



6 November 2008

Our ref : (25) in HAHO(S)/Z/56

To Whom It May Concern

Dear Sirs,

Revision To The Terms In The Tender Documents For Drugs

We wish to advise that with effect from 17 November 2008, we shall incorporate the following revisions in our tender templates for drugs:-

- i. Specifying product presentation and labelling requirements
- ii. Specifying maximum pack-size for tablets and capsules
- iii. Addition of a Confidentiality clause

The full documents with highlight of the revisions can be downloaded from our website at [www.ha.org.hk](http://www.ha.org.hk) under Business Opportunities section.

Your particular attention is drawn to revisions i. and ii. as failure to comply with the revised requirements may lead to rejection of the tender offers.

For any enquiry, please contact either Mr. Stephen LEE at telephone no. 3692 5113 (e-mail [leecss@ha.org.hk](mailto:leecss@ha.org.hk)) or Mr. Anthony WONG at 2515 2475 (e-mail [aycwong@ha.org.hk](mailto:aycwong@ha.org.hk)).

Yours sincerely,

(Stephen LEE)  
for Chief Executive  
Hospital Authority

SL/

**ESTABLISHED SOURCE TENDER**

Name of Hospital: Hospital Authority Head Office

Tender Ref.: \_\_\_\_\_

Contract No.: .....

File Ref.: .....

**TENDER FOR THE SUPPLY OF [●]**

---

**LODGING OF TENDER**

To be acceptable as a Tender, this Tender, properly completed **in duplicate** and enclosed in a sealed plain envelope marked “Tender for the supply of [●]” and addressed to the Chairman, **Tender Opening Committee**, must be deposited in the **Hospital Authority Head Office** Tender Box situated at 7th Floor, Multi-centre Block A, Pamela Youde Nethersole Eastern Hospital, 3 Lok Man Road, Chai Wan, Hong Kong on or before 12:00 Noon (Hong Kong time) on [●] (date). Late Tenders will not be accepted.

**INTERPRETATION**

In these Tender Documents (except Part III (Contract)), the following words and expressions shall have the following meanings, unless the context otherwise requires:

- |                                   |   |
|-----------------------------------|---|
| <b>“Authority”</b>                | the Hospital Authority, a body corporate established under the Hospital Authority Ordinance;  |
| <b>“Authority Representative”</b> | the Chief Executive, acting for and on behalf of the Authority or any duly authorized officer for the time being performing his duties;     |
| <b>“Contract”</b>                 | the contract for the Tender Subject Matter to be entered into between the Contractor and the Authority in Part III of the Tender Documents; |
| <b>“Contractor”</b>               | the Tenderer whose Tender is accepted as hereinafter provided;  |

<b>“Department of Health”</b>	the Department of Health of Hong Kong Special Administrative Region;
<b>“Established Source”</b>	a supplier whose pharmaceutical products are from a particular manufacturer and of a specific country of origin and have been used by the Department of Health and/or the Authority through bulk supplies contracts arranged by the GLD or the Authority;
<b>“GLD”</b>	the Government Logistics Department of Hong Kong Special Administrative Region;
<b>“Tender”</b>	the tender for the Tender Subject Matter;
<b>“Tender Closing Date”</b>	the latest date by which Tenders must be lodged as stated above;
<b>“Tender Documents”</b>	comprising Part I (Terms of Tender), Part II (Tender Subject Matter), Part III (Contract), Part IV (Tenderer’s Schedule) and Part V (Offer to be Bound);
<b>“Tender Prices”</b>	the price for the Tender Subject Matter;
<b>“Tender Subject Matter”</b>	the tender subject matter to be performed and/or supplied by the Contractor under the Contract, the specifications for which are set out in Part II of the Tender Documents;
<b>“Tenderer”</b>	the person or persons and/or the firm or the company whose details are set out in Part V of the Tender Documents.

## **PART I**

### **TERMS OF TENDER**

#### **1. Tender and Tender Documents**

This Tender consists of the following Tender Documents:

- (a) Part I - Terms of Tender
- (b) Part II - Tender Subject Matter
- (c) Part III - Contract
- (d) Part IV - Tenderer's Schedule
- (e) Part V - Offer to be Bound

All supplementary information to this Tender will be in writing and forwarded by post, e-mail or fax to all Tenderers known to be in receipt of this Tender. Tenderers must acknowledge receipt of all such supplementary information.

Tenderers are also provided with the following documents for information:

- (a) Notice for Submission of Tenders
- (b) Review Body on Bid Challenges

#### **2. Invitation to Tender**

- (a) Tenders are invited for the supply of the Tender Subject Matter subject to and in accordance with the Contract. Tenderers should be aware that the Tender Subject Matter is to be used, administered, supplied or distributed by the Authority's public hospitals on or to their patients.
- (b) Tenderers should note that the Tender Subject Matter must be properly registered under the relevant ordinance(s) and allowed to be freely sold in Hong Kong and not the subject matter of any product recall in Hong Kong or elsewhere.
- (c) The Authority has the intention to choose a Tenderer based on its Tender Prices and level of compliance with the requirements in the Tender Documents and (where applicable) the recommendations of its Drug Selection Committee. Tenders not in compliance may not be considered.
- (d) Subject to paragraph 2(c) above:
  - (i) where the Tender Subject Matter comprises more than one item, the Authority may at its option, either award the Tender based on an overall assessment of all items under offer or award the Tender based on an assessment of each individual item. Notwithstanding the foregoing, the

Authority may, on the recommendations of its Drug Selection Committee, award part(s) of the Tender for any quantity of the Tender Subject Matter to one or more Tenderer(s) and/or part(s) thereof to Tenderer(s) representing manufacturer(s) who have previously supplied the Tender Subject Matter to the Authority through bulk supplies contracts arranged by the GLD or the Authority;

- (ii) where the Authority has specified in the Tender Subject Matter a desirable range of pack sizes for some or all of the items (“**Range**”), the Authority shall firstly evaluate those items on offer which are within the Range and the Tender may be awarded in respect of some or all of such items. It is only when the Tender cannot be awarded in respect of item(s) within the Range will the Authority proceed to evaluate identical item(s) outside of the Range and the Tender may be then awarded;
  - (iii) where the Authority has specified in the Tender Subject Matter requirements on product presentation (its packaging and [if applicable] marking on the product to uniquely identify the product) (“**Product Presentation Requirements**”) and product labelling in respect of some or all of the items (“**Product Labelling Requirements**”), those items on offer which do not comply with the Product Presentation Requirements and Product Labelling Requirements shall be rejected.
- (e) The Authority is not bound to accept any conforming Tender or the lowest price and reserves the right to cancel the Tender or to accept all or part of any Tender.
  - (f) All costs associated with a Tender submission shall be entirely the responsibility of the Tenderer.

### 3. **Tender**

- (a) Tenderers must complete Part IV (Tenderer’s Schedule) and Part V (Offer to be Bound).
- (b) The Tender Documents are to be completed in English or Chinese (except where technical information is expressly required to be provided in English) and in permanent ink or typescript and submitted in the manner stipulated. Where documents to be provided under the Tender Documents are in a language other than the English or Chinese language, a true, accurate and complete English or Chinese translation certified by the translator stating his/her relevant qualifications shall be provided with the original foreign-language document. Tenders not so completed may not be considered.
- (c) In the event that the Authority determines that clarification of, or further information on any Tender is necessary, it will advise the Tenderers of such fact and the Tenderers shall thereafter have 5 working days or such further period as the Authority Representative may specify to submit such clarification or further

information in the form requested (if any). Failure to provide the clarification or further information as may be required may deem the Tender incomplete and such Tender may not be considered.

- (d) Tenderers should inform the Authority in writing immediately of any circumstance or information which may affect their qualification to tender in the Tender.
- (e) Any enquiries from Tenderers concerning this Tender up to the date of lodging their Tenders with the Authority shall be in writing and shall be submitted to:

Hospital Authority Head Office,  
Pharmaceutical Supplies Services Team,  
7<sup>th</sup> Floor Multi-centre Block A, Pamela Youde Nethersole Eastern Hospital,  
3 Lok Man Road, Chai Wan, Hong Kong.  
(Attn: Ms. ?????, Category Manager)  
Telephone No.: 3692 511?  
Facsimile No.: 3692 5138  
Email: ???????@ha.org.hk

Subject to paragraph 3(d) above, after lodging a Tender with the Authority, the Tenderer shall not attempt to initiate any further contact, whether direct or indirect, with the Authority on its Tender. The Authority shall have the sole right to initiate any such further contact and any replies of the Tenderer thereto shall be in writing or formally documented in writing.

#### **4. Tenders to Remain Open**

In consideration of the Authority expending time and manpower in considering its Tender, the Tenderer undertakes and agrees that its Tender shall remain open for not less than one hundred eighty (180) days after the Tender Closing Date and the Tenderer agrees not to withdraw the offer constituted by such Tender for this period.

#### **5. Prices**

- (a) Tenderers must set out its Tender Prices in Part IV (Tenderer's Schedule).
- (b) Tender Prices shall be net prices allowing for all trade and cash discounts.
- (c) The Tender Prices shall include all other costs and expenses incurred by the Tenderer in performance of the Contract.

**6. Accuracy of Tender Prices**

Tenderers should ensure that the Tender Prices quoted are accurate before submitting their quotations. Under no circumstances will the Authority accept any request for price adjustment on grounds that a mistake has been made in the Tender Prices quoted by a Tenderer.

**7. Prices Quoted**

Offers must remain valid for the duration of the Contract unless Tenderers clearly stipulate otherwise. Therefore no request for price variation will be considered. If however a Tenderer wishes to submit an offer which contains a price variation clause, it may do so, with the clear understanding that such an offer may prejudice the award of the Contract. In such case the basis of the price variation formula should be clearly stipulated by the Tenderer in Part IV (Tenderer's Schedule) and will be subject to acceptance by the Authority in writing.

For price comparison purposes any prompt payment discount offered by the Tenderer as set out in Part IV (Tenderer's Schedule) will not be taken into consideration in the tender price assessment.

**8. Payment**

Tenderers should quote the prices in Hong Kong Dollars. Prices quoted in other currencies may be considered and if accepted, payment will be made in the quoted currency. All bank charges incurred by the Contractor will be borne by the Contractor.

**9. Company/Business Organization Status**

- (a) Tenderers must provide the following details to the Authority with their Tenders:
- (i) Name and address of the company/business organization;
  - (ii) Length and nature of business experience including without limitation experience in the performance and/or supply of the Tender Subject Matter;
  - (iii) Shareholders/partners of the company/business organization;
  - (iv) Recent three (3) years audited financial reports which will indicate the financial viability of the Tenderer and the names and addresses of bankers who are prepared to provide references;
  - (v) A copy of its Memorandum and Articles of Association or other documents evidencing its business status;

- (vi) A copy of the organization's Certificate of Incorporation with the Companies Registry (if incorporated), its current business registration certificate and its application form for registration of business;
  - (vii) A copy of all current licence(s) or permit(s) issued in favour of the Tenderer by the relevant authorities that are required to legally perform the Contract and/or supply the Tender Subject Matter; and
  - (viii) Documentary evidence of any agency claimed by the Tenderer in relation to the Tender Subject Matter.
- (b) Tenderers should also provide to the Authority the following documents with their Tenders:
- (i) Audited accounts of the Tenderer for the past three years. The audited accounts must include Director's report, Auditor's report, profit and loss statement, balance sheet, statement of cash flow and notes to the accounts. The accounts shall be prepared on the same basis for each year in accordance with accounting principles generally accepted in the Hong Kong SAR and the disclosure requirements of the Companies Ordinance, Cap 32, or for overseas company the equivalent requirements of the local government; and
  - (ii) Projected profit and loss accounts and cash flow statements for the period of Contract, showing the revenue, operating expenses, capital expenditure and the sources of finance such as upfront investment and/or debt financing.
- (c) Where a Tenderer has previously provided the information requested in paragraphs 9(a) and 9(b), the Tenderer shall specify the tender reference number and date when such information was provided and the Tenderer shall only need to provide any up-to-date information. Notwithstanding the foregoing, the Authority may at any time require all Tenderers to provide complete information requested in paragraphs 9(a) and 9(b) afresh.
- (d) Before the award of this Tender, if a Tenderer is a company not incorporated in Hong Kong, the Authority may require the Tenderer to provide an opinion from a lawyer qualified in the jurisdiction of incorporation and acceptable to the Authority, at the costs and expenses of the Tenderer, in such form as may be required by the Authority. Such legal opinion should cover the following areas:
- (i) whether the Tenderer company is duly incorporated and validly existing under the relevant law and has full power and authority to carry on the business as it is now being conducted;
  - (ii) whether the Tenderer has the power to enter into and perform the proposed Contract with the Authority and whether it has taken all necessary corporate legal actions to authorize the execution and the performance of the proposed Contract; and

- (iii) whether the proposed Contract with the Authority will, upon execution by the authorized signatory or attorney of the company, constitute legal, valid and binding obligations of the Tenderer in the jurisdiction of incorporation as if the proposed Contract is lawful under the laws of Hong Kong SAR.

**10. Tenderer's Commitment**

- (a) All Tenders, information and responses from each Tenderer must be submitted in writing. The Tenderer must submit its Tender on the basis that it accepts and agrees to all the terms of the Tender, including the Contract. In particular, all Tenderers must provide the Certificate of Non-Collusion in Part IV (Tenderer's Schedule).
- (b) The Authority reserves the right to disqualify any Tenderer who submits a Tender that directly or indirectly attempts to preclude or limit the effect of this requirement.
- (c) If the Tenderer is not the manufacturer of the Tender Subject Matter, the Tenderer should note that the Authority reserves the right to make enquiries with the manufacturer at any time, without any prior reference to or consent from the Tenderer.

**11. Acceptance**

- (a) The successful Tenderer will receive by way of letter notification of acceptance of the Tender. Thereafter the successful Tenderer must execute a copy of the Contract prepared by the Authority dated the date of notification of acceptance of Tender by the Authority within the time frame stipulated by the Authority. Tenderers who do not receive any notification within 180 days of the Tender Closing Date should assume that their Tenders have not been accepted.
- (b) If the Tenderer is not the manufacturer of the Tender Subject Matter, the Authority may make acceptance of the Tender conditional upon the manufacturer of the Tender Subject Matter giving representations, warranties and indemnification to the Authority in relation to the Tender Subject Matter in respect of (and in addition to those given by the Contractor in) Clauses 10.1(b), 10.1(d), 10.1(e), 10.1(f), 10.1(g), 10.1(h), 10.1(i), 10.1(k) and 12 of the Contract.

**12. Acceptance Notification Binding on the Tenderer**

Written notification of acceptance by the Authority Representative shall be binding on the Tenderer notwithstanding that the formalities of contract execution have not been completed.

**13. Samples**

- (a) Tenderers are required to submit at least one sample of each item of the Tender Subject Matter under offer in this Tender in original sales pack proposed to be supplied to the Authority for evaluation, free of all costs and expenses, to:

Hospital Authority Head Office  
Pharmaceutical Supplies Services Team,  
7<sup>th</sup> Floor Multi-centre Block A, Pamela Youde Nethersole Eastern Hospital,  
3 Lok Man Road, Chai Wan, Hong Kong.  
(Attn: Ms. ??????, Sample Unit in-charge)

(Working Hours: Monday to Friday - 9:00 a.m. to 5:30 p.m.)

BEFORE THE TENDER CLOSING DATE.

- (b) Samples submitted may be subject to laboratory testing and/or evaluation so as to ascertain whether or not the Tender Subject Matter complies with the specifications. If a sample has been subjected to laboratory testing/evaluation and fails such testing/evaluation (or is found to be of inferior quality), the whole of the Tenderer's Tender will not be further considered.
- (c) Tenderers are requested to seal their samples in such a manner that they will not become loose or cannot be replaced without breaking the seal. Tenderers shall be solely responsible for ensuring that the samples are so packaged that they will not be tampered with or contaminated prior to the breaking of the seal. Samples may be rejected if they are not properly sealed in the manner provided herein.
- (d) A label bearing the following information should be attached to each of the samples:
- (i) Tender reference number;
  - (ii) Company chop;
  - (iii) Brief description of the item;
  - (iv) Item number which is identical to the item number indicated in Part II;  
and
  - (v) Tender Closing Date.
- (e) For chemicals and dangerous goods, Tenderers should submit a Material Safety Data Sheet ("MSDS") together with the tender samples. MSDS shall provide procedures for proper handling and storage and shall include information such as physical data, chemical composition, health effects, first aid (e.g. correct treatment for eyes, skin, ingestion) and spill or leak procedures.

- (f) A receipt for samples duly signed by the Sample Unit in-charge should be obtained as proof of delivery. TENDERERS ARE REMINDED THAT THEIR OFFERS WILL BE JEOPARDIZED IF SAMPLES HAVE NOT BEEN SUBMITTED IN ACCORDANCE WITH THE ABOVE REQUIREMENTS. Samples submitted may not be returned. Additional samples should also be supplied when requested.
- (g) The successful Tenderer will be notified by the Authority Representative of the accepted Tender sample(s) for the purposes of the Contract.

**14. Destruction of unsuccessful Tenders**

Unsuccessful Tenders (including any documents submitted therewith) shall be destroyed three (3) years after the date the Contract has been awarded and signed.

**15. Environmental Friendly Measures**

The following environmental friendly measures are recommended in the preparation of the Tender:

- (a) All documents should preferably be printed on both sides and on recycled papers. Papers exceeding 80 gsm are not recommended as a general rule.
- (b) Excessive use of plastic laminates, glossy covers or doubled covers should be avoided as far as possible. Use of recyclable non-glossy art board paper as document covers is recommended.
- (c) Single line spacing should be used and excessive white space around the borders and in between the paragraphs should be avoided.

**16. Contractor Performance Monitoring**

Tenderers should note that in the event a Tenderer is awarded the Contract, the Tenderer's performance in the Contract shall be monitored and taken into account in evaluating the Tenderer's tenders in response to invitations for tenders by the Authority in the future. If in the sole opinion of the Authority, the performance of the Tenderer in the Contract is unsatisfactory, the Authority may in its absolute discretion disqualify that Tenderer, its holding company and subsidiaries from participation in any future tenders issued by the Authority, for such period as the Authority may in its entire discretion consider appropriate. Tenders from the Tenderer who has been so disqualified from tendering by the Authority shall be rejected.

**17. Consent to Disclosure**

The Authority shall have the right to disclose, whenever it considers appropriate or upon request by any third party (written or otherwise), information on the awarded Contract, without any further reference to the successful Tenderer, the name and address of the successful Tenderer, product description, brand name, model number and country of origin and the Contract amount.

**18. Tender Closing Time in case of Rainstorm/Typhoon**

In case a black rainstorm signal or tropical cyclone warning signal No. 8 or above issued by the Hong Kong Observatory is still in force three hours before the Tender closing time, the Tender closing time will be extended to 12:00 noon (Hong Kong time) on the working day next following (Monday to Friday).

Dated this      day of      .

Mr. Shane Solomon, Chief Executive, HA

*Authority Representative*

## PART II

### TENDER SUBJECT MATTER

#### 1. Tender Subject Matter

(a)

Item No.	(i) Tender Subject Matter	(ii) Specifications	(iii) Minimum Quantity	(iv) Estimated Quantity
1.				
2.				
3.				

Notes: (i) The Authority expects that all items on offer under the Tender Subject Matter are off patent and that their manufacture in the country of origin, and their importation, sale and use in Hong Kong do not contravene any applicable patents/patent applications remaining valid (including those of any former proprietary drug of which any item on offer is a generic version) in any relevant jurisdictions. Any acceptance of the Tender is made on this basis unless clearly indicated otherwise by the Tenderer.

(ii) The Authority's Product Presentation Requirements and Product Labelling Requirements on the items on offer under this Tender Subject Matter are set out on Annexure 1 to this Part II (Tender Subject Matter). Tenderers should note that the Authority reserves the right to amend or substantially alter any of the requirements stipulated in Annexure 1 during the Contract, subject to agreeing with the Contractor on the implementation (such as time table) of the new requirements.

(iii) The minimum quantity represents the minimum quantity of each item of the Tender Subject Matter that the Authority shall purchase under this Contract.

(iv) The estimated quantity for each item is an estimate of the Authority's requirement only. The Tenderer should note that the Authority may require the Tenderer to supply any item or a mixture of items of the Tender Subject Matter under offer up to [●]% of the total estimated contract value.

(b) Duration of the Contract

[●] months.

The Tenderer should note that the Authority can, during the term of the Contract, extend the Contract for a further period up to [●] months with the agreement of the Contractor.

(c) Minimum stock level

The Tenderer is required to maintain a minimum level of stock of each item on offer of not less than [●]% of the estimated quantity of that item awarded under the Contract.

## **2. Information and Documentation**

For each item on offer under the Tender Subject Matter, the Tenderer must submit complete information, descriptive and technical literature, which shall include but not be limited to those set out in this paragraph 2. The Tender may not be reviewed nor considered if any item set out in this paragraph is not submitted or is incomplete.

### **2.1 Technical and Registration Requirements**

- (a) For each item on offer under the Tender Subject Matter, a list setting out:
- (i) Product description;
  - (ii) Product licensed indications in Hong Kong;
  - (iii) Country of origin;
  - (iv) Name of manufacturer;
  - (v) Address of manufacturer;
  - (vi) Brand name;
  - (vii) Packing;
  - (viii) Product shelf-life;
  - (ix) Hong Kong Product Registration number; and
  - (x) Hong Kong Product Registration expiry date.
- (b) For each item on offer under the Tender Subject Matter, the following information and documentation in respect of each manufacturer:
- (i) A certified true copy of the valid Pharmaceutical Manufacturer's Licence issued by the national control authority of the country of origin indicating the manufacturer's compliance with Good Manufacturing Practices as recommended by the World Health Organization, or equivalent;
  - (ii) A copy of the Site Master File of the manufacturer;
  - (iii) Detailed information on the production and quality control facilities; and

- (iv) Qualification and experience of professional and technical personnel involved in production and quality control.

Information and documentation required under sub-paragraphs (b)(ii) to (iv) above in respect of an item under offer may be waived by the Authority if an identical item from an identical manufacturer at identical manufacturing site(s) has previously been supplied to the Authority through bulk supplies contracts arranged by the GLD or the Authority. Tenderers may apply to the Authority for such a waiver in Part IV (Tenderer's Schedule).

- (c) For each local supplier of each item on offer under the Tender Subject Matter, the following information and documentation:
  - (i) A certified true copy of the relevant registrations/licences, such as the Wholesale Poisons Licence and the Wholesale Dealer's Licence to supply Dangerous Drugs; and
  - (ii) Details of the product recall system in place.
- (d) For each item on offer under the Tender Subject Matter, the following information and documentation in respect of that item:
  - (i) A certified true copy of the Certificate of Drug/Product Registration of the Tender Subject Matter issued by the Pharmacy and Poisons Board of Hong Kong SAR;
  - (ii) For those Tender Subject Matter manufactured outside Hong Kong, a certified true copy of the marketing authorization for the Tender Subject Matter issued by the national control authority of a member country of the International Conference on Harmonization ("ICH") or the national control authority of the People's Republic of China ("PRC"), Australia or Canada (hereinafter collectively referred to as "Marketing Authorization")\*;

(Note: The following are currently ICH member countries - Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, U.K. and U.S.A.)

\*The Marketing Authorization may be waived if either (a) the Tender Subject Matter is supplied by an Established Source in which case a certified true copy of the marketing authorization from the country of origin must be provided or (b) evidence is available to demonstrate that the Tender Subject Matter is registered with product registration for export only by the national control authority of a member country of ICH, PRC, Australia or Canada;

- (iii) Information on the registration status of the Tender Subject Matter in any other countries;
- (iv) A copy in English of the complete master formula, method of assay, finished product specifications, stability data with recommended shelf-life and storage condition of the Tender Subject Matter. Evidence showing compliance with appropriate current guidelines of the World Health Organization, where applicable, is also required;
- (v) A copy of the certificate of analysis of a representative batch of the Tender Subject Matter;
- (vi) A copy in English of the bioequivalence studies report of the Tender Subject Matter as compared with the \_\_\_\_\_ brand or a brand that has been used by the Authority through bulk supplies contracts arranged by the GLD or the Authority. The bioequivalence studies must be conducted in accordance with the World Health Organization guidelines; and
- (vii) Information on annual sales volume of the Tender Subject Matter in the country of origin and other countries in which they were sold for the past three years.

Information and documentation required under sub-paragraphs (d)(iii) to (vii) above in respect of an item under offer may be waived by the Authority if an identical item from an identical manufacturer at identical manufacturing site(s) has previously been supplied to the Authority through bulk supplies contracts arranged by the GLD or the Authority. Tenderers may apply to the Authority for such a waiver in Part IV (Tenderer's Schedule).

## **2.2 Patent and Infringement Information Requirements**

- (a) The Tenderer shall in Part IV (Tenderer's Schedule):
  - (i) confirm that the Tenderer is the manufacturer or authorized distributor in Hong Kong of the Tender Subject Matter; and
  - (ii) provide the date(s) from which the manufacturer of the Tender Subject Matter has manufactured and sold any item(s) on offer under the Tender Subject Matter without licence from any former patent holder of any proprietary drug.
- (b) The Tenderer shall also:
  - (i) confirm that having regard to the patent/patent application position, the manufacture of all items on offer under the Tender Subject Matter in the

country of origin and their importation, sale and use in Hong Kong do not contravene any applicable patents/patent applications remaining valid (including those of any former proprietary drug of which any item on offer is a generic version) in any relevant jurisdictions; and

- (ii) state any relevant reasons in support of its confirmation.
- (c) Where there is or has been any validity or infringement litigation or threatened validity or infringement claim (collectively “Infringement Claim”) (for example, any validity or infringement litigation instituted in the jurisdiction where the Tender Subject Matter is manufactured or sold) which may impact upon the Tenderer’s ability in Hong Kong to supply to the Authority any item on offer under the Tender Subject Matter, whether such pertains to the matters set out in paragraph 2.2(b) above or otherwise, the following shall be provided:-
- (i) details of the same including the relevant jurisdiction, the date(s) the threat was made, the content of the threat, the patent(s) under dispute, copies of any warning letter/interlocutory injunction, and how the Tenderer proposes to deal with it;
  - (ii) if there is a pending trial, a synopsis which includes the names of the parties involved in the litigation, the date of commencement of proceedings, the relevant jurisdiction, the name of the court, the patent(s) under dispute and an estimate of the trial date; and
  - (iii) if a court decision has been delivered, a copy of the decision, and whether the time for appeal has expired or not.
- (d) Following submission of the Tender, the Tenderer shall provide such further or supplementary information or documentation (including third party opinions) as the Authority may require to assist its assessment of potential infringements of patent rights or other intellectual property rights if item(s) on offer under the Tender Subject Matter is/are sold by the Tenderer or purchased by the Authority in Hong Kong in accordance with the Contract.
- (e)
- (i) Tenderers should note that, under the Contract, the Contractor shall be required to promptly inform the Authority of, *inter alia*, all developments in connection with any Infringement Claim (and any new Infringement Claim made after any award of Contract), and provide such information or documentation (including third party opinions) as the Authority may from time to time request.
  - (ii) The Tenderer hereby expressly acknowledges the Authority's unilateral right to provide items listed in paragraph 2.2 and/or information therein to third parties to seek advice, comments, confirmations and/or clarifications and by this paragraph authorises such third parties to respond to the Authority, which includes the provision to the Authority

of any relevant information relating to the Tender Subject Matter in their possession. The Tenderer expressly agrees that no such advice, comments, confirmations and/or clarifications from third parties will modify, reduce or otherwise affect any representations or warranties given by the Tenderer (express or implied) or reduce or negate the Authority's reliance on information provided by the Tenderer under this Tender.

- (f) Without prejudice to paragraph 2.2(d) above, confirmations/information/documentation which the Tenderer is to provide under this paragraph 2.2 is to assist the Authority and although such confirmations/information/documentation is intended to cover the period up to the date of the Tender submitted by the Tenderer, the Authority may require such confirmations/information/documentation up to the date of the award of the Tender and the Tenderer shall provide such confirmations/information/documentation. If the Authority is satisfied that it is not necessary, the Authority may not require such confirmations/information/documentation up to the date of the Tender submitted by the Tenderer or up to the date of the award of the Tender.

### **3. Confidentiality**

- (a) Where the Tenderer has provided to the Authority its proprietary information on the regulatory status, the patent status, and the technical data (such as the master formula, method of assay, finished product specifications) of the Tender Subject Matter, which by its nature is confidential (“**Items of Information**”), the Authority shall keep the Items of Information confidential save to the extent that they have to be used (including disclosure to third parties) for the purposes of this Tender, the Contract and other related purposes (such as for drug efficacy and safety, patient treatment, laboratory testing etc).

This confidentiality obligation shall apply for so long as the Authority or the third parties are in possession of the Items of Information or copies thereof, and shall no longer apply when they are destroyed.

For the avoidance of doubt, the confidentiality obligation shall not apply if any of the Items of Information have:

- (i) become part of the public domain or are obvious or trivial;
- (ii) been received by the Authority via a third party who is entitled to disclose such information;
- (iii) been independently developed by the Authority;
- (iv) to be disclosed by law or court order provided notice has been given to the Tenderer; or
- (v) to be disclosed, in the absolute discretion of the Authority, to the competent authorities or Government of Hong Kong SAR provided notice has been given to the Tenderer.

(b) When the Authority provides to any third party Items of Information for the purposes described in paragraph 3(a) above, its sole obligation to the Tenderer is to notify the third party of its obligation to keep such Items of Information confidential substantially in the form of Annexure 2 to this Part II (Tender Subject Matter), and on notification the Authority's sole obligation is discharged and the third party has thereby undertaken the confidentiality obligation to the Tenderer.

#### **4. Contract Deposit**

- 4.1 Tenderers should note that the Contractor is required to place and maintain during the term of the Contract a deposit in the amount equivalent to [●] percent ([●]%) of the total estimated value for the Contract as security for the due performance of all the Contractor's warranties, undertakings and obligations under the Contract, either in cash or in the form of a duly executed and valid irrevocable banker's guarantee issued by a licensed bank under the Hong Kong Banking Ordinance. The banker's guarantee must be approved by the Authority. The Tenderer shall specify in Part IV whether it wishes to pay the deposit in cash or by way of banker's guarantee (in which case the Tenderer must provide the name of the issuing bank and a draft banker's guarantee for the Authority's approval). The Tenderer should note that a banker's guarantee pre-approved by the Authority is annexed to Part IV.
- 4.2 The Contractor shall maintain the full amount of the deposit throughout the term of the Contract (including the renewed period if the Authority and the Contractor agree to renew the Contract) and for a period of not less than three (3) months after termination.

#### **5. Special Requirements**

(a) Basis for Acceptance

Tenderers should note that the award of this Tender will be based, amongst other considerations, on an overall assessment of all items on offer. Tenderers who submit some, but not all, of the items required will not be considered.

Or

Tenderers should note that the award of this Tender will be based, amongst other considerations, on an assessment of each individual item on offer.

(b) Estimated Sample Quantity for Tests under the Contract

Tenderers should note that the estimated sample quantity for tests under the Contract is as follows :

Item No.	Tender Subject Matter	Estimated sample quantity for tests
----------	-----------------------	-------------------------------------

1		
2		
3		
4		

(c) Basis for Price Comparison

The Authority may specify a Range for any item to be offered under this Tender. Tenderers should note that the Tender Price in respect of the item on offer by the Tenderer, regardless of its actual pack size so long as it is within the Range, shall be taken into account in price comparison.

**Product Presentation Requirements**  
**Product Labelling Requirements**

**Instructions to Third Parties**

To: [Third Parties]

Re: Tender for the supply of: [●] (“**Tender Subject Matter**”)

Tender Reference: [●]

Tenderer: [●] (“**Tenderer**”)\*

Contractor: [●] (“**Contractor**”)\*

Please note that the [Tenderer’s/Contractor’s] proprietary information on the regulatory status, the patent status and the technical data (such as the master formula, method of assay, finished product specifications) of the Tender Subject Matter (as the case may be) which by its nature is confidential (“**Items of Information**”) will remain confidential after the Hospital Authority (“**HA**”) has provided it to you and you shall use it only to the extent necessary and appropriate for the purposes required by HA. You shall not use the Items of Information for other purposes or make them available to third parties.

This confidentiality obligation shall apply for so long as you are in possession of the Items of Information or copies thereof, and shall no longer apply when they are destroyed.

For the avoidance of doubt, this confidentiality obligation shall not apply to the extent that the Items of Information:

1. have become part of the public domain or are trivial or obvious;
2. have been received by you via a third party who is entitled to disclose such information;
3. have been independently developed by you;
4. are required to be disclosed by law or court order (including any materials developed by you from the Items of Information) provided that in such event you shall have given the HA and the Tenderer/the Contractor specified above prior notice of such requirement;  
or
5. are required by the HA to be disclosed by you (including any materials developed by you from the Items of Information) to the competent authorities or Government of Hong Kong SAR, provided that in such event the HA shall have given you prior notice of such requirement.

From the Hospital Authority

**PART IV**

**TENDERER'S SCHEDULE**

Notes:

A Tenderer is required to submit details of its proposals in response to this Tender, including but not limited to the information/documentation under request in Part I (Terms of Tender), Part II (Tender Subject Matter) and those set out in these Notes and paragraphs 1 to 7 below. A Tenderer can use separate sheets if needed.

The Tenderer should note that if its proposals depart from any term in Part I (Terms of Tender), Part II (Tender Subject Matter) or Part III (Contract), the Tenderer should specify a list of those departures and reference each departure to the appropriate paragraph(s) and part(s) of the Tender and each should be fully identified, explained and discussed, including the effect of the departure. Specifically, if a Tenderer wishes to make any change to Part III (Contract), it must submit its Tender with a copy of the Contract with the required amendments marked in manuscript. All such manuscript changes should be made and initialed by the Tenderer in permanent ink.

**1. Supply of Tender Subject Matter**

(a)	Tender Subject Matter under offer (item no. must correspond with item no. assigned under Part II)	Specifications	Minimum Quantity	Estimated Quantity	Pack Size (units per container)	Tender Prices (F.I.S. Hong Kong)		First Delivery Lead Time
						Unit Rate HK\$	Total HK\$ (Estimated Quantity)	

(b) Duration of the Contract: [●] months.

(c) The Tenderer is prepared to maintain a minimum level of stock of each item on offer of not less than [●]% of the estimated quantity of that item awarded under the Contract.

**2. Information and Documentation**

For each item on offer under the Tender Subject Matter, the Tenderer must by way of Annexure 1 to this Part IV submit complete information, descriptive and technical literature, which shall include but not be limited to those set out in paragraph 2 of Part II. Without limiting this general requirement, the Tenderer must provide the information/documentation set out below:

**2.1 Technical and Registration Requirements**

- (a) Information on each item on offer under the Tender Subject Matter:
- (i) Product description: \_\_\_\_\_
  - (ii) Product licensed indications in Hong Kong: \_\_\_\_\_
  - (iii) Country of origin: \_\_\_\_\_
  - (iv) Name of manufacturer: \_\_\_\_\_
  - (v) Address of manufacturer: \_\_\_\_\_
  - (vi) Brand name: \_\_\_\_\_
  - (vii) Packing: \_\_\_\_\_
  - (viii) Product shelf-life: \_\_\_\_\_
  - (ix) Hong Kong Product Registration number: \_\_\_\_\_
  - (x) Hong Kong Product Registration expiry date: \_\_\_\_\_
- (b) For each item on offer under the Tender Subject Matter, the following information and documentation in respect of each manufacturer:

*(Please tick “✓” as appropriate)*  
Yes      No

Yes    No

(i)	A certified true copy of the valid Pharmaceutical Manufacturer's Licence issued by the national control authority of the country of origin indicating the manufacturer's compliance with Good Manufacturing Practices as recommended by the World Health Organization, or equivalent.		
(ii)	A copy of the Site Master File of the manufacturer.		
(iii)	Detailed information on the production and quality control facilities.		
(iv)	Qualification and experience of professional and technical personnel involved in production and quality control.		

Any Tenderer who wishes to apply to the Authority for a waiver of the requirements under sub-paragraphs (b)(ii) to (iv) above must state below the contract number(s) of bulk supplies contract(s) arranged by the GLD or the Authority through which an identical item from an identical manufacturer at identical manufacturing site(s) has previously been supplied to the Authority:

Contract No(s):

- (c) For each local supplier of each item on offer under the Tender Subject Matter, the following information and documentation:

*(Please tick "✓" as appropriate)*

Yes    No

(i)	A certified true copy of the relevant registrations/licences, such as the Wholesale Poisons Licence and the Wholesale Dealer's Licence to supply Dangerous Drugs.		
(ii)	Details of the product recall system in place.		

- (d) For each item on offer under the Tender Subject Matter, the following information and documentation in respect of that item:

*(Please tick “✓” as appropriate)*

Yes      No

(i)	A certified true copy of the Certificate of Drug/Product Registration of the Tender Subject Matter issued by the Pharmacy and Poisons Board of Hong Kong SAR.		
(ii)	For those Tender Subject Matter manufactured outside Hong Kong, a certified true copy of the marketing authorization for the Tender Subject Matter issued by the national control authority of a member country of the International Conference on Harmonization or the national control authority of the People's Republic of China, Australia or Canada.		
(iii)	Information on the registration status of the Tender Subject Matter in any other countries.		
(iv)	A copy in English of the complete master formula, method of assay, finished product specifications, stability data with recommended shelf-life and storage condition of the Tender Subject Matter, and, where applicable, evidence showing compliance with appropriate current guidelines of the World Health Organization.		
(v)	A copy of the certificate of analysis of a representative batch of the Tender Subject Matter.		
(vi)	A copy in English of the bioequivalence studies report of the Tender Subject Matter as compared with the _____ brand or a brand that has been used by the Authority through bulk supplies contracts arranged by the GLD or the Authority. The bioequivalence studies must be conducted in accordance with the World Health Organization guidelines.		
(vii)	Information on annual sales volume of the Tender Subject Matter in the country of origin and other countries in which they were sold for the past three years.		

Yes      No

--	--	--	--

Any Tenderer who wishes to apply to the Authority for a waiver of the requirements under sub-paragraphs (d)(iii) to (vii) above must state below the contract number(s) of bulk supplies contract(s) arranged by the GLD or the Authority through which an identical item from an identical manufacturer at identical manufacturing site(s) has previously been supplied to the Authority:

Contract No(s):

## 2.2 **Patent and Infringement Information Requirements**

(a) I/We hereby confirm that:

(i) I am/we are (*tick where appropriate*):

- the manufacturer
- the authorized distributor in Hong Kong

of the Tender Subject Matter.

(ii) the date(s) from which the manufacturer of the Tender Subject Matter has manufactured and sold any item(s) on offer under the Tender Subject Matter without licence from any former patent holder of any proprietary drug is/are as follows:

Date:

(b) I/We hereby:

(i) confirm that having regard to the patent/patent application position, the manufacture of all items on offer under the Tender Subject Matter in the country of origin and their importation, sale and use in Hong Kong do not contravene any applicable patents/patent applications remaining valid (including those of any former proprietary drug of which any item on offer is a generic version) in any relevant jurisdictions; and

(ii) state the following relevant reasons in support of my/our confirmation above:

---

---

- (c) I/We hereby confirm that the following items on offer under the Tender Subject Matter is not/has not been subject to any validity or infringement litigation or threatened validity or infringement claim (collectively “Infringement Claim”) which may impact upon my/our ability in Hong Kong to supply to the Authority any item on offer under the Tender Subject Matter, whether such pertains to the matters set out in paragraph 2.2(b) of Part II (Tender Subject Matter) or otherwise.

Item no. (the item no. must correspond with the item no. assigned under Part II)	No validity or infringement litigation (please tick if affirmative)	No threatened validity or infringement claim (please tick if affirmative)

The Tenderer must provide details (if any) of any Infringement Claim as specified in sub-paragraphs 2.2(c)(i), 2.2(c)(ii) and 2.2(c)(iii) of Part II. Non-provision of information or a “nil” return (in whatever wording which indicates such) shall be construed by the Authority as the Tenderer’s confirmation that there is/has been no such Infringement Claim which may impact upon the Tenderer’s ability in Hong Kong to supply to the Authority any item on offer under the Tender Subject Matter.

**3. Statement of Compliance**

- \*(a) I/We confirm that all the items on offer do comply with the Tender Subject Matter.
- \*(b) I/We confirm that all the items on offer do not comply with the Tender Subject Matter in the following aspects.

---



---



---

(N.B.: \*Please delete (a) or (b) as appropriate and provide details in case of a negative reply.)

**4. Compliance with Previous Offer**

I/We confirm that the Tender Subject Matter offered \*do/do not originate from the same source(s) and \*are/are not identical in every respect to those previously supplied under Contract No. \_\_\_\_\_.

(N.B.: \*Please delete as appropriate and provide details in case of a negative reply.)

**5. Method for Contract Deposit**

Contract deposit can be by cash or banker's guarantee (which requires approval by the Authority). The Tenderer shall indicate below the method for payment of the deposit required under the Contract. If the Tenderer elects to pay the deposit by way of banker's guarantee, it shall attach a draft thereof to this Part IV for approval by the Authority. A banker's guarantee pre-approved by the Authority is attached at Annexure 2 to this Part IV.

\* I/We am/are prepared to pay the contract deposit by:

- Banker's guarantee to be issued by \_\_\_\_\_
  - a draft printed on the bank's letter paper (which does not conform with the Authority's pre-approved banker's guarantee) is attached for the Authority's approval.
  - a draft printed on the bank's letter paper (which conforms with the Authority's pre-approved banker's guarantee) is attached.
- Cash.

(N.B. \*Please delete and tick "✓" as appropriate.)

**6. Payment Discount**

Tenderers are requested to indicate in the spaces provided below what discount they would allow on the tendered prices if payment for each consignment is made in full within:

- (a) seven (7) clear working days from the date of receipt of invoice: \_\_\_\_\_% discount.
- (b) fourteen (14) clear working days from the date of receipt of invoice: \_\_\_\_\_% discount.
- (c) twenty-eight (28) clear working days from the date of receipt of invoice: \_\_\_\_\_% discount.
- (d) Other discount terms offered:  
\_\_\_\_\_  
\_\_\_\_\_

7. **Certificate of Non-Collusion**

I/We certify that this is a bona fide tender, and that I/we have not fixed or adjusted the amount of the Tender by or under or in accordance with any agreement or arrangements with any other person. I/We also certify that I/we have not done and I/we undertake that I/we will not do at any time before the date of notification of acceptance of this Tender any of the following acts:

- (a) Communicate to any person other than the person calling for those Tenders the amount or approximate amount of the proposed Tender, except where the disclosure, in confidence, of the approximate amount of the Tender was necessary to obtain insurance premium quotations required for the preparation of the Tender;
- (b) Enter into agreement or arrangements with any other person that he shall refrain from tendering or as to the amount of any Tender to be submitted;
- (c) Offer or pay or give or agree to pay or give any sum of money or valuable consideration directly or indirectly to any person for doing or having done in relation to any other tender or proposed Tender any act or thing of the sort described above.

In this certificate, the word “person” includes any person and any body or association, corporation or unincorporated, and “any agreement or arrangement” includes any such transaction, formal or informal, and whether legally binding or not.

I/We expressly acknowledge and agree that, without prejudice to any other rights of the Authority, if this certification is in anyway incorrect, or becomes incorrect prior to the award of this Tender, the Authority may:

- (i) disqualify my/our Tender from consideration;
- (ii) withdraw any confirmation of award of tender already made, without penalty or liability;
- (iii) disqualify me/us, our holding company and subsidiaries from participation in any future tenders issued by the Authority for such period as the Authority may in its entire discretion consider appropriate;
- (iv) take such other actions, including reporting me/us to the government or regulatory authorities in Hong Kong or elsewhere, as the Authority considers appropriate.

Name of Tenderer:

\_\_\_\_\_

Signature and Name  
of Person Authorized  
to Sign Tender:

\_\_\_\_\_

Telephone Number:

---

---

Fax Number:

---

Date:

---

---

Affix company chop