Sultanate of Oman
Ministry of Health

Ministerial Decision
No. 109/2008

Regarding issuance of the Regulations for pre-qualification of Companies and Factories of Medical supplies to participate in the tenders of the Ministry of Health.

In accordance with the Law of Tenders issued by the Royal Decree No. 36/2008,
and the Ministerial Decision No. 9/94, regarding restructuring of the Ministry of Health and its amendments,
and for the public interest…

it has been decided:

Article (1): The provisions of the attached Regulations shall be applied for pre-qualification of Companies and Factories of Medical Supplies to participate in the tenders of Ministry of Health.

Article (2): This Decision shall come into effect from the date of its issue, and shall be implemented by the Concerned Authorities each in his respective field of specialization.

Dr. Ali bin Mohammed bin Moosa
Minister of Health

Issued on:20/06/1429H
Corresponding to:24/06/2008

Regulations for Pre-Qualification of Companies and Factories of Medical Supplies

Article (1): **In the implementation of the provision of this Rule, the following terms and phrases will have the same meaning shown against them:**

The Ministry: Ministry of Health.

The concerned Directorate: Directorate General of Medical Supply.

Medical Supplies: Surgical items used in Hospitals, Orthopedics & Spine Surgeries, Medical Rehabilitation, Renal Dialysis, Oral & Dental Care, Medical Laboratories and Blood Bank Supplies.

Technical Pre-Qualification Committee: The Technical Committee for Pre-Qualification of Companies and Factories manufacturing Medical Supplies.

Article (2): **For pre-qualification of Companies and Factories to participate in the Ministry's tenders, the following requirements should be fulfilled:**

a. The company shall either be a manufacturer or assembling and licensed to manufacture medical supplies in the country of origin, provided that, pre-qualification of companies producing specialized medical supplies shall be confined to the manufacturing companies only and not the assembling ones.

b. The Company/Factory shall follow the principles of Good Manufacturing Practice (GMP) in the manufacturing of its products.

c. The Company/Factory products shall be in circulation in the country of origin or marketed in one of the developed countries.

d. The Company is subject to a periodical technical inspection by the concerned authorities in the country of origin.

e. Dully fulfill the technical requirements specified by the concerned Directorate in the form allotted for pre-qualification of Companies/Factories of medical supplies.

f. There shall not be a history of judicial verdict against the company in the country of origin or in any other country with regard to crimes of fraudulence or forgery.

g. Payment of pre-qualification fees.

Article (3): **The application for the pre-qualification of Companies of medical supplies shall be submitted by its agent or its representative to the concerned Directorate on the form prepared for that purpose, along with certificates and documents which proves that, the requirements are met. The certificates shall be attested by the concerned authorities in the country of origin and the Embassy of the Sultanate of Oman or its representative, according to the following basis:**

a. A certificate issued by the company nominating its representative as a Local Agent and authorized to submit the pre-qualification requirements to the Ministry.

b. A certificate issued by the Concerned Authorities in the country of origin stating that, the company is either a manufacturer or assembler and licensed to manufacture medical supplies in the country of origin, subject to periodical technical inspection and its products are circulated in the country of origin.

c. Quality Assurance Certificate issued by the Concerned Authorities indicating that the manufacturing company follows the principles of Good Manufacturing Practice (GMP) in the manufacturing process, such as: FDA, CE, ISO, TUV certificates.

d. Good Quality Certificate issued by the concerned parties for the companies manufacturing devices and medical diagnostic reagents such as: (ISO 9001-2000), (EN 46001), (ISO 13485) certificates.

e. A certificate issued by the Concerned Authorities in the country of origin for products made from plasma and blood derivatives to ensure that these items are free of any component that causes any of the different types of hepatitis viruses, HIV viruses and other infective viruses.

f. For surgical implants manufactured by orthopedics & spine surgery supplies companies, supportive Certificates, scientific researches and clinical studies carried out in the specialized medical centers in the country of origin and the developed countries should be submitted to confirm the quality, efficiency and safety of their use.

g. Statement of the products of the manufacturing company, their trade and scientific names and catalogues' numbers.

h. Statement of the company capital, the date of its establishment, its type, number of the technical staff, their qualifications in addition to the details of activities of company.

i. Statement of the company branches and their activities. The parent company shall guarantee its responsibility towards the branches in terms of quality of products together with technical, financial and legal aspects.

j. A list issued by the company indicating the names of other countries where its products are marketed along with documentary evidence proving marketing of these products in three of these countries.

k. Samples in Original packing, bearing the product name, name of manufacturing company, its logo, batch number, date of manufacture, expiry date, catalogue number, storage conditions and the product catalogue.

Article (4): **The Company shall submit a separate pre-qualification application for each branch/ factory, in the event that, it has many branches or Factories. Branches of the companies will be dealt with as separate factories and all terms of pre-qualification shall be applied.**

Article (5): **The application shall be entered in a register designated for this purpose by the concerned Directorate and a receipt shall be given to the applicant. The application shall be referred to the Technical Committee responsible for pre-qualification of Companies of medical items for necessary decision.**

Article (6): **The Technical Pre-Qualification Committee shall determine the companies, whose factories will be visited, in order to verify their adherence to good manufacturing practice and to inspect their production lines including those Companies already pre-qualified by the Executive Board of the GCC Health Ministers' Council but not visited by the Gulf Committees. Costs of the visit shall be borne by the company.**

Article (7): **Pre-qualification of Companies of medical supplies that have been approved by the Executive Board of the GCC Health Ministers' Council, will be carried out automatically in the Ministry, provided that, the required pre-qualification certificates and documents shown in article (3) are submitted and fees prescribed for Pre-qualification are paid.**

Article (8): **Upon pre-qualification of the company; its products will be evaluated at the specialized hospitals of the Ministry according to the mechanism applied in the concerned Directorate to evaluate the products of Companies of medical supplies.**

Article (9): **Upon pre-qualification or renewal; the company will be granted a Qualification Certificate, issued by the concerned Directorate on the form prepared for this purpose.**

Article (10): **The concerned Directorate shall prepare a register to record the pre-qualified companies with their name, nationality, headquarters, number and date of pre-qualification and address & name of its Local Agent.**

***Article (11): Pre*-qualification of Company/Factory or the branch shall be cancelled in the following cases:**

a. Detection of counterfeit or forgery in the certificates provided.

b. If it is included in the list of boycotted Companies/ Factories.

c. In case of confirmed repeated violations or when the principles of Good Manufacturing Practice (GMP) are not being followed.

d. If the Company/ Factory registration has been cancelled, or its production has been ceased in the country of origin, or circulation of its products have been stopped in any country due to technical reasons.

e. In the event that, incorrect particulars have been stated in the application form.

f. Lack of any necessary condition of pre-qualification.

Article (12): **The Technical Committee may reject pre-qualification application or cancel pre-qualification of any Company/Factory or Branch, indicating the reasons. The Company/Factory may appeal to The Minister of Health within two months from the date of notification to their Local Agent / representative about the discontinuation of pre-qualification due to non compliance with pre-qualification requirements or the refusal for factory visit.**

Article (13): **Re-qualification of the company could be considered if cancellation reasons are no longer exist. Re-qualification will be conducted with the same conditions and procedures of Pre-qualification.**

Article (14): **The Company/Factory shall notify the concerned Directorate in the following cases:**

a. In case, the Company/Factory ownership' particulars have been changed.

b. In case, the Company/Factory Local Agent has been changed.

Article (15): **The Tenders Board will be notified of the lists of Companies/Factories of specialized medical supplies that have been pre-qualified by Ministry including the name and address of their Local Agent, in order to allow their participation in the tenders.**

Article (16): **Pre-qualification of Companies/Factories of medical supplies shall be valid for five years from the date of pre-qualification. Re-qualification could be carried out for similar periods with the same conditions and procedures.**