Guidelines for the update of the mechanism of addition/ transfer of manufacturing site of registered local human and veterinary medicinal products Year 2026

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1- Introduction:

In light of the support of the Egyptian Drug Authority for investment and increase local manufacturing and in order to ensure the availability of safe, high quality and effective medical preparations, which benefit the health of the Egyptian citizen, the mechanism for adding/ transferring manufacture site of local registered human and veterinary medical preparations has been updated**.**

2- Scope of application:

A. Transfer/addition of the manufacture site.

B. Transfer/addition of an intermediate (Internal bulk) manufacture site

3- Procedures:

1- The company submits the request to add/ transfer manufacture site to the Variation Administration to the products to be add/ transfer manufacture site for each concentration separately by uploading the file according to the procedures followed and according to the submission dates announced on the website of the Egyptian Drug Authority with payment fees for the service of adding/ transferring manufacture site according to the services fees published on the website of the Egyptian Drug Authority.

2- The documents submitted by the company are reviewed according to the submission Guidance for the addition/transfer of manufacture site of local preparations as well as the review of the specified timeframes for production and marketing.

Companies should follow one of the two paths:

Track I:

1- A transfer letter is issued to the company addressed to the Central Administration of Inspection on Pharmaceutical Institutions for examination and classification (category) related to the process of adding/ transferring the manufacturing site, whether Minor or Major.

*The validity period of the transfer letter shall be three months from the date of issuance of the letter, during which the company shall submit to the Central Administration for the inspection on pharmaceutical institutions and shall be followed up by the Central Department for the inspection of pharmaceutical institutions.

2- The company submits the letter of transfer to the Central Administration of Inspection on Pharmaceutical Institutions with service fees for inspection and classification (category) for the process of adding/ transferring the manufacturing site, whether Minor or Major.

The method of determining the classification (category) is as follows:

**The classification is selected according to the technique similarity; This item is evaluated based on the protocol sent from the company according to WHO guidelines.

1 According to WHO Guidelines TRS 961

(Comparison and assessment of suitability and qualification of facility and equipment description of the manufacturing process and flow of personal and materials at the RU (narrative and or process maps or determination of critical steps in manufacture, including hold times endpoints flow charts), and sampling technique), sampling points.

The classification is based on the following:

Classification:	**Minor**	**Major**
	Technique Similarity	No Technique Similarity
Requirements:	- Batch analysis for the first three consecutive production batches (conformity is a condition for release) - Conduct a long-term stability study on The first production batch of the product and inform the Variation Administration in case of any change in the specifications of the product that has negative impact on the quality and effectiveness of the preparation.	- Batch analysis for the first three consecutive production batches (conformity is a condition for release) - Conduct accelerated stability study for 6 months on the first three production batches (the approval of the stability study is a condition for release). - Conduct a long-term stability study on the first production batch of the product and inform the Variation Administration in case of any change in the specifications of the product that has negative impact on the quality and effectiveness of the preparation.
The Central Administration of Pharmaceutical Products has the right to add other tests as it deems appropriate, according to the pharmaceutical dosage form of the product.		

*With regard to the analysis on the first three production batches, the Central Administration of Inspection on Pharmaceutical Institutions determines whether the analysis is carried out in the company's laboratories or in the Authority's laboratories (CADC) based on the factory's evaluation on the latest periodic inspection report of the factory.

3 - The company submits a request for a statement of the technical studies required to be conducted for the addition/ transfer of the manufacturing site with the services fees, to be submitted to the Variation Administration within a month from the date of issuance of the technical report issued by the Central Administration of Inspection on Pharmaceutical Institutions, that clarifies the classification (category) of the process of manufacturing site transfer/ addition, whether minor or major, the required studies and the type of analysis in the company's laboratories or in the Authority's laboratories, provided that this is followed up by the Variation Administration.

* Otherwise, the statement received from the Central Administration of Inspection on Pharmaceutical Institutions is considered invalid and the company has the right to resubmit the request.

4- A statement of the technical studies is issued for adding/ transferring the manufacturing site, mentioning the technical studies required to be conducted in accordance with the guidelines of the Variation Administration and in accordance with the technical report issued by the Central Administration of Inspection on Pharmaceutical Institutions.

**The release must be in accordance with the procedural rules followed, and to be followed up by the Central Administration of Inspection on Pharmaceutical Institutions.

5- The company shall apply for final approval upon completion & approval of the required technical studies with payment of the services fees.

Track II:

* If the company submits to comply with the technical requirements of the major classification or the product has not has been produced before:

1- A preliminary approval shall be issued, including the following technical studies:

- Analysis of the first three production batches produced by the new factory in the laboratories of the Central Administration of Drug Control (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 and 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 and the conformity report is a condition for release.
- Submit an accelerated stability study (for 6 months) on the first three production batches by the new factory, provided that this is done within thirty months from the date of production in the

new factory, after which the production of the product is stopped until all the requirements are fulfilled, and those three batches are released only after the approval of an accelerated 6-month stability study is approved on these batches.

- Conducting a long-term stability study on the first batch of the final product with the new variable as the company commits to inform the Variation administration for veterinary/ human pharmaceutical products in the event of any change in the specifications of the final product that has a negative impact on the quality and effectiveness of the product.
- In addition to any other tests that the Central Administration of Pharmaceutical Products may add to human/veterinary products in their respective areas.

2-The company shall apply for final approval upon completion & approval of the required technical studies with payment of the services fees.

3.Versions

History Table

Version No.	Issue date	Summary of Changes
First version	4/8/2025	
Second version	9/12/2025	-Procedures : Adding a new path to comply with the technical requirements of major classification in case of the company's desire or in case of non-production.
Third version	1/3/2026	- Modify the scope of application of the mechanism to include the transfer/addition of an intermediate (Internal bulk) manufacture site.