Notice to applicant

Central Administration of Drug Control
Technical Office Unit

The mechanism for obtaining subsidized-price reference standards from the American Pharmacopeia Year 2024

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1. •Filling out a purchase request form for a standard material through the website of the US Pharmacopeia (Store.usp.org), specifying the purpose of use within the laboratories of the Egyptian Drug Authority, with electronic payment for the service.
   •**Responsible party: Pharmaceutical Company.**
2. •Sending the standard material to the contracted shipping company.
   •**Responsible party: US Pharmacopeia.**
3. •Paying all required fees and settling any necessary procedures to complete customs clearance.
   •**Responsible parties: Pharmaceutical Company & Shipping Company.**
4. •Delivering the standard material to the Central Administration of Drug Control.
   •**Responsible party: Shipping Company.**
5. •Notification to both the US Pharmacopeia and the pharmaceutical company via e-mail regarding the received standard materials.
   •**Responsible party: Central Administration of Pharmaceutical Control.**
6. •Delivery of a copy of the email sent to the company along with the samples required to be analyzed using those standard materials to the Central Administration of Pharmaceutical Control.
   •**Responsible party: Pharmaceutical Company.**

Instructions:

- The pharmaceutical company sends an email to the Central Administration of Drug Control using the following email address of the mechanism (dc.usp.rs@edaegypt.gov.eg), specifying the official email address used for any correspondence regarding the implementation of this protocol.
- The pharmaceutical company sends a sealed and certified general undertaking allowing the Central Administration to retain the received standard materials until they are utilized for analysis purposes at the Egyptian Drug Authority laboratories.
- The company takes responsibility for coordinating with the shipping company to complete the necessary authorization procedures for customs clearance of all incoming shipments in accordance with this protocol.
- The pharmaceutical company is responsible for ensuring the accuracy of all data regarding the standard materials outlined in the documents received from the US Pharmacopeia upon shipment.
- The responsible individual at the Central Administration of Drug Control sends an email to the pharmaceutical company upon receipt of the standard materials.
- The pharmaceutical company commits to delivering samples of the products intended for analysis using the received standard materials within the validity period of those materials, knowing that the necessary number of units will be used for analysis as per the communication with the company providing the product.
- If the company deviates from the specified path for completing customs procedures and delivery to the Central Administration of Drug Control, communication will be made with the US Pharmacopeia to take necessary actions.