

Guidance of Fast Track Pathway for submission of files to Follow up Unit

**Appeals Evaluation Department - Regarding the presentation to the Technical Committee -
For the year of 2024**

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1. introduction:

In light of the Egyptian Drug Authority's commitment and efforts to proactively ensure the availability of medicines for the Egyptian patient.

And In view of the strenuous efforts made by the Central Administration of Pharmaceutical Products to keep pace with the development of the pharmaceutical industry and the constant concern for investments included in the field of pharmaceutical manufacturing and to encourage the production, and what this requires in terms of accelerating the process of evaluation of files submitted for the presentation to the technical committee and issuing the necessary approvals for various human pharmaceutical products, so the following has been decided :

A fast track pathway will be introduced for files submitted to the Follow-up(Appeals Evaluation department) after payment of the prescribed fee of (10000 Egyptian pounds) in addition to the fee of each service. The evaluation period for the submitted file by the Follow-up Unit- Appeals Evaluation department is 7 working days from the date of receiving complete file that meets all requirements ,and it will be presented to the first technical committee that will be held after the specified deadline, and the approval will be issued within 3 working days from the date of fulfillment the required supplementary documents and/or receiving the decisions from the Technical Committee for Drug Control.

2. procedure:

The Market Authorization Holder of the product selects the fast track pathway and enters the receipt number for the service (10000 Egyptian pounds) and submit through the same specific link of follow up unit at the same scheduled time .

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History Table

Version No.	Issue date	Summary of Changes
Version 1	1/7/2024	
Version 2	10/7/2024	Changing Submission Link