

Circular Communication

**MINISTRY OF EXTERNAL AFFAIRS
SRI LANKA**

(Fax General: 2446091/5357407, Economic Affairs Division: 2422644)
E-mail: arthikakatayuthu@gmail.com

To : All Heads of Mission/Post - Circular No. 157
Copy : Secretary, Ministry of Health [Fax 2672883, E-mail postmaster@health.gov.lk]
From : FOREIGNSEC/COLOMBO
Date : October 15, 2012

Reference: EA/GEN/560[Vol ii]

Following for Heads of Missions/Posts from DG/EA

INVITATION FOR EXPRESSION OF INTEREST [EOI] TO SET UP AN INTRAVENOUS [IV] SOLUTION MANUFACTURING PLANT IN SRI LANKA.

1. The Ministry of Health [MOH] has called Expression of Interest [EOI] from interested parties globally to set up an Intravenous [IV] Solution plant in Sri Lanka
2. Grateful if you could make necessary arrangements to provide adequate and effective publicity in this regard. (ENDS)



MINISTRY OF HEALTH

INVITATION FOR EXPRESSION OF INTEREST (EOI) TO SET UP AN INTRAVENOUS (IV) SOLUTION MANUFACTURING PLANT IN SRI LANKA

1. BACKGROUND

Establishment of Intravenous (IV) Solution Manufacturing Plant in Sri Lanka is a long felt need and it has been identified as a priority requirement for the country by the Ministry of Health (MOH). Sri Lanka spends considerable sum of foreign exchange for importation of IV Infusion Solutions (mainly Saline and Dextrose solutions) for health care needs of over 20 million people in Sri Lanka. Further in case of a sudden disaster country may need to import large quantities of IV Fluids urgently, which could be very costly. The current annual requirement of IV Solutions is approximately 12 million of 500 ml bottles for government health institutions.

2. OBJECTIVE

Considering above, Ministry of Health is planning to establish an IV Solution Plant in Sri Lanka and in this regard MOH invites Expression of Interest (EOI) from well established local and international investors/organizations to set up a suitable IV Solution Plant in Sri Lanka as a resource to the country. MOH proposes to have an agreement with selected investor for buy back guarantee for public sector requirement of IV solution as decided by the Ministry of Health for a period which will be determined by Ministry of Health with negotiated price formula.

3. Requirement

Ministry of Health requires a Plant capacity of minimum 20 million units of IV solution bags per annum of Form Fill/Blow Fill Seal (FFS) technology with 'Eurohead' rubber bung type (complete fusion technique at the collar) bags/bottles giving consideration to the current and future requirement. The plant operation compatibility shall be with 300 days per year with 3 shifts working.

4. SUBMISSION OF PROPOSAL

A detail proposal and relevant information with regard to EOI for the establishment of IV Solution Plant should be forwarded to the Secretary, Ministry of Health of under mentioned address in a sealed envelope by hand or registered post on or before 10.00 a.m. on 09th November 2012 and the top left hand corner of the envelope should be marked 'EOI FOR ESTABLISHMENT OF IV SOLUTION PLANT'.

5. PARTICULARS TO BE SUBMITTED

5.1 General Information

- i. Company Profile
- ii. Capability of managing the project with having past experiences in the field of manufacturing of IV solution and experience in establishing of IV plants with similar or higher capacity in countries other than parent country.
- iii. Staff profile with details of their technical qualifications
- iv. Details of Local agent in Sri Lanka if available

5.2 Financial Information

- i. Source of funding and method of funding for this project and terms and conditions applicable.
- ii. Details of statements of business accounts.
- iii. Statements of overall business turnover for three consecutive business years (i.e. 2009, 2010 & 2011) along with the audited financial reports.

- iv. Calculation on the cost per unit produced in the proposed plant considering Normal saline and 5% dextrose infusions as the major products.
- v. Debt service arrangement.
- vi. Statements about outstanding and contingency liabilities for last three years.

5.3 Technical Information

- i. Proposed layout (general arrangement) drawing for complete facility including utility.
 - ii. Project timeline till trial run and commercial production.
 - iii. Detailed list of Production equipments, Laboratory equipments and instruments, utility equipments with proposed make, capacity quantity required and cost. These should include required spares for 2 years operation.
 - iv. Description of packaging material proposed and the reason for the same.
 - v. Description of capacity balancing with manufacturing flow chart.
 - vi. Qualification and validation required for equipments, systems and process and time required for the same.
 - vii. Quality systems proposed with documents required as per World Health Organization (WHO) cGMP guidelines as required by the Cosmetics, Devices and Drugs Authority (CDDA) of Sri Lanka.
 - viii. Manufacturing facility should conform to the World Health Organization current Good Manufacturing Practices (cGMP) requirements.
 - ix. The final product should conform to either British Pharmacopeia (BP) or United States Pharmacopeia (USP) standards.
 - x. Description and cost of each of the following items;
 - a. Land with suitable and adequate water supply.
 - b. Buildings
 - c. Production equipments, sterilization and packing
 - d. Quality Assurance/Quality Control equipments
 - e. Utility equipments
 - f. water treatment plant
 - g. Warehousing facility and equipments
 - h. Safety equipments and facility
 - i. Electrical equipment and lightings
 - j. Piping
 - k. Clean room panels
 - l. Air Handling Unit and ducting
 - m. office equipment and other ancillary equipment
 - n. Canteen facility
 - o. Laundry facility (for general clothes and clean-room clothes)
 - p. Effluent treatment plant
 - q. Water storage facility
6. The investor may develop additional capacity to purify water for producing Water for Injection and for any other IV injections.
7. The proposal must cover all the details of each and every item mentioned in this advertisement. Otherwise the proposal may be rejected.
8. The successful investor will be entitled to the concessions and facilities provided by the Board of Investments (BOI). Details are available at BOI web site <www.investsrilanka.com>. For further details contact Executive Director (Investment) BOI, Tel. +94 11 2438972, E-mail <gowrir@boi.lk>.
9. Further, it is hereby informed that the Ministry of Health will not proceed with any previously submitted and received national and international project proposals, Expression of Interest (EOI) and Tenders with regard to the establishment of IV solution manufacturing plant in Sri Lanka.

Secretary

Ministry of Health, "Suwasiripaya"

No 385, Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka

Tel/Fax + 94 11 2672883