Republic of the Philippines
National Kidney and Transplant Institute
Bids and Awards Committee
East Avenue, Quezon City 1100
981-0300 / 981-0400 Local 1157
http://www.nkti.gov.ph/

MINUTES OF PRE-BID CONFERENCE
ITB No. 20-004

Present were:

BAC Vice Chairperson:
Mercedita Jocson

BAC Members:
Salvacion Munda, RPh
Ma. Victoria Santos

BAC Secretariat:
Mary Jane Ancheta – Head, BAC Secretariat
Giena Ramos

Technical Working Group:
Marita Dantes, MD
Adoracion Sevilleja
Ma. Cristina Tordilla

Purchasing:
Dave Hernandez

End-user:
Roberto Arco

The **Pre-Bid Conference** for the with **ITB No. 20-004,** held at BAC Conference, G/F NKTI Main Building was called to order by **Ms. Jocson, BAC Vice Chairman at 2:30 PM of December 6, 2019.**

1. Agenda:

   - Presentation of the following:
     a. technical and financial components of the Bid, and
     b. the explanation of the different documents to be submitted by each bidder.

   - Discussion of:
     a. the requirements in the Instructions to Bidders,
     b. the replies to the bidders' queries about the requirements, specifications and other conditions of the contract,

2. Business arising:

   - Upon ascertaining proper BAC quorum, Ms. Mary Jane Ancheta, the BAC Head announced the formal start of the Pre-Bid Conference for ITB No. 20-004.

   - Ms. Jocson introduced the project and acknowledged the presence of various interested parties and prospective bidders, namely:

     1. NO BIDDERS

3. Ms. Jocson declared that no bidders attended the Pre-Bid Conference and will proceed with the scheduled opening of bids on December 19, 2019 at 2:00 PM.

4. The End-user presented the Section VII Technical Specification of the project.

Technical Specifications Particulars	Quantity	Requirements
Budesonide	6,000	250mcg/mL 2mL (unit dose), nebules
Ipratropium + Salbutamol	50,000	500mcg ipratropium (as bromide anhydrous) + 2.5mg salbutamol (as base) x 2.5mL (unit dose), nebules
Ipratropium Bromide	3,000	250mcg/mL, 2mL (unit dose), nebules
NSS	20,000	0.9% 2mL, nebules
Acetylcysteine	2,000	100mg/mL, 3mL solution for inhalation, ampule
Salbutamol	45,000	1mg/mL 2.5ml, nebules

TERMS OF REFERENCE

SUPPLY AND DELIVERY OF VARIOUS MEDICINES

A. DEFINITION OF TERMS:

1. ***Batch (or Lot):***
   A defined quantity of any drug product processed in a single process or series of processes such that it can be reasonably expected to be homogeneous or uniform in character and quality.
2. ***Batch number (or Lot number):***
   A distinctive combination of numbers and/or letters that specifically identifies a batch on the labels, the batch record, the certificate of analysis, etc.
3. ***Drug (or pharmaceutical product or medicine):***
   Any substance or mixture of substances that is manufactured for sale or distribution, sold, supplied, offered for sale or presented, which, when ingested or introduced to the body, causes physiologic effects that will be for use in the following:
   (i) the treatment, mitigation, cure, or prevention or diagnosis of disease, an abnormal physical state or the symptoms thereof and abnormal physiological conditions in humans or animals; or
   (ii) the restoration, correction or modification of organic functions in humans or animals.
4. ***Finished pharmaceutical product:***
   A pharmaceutical product that has undergone all stages of production and quality control, including being packaged in its final container and labeled.
5. ***Good manufacturing practice:***
   The part of quality assurance that ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
6. ***Manufacture:***
   All operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.
7. ***Manufacturer:***
   A company that carries out operations such as production, packaging, repackaging, labeling and relabeling of pharmaceuticals.
8. ***Packaging:***
   All operations, including filling and labeling, that a bulk product has to undergo in order to become a finished product.
9. ***Packaging material:***
   Any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
10. ***Quality assurance:***
    The wide-ranging concept covering all matters that individually or collectively influence the quality of the product. It is the totality of the arrangements made with the objective of ensuring that pharmaceutical products are of the quality required for their intended use.

11. ***Quality control:***
Covers all measures taken including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.

12. ***Specifications:***
A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.

13. ***Starting materials:***
Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

B. POST-QUALIFICATION REQUIREMENTS

1. **Certificate of Product Registration** (CPR) or **Certificate of Listing of Identical Drug Product** (CLIDP):

   1.1. A Certified True Copy of either the CPR or the CLIDP must be submitted. (The Original Copy will be presented to the BAC Technical Working Group within two (2) days after receipt of the Notice for submission of the required Post Qualification Documents to Lowest Bidder).

   1.2. The CPR or the CLIDP must have been signed and sealed by the Philippine Food and Drugs Administration (FDA) ***at least two (2) years prior*** to date of bidding.

   1.3. CPR must be ***valid for the entire period*** of the award. If expiring during the duration of the contract, the proof of renewal must be submitted to the BAC secretariat not later than 2 months before the expiry date.

   1.4. Registration status of Monitored Release (MR) is allowed only for innovator medicines.

2. **Certificate of Current Good Manufacturing Practice** (cGMP):

   2.1 A Certified True Copy of the Certificate of cGMP may be required for submission for special cases.

   2.2 The cGMP must be ***valid for the entire period*** of the award.

   2.3 It must be in ***English*** or should have the ***English translation***.

   2.4 It must state both the same authorized manufacturer cited in the CPR and the same product to be bidded.

   2.5 The generic name and the brand name (if applicable) of the bidded product must be clearly written on the right upper corner of the certified true copy.

   2.6 It must clearly state the validity date or duration of validity.

   2.7 A cGMP with no validity date indicated will be presumed to have a one (1) year validity from the date of last inspection of the plant

   2.8 If the cGMP was issued from a foreign country, it should be authenticated by the Philippine Consular Office or Embassy of that country.

3. The finished pharmaceutical product must have at least one (1) of the following:

   3.1 The result of either **local or foreign chemical assays or bio-assays** conducted at any of the local laboratory facilities that are ***accepted by the NKTI*** (see Appendix I) or at the testing center or laboratory facility of a manufacturing plant that is located in a foreign country and that has a valid certification awarded by the WHO, USA, EU, Australian, UK, Japanese, Korean, Singapore or Canadian pharmaceutical accrediting and inspection authorities. The sample used during the analysis ***must not be expired*** during the time of bidding.

   3.2 A Certified True Copy stating that the finished product is listed in the **latest US FDA Orange Book** or in the **latest Philippine FDA list of equivalent products,** if applicable. The Certified True Copy must be duly signed by the company president or his authorized representative.

   3.3 A Certified True Copy of the **Certificate of Approval issued by the UP – Philippine General Hospital Drug Committee.** The copy must be duly signed by the company president or his authorized representative. The Certificate of Approval from the UP-PGH Drug Committee must be ***valid during the entire duration of the award***.

   3.4 The certificate that it is the **innovator drug**.

4. Affidavit:
   The bidder/company shall submit a notarized affidavit certifying that all documents submitted are true and correct (see attached Form 1).

5. Certificate of exclusive / authorized distributorship from the principal valid for the entire period of the award must be submitted.

6. Distributors/suppliers must submit a certification from their principals that they are the exclusive / authorized distributor of the drug products authorized to submit tenders for the product on behalf of the principal and that all commitments made by them shall be honored by the principal in case of termination of distributorship agreement.

7. **Technical Requirements for Finished Pharmaceutical Products and Packaging:**

7.1 **General Technical Specifications:**

7.1.1 The bidded drug or the finished pharmaceutical product ***must not have a documented negative or adverse feedback report from NKTI or any other hospital or health facility within the last three (3) years***. The negative feedback includes the following: visual deterioration of the drug, poor or absent therapeutic efficacy, adverse drug reactions or other adverse drug events that have been unequivocally determined to be attributed to the poor quality of the drug or the finished drug product after proper and appropriate investigation conducted by the Pharmacy and Therapeutics Committee of the said hospital or health facility. A drug or finished drug product that is under investigation at the time of the bidding will not be included during the current or present bidding.

7.1.2 The finished pharmaceutical products must conform to the latest Philippine Food and Drug Administration (FDA) Administrative Order governing the generic labeling and packaging requirements.

7.1.3 The finished pharmaceutical product and its labeling and packaging shall conform to the following required features:

a) The name of the drug and the lot or batch number and the expiry and manufacture dates are readable from the container or inner packaging.

b) There should be no leakages of intravenous fluids or other parenteral solutions through the closures (e.g., rubber stoppers) of the containers (plastic or glass bottles, vials, or syringes) or through infusion sets.

c) The inner label shall be the same as the outer label.

d) Absence of any of the following negative features during inspection conducted by the Pharmacy and Therapeutics Committee or the Technical Working Group or the Pharmacy Department duly designated by the PTC to conduct the inspection: impurities/ sediments/ precipitates/ discoloration; disintegration of tablets; breakages in glass or plastic containers; and other evidences of physical deterioration of the drug product.

e) When applicable, a complete instruction for reconstitution of the drug product and the inclusion in the label of the specific solvent as well as information regarding the stability of the reconstituted solution must be provided.

7.1.4 A complete and legible drug literature/product insert must accompany the product.

7.2 **Specific Product Technical Requirements:**

7.2.1 The particular technical specifications for each of the finished pharmaceutical product shall be enumerated in the master list. These include specifications with regards to: dosage form, dosage strength, volume, packaging material, specifications for closures (e.g., elastomerics such as rubber stoppers) and their caps or overseals.

7.2.2 ***For Anesthetic Agents:***

7.2.2.1 All anesthetic agents must come in sterile packaging.

7.2.2.2 *Local Anesthetics* used for spinal and/or epidural regional anesthesia should come in sterile packaging or in an "individual peel away form". Sterility should be indicated on the outer cover.

7.2.2.3 *Inhalational Anesthetic* products shall comply with the following:

a) Must have certification with regards to the stability of the solution or the water content, if applicable.
b) Water content of 150 ppm and above to avoid the adverse effects of Lewis acid degradation.
c) Must not exhibit discoloration nor sedimentation once exposed to the elements.
d) At least twenty-five (25) units of Vaporizers must be supplied together with the anesthetic agent. The vaporizer shall be calibrated by the winning bidder every six (6) months while in use.
e) Closed Delivery System bottle in order to maintain sterility, prevent spillage, prevent spillage for the safety of the end-users and to assure correct and optimum administration of the anesthetic agent.
f) The anesthetic agent must come in a non-breakable container.

7.2.2.4 All preparations of *Propofol:* The Medium Chain Triglyceride-Long Chain Triglyceride (MCT-LCT) is the acceptable product preparation (either as 20 ml ampule and 50 ml vial). The 50 ml prefilled syringe is also acceptable.

7.2.3 ***For Intravenous (I.V.) Fluids:***

7.2.3.1 The intravenous fluids should be sterile and pyrogen-free. These shall be indicated in the label and the product literature.

7.2.3.2 The fluid should be clear and colorless in appearance, with no floating particulate matter.

7.2.3.3 The intravenous fluid bottle should conform to the following:

a) the plastic bottle must be made of **medical grade plastic;**
the bottle should be free of the following materials: polyvinyl chloride (PVC), and Di-(2-ethylhexyl) phthalate (DEHP).

b) the manufacturer shall provide Material Data Sheet attesting to the above.

7.2.3.4 The product label on the intravenous fluid bottle must be clear and readable.

7.2.3.5 The graduations used to indicate the volume of the fluids should be clear, visible, easy to read, and must accurately reflect the volume of the fluid at any time during the infusion.

7.2.3.6 The holder of the bottle should have adequate tensile strength to allow it to withstand a pressure or weight that is above the combined weight of the bottle and its full contents.

7.2.3.7 The rubber stoppers (for the single and the dual/twin port) of the intravenous fluid bottle should be durable but easy to puncture. It should be sufficiently firm to allow the passage of the needle with the least possible shedding of particles.

7.2.3.8 The volume of the intravenous fluid must be consistent with the product label.

7.2.3.9 There must be sufficient space available for the addition of other drugs.

7.2.3.10 The supplier should have no history of complaints regarding the quality of the product received from National Kidney and Transplant Institute and that are properly documented by the Pharmacy and Therapeutics Committee in the past three (3) years.

7.2.3.11 For the 0.9% Sodium Chloride used for the Operating Room and all other surgical procedures, the following additional features shall be conformed with:

a) Particular volume: 1 liter;
b) Comes in flexible primary double sterile packaging;
c) Plastic bag-container is fully collapsible and does not require external venting for the bag to empty;
d) The plastic bottle material is non-PVC.

7.2.3 ***For the Inhalational Bronchodilators*** (including Ipratropium-Salbutamol and plain Salbutamol), a biochemical assay is required.

7.2.4 ***For Phytomenadione:*** Preparation is preferably the mixed micelle preparation.

7.3 Technical Specifications for Product Labeling:

The mandatory information for labeling are as follows ("Revised Labelling Regulation Annex A," DOH FDA, 2013)

7.3.1 ***For the Unit Carton:***

a) Product name
b) Dosage form and strength
c) Pharmacologic category
d) Formulation/ composition
e) Indication(s)
f) Warning(s) if applicable
g) Storage condition(s)
h) Pack size
i) Name and address of Manufacturer Authorization Holder (MAH)
k) Rx symbol and caution statement
l) ADR reporting statement
m) Registration number
n) Batch number and Lot number (if any)
o) Expiration date and Date of manufacture
p) Only stickers that indicate the name of the local distributor will be allowed. All other alterations will not be allowed.

7.3.2 ***For Primary Label (excluding blister packs, foil strip and small containers:***

a) Product name

b) Dosage form and strength
c) Pharmacologic category
d) Formulation/ Composition
e) Indication(s)
f) Warning(s) if applicable
g) Storage condition(s)
h) Net content
i) Name and address of MAH
j) Name and address of manufacturer
k) Rx symbol and Caution statement
l) ADR reporting statement
m) Registration number
n) Batch number and Lot number (if any)
o) Expiration date and Date of manufacture

7.3.3 ***For Blister Packs and Foil Strips:***

a) The product name should appear on each unit, or, for multiple Active Pharmaceutical Ingredients (API), the product name should appear on every two (2) units;
b) Dosage form and strength of APIs should appear on each unit or every two units for multiple APIs; however, if the product is visible from its packaging, the dosage form may no longer be indicated;
c) Name and/or logo of the Manufacturer Authorization Holder (MAH) should appear on each unit or every two units for multiple APIs for unbranded products only;
d) The Rx symbol should appear on each unit or every two units for multiple APIs;
e) Batch number and expiration date should appear on every standard blister pack/foil strip; however, if the product is not restricted for dispensing in quantities less than the standard blister pack or foil strip, the batch or lot number and expiry date should appear on each unit.

7.3.4 ***For Primary Label of Small Containers:***

a) Product name
b) Dosage form and strength
c) Warning(s)
d) Net content
e) Name and/or Logo of MAH
f) Rx symbol
g) Registration number
h) Batch and/or Lot number
i) Expiration date and Date of Manufacture

8. The NKTI Therapeutics Committee reserves the right to request for other information, e.g., on raw materials, background of manufacturer and other data as needed to validate its evaluation.

9. The Therapeutics Committee may request for an evaluation of samples of the finished pharmaceutical products when indications arise for this. Indications for evaluation of samples include the following:

a) the particular product has not yet been used nor dispensed at the NKTI previously;
b) the bidding company has not previously joined or offered a bid for the particular product.

The bidder must submit the samples at no charge to the BAC secretariat within two (2) working days from the receipt of the request for samples. In situations where the product cannot be submitted within the prescribed time, the company is required to write a letter of explanation to the PTC within 24 hours. If the justification is acceptable, the PTC can extend the time allotted for submission of the sample.

The Technical Working Group (TWG) or their authorized representatives may be assigned during special situations to obtain samples from the warehouse/ storage area where the products are kept or from other sources (e.g., pharmacies). The bidder shall pay for the expenses incurred by the TWG.

The sampling process and evaluation will be conducted by the TWG specifically assigned to perform such tasks. The TWG shall strictly adhere to the appropriate protocol designed by the NKTI Pharmacy and Therapeutics Committee for sampling (in conformity with the ISO/WHO standards). The number of samples to be submitted will depend on the indications as determined by the TWG. The remaining samples that have not been opened, cut, dissolved, pierced or punctured during the process of evaluation shall be returned to the bidding company if applicable.

10. The **sensitivity disks shall be provided by the principal/distributor to the NKTI laboratory for all parenteral antibiotics** that will win in the bidding. The discs will be submitted directly to the NKTI Laboratory in the presence of representatives from the Pharmacy Division and the Materials Management and Inventory Division (MMID). The number of sensitivity disks shall be determined by the NKTI Bacteriology Section.

C. GENERAL PROVISIONS

1. All deliveries must conform to the conditions under Drug Product/Drug Product Packaging. In addition, the Sales Invoice must state the lot/batch number and expiry date. Each batch of antibiotics must be accompanied by ***Batch Certification,*** or ***Antibiotic Drug Product Batch Notification,*** whichever is applicable.

2. Random chemical assay can be performed on any drug product accepted in NKTI. Cost and charges for all chemical assays or bacterial/sterility testing will be at the expense of the supplier/distributor/principal and shall be done at the laboratory facility chosen by the NKTI Therapeutics Committee.

3. **Non-conforming or adverse result of item C.2** shall be considered as a ***negative feedback*** and as a ***ground for the termination*** of the contract in whole or in part without prejudice to the filing of civil and criminal charges, or imposition of penalties under government applicable rules and regulations.

4. All biological products and all thermolabile medicines must be maintained in a cold chain during transport as evidenced by a ***thermostrip*** to be presented upon delivery. ***Each outer packaging or container*** used for transportation or shipment of the thermolabile medicine must have a thermostrip attached to it.

5. The License to Operate of both distributor and principal must be valid and current.

6. The distributor, principal company, and the manufacturer must have good track records related to prompt delivery, rapid and adequate response to non-conforming or expiring stocks and NKTI rating of the supplier, among others. They should have no history of failure to deliver or delay in delivery of the purchased products that are not due to natural or man-made calamities, to force majeure, or to extraordinary circumstances that are not within the control of the manufacturer or distributor.

   Failure to deliver or delay in delivery, poor response to non-conforming or expiring stocks and poor NKTI ratings will be considered as a ***negative feedback***. A history of recurrent negative feedback may result to imposition of administrative penalties under Sec. 69 of Revised IRR of RA 9184.

7. Manufacturer or principal/distributor must ensure ***availability of at least three (3) months inventory supply at any given time*** during the contract period.

8. Should the winning bidder offer a lower price to any other agency or company after the awarding of the contract, the winning bidder shall reduce its contract price to the afore-mentioned price in the subsequent orders.

9. Duration of contract is one (1) year from date of Notice to Proceed.

10. Quantities ordered shall be adjusted based on the actual usage for the past months.

11. **Expiration** of goods to be delivered must be ***at least one (1) year*** from date of delivery.

12. In case of failure to deliver which is *not* due to natural or man-made calamities, to force majeure, or to extraordinary circumstances beyond control, the supplier shall be subjected to the following penalties:

    - Forfeiture of Performance Bond in aggregate amount, if applicable; and,
    - Payment of liquidated damage equivalent to 1/10 of 1% of the unperformed portion of the delivery for each day of delay including Saturdays, Sundays, and holidays, or, payment of the difference in the price of the undelivered product, plus transportation and other expenses incurred during the purchase by NKTI of such items.

13. The distributor must deliver using "First-Expiry-First-Out" policy, i.e., current delivery must have same or later expiry date compared to its last delivery.

14. In case of a tie after post-qualification of the bidders, the BAC shall use the "drawing of lots" to determine the winner in accordance with GPPB Circular 06-2005.

APPENDIX I

NKTI Accepted Testing Centers for Chemical Assay

1. Institute of Pharmaceutical Sciences, U.P.-N.I.H.
2. Interphil Laboratories
3. Center for Drug Research Evaluation and Studies (CeDRES)
4. Philippine Institute of Pure and Applied Chemistry (PIPAC), Ateneo de Manila University
5. SentroTek
6. Association of Drug Industries of the Philippines (ADIP)
7. Drug Testing Laboratory, Angelo King Medical Research Center, De La Salle Health Sciences Institute
8. Testing centers owned and operated by reputable local manufacturing companies that fulfill the following criteria:
    a. the manufacturing plant must be duly licensed/ registered and fully operational in the Philippines for at least the last 5 years with a Certificate of Good Manufacturing Practice valid for the entire duration of the contract; and,
    b. absence of any negative feedback from the NKTI or other health facilities and the FDA.

    Approval of these testing centers is ***subject to further evaluation*** by the Technical Working Group of the NKTI.
9. Testing centers owned and operated by reputable foreign manufacturing companies that fulfill the following criteria:
    a. the manufacturing plant must be duly licensed/registered and fully operational in the country where it is located for at least the last five (5) years with a Certificate of Good Manufacturing Practice valid for the entire duration of the contract;
    b. the plant must be recognized and accredited by any of the following countries: USA, United Kingdom, Australia and the European Union, with valid corresponding certificates awarded to it. Examples of these certificates include the following:
        - USA FDA certificate
        - UK MHRA (Medicines and Healthcare Products Regulatory Agency) certificate
        - Australian GMP and HTA certificate
        - EU GMP or PICS (Pharmaceutical Inspection Cooperation Scheme) certificate.
        - Japan PDNA certificate.

    c. absence of any negative feedback from the NKTI or other health facilities and the FDA.

    Approval of these testing centers is ***subject to further evaluation*** by the Technical Working Group of the NKTI.

APPENDIX II

THE FOLLOWING DRUGS ARE EXEMPTED FROM THE REQUIREMENT OF HAVING A DRUG/CHEMICAL ASSAY:

1. Anti-allergy
2. Anti-dizziness/anti-vertigo medication
3. Anti-spasmodics
4. Colchicine
5. Enemas (oral and rectal)
6. Estrogen/Progesterones and their combination
7. Fixed dose combination of:
    a. Antituberculosis medicines
    b. Antihypertensives
8. Heparins-- low molecular weight heparins, and unfractionated heparin
9. Immunologicals, namely, sera & immunoglobulins, Turberculin Purified Protein Derivative, vaccines & toxoids
10. Inhalation solution/ nebules; inhalers; dry powder for inhalation
11. Innovator drugs
12. Insulins
13. Intravenous fluids (amino acids, lipids, or dextrose plain or with combination)
14. Intravenous electrolyte additives
15. Intravenous iron
16. Laxative, oral

17. Medication in syrup (e.g., cough syrup and other meds in syrup dosage form); and drops form
18. Medication in sachet forms
19. Muscle relaxants oral form
20. Oral antiseptic solution
21. Sambong
22. Sterile Water for Injection
23. Suppositories (rectal, vaginal)
24. Suspension for hyperacidity
25. Topical medication (cream, ointments, jelly, gels, eye drop)
26. Vitamins and minerals, separately or in combination

5. Any changes in the specifications and requirements discussed in this Pre-Bid Conference shall be issued in the form of Bid Bulletin. Supplemental/Bid Bulletins will be issued not later than seven (7) calendar days before the deadline for the submission and receipt of bids. Any modification to the Bidding Documents shall be identified as an amendment.

There being no other remaining topics for discussion, the **Pre-Bid Conference** was adjourned at **2:32 PM** after the BAC reiterated that deadline and opening of bids shall be on December 19, 2019 at 2:00 pm at BAC Conference, G/F Main Building of NKTI.

Minutes taken by:

TERESA MAE FINES
BAC Support Staff

Reviewed by:

MARY JANE ANCHETA, LLB
Head, BAC Secretariat

Approved by:

ARNOLD S. UY, MD
BAC Chairman