Certificate of Good Manufacturing Practice (GMP) For new MFG/Packaging site. Valid Authenticated from chamber of commerce & Egyptian consulate/embassy
3	Manufacturing Waiver From old manufacturer The product trade name & reg. no. is mentioned Authenticated from Bank.

Change Reg. Type from UL to Local	
1	Letter of Variation From LH/MAH Stating the transfer of ownership of the product with clarification of the consequential changes and <u>justification</u> for this change The product trade name & reg. no. is mentioned Authenticated by the chamber of commerce & Egyptian consulate/embassy
2	Manufacturing Waiver From old manufacturer (In case of changing manufacturing site) The product trade name & reg. no. is mentioned Authenticated from Bank.
3	In case of Toll Manufacturing: Manufacturing contract: Between new LH & new manufacturer/packager. Authenticated from bank.
4	Attached Annex of the contract The product trade name & reg. no. is mentioned. Authenticated from bank.

5	Latest New Manufacturing site license Production line &/or area needed for manufacturing the product is present.
6	Storage contract: Between new LH & Storage site. Valid. Authenticated from bank.
7	Storage Site License
8	Copies Composition declaration: On new LH Paper Signed & stamped Identical to the one attached with the registration license or to the latest finally approved composition

5. Annexes:

Annex I: Glossary

EDA	Egyptian Drug authority
FPP	Finished Pharmaceutical Product
CPP	Certificate of pharmaceutical products
cGMP	Current Good Manufacturing Practice
COA	Certificate of Analysis
NRA	National Regulatory Authority
SRAs	Stringent regulatory authorities
LH	License holder
MAH	Marketing Authorization Holder
CADC	Central Administration of Drug Control
API	Active Pharmaceutical Ingredient

Annex II: EDA's approved list of reference countries.

The current list consists of 22 countries

- Australia
- United States of America
- Austria
- Belgium
- Norway
- Canada
- Sweden
- Denmark
- Finland
- France
- Switzerland
- United Kingdom
- Germany
- Iceland
- Ireland
- Italy
- Portugal
- Spain
- Luxembourg
- Netherland
- New Zealand
- Japan

Annex III: Common Administrative Documents:

Should be submitted with all variations in addition to Relevant Documents According to the Variation Type

Section (1)	
Variation Application form (Signed and Stamped) + Payment receipt	
Required Documents	
1	Variation Application form (Template1)
2	Payment receipt
Section (2)	
EDA License & Approvals	
Required Documents	
1	EDA Valid Registration License - If invalid: valid Approval for registration or a proof of submission for reregistration
2	Any other EDA or Variation approvals.
3	Any Previous Stability Approvals (Accelerated Stability or Long-term Stability).
4	EDA labs certificate of analysis.
5	EDA labs composition certificate.
Section (3)	
Other Documents (In Case of Imported / UL Products)	
Required Documents	
1	Valid CPP/e CPP (With All Attachment) Authenticated by the Health Authority in country of origin, Chamber of commerce & Egyptian consulate/embassy.
2	Declaration Letter from LH/MAH in country of origin - Clarifies the change if not stated in CPP & Stating the reasons of change
Section (4)	
Applicant Documents	
Required Documents	
1	Last Updated Commercial Register
2	Toll Card In case of toll companies
3	Factory License In case of local companies
4	Scientific office License In case of scientific office
5	In Case of Imported finished veterinary Pharmaceutical Product if the applicant is either Scientific Office or Company the following documents to be submitted: -

	Scientific Office: a) Authorization letter for the scientific office to register finished Imported veterinary Pharmaceutical Products” issued by inquiry requests unit for veterinary pharmaceuticals. b) Declarations Letter Clarifying the Company's profile Code signed & stamped Company: - Last updated importer record.
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Annex IV: Final approvals submission guidance:

<u>Section (1)</u>	
1-	Latest issued EDA registration license
2-	Variation Application Form of Post Marketed Veterinary Products (Template 1)

<u>Section (2)</u>	
Composition variation final approval	
1	A copy of primary approval
2	All Studies issued on primary approval for the product and its original copies (to be seen): a) EDA Labs COA & Composition b) Stability Approval
3	Approved Composition "on company paper signed and stamped".
Pack variation final approval	
1	A copy of primary approval
2	All Studies issued on primary approval for the product and its original copies (to be seen): a) EDA Labs COA & Composition b) Stability Approval
API manufacturer variation final approval	
1	A copy of primary approval
2	All Studies issued on primary approval for the product and its original copies (to be seen): a) EDA Labs COA & Composition b) Stability Approval

Annex V: Updating analysis file submission guidance

1-Common Administrative Documents: Refer to Annex III

2- Relevant Documents:

1	Composition "on company paper signed and stamped".
2	CADC Labs Analysis Certificate Or A "Not Found" Letter from CADC
3	CADC Labs Composition Or A "Not Found" Letter from CADC

6. Templates

6.1 Template 1

Variation Application Form of post Marketed Veterinary Products

Name of the product/s:	Applicant:		
Active substance(s):	Manufacturer of Finished Pharmaceutical product:		
Concentration:	Manufacturer of solvent:		
Dosage form:	Name of contact:		
Registration number:	Telephone number:		
E-mail:			
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			
Excipient			
Changes in components of the flavoring or coloring system			
Specification of Active ingredient			
Specification of Inactive ingredients			
API form as salt equivalence and/or crystalline state			
The particle size of API (state D90)			
Addition of an overage			
Tightening of Specification limits			
Deletion of a non-significant specification parameter			
Widening of specification limits			
Change the Pharmacopeial product			
Shelf life			
Storage Conditions			
Change in range of color			
Scoring			

	<u>Change</u>	<u>Addition</u>	<u>Clarify</u>
B) Container Closure System Changes As:			
Primary packaging of finished pharmaceutical product			
Pack size of finished pharmaceutical product			
Change in shape or dimensions of the container or closure (immediate packaging)			
Part of primary packaging material not in contact with the finished product formulation			
C) API Manufacturer changes as:			
Name of API Manufacturer			
Address of API Manufacturer			
Deletion of API Manufacturer			
API Manufacturer			
D) Ownership / Manufacturer Changes As:			
Name of License holder			
Address of License holder			
Name of Manufacturing site			
Address of Manufacturing 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			
Batch releasing site of FPP			
Storage Site			
Change Registration Type			
E) Miscellaneous			<u>Tick for required Issue</u>
Updating Analysis File			
Final Approval for Composition/Specification			
Final Approval for Pack			
Final Approval for API			
Appeal			
Cancelling previous variation approvals			
F) others			

<u>BACKGROUND & JUSTIFICATION FOR REQUIRED CHANGE/S</u> (Please give brief background explanation for the proposed changes)	
<u>Current</u>	<u>Proposed</u>
<u>In case of Appeal / Final Approvals:</u> (Please Clarify exactly the issue required)	
The applicant is committed to the following	<u>Yes</u>
1- All documents & information submitted in the file are correct and on the responsibility of the company	
2- The submitted file contains all the approvals for the product that were not mentioned in the last released registration license	
3- The submitted file contains the latest issued registration license	
4- The submitted file contains all approvals, variations & decisions issued for the product from different EDA departments	
Kindly state the following data:	
1- In case of Any previous variations' approvals, variations & decisions 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:	
3- 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.	
Signature by the Authorized Person:	Company Stamp:

6.2 Template 2

(API Variation Notification Form)

السيد الدكتور / رئيس الادارة المركزية للمستحضرات الصيدلانية
الإدارة العامة للمستحضرات البيطرية
إدارة المتغيرات

Product Name:	
Dosage Form:	
Reg. No.:	
License Holder:	
Manufacturer:	

Current API(s) Manufacturer (s):	Proposed API (s) Manufacturer(s):
1-	1- Address:
2-	2- Address:
3-	3- Address:
4-	4- Address:

تتعهد الشركة بتقديم الـ GMP وشهادات التحليل الخاصة بالمادة الخام وذلك عند التقدم لإستيراد المادة الخام بهيئة الدواء المصرية.

و تفضلوا بقبول وافر الإحترام والتقدير

ختم الشركة

رئيس مجلس ادارة الشركة



6.3 Template 3

السيد الدكتور / رئيس الإدارة المركزية للمستحضرات الصيدلانية
الإدارة العامة للمستحضرات البيطرية
إدارة المتغيرات

تحية طيبة وبعد

أتعهد أنا رئيس مجلس إدارة شركة بأن المستحضرات المملوكة
للشركة التي تحتوي علي نفس المواد الفعالة هم كالأتي:

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

و تفضلوا بقبول وافر الإحترام والتقدير

ختم الشركة

رئيس مجلس ادارة الشركة



6.4 Template 4

السيد الدكتور / رئيس الإدارة المركزية للمستحضرات الصيدلانية
الإدارة العامة للمستحضرات البيطرية
إدارة المتغيرات

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	Trade Name / Dosage Form	API/Strength

و تفضلوا بقبول وافر الاحترام والتقدير

ختم الشركة

رئيس مجلس إدارة الشركة



6.5 Template 5

السيد الدكتور / رئيس الإدارة المركزية للمستحضرات الصيدلانية
الإدارة العامة للمستحضرات البيطرية
إدارة المتغيرات

تحية طيبة وبعد

بخصوص المستحضر البيطري الآتي:

Trade Name:	
Dosage Form:	
Active Ingredients / Strength:	
Registration No.:	
Applicant Company:	
License Holder / MAH:	
Manufacturer:	

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

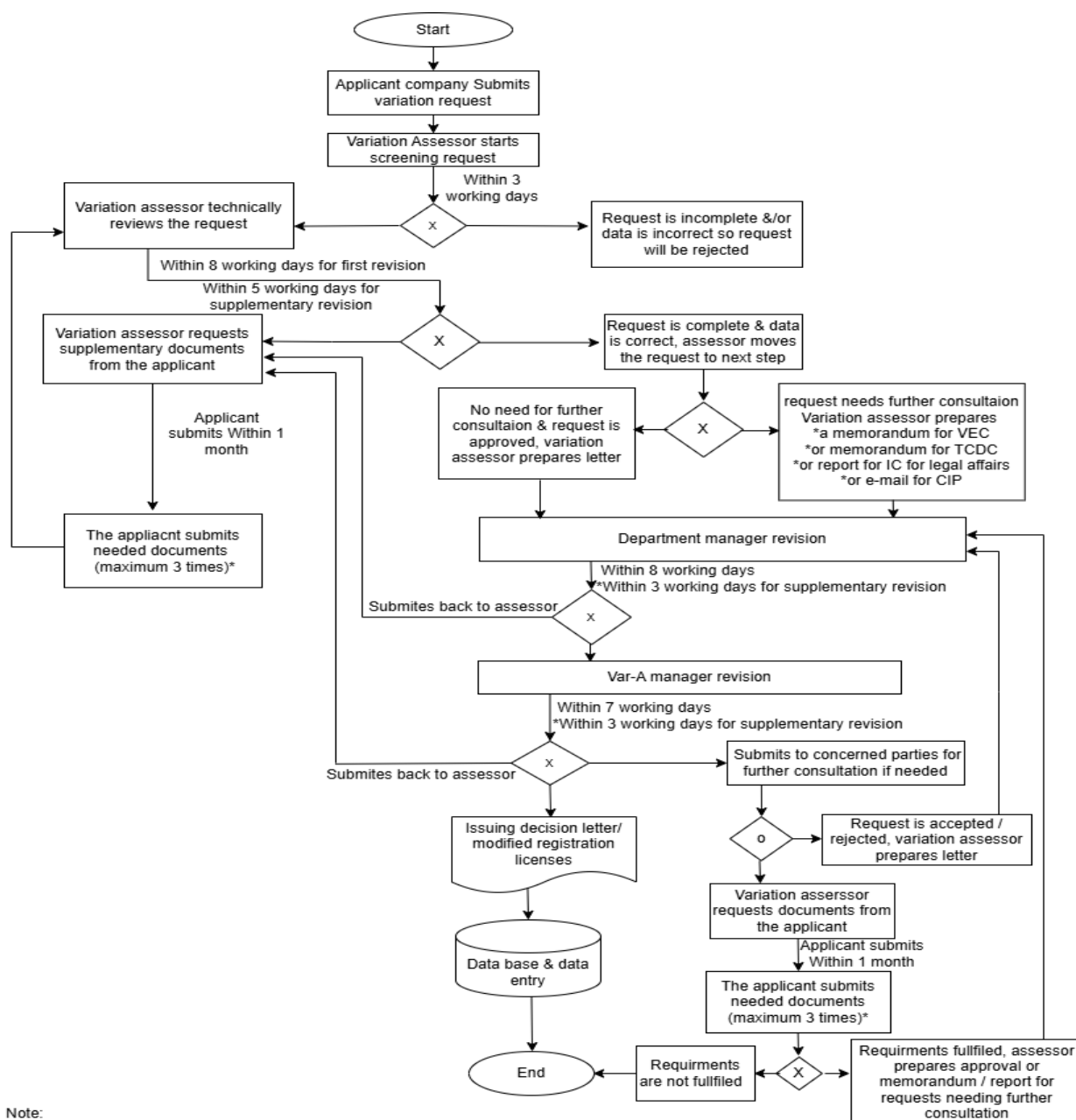
و تفضلوا بقبول وافر الإحترام والتقدير

ختم الشركة

رئيس مجلس إدارة الشركة



7-Variation Flow Chart:



Note:

The request will be cancelled if:

*The applicant submitted the required documents incorrect for more than 3 times.

*The requested documents are not submitted within one month.

8. References:

- Guidance from the European Medicines Agency (EMA) on variations for centrally authorized veterinary medicines not requiring assessment under the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) dated on 8 January 2021.
- Guidance from the European Medicines Agency (EMA) on variations for centrally authorized veterinary medicines requiring assessment under the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) . Last updated on 25/4/2023
- WHO guidelines on variations to a prequalified product (Annex III).
- Guidelines on Human Pharmaceuticals Variations (Sixth Edition).
- Technical Committee of Drug Control relevant decisions.

رئيس الإدارة المركزية للمستحضرات الصيدلانية

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مدير إدارة المتغيرات

د. مروة حمدي

9. History of Change

Version	Issuing date	Summary of Changes
1	26/2/2024	New Issue
2	17/9/2026	- Update flow chart - Update requirements of Addition or replacement of manufacturing sites of local pharmaceutical products.