Importation Guideline
For
Unregistered Tender-Medicine

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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**Introduction**

Importation of Medicines to Bahrain is restricted to authorized agents only; it is the responsibility of the agent to assure the medicine is registered with valid license before importing.

This guideline is a simplified procedure for importing unregistered medicines for Tenders for governmental hospitals.

The Following terms should apply for requesting Tender-Medicine import permit:

1. NHRA Tender-Medicine Import Permit must be obtained before any importation.
2. Tender-Medicine Import permit will contain the full information and importation must comply with the approved information.
3. The medicine subject to this procedure must be needed by the Hospitals.
4. Unregistered medicine only is subject to this procedure.
5. If there is an alternative to the medicine in the local market justification must be submitted to NHRA.
6. The manufacturer of the medicine must be GMP certified.
7. The Medicine must be marketed in the country of origin (otherwise must be justified and subject to NHRA decision).
8. The supply of the medicine must be for the beneficiary Hospital only. In case of need to provide for a third party NHRA pre approval is required.
9. Payment of 5 BD for each medicine in the Tender-Medicine import permit is required.
Requirements for obtaining Tender-Medicine import permit:

1. Letter from the beneficiary Hospital to NHRA clarifying the following:
   
   a. Medicine generic & Trade name.
   b. The desired concentration of the drug and its pharmaceutical form.
   c. The manufacturer's name and country of origin.
   d. The name of the Local agent.
   e. Quantity.
   f. Size of the packaging unit.
   g. The price of the product.
   h. Copy of the Tender Document.

2. Letter from the local agent to NHRA requesting Tender-Medicine import permit with a copy of the purchase order.

3. Justification in case of none compliance with any of the terms for Tender-Medicine import permit procedure.

4. Letter from the Hospital declaring that the approved medicine will be used for their patients only, Otherwise NHRA approval is required.

5. Letter from the local agent declaring that the approved medicine will be supplied to the beneficiary Hospital only, Otherwise NHRA approval is required.

6. Copy of Valid CPP for the medicine from the country of origin.
Important Notes:

1. Tender-Medicine Import permit is issued for the entire amount; copy of the permit must be submitted with each invoice in case of more than one delivery.
2. Copy of the delivery note to the beneficiary Hospital must be submitted to NHRA after each delivery.
3. Invoices must be only for tender medicines and clearly mention tender invoice and must show the beneficiary Hospital name.
4. In case of cancellation of import NHRA must be informed.
5. In case of rejection of the medicine by the Beneficiary Hospital for any reason NHRA must be informed.
6. In case of any change occurred after issuing the Tender-Medicine import permit, NHRA approval must be obtained before Importation.