SUPPLIER REGISTRATION AND PRE-QUALIFICATION POLICIES

NUPCO require all suppliers requesting to be registered in its approved suppliers list to carefully read the following policies, and fulfil the registration requirements.

1. The supplier shall provide accurate and complete registration documentation.

2. Criteria for pre-qualification include (but not be limited to) the following:

   2.1 The supplier should possess the necessary professional and technical competence, financial resources, other physical facilities, managerial capability, reliability, experience, and reputation, and the personnel.

   2.2 The supplier should have valid SFDA registration certificate, A Commercial registration number, Chamber of Commerce Membership, and legal capacity.

   2.3 The supplier should have good processes in controlling quality, automation level, temperature, humidity, cleanliness, pest control, fleet temperature, fleet hygiene system, after-sales service and any other defined criteria.

   2.4 The supplier should have Manufacturing, Warehouse, and Service quality certifications.

   2.5 The supplier should have a good history in dealing with product recalls/lawsuits in addition to having an authorization to sell product.

3. In the case of non-registered items, the following must be provided:

   3.1 For Pharmaceuticals, a valid certificate of registration (Certificate of Pharmaceutical Product (COPP)) issued by the regulatory/competent authority in the country of manufacture to prove that the pharmaceutical item to be procured has been authorized to be placed in the market for sale and use in the country of manufacture. This certificate should indicate the number of permit and date of issue. If the product is not permitted to be marketed and used in the country of manufacture, reason for such action should also be stated. COPP should also certify that the manufacturing plant in which the particular Pharmaceutical to be procured is produced, has received a satisfactory GMP inspection certificate in line with the SFDA certification scheme and has demonstrated compliance with the quality standards during the past two years

   3.2 For Medical Equipment, certification that the manufacturing plant in which the particular Medical equipment to be procured is produced has received a satisfactory GMP inspection certificate in line with SFDA has to be submitted. A valid free sale certificate issued by the regulatory/competent authority and must satisfy the requirement of the SFDA

4. In the case of suppliers who are not manufacturers, the supplier shall provide evidence of being duly authorized and certified by the manufacturer. In addition, the supplier should meet all criteria mentioned above.

5. The supplier should have manufactured and (or) marketed the specific Pharmaceuticals, medical supplies, and medical equipment (in the country of origin) for brand and for generic items at least one year. Suppliers wishing to pre-qualify for products that they do not manufacture must submit documentary evidence corresponding to the primary manufacture of products who shall comply with these manufacturing requirements.

6. The supplier should provide proof of experience with knowledge of modes of packing, distribution and transportation of Pharmaceuticals, medical supplies, and medical equipment under logistical and climatic conditions of Saudi Arabia in accordance with the SFDA.

7. For any supplier/manufacturer of Multi-Source products whose performance is deemed unsatisfactory, particularly in product quality and delivery time, NUPCO may at its own discretion shall suspend supplier/manufacturer from participation in any future bidding process for that particular product, for a period of time decided by NUPCO.

8. NUPCO may conduct (or hire a second party to conduct) an audit on supplier / manufacturer operations to ensure all NUPCO and international requirements are being fulfilled.

9. NUPCO may at its own discretion and where it deems necessary, carry out physical inspections of the facilities of any supplier / manufacturer which it intends to pre-qualify for a particular product(s) for purposes of verifying the information provided by such supplier/manufacturer. NUPCO may outsource inspection as deemed necessary.

10. Supplier who provides a counterfeit or illegal product (deliberate and fraudulent mislabeling with respect to the identity, authenticity, effectiveness, composition and/or source of a finished medicinal product, or ingredient for the preparation of a medicinal product) shall be blacklisted and a legal action shall be taken.

11. SFDA disqualified suppliers list shall be reviewed regularly and reflected in the NUPCO disqualified suppliers list.

12. The supplier shall be considered permanently blocked in case of one of the following:

    12.1 Supplier does not comply with NUPCO policies.
    12.2 Counterfeit product detection is raised.
    12.3 Regulatory authorities blacklisted suppliers.

13. The supplier shall be temporary suspended (blocked) in case of the following:

    13.1 Minor slips in performance.
    13.2 Credentialing/Capability assessment yields negative results.

14. The supplier shall be discontinued (totally blocked) in case of the following:

    14.1 Supplier failed to re-qualify after being partially suspended.
    14.2 Re-assessment of their capabilities yields a negative result.
    14.3 Major slips in performance.

15. NUPCO shall have the right to disqualify a supplier if it finds at any time that the information submitted concerning the qualification of the supplier or contractor was false, However, in case the information submitted was materially inaccurate or materially incomplete, NUPCO shall give the supplier the opportunity to complete such, and shall disqualify or blacklist the supplier if it fails to remedy such deficiencies promptly upon request.

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