

#### PHILIPPINE GENERAL HOSPITAL

The National University Hospital University of the Philippines Manila Taft Avenue, Manila

PHIC-Accredited Health Care Provider

ISO 9001 Certified

#### **INVITATION TO CONSIGN**

## VARIOUS HEARING DEVICES FOR THE DEPARTMENT OF OTORHINOLARYNGOLOGY – HEAD AND NECK SURGERY

- 1. The **PHILIPPINE GENERAL HOSPITAL (PGH)** with its mandate to sustain the demands of public health services and ensure the continuous availability of low cost but high quality essential medical devices/implants, drugs and medicines, and medical supplies, without entailing additional cost or investment from the government, has adopted the "Consignment System".
- 2. The Consignment System is a method wherein consignors place its goods at the PGH (consignee), and the former is being paid by the latter for the actual quantity sold or consumed only, using the proceeds generated from the sale of the consigned goods as recognized by Section 7.3.2, second and third paragraphs, of the 2016 Revised Implementing Rules and Regulations of Republic Act 9184.
  - The PGH Consignment Committee (PGH-CC) now invites eligible Consignors to submit consignment offers for the consignment of **Various Hearing Devices** for one (1) year subject to renewal.
- 3. Eligibility requirements of the Consignor is contained in the Checklist of Requirements (please see attached). Submitted eligibility documents and evaluation of consignment offers/proposals shall be undertaken by the PGH-CC.
- 4. The complete set of consignment documents may be acquired by the interested Consignor or his/her duly authorized representative from the PGH Consignment Office from **Monday to Friday**, except holidays or suspension of work, **8:00 AM to 4:30 PM** upon payment of the participation fee in the amount of Ten Thousand Pesos (PhP10,000.00) as per PGH Memorandum No. 2018-118.

It may also be downloaded free of charge from the website of the <u>Philippine General Hospital</u>, provided that Consignors shall pay the applicable fee for the Consignment Documents not later than the submission of their consignment offer.

5. The PGH-CC will hold the following consignment activities, which shall be open to prospective consignors who availed of the consignment documents:

Activities	Schedule
Deadline for Submission of	Date: 28 July 2023 (Friday)
Consignment Offers	Time: <b>3:00PM</b>
	Venue: Consignment Unit

Activities	Schedule
	Property and Supply Division

- 6. Submission of consignment offers/proposals beyond the stated time and date shall no longer be accepted.
- 7. The PGH reserves the right to accept or reject any and all offers/proposals, cancel or declare a failure of consignment, or not award the contract at any time prior to contract award, without incurring any liability to any Consignor or Consignors.
- 8. For further information, please refer to:

PGH CONSIGNMENT UNIT
PROPERTY AND SUPPLY DIVISION

Philippine General Hospital Taft Avenue, Ermita, Manila

Trunk Line: +63(2)8554-8400 local 3018

Approved by:

PETER B. BERNARDO, MD

PGH-CC Chairperson



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#### TERMS OF REFERENCE

# FOR CONSIGNMENT OF VARIOUS MEDICAL DEVICES FOR THE DEPARTMENT OF OTORHINOLARYNGOLOGY – HEAD AND NECK SURGERY

#### I. PROJECT DESCRIPTION

PGH is in need of a **CONSIGNOR** to consign a brand new medical devices for the different clinical department of the Philippine General Hospital.

For this purpose, the project medical device shall be understood as "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

- a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
  - Investigation, replacement, modification, or support of the anatomy or of a physiological process;
  - Support and sustenance of life, control of conception, or disinfection of medical devices;
  - Provision of information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body
- b) Which does not achieve its primary intended action in or on the human body by pharmacologic, immunologic, or metabolic means, but which may be assisted in its intended function by such means.

The number of source/s for CONSIGNOR/s, whether single or multiple shall be determined by the PGH-Consignment Committee.

Multiple sources shall be allowed in instances when the responsive **CONSIGNOR** with the lowest price offer cannot adequately fill-up the quantity demanded by the Hospital within a given consignment period.

In case that the contract is awarded to multiple sources, the schedule shall be set on the

sourcing of said item(s) from all the **CONSIGNOR/s**. However, identification of specific **CONSIGNOR**/s may be allowed for items considered highly specialized, or where small variations may significantly influence the safety, efficacy, and general outcome of the treatments or procedures where the item will be used, provided that it is supported with valid justification by the respective Department Head and approved by the PGH Director.

#### II. CONTRACT DURATION

The Consignment Agreement shall be valid for one (1) year, renewable subject to satisfactory performance to be recommended by the Consignment Committee and approval by the Director.

#### III. ELIGIBILITY REQUIREMENTS (Please refer to ANNEX A)

#### IV. SCOPE OF WORK

Ensure high quality, brand-new, timely or immediate delivery, and stock availability of the medical devices for operational use of the said selected clinical departments at reasonable prices based on the Consignment List (*Please refer to ANNEX B*)

#### V. TERMS AND CONDITIONS

- 1. The **CONSIGNOR** shall be required to fulfill the following:
  - 1.1. Deliver, as the need arises, brand-new medical devices indicated in the consignment orders;
  - 1.2. Deliver variable items (as to size, models, quality) to be confirmed by the Doctor based on the actual need of the patient/s in case the items to be used are not yet determined due to compatibility concerns, which will then be reflected in the Consignment Order;
  - 1.3. Deliver/supply consigned items within 48 hours upon receipt of order, with commitment to stock availability;
  - 1.4. Deliver a "custom-made medical device" which refers to a medical device, other than a mass-produced medical device, that is.—
    - (i) Assembled or adapted in the manner that is intended for individual patient; or

- (ii) Specially fabricated or imported for the sole use of a particular person, in accordance with the specifications of a qualified practitioner;
- 1.5. Open to inspection and/or testing of all deliveries by the PGH to the extent practicable and necessary prior to acceptance;
- 1.6. Comply with the security, safety, and PGH house rules related to the issuance of medicines and other pharmacy products to patients;
- 1.7. Is subject to the investigation and submission of report/s to PGH for any incident or medication safety issue related to the activities done by the **CONSIGNOR**;
- 1.8. Relieve the PGH from any responsibility for any loss of consigned items arising from fortuitous events beyond the control of the PGH; provided, however, that such loss is not due to negligence resulting to theft or pilferage, and in which case the PGH Pharmacist-on-Duty/Nurse-on-Duty/Administrative Officer-on-Duty, or those staff physically present within the immediate vicinity of incident, including the security guards shall be held jointly and severely liable for the monetary value of the goods pilfered/stolen;
- 1.9. Certify that all the documents submitted are complete and authentic copies of the original, and that all statements and information provided therein are true and correct
- 2. The consigned items shall be delivered and accepted as follows:
  - 2.1. Just-In-Time Inventory Item/s<sup>1</sup> the CONSIGNOR agent delivers item directly to Operating Room (OR)/Procedure Supply Center;
  - 2.2. Non-General/Special Inventory Item/s<sup>2</sup> the CONSIGNOR delivers initial stock items to OR/Procedure Supply Center and the item shall be inspected immediately together with the representatives of the Internal Audit Services Staff (IASS) assigned to do inspection; and
  - 2.3. General Inventory Item/s (Property and Supply Division or PSD Floor Stocks)<sup>3</sup> the CONSIGNOR delivers initial stock items to PSD Warehouse

<sup>&</sup>lt;sup>1</sup> Item V. (11) of the Consignment Guidelines, *Just in Time Inventory* - refers to the inventory management system where items are made available only when the need for the item arises and no stocks are kept on standby.

<sup>&</sup>lt;sup>2</sup> Item V. (17) of the Consignment Guidelines, Special/Non-General Inventory Item/s - refers to the inventory management system where special use supplies are directly requested by concerned department/area and made available as floor stocks to cater the needs of individual patients and usage charged directly by the OR/Procedure Supply Center to their patients' accounts.

<sup>&</sup>lt;sup>3</sup> Item V. (10) of the Consignment Guidelines, *General Inventory Item/s (PSD Floor stocks)* - refers to the inventory management system where items are made available to a) wards/areas through their respective departments; regarded as floor stock items considered to be part of the operational costs and not charged to individual patients, and b) supply outlet, charged items used to individual patients.

and the items shall be inspected immediately together with the representatives of the IASS assigned to do inspection.

- 3. The CONSIGNORs are prohibited from the following acts:
  - 3.1. Offer/Deliver "counterfeit medical device", that is, a medical device, the label or outer packing of which is an imitation of, or resembles or so nearly resembles that of another medical device, as calculated to deceive into believing that it is the label or outer packing of a medical device of another manufacturer;
  - 3.2. Offer/Deliver "misbranded medical device", that is, a medical device
    - (a) Which is not labelled in the prescribed manner;
    - (b) Which has on the label or labelling, any word, statement, other matter or information required by these rules, to appear not prominently or with such conspicuousness as compared with other words, statements, designs, or devices on the label or labeling, and in such terms as may render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
    - (c) Which is not labeled with directions for use and such warnings against use in indications wherein its use may be dangerous to health, or against unsafe administration or application, in such manner and form as are necessary for the protection of users, or as may be prescribed;
    - (d) With a label or container, or anything accompanying which, bearing any statement, design, or device which makes any false claim for the medical device or which is false or misleading in any particular; or
    - (e) Which is so colored, coated, polished, or treated that damage is concealed, or which is made to appear of better or of greater performance than it really is;
  - 3.3. Offer/Deliver "substandard medical device", that is, a medical device that is not of specifications;
  - 3.4. Offer/Deliver "refurbished medical device", that is, a medical device that was previously owned and reconditioned for resale, even if it meet the safety and performance parameters set by the manufacturer

## VI. TERM OF REMITTANCE OF THE SALES PROCEEDS

All payments shall be referred to the payment provision of the Consignment Agreement that is "the consignee agrees to remit the sales proceeds to the CONSIGNOR in fourteen (14) days, after receipt of any of the following, whichever is applicable:

- (a) Receipt by the consignee of the funds from the funding agency/ies;
- (b) Receipt by the consignee of the patient's payment."

#### VII. PARTICIPATION FEE

A complete set of Consignment Documents may be acquired by interested Consignors from the PGH Consignment Office upon payment of the participation fee in the amount of Ten Thousand Pesos (PhP10,000.00) as per Memorandum No. 2018-118.

It may also be downloaded free of charge from the website of the <u>Philippine General Hospital</u>, provided that Consignors shall pay the applicable fee for the Consignment Documents not later than the submission of their consignment offer.

#### VIII. POINT OF CONTACT

The **CONSIGNOR** will liaise with only six (6) offices and will receive Job orders only from the following:

- Office of the Deputy Director for Health Operations Represented by the Deputy Director, Dr. Rodney B. Dofitas;
- Department of Otorhinolaryngology Represented by the Chairperson, Dr. Maria Rina T. Reyes-Quintos;
- 3. PGH-Consignment Committee Represented by the Chairperson, **Dr. Peter B. Bernardo**; and
- 4. PGH-Consignment Office Represented by the Head, Ms. Anna Leah G. Vinluan

All communications and requests are to be directed to the above named individuals. The above named individuals may designate a point person-in-charge of all requests and other communications regarding the **CONSIGNOR**.

PETER B. BERNARDO, MD Chair, PGH-CC

## **ANNEX "A"**

## CHECKLIST OF REQUIREMENTS FOR CONSIGNMENT OF VARIOUS MEDICAL DEVICES FOR THE DEPARTMENT OF OTORHINOLARYNGOLOGY – HEAD AND NECK SURGERY

#### **ENVELOPE NO. 1**

#### **Eligibility Documents**

- 1. Appropriate Registration Certificate from the:
  - Securities and Exchange Commission (SEC), for corporation
  - ➤ Department of Trade and Industry (DTI), for sole proprietorship
  - ➤ Cooperative Development Authority (CDA), for cooperatives;
- 2. Mayor's permit issued by the city or municipality where the principal place of business of the prospective **CONSIGNOR** is located;
- 3. Company profile indicating the following
  - 3.1 Company background;
  - 3.2 That the company is a major distributor of medical devices in the Philippines for at least five (5) years; and
  - 3.3 Preferably, with supply chain presence in major areas of the country;
- 4. List of completed and all its ongoing government and private contracts, including contracts awarded but not yet started, if any, whether similar in nature and complexity to the contract to be consigned using the attached prescribed format regardless consignment or procurement contract;
- 5. Sworn and duly notarized statement that the prospective **CONSIGNOR** has not been "blacklisted" to participate in biddings by any government agency;
- 6. ISO 13485-Medical devices-quality management systems for manufacturer. In case the prospective CONSIGNOR is not a manufacturer, its principal manufacturer's certified true copy of ISO 13485 and Good Distribution Practice for Medical Devices (GDPMDS) must be submitted. In case, the CGMP is in foreign language, it shall be officially translated to English language by an appropriate foreign entity.
- 7. List of Consigned Items that is intended to be consigned using the attached prescribed format with the corresponding duly certified copies of Certificate of Product Registration (CPR) issued by the Bureau of Health Devices and Technology of the Department of Health or in the absence of CPR, a Certificate of Compassionate Use issued by FDA for consigned item that requires FDA registration. In case a consigned item is non-registrable, a Certificate of Exemption issued by the FDA shall be submitted indicating specific item number therein;

- 8. Tax Clearance per Executive Order No.398, s. 2005, as finally reviewed and approved by the Bureau of Internal Revenue.
- 9. Valid License to Operate (LTO) issued by the Food and Drug Administration
- 10. Memorandum of Agreement (MOA) between the distributor and manufacturer.

#### Other Requirement

11. Notarized Letter of Conformity with the Terms of Reference to be printed in the CONSIGNOR's letterhead using the attached prescribed format together with a notarized certificate from the CONSIGNOR to assure that manufacturing defects will be corrected within a given time from receipt of the written notice of the defect by the authorized officer, and that the consigned items supplies/delivered are free from expiration, defects, and/or all the conditions imposed under the contract.

#### **ENVELOPE 2**

#### Consignment Price Offer shall contain:

- 1. Accomplished Consignment Form / List;
- 2. An electronic format of their accomplished Consignment List / Form in USB Flash Drive (virus-free); and
- 3. Accomplished List of Consigned Items Intended for Consignment
- 4. An electronic format of the accomplished List of Consigned Items Intended for Consignment in USB Flash Drive (virus-free)

## CONSIGNOR's Letterhead

## List of Completed and All Its Ongoing Government and Private Contracts

Name of the Contract	Consignee	Contract Period
ON-GOING SIMILAR CONTI	RACTS(including contracts awara	led but not yet started)
COMPLETED SIMILAR COM	NTRACTS	
	Representative)	rinted Name of the Authorized d:

## **CONSIGNOR**'s Letterhead

## List of Consigned Items Intended for Consignment

Item No.	Consigned Item(s)	CPR Numbers	Date of Issuance	Date of Validity

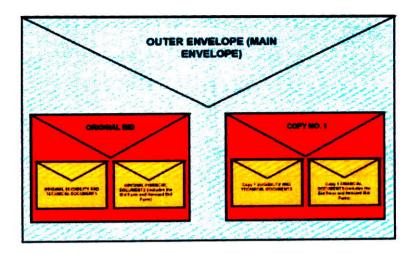
(Signature	over	Printed	Name	of	the	Authorized
Representa	tive)					
Dat	te Sig	ned:				

## CONSIGNOR's Letterhead

## **LETTER OF CONFORMITY**

Title	e of the Project:	CONSIGNMENT OF VARIOUS MEDICAL DEVICES FOR THE DEPARTMENT OF OTORHINOLARYNGOLOGY – HEAD AND NECK SURGERY
To:	PETER B. BERNAL Chairperson PGH CONSIGNMENT Philippine General H Ermita, Taft Avenue,	r COMMITTEE (PCC) ospital
<b>FOR</b>	Terms and Reference o	ne PGH CONSIGNMENT COMMITTEE that our company,, located at conforms f this project: CONSIGNMENT OF VARIOUS MEDICAL DEVICES NT OF OTORHINOLARYNGOLOGY - HEAD AND NECK s) to be issued.
		(Signature over Printed Name of the Authorized Representative)  Date Signed:

Please be guided with the following illustration:



ALL envelopes shall be sealed and marked, which shall contain the following details:
For the Main Envelope:
☐ Name of the Consignment Project in CAPITAL LETTERS
☐ Name and address of the prospective CONSIGNOR in CAPITAL LETTERS;
☐ Be addressed to the PGH-Consignment Committee in CAPITAL LETTERS
Bear a warning "DO NOT OPEN BEFORE" the date and time for the Opening Of
Consignment Offer as stated in the Invitation to Consign or as change through a Bid Bulletin.
For other Envelopes (Original and Copy 1):
For Envelope 1:
☐ Bear a marking "ORIGINAL" or "COPY 1" for photocopy in CAPITAL LETTERS
☐ Below it "ENVELOPE 1: ELIGIBILITY"
For Envelope 2:
☐ Bear a marking "ORIGINAL" or "COPY 2" for photocopy in CAPITAL LETTERS
☐ Below it "ENVELOPE 2: ACCOMPLISHED CONSIGNMENT FORM"

#### Annex B

#### List of Medical Devices / Implants of the PGH

**Definition of Terms:** 

Generic Name Chemical or non-proprietary name of the drugs/supplies/devices

Distributor Company who was appointed by the manufacturer to distribute or deliver the products to the retailer Principal/Manufacturer and/or owner of the brand name or proprietary name of the drug/supplies/devices

Brand Name Proprietary name of the drug/supplies/devices

Estimated Quantity quantity in pieces per month

Consigned Price to PGH The least and best price offered by the Consignor to PGH

Market Price (Hospital/ Drugstore) Prevailing price in the market i.e. leading drugstore (Mercury) or nearby hospitals (if product is not available in Mercury)

Suggested Retail Price per pc. Suggested retail price of PGH to the public (lower than the market price)

Requesting Unit: DEPARTMENT OF OTORHINOLARYNGOLOGY - HEAD AND NECK SURGERY

reques	questing offit. DEPARTMENT OF OTORNINOLARTINGOLOGY - HEAD AND NECK SURGERY							
	Osnorio Herre		Principal Manufacturer	Distributor	Brand Name	Consigned Price to	Market Price to	REPRESENTATE OF STREET
1	Cochlear Implant - Moderate-severe to profound hearing loss, bilateral - Single-sided deafness	20					Other Hospital/ Drugstore	
2	Middle ear implant, incus vibroplasty - Moderate sensorineural hearing loss	10						
3	Middle ear implant, round window vibroplastt - Mixed conductive/sensorinueral hearing loss	10						
4	Active bone conduction implant, transcutaneous - Conductive hearing loss - Mixed conductive/sensorineural hearing loss - Single sided deafness	10						
5	Passive bone conduction implant, transcutatneous - Conductive hearing loss - Mixed conductive/sensorineural hearing loss - Single sided deafness	10						
6	Bone conduction wearable device with bilateral stimulation - Conductive hearing loss - Mixed conductive/sensorineural hearing loss - Single sided deafness	20						

#### Annex B

Requesting Unit: DEPARTMENT OF OTORHINOLARYNGOLOGY - HEAD AND NECK SURGERY

No. of	Generio (Sama	Edmard Quality	Ofetabetas	Brand Name	Charlened Price to PGH	Market Price to Other Hospital/	Price per pr
7	Bone conduction adhesive device with unilateral stimulation - Conductive hearing loss - Mixed conductive/sensorineural hearing loss - Single sided deafness	20				Undstone	
8	Craniomaxillofacial osteosynthesis instruments						
9	Titanium mini-plates, mesh and screws for the mandible						
10	Titanium micro-plates, mesh and screws for the midface						
11	Titatanium reconstruction plates and screws						

Approved by:

PETER B. BERNARDO, MD

Chairperson, PGH Consignment Committee