醫院管理局
HOSPITAL AUTHORITY

Name of Hospital: Hospital Authority Head Office

Tender Ref.: HAHO(S)/T/26-D113 Contract No.: _____

File Ref.: _____

TENDER FOR THE SUPPLY OF
LACOSAMIDE TABLETS 50MG AND 100MG

LODGING OF TENDER

Each Tender Submission must be submitted in the following manner:

(a) The Tender Submission must be submitted **in duplicate** in hard copy and enclosed in a sealed plain envelope marked "Tender for the supply of Lacosamide Tablets 50mg and 100mg; Closing Date 23 December 2026; Tender Reference: HAHO(S)/T/26-D113", addressed to the Chairman, Tender Opening Committee;

(b) A soft copy (i.e. a CD-rom) of Tenderer's Schedules B1 to B4 and the documents required under Tenderer's Schedules B1 to B4 in Part III of the Tender in text searchable pdf format where applicable must also be submitted as part of the Tender Submission. Each such document should be saved as a separate file with file name in such format as specified in each Tenderer's Schedule. The CD-rom must be properly labelled and included in the sealed envelope of the Tender Submission which is marked with the details as mentioned above. Tenderers should ensure that the hard copy and the soft copy contain the same documents and in case of discrepancies between the two, the soft copy will be treated as the final version; and

(c) The Tender Submission must be deposited in the **Hospital Authority Head Office** Tender Box situated at 7th Floor, Multicentre Block A, Pamela Youde Nethersole Eastern Hospital, 3 Lok Man Road, Chai Wan, Hong Kong on or before 12:00 noon (Hong Kong time) ("**Tender Closing Time**") on 23 December 2026 (date) ("**Tender Closing Date**").

Late submission of Tender Submissions will not be accepted, subject to the Authority reserving its right in its absolute discretion to accept a late tender in circumstances where the Tenderer can demonstrate were beyond the Tenderer's control.

Where a Tenderer submits its Tender Submission via courier and a receipt is needed, the Tenderer should give instruction to the courier to contact the Tender Opening Committee Registry at 7th Floor, Multicentre Block A, Pamela Youde Nethersole Eastern Hospital, 3 Lok Man Road, Chai Wan, Hong Kong before the courier deposits the Tender Submission into the Tender Box.

TENDER CLOSING TIME IN CASE OF RAINSTORM / TYPHOON / "EXTREME CONDITIONS"

The Tender Closing Time and Tender Closing Date will be extended to 12:00 noon the next working day in Hong Kong (i.e. any day from Monday to Friday which is not a public holiday) under the following situations:

(i) a black rainstorm signal or tropical cyclone warning signal No. 8 or above or "Extreme Conditions" issued by the Government is still in force between 9:00 am and 12:00 noon on the Tender Closing Date; or

(ii) it is announced by the Government between 9:00 am and 12:00 noon on the Tender Closing Date that a black rainstorm signal or tropical cyclone warning signal No. 8 or above or "Extreme Conditions" will be issued in Hong Kong between 9:00 am and 12:00 noon on the Tender Closing Date. For the avoidance of doubt, if it is announced by the Government that such signal will be issued at or before a time that falls beyond 12:00 noon on the Tender Closing Date, there will not be any extension of the Tender Closing Time or Tender Closing Date unless the relevant signal is actually issued and is in force between 9:00 am and 12:00 noon on the Tender Closing Date.

PART I

TERMS OF TENDER

1. ABOUT THIS TENDER

(a) This tender relates to the Goods and comprises the following parts ("**Tender**"):

Front Page	Lodging of Tender
Part I	Terms of Tender
Part II	The Goods
Part III	Specific Requirements (including the appendices) and Tenderer's Schedules
Part IV	Terms and Conditions ("**T&Cs**")
Part V	Offer to be Bound
Part VI	Memorandum of Acceptance
Part VII	Annexures to this Tender, including the following:
	Annexure 1: Notice for Tender Submissions.
	Annexure 2: Instructions to Third Parties.
	Annexure 3: Invoice and Delivery Note Information.
	Annexure 4: Review Body on Bid Challenges.

(b) All supplementary information to this Tender will be in writing and forwarded by post, email or fax to all Tenderers known to be in receipt of this Tender. Tenderers must acknowledge receipt of all such supplementary information.

(c) Tenderer's schedules which provide information from the Tenderer in response to "**Specific Requirements**" ("**Tenderer's Schedules**") shall form part of its Tender Submission.

2. INTERPRETATION

(a) In this Tender, the following words and expressions shall have the following meanings unless otherwise stated:

"**Authority**" or "**HA**"	means the Hospital Authority, a statutory body established under the Hospital Authority Ordinance, Cap. 113 of the laws of Hong Kong to manage and control public hospitals in Hong Kong;
"**Authority Representative**"	means the Chief Executive, acting for and on behalf of the Authority or any duly authorised officer for the time being performing his duties;

"**Bulk Supplies Contracts**"	means contracts awarded pursuant to the Authority's tenders or standing quotations, but excludes direct quotations (such as those with reference number beginning with "DQ"), short-term tenders (such as those with reference number beginning with "DST" or ST") and direct purchases pursuant to purchase orders issued by the Authority or the HA Hospitals, save that the Authority may in its absolute discretion decide whether or not a contract qualifies as a Bulk Supplies Contract for the purpose of this Tender;
"**BP**"	means British Pharmacopoeia;
"Community Drug Formulary" or "CDF"	means the drug list established by Primary Healthcare Commission for (i) prescribing and dispensing by doctors under specified Government primary healthcare programme(s); and (ii) dispensing by Community Pharmacies participating in the Community Pharmacy Programme (Community) in accordance with the prescriptions by doctors under the specified Government primary healthcare programme(s);
"**certified true copy**"	means a copy of a document that is certified as a true copy by any one of the following persons: (a) an official of the government to whose custody the original of the document is committed; (b) a notary public (practising in the place where the copy is certified); (c) a lawyer (practising in the place where the copy is certified) and if the copy is certified in Hong Kong, a solicitor practising in Hong Kong; (d) a professional accountant (practising in the place where the copy is certified) and if the copy is certified in Hong Kong, a certified public accountant practising in Hong Kong; or (e) an officer of a court of law who is authorised by law to certify documents for any judicial or other legal purpose;
"**Chief Executive**"	means the Chief Executive of the Authority;
"**Contract**"	means the contract made between the Authority and the Contractor for the supply of the Goods on (i) the terms set out in this Tender; (ii) to the extent agreed

	by the Authority, the terms set out in the Tender Submission by the Contractor; and (iii) any other terms agreed between the Authority and the Contractor;
"**Contractor**"	means the Tenderer whose Tender Submission is accepted by the Authority;
"Community Pharmacy Programme" or **"CPP"**	means any or all of the service models of the Community Pharmacy Programme set out in **Appendix 5.2 to Part III** which include CPP (Community) and CPP (RCH);
"Community Pharmacies"	means community pharmacies contracted by the Health Bureau to participate in the Community Pharmacy Programme (CPP);
"CPP Drug List"	means the designated drug list compiled for HA patients under CPP (Community) and CPP (RCH);
"**Department of Health**"	means the Department of Health of Hong Kong;
"**Deposit**"	has the meaning given in Part II (The Goods);
"**Established Source**"	means item(s) of the Goods manufactured by a particular manufacturer in a specific country/place of origin, which have been used by the Authority through Bulk Supplies Contracts;
"**Estimated Contract Value**"	has the meaning given in Part II (The Goods);
"Family Doctors"	means doctors enlisted in Primary Care Directory or Primary Care Register and engaged by the Health Bureau to participate in specified Government primary healthcare programme(s);
"**Goods**"	means an item of the goods offered or awarded under the Contract, and where the Contractor is the relevant PPP Contractor, including the relevant PPP Goods unless the context otherwise requires;
"GOPC PPP Doctor"	means private doctors engaged by the Authority to participate in the General Outpatient Clinic Public-Private Partnership Programme of the Authority;
"GOPC PPP Good"	means, if applicable, an item of Good identified as a GOPC PPP Good in the Attachment to **Appendix 1** in Part III;

"Glaucoma PPP Good"	means, if applicable, an item of Good identified as a Glaucoma PPP Good in the Attachment to **Appendix 1** in Part III;
"**HA Hospitals**"	means the public hospitals and institutions under the management and control of the Authority;
"**Hong Kong**"	means the Hong Kong Special Administrative Region;
"**HKG**"	means the Government of Hong Kong and its departments;
"**Intellectual Property Rights**"	means any patents, trade marks, service marks, copyright, design rights, confidential information and other intellectual property rights (whether or not registrable) including applications for the grant of any such rights;
"**Invoice**"	means an invoice issued by the Contractor containing such information required by the Authority from time to time, the current requirements are at **Annexure 3**;
"**JP**"	means Japanese Pharmacopoeia;
"**Laboratory**"	means, in relation to a specific test of pharmaceutical product (namely, physical and chemical tests (covering identification and assay) and/or microbiological examination), (a) an independent laboratory accredited to perform the relevant test by the Hong Kong Laboratory Accreditation Scheme ("**HOKLAS**") which is operated by the Hong Kong Accreditation Service of the Innovation and Technology Commission of HKG ("**HKITC**"), or (b) an independent laboratory accredited to perform the relevant test by an accreditation body that is recognised as a Mutual Recognition Arrangement ("**MRA**") Partner of HOKLAS, the certificate of accreditation of which must be provided to the Authority upon request. The current list of MRA Partners of HOKLAS is published on the HKITC website, or (c) such laboratory as approved by the Authority;

"**Permits**"	means such permit(s) or licence(s) issued in favour of the Contractor by competent authorities as may be required (if any) under any applicable law for the performance of the Contract;
"**Ph. Eur.**"	means European Pharmacopoeia;
"**Ph. Int.**"	means International Pharmacopoeia;
"**Pharmacopoeia**"	means Pharmacopoeia of the People's Republic of China, BP, Ph. Eur., Ph. Int., JP and/or USP;
"PPP Contractor"	means the PPP Contractor as selected to participate in any or all of the PPP Programme(s) by supplying the relevant PPP Goods at the relevant PPP Price and delivering such goods to the relevant PPP Doctors during the Term, and notified as such in the Memorandum of Acceptance;
"PPP Doctors"	means private doctors participating in any or all of the PPP Programme(s);
"PPP Good"	means, if applicable, an item of Good identified as a PPP Good in the Attachment to **Appendix 1** in Part III;
"PPP Price"	means the price at which the relevant PPP Contractor(s) shall supply the relevant PPP Goods under the relevant PPP Programme(s) during the Term;
"PPP Programmes"	means any or all of the Public-Private Partnership Programmes of the Authority more particularly set out in **Appendix 5.1** in Part III;
"**Price**"	means the price of the Goods agreed by the Authority, which is inclusive of all sales tax, import or custom duties and any other duties, levies, surcharges, charges or disbursements for packing, packaging, shipping, carriage, insurance, delivery, stacking, installation or testing of the Goods or that may be applicable or incurred by the Contractor in the provision of the Goods under the Contract;
"**Supporting Documents**"	means all documents required by the Authority to evaluate the Tender Submissions which include descriptive and technical literature, catalogues, operating manuals, drawing diagrams and documentary evidence;

"**Tender Closing Date**"	has the meaning given on the front page of this Tender;
"**Tender Closing Time**"	has the meaning given on the front page of this Tender;
"**Tender Submission**"	means, in relation to a Tenderer, the completed tender (including Tenderer's Schedules) submitted by the Tenderer to the Authority under the Tenderer's Offer to be Bound;
"**Tenderer**"	means the person, firm or company who submits a Tender Submission under this Tender.
"Term"	has the meaning given in Part II (The Goods);
"Total Contract Value"	has the meaning given in Part II (The Goods);
"UI" or "Unique Identifier"	means an alphanumeric string captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is associated with a single product or product group. HA's requirements on UI are set forth in Clause 7 of Part II (The Goods) and **Appendix 6** to Part III;
"USP"	means United States Pharmacopeia;
"WTO GPA"	means the Agreement on Government Procurement of the World Trade Organisation.

(b) Definitions used in one part of this Tender shall apply to other parts, unless otherwise stated.

(c) References to paragraphs, sub-paragraphs, clauses or sub-clauses are references to paragraphs, sub-paragraphs, clauses or sub-clauses of this Tender unless otherwise specified.

(d) Headings are for ease of reference only and do not form part of this Tender.

(e) The masculine includes all other genders and vice versa. The singular includes the plural and vice versa.

(f) References to an Ordinance, statutory provision or statutory instrument include a reference to that Ordinance, statutory provision or statutory instrument as amended, extended or re-enacted from time to time and to any regulations made under it.

(g) The meaning of general words is not limited by specific examples introduced by including, for example or similar expressions.

(h) In this Tender, where the Authority's "agreement", "acceptance", "approval", "discretion" or "consent" is required or where the Authority has any right or power under this Tender or where it is entitled to form an opinion (including words to such effect), the Authority may do so in its absolute discretion.

(i) A reference to a specific time for the performance of an obligation is a reference to the time in Hong Kong unless otherwise stated.

(j) A reference to working day means a day on which banks in Hong Kong are generally open for normal banking business to the public, excluding Saturdays, Sundays and public holidays in Hong Kong.

3. INVITATION TO TENDER

(a) Tenderers should be aware that the Goods are to be supplied by HA Hospitals, and, where applicable, Community Pharmacies or Family Doctors and used by HA patients and, where applicable, patients participating in the specified Government primary healthcare programme(s), and that, where applicable, the relevant PPP Goods are to be supplied by the relevant PPP Doctors participating in the relevant PPP Programme(s).

(b) Tenderers must note that their Tender Submissions must comply with the mandatory requirements/specifications of this Tender in every respect for the purpose of evaluation of the Tender Submissions by the Authority. Tender Submissions which do not comply with the mandatory requirements/specifications shall be rejected.

(c) Tenderers must also note that the Goods must be properly registered under the relevant ordinance(s) as applicable, and allowed to be sold in Hong Kong and not the subject matter of any product recall in Hong Kong or elsewhere.

(d) All costs associated with a Tender Submission shall be entirely the responsibility of a Tenderer.

(e) The Authority reserves the right to make enquiries with the manufacturer of the Goods or the relevant authorities at any time, without any prior reference to or consent of the Tenderer.

(f) Tenderers must note that if the Authority has identified a Good as a PPP Good in the Attachment to **Appendix 1** in Part III, and

(i) where there is only one Contractor for such Good, the Contractor, or

(ii) where there are two Contractors for such Good, the Contractor with the lowest Price,

shall be selected as the relevant PPP Contractor for such PPP Good and shall participate in the relevant PPP Programme by supplying such PPP Good at the relevant PPP Price and delivering it to the relevant PPP Doctors during the Term pursuant to

the terms and conditions set out in the Contract, including the relevant part of **Appendix 5.1 and Appendix 5.2** to Part III**.** If the Prices offered by the two Contractors for such Good are the same, both Contractors shall be selected as the relevant PPP Contractors for such PPP Good to participate in the relevant PPP Programme, one for the first half of the initial term and the other for the remaining period of the initial term and any extension of the initial term, and the Authority will select randomly which Contractor to first participate as the relevant PPP Contractor for such PPP Good (or in case the initial terms of the two Contractors are different, the Contractor whose initial term is shorter will be the relevant PPP Contractor for the first half of the longer initial term and the other Contractor will be the relevant PPP Contractor for the remaining period of the longer initial term and any extension thereof). The Contractor(s) in subparagraph (i) or (ii) above shall be notified in the Memorandum of Acceptance whether it is selected as the relevant PPP Contractor for such PPP Good or not, and if applicable, the period of its/their participation.

(g) The Community Pharmacy Programme (CPP) is launched by the Health Bureau (HHB) to strengthen the primary healthcare system in Hong Kong. It expands the role of community pharmacies and pharmacists in line with the Primary Healthcare Blueprint. The CPP aims to alleviate the burden on the public healthcare system by engaging community pharmacies to provide more frequent dispensing services, thereby expanding the clinical roles of community pharmacists and enhancing their involvement in patient care. For details of service models of CPP, please refer to Appendix 5.2 to Part III.

As a government initiative, the Community Drug Formulary (CDF) aimed at enhancing access to affordable drugs within Hong Kong's primary healthcare system. It provides a list of drugs that supports specified Government primary healthcare programme(s) and enables the acquisition of listed drugs at affordable prices while ensuring high standards of safety, efficacy, quality, and cost-effectiveness. Patients receiving care under specified Government primary healthcare programme(s) have the choice to obtain their medications either from participating doctors (i.e. Family Doctors) or community pharmacies (i.e. Community Pharmacies). (Note: details of Community Drug Formulary can be found at https://www.healthbureau.gov.hk/phcc/files/community_drug_formulary.pdf)

When the Goods are listed in the CPP Drug List and/or CDF, the Contractor is required to deliver the Goods to the Community Pharmacies and/or the Family Doctors, in addition to the HA Hospitals. While the Goods to be delivered to the Community Pharmacies may include (1) any drug items listed in the CPP Drug List for dispensing to HA patients and (2) any drug items listed in the CDF for dispensing to patients participating in specified Government primary healthcare programme(s), only drug items listed in the CDF will be delivered to the Family Doctors for prescribing and dispensing to patients participating in specified Government primary healthcare programme(s).

Unless specified in Appendix 5.2 to Part III, all the requirements set out in this Tender also apply to the Goods to be delivered to Community Pharmacies and Family Doctors.

4. TENDER SUBMISSION

(a) Each Tender Submission must be lodged in accordance with the requirements under "**Lodging of Tender**" and completed in English or Chinese (except where certain Supporting Documents are expressly required to be in English). In particular:

(i) Tenderers must complete all parts of the Tender in permanent ink or typescripts. Proposed changes must be in manuscript and initialled by the Tenderer in permanent ink.

(ii) Subject to Clauses 4(c) and 5 below (and except where the Tender expressly provides for the submission of information or a document or sample after the Tender Closing Date), all information requested in the Tender which is necessary to enable the Authority to evaluate the Tender Submission, including without limitation, the Supporting Documents, must be provided with the Tender Submission lodged on or before the Tender Closing Time. Where certain information is in a language other than English or Chinese, a true, accurate and complete English or Chinese translation certified by the translator stating his relevant qualifications must be provided with the original foreign language document.

(b) After a Tenderer has submitted its Tender Submission, the Authority may require the Tenderer to provide further information which the Authority considers necessary or desirable for evaluation of the Tender Submissions within such time as specified (and if no time is specified, within 5 working days), failing which the Authority may deem the Tender Submission incomplete.

(c) The Authority may reject any incomplete/non-compliant Tender Submission. Without prejudice to the generality of the foregoing and subject to Clause 5 below, a Tender Submission may not be considered if any of the required information, document(s) or sample(s) is missing in the Tender Submission lodged on or before the Tender Closing Time. To avoid any potential disqualification or delay, Tenderers are urged to ensure that a complete set of the required information, document or samples is submitted at the time of making their Tender Submissions.

(d) After lodging a Tender Submission, the Tenderer must not attempt to initiate any direct or indirect contact with the Authority. The Authority shall have the right to initiate contact and the Tenderer's response must be in writing. Notwithstanding so, each Tenderer must inform the Authority in writing immediately of:

(i) any circumstance or information which may affect its qualification to tender in the Tender;

(ii) any changes to any information supplied or relevant to its Tender Submission (together with a copy of the new Supporting Document highlighting the changes).

The Authority reserves the right to review the Tenderer's qualified status in light of any new information relevant to its qualification.

(e) Any potential Tenderer may make enquiries before delivering its Tender Submission by writing to:

Hospital Authority Head Office
Procurement (Pharmaceutical Supplies)
7th Floor, Multicentre Block A, Pamela Youde Nethersole Eastern Hospital,
3 Lok Man Road, Chai Wan, Hong Kong

(Attn: Ms. April LEUNG, Supplies Officer)

Telephone No.: (852) 3912 5294
Facsimile No.: (852) 3692 5138
Email: lyt280@ha.org.hk

(f) Any complaints from Tenderers about tendering process or contract award must be in writing and shall be submitted to:

Hospital Authority Head Office
Procurement & Materials Management Section
Attention: Senior Manager (Business Support Service)1
Address: Room 317N, 3/F., Hospital Authority Building, 147B, Argyle Street, Kowloon, Hong Kong

E-mail Address: haho_bss_sm@ha.org.hk
Telephone No.: (852) 2300 6889

(g) Any statement (oral or written) or any action by the Authority in response to a Tenderer's enquiries is for guidance or reference only. Unless specifically stated otherwise, such statement or action will not form part of, or negate, waive or vary this Tender.

(h) The Tenderer agrees that if it is awarded the Contract, it will comply with and give effect to all the terms and conditions of the Contract and that no waiver given by the Authority under paragraph 7 shall affect such obligation.

(i) Clarifications made to Tenderers' enquiries may be published on the following webpage of the Authority or such other applicable website of the Authority if the Authority considers that such clarifications are relevant to the Tenderers in general:

(http://www.ha.org.hk/visitor/ha_visitor_index.asp?Parent_ID=2001&Content_ID=220021&Lang=ENG)

Tenderers shall refer to all published information before submitting their Tender Submissions.

(j) All Supporting Documents must be valid and up to date as at the date of the Tender Submission. The Authority reserves the right to request an updated copy of any Supporting Documents if the Authority considers necessary.

5. REQUEST FOR INFORMATION

(a) In the event that the Authority considers that:

(i) clarification in relation to any part of a Tender Submission is necessary; or
(ii) a document or a piece of information or a sample is missing from the Tender Submission,

it may, but is not obliged to, request the Tenderer concerned to make the necessary clarification, or submit the required document, information or sample. Each Tenderer shall within 5 working days from the date of the request or such other period as specified in the request submit such clarification, information, document or sample in the form required by the Authority. Without prejudice to Clause 4(c), a Tender Submission will not be considered further if complete information, document or sample is not provided as required within 5 working days of the request or such other period as specified in the request, or in the case of clarification, such clarification is not provided by such deadline or is not acceptable to the Authority. As an alternative to seeking a clarification, or the provision of missing information, or a missing document or sample, the Authority may at its absolute discretion decide to proceed to evaluate the Tender Submission on an "as is" basis or not to consider the Tender Submission further.

(b) Any excess clarification, information, document or sample supplied by a Tenderer which goes beyond what has been requested by the Authority pursuant to Clause 5(a) above will be ignored for the purposes of the Tender evaluation.

(c) Tenderers should also note that if the Authority considers that any clarification, information, document or sample submitted by a Tenderer after the Tender Closing Time would alter the Tender Submission in substance in a manner which the Authority considers may be unfair to any other Tenderer, or may give the Tenderer an advantage over any other Tenderer, the Authority will not consider such clarification, information, document or sample irrespective of whether the clarification, information, document or sample is submitted at the request of the Authority.

6. OFFERS TO REMAIN OPEN

In consideration of the Authority expending time and manpower in considering its Tender Submission, the Tenderer agrees that its offer shall remain open for not less than 360 days after the Tender Closing Date, which may by the Authority's written notice prior to the expiry of such period be extended by:

(a) a further period of 90 days; and
(b) such further period(s) as the Authority may specify in order to enable the Authority to complete its consideration of the Tender.

The above period(s) shall be referred to as "**Tender Validity Period**" and each Tenderer agrees not to withdraw its offer during the Tender Validity Period.

7. TENDER PRICES AND PAYMENT

(a) Tender prices must be quoted in Hong Kong dollars, which must be net prices allowing for all trade and cash discounts and inclusive of all cost and expense to be incurred by the Tenderer in the performance of the Contract ("**Tender Prices**").

(b) Tenderers are required to insert accurate Tender Prices in the relevant Tenderer's Schedule. 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.

(c) For price comparison purposes, any prompt payment discount offered by the Tenderer will not be taken into consideration in assessment of Tender Prices.

(d) Prices must remain valid for the duration of the Contract unless otherwise specified or allowed under Part II (The Goods) or other parts of the Contract. No request for price variation or any price variation mechanism will be considered.

(e) Payment must be made in Hong Kong dollars only.

8. APPLICATION TO WAIVE THE PROVISION OF INFORMATION

(a) The Authority may specify in Tenderer's Schedules that a Tenderer may apply for waiver from supplying information under certain items. If so, a Tenderer may apply for a waiver, supported by written justification. The Authority may in its absolute discretion decide to grant or not grant a waiver and may determine the extent of any such waiver, on an individual Tenderer by Tenderer basis.

(b) Any waiver granted to a Tenderer will be subject to any restrictions or conditions imposed by the Authority on that waiver, and in addition (whether specifically stated in the waiver or not) will be subject to the conditions that:

(i) the Authority may revoke the waiver at any time prior to the award of the Contract and that the waiver does not constitute in any respect a waiver or modification of the terms of the Tender (or the Contract if awarded). As such, each Tenderer acknowledges the conditionality of any waiver and must make arrangements to be able to supply the relevant information in time if the waiver is revoked; and

(ii) notwithstanding the approval of the waiver application and without prejudice to the terms of the Tender (or the Contract, if awarded), the Tenderer/Contractor shall at its own cost provide the Authority with such information or documentation (including third party opinion and documents covered by the waiver application) as the Authority may require to assess the intellectual property rights position of the Goods at any time during or after the Term.

9. COMPANY/BUSINESS ORGANISATION STATUS

(a) Tenderers must provide information as specified in "**Company/Business Organisation Status**" and "**Accounts Information**" requirements under the relevant Tenderer's Schedules.

(b) (i) To safeguard the Authority's interests, the Authority will need to be satisfied that a Tenderer has sufficient financial capability to undertake and fulfill the obligations that the Contract may impose on it before such Tenderer can be considered for Contract award. Thus, in addition to the requirements under "**Company/Business Organisation Status**" and "**Accounts Information**", the Authority may need additional information in order to assess the financial capability of the Tenderer(s).

(ii) The Authority reserves the right to reject any Tender Submission or impose further requirements for the award of the Contract if in the opinion of the Authority (I) the result of the financial assessment is not satisfactory or (II) a Tenderer fails to provide accurate and adequate information requested by the Authority for the financial assessment. The further requirements which may be imposed by the Authority include, without limitation, the provision of guarantee from the parent company/fellow subsidiary of the Tenderer having a healthy financial position to the satisfaction of the Authority in a form approved by the Authority and/or the increase of the Deposit from 2% to 5% of the Estimated Contract Value.

(c) Before the award of this Tender, if a Tenderer is a company not incorporated in Hong Kong, the Authority may require the Tenderer at its own cost to provide an opinion from a lawyer qualified in the jurisdiction of incorporation and acceptable to the Authority. Such legal opinion (in such form as the Authority may require) 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 and whether it has taken all necessary corporate legal actions to authorise the execution and the performance of the proposed Contract;

(iii) whether the proposed Contract will, upon execution by the authorised signatory or attorney of the Tenderer, constitute legal, valid and binding obligations of the Tenderer in the jurisdiction of incorporation; and

(iv) whether there is any order or resolution passed, or proceedings commenced or pending for the winding up or for appointment of a receiver in respect of the assets or for entering into any composition or arrangements with the creditors of the Tenderer.

10. TENDERER'S COMMITMENT

(a) The Contract does not grant an exclusive right (i) to the Contractor to provide the Goods to the Authority or (ii) to the relevant PPP Contractor to provide the relevant PPP Goods for delivery to the relevant PPP Doctors. The Authority reserves the right to award other contracts to third parties for the provision of goods identical or similar to the Goods.

(b) Each Tenderer is required to sign and return a Certificate of Non-Collusion as set out in the relevant Tenderer's Schedule to certify that its Tender Submission is bona fide.

(c) Having due regard to the Authority's corporate image and reputation and the Authority's need to uphold the same, the Tenderers shall propose under the relevant Tenderer's Schedule a code of conduct by reference to the "Sample Code of Conduct for NGO" or "Sample Code of Conduct for Private Sector" which can be accessed via the following link in the Authority's website under "Tender Notice" or such other applicable website of the Authority:

http://www.ha.org.hk/visitor/ha_visitor_index.asp?Content_ID=2001&Lang=ENG&Dimension=100

11. ACCEPTANCE AND CONSENT TO DISCLOSURE

(a) The Memorandum of Acceptance duly signed by the Authority Representative shall signify the creation of the Contract between the Authority and the successful Tenderer. Tenderers who do not receive the Memorandum of Acceptance during the Tender Validity Period should assume that their Tender Submissions have not been accepted.

(b) If the Tenderer is not the manufacturer of the Goods, the Authority may make acceptance conditional on the manufacturer of the Goods giving representations, warranties and indemnification to the Authority in respect of the Goods on the same term as, and in addition to those given by, the Contractor in the T&Cs.

(c) The Authority shall have the right to disclose whenever it considers appropriate, or upon request (verbal or written) by any third party (including unsuccessful Tenderers) information on the Contract, such as the name and address of the Contractor, product description/brand/model/country or place of origin (if applicable), description of the relevant services (if applicable) and the value of the Contract, without reference to or consent from the Contractor. Unsuccessful Tenderers may also enquire as to the reason for the rejection of their Tender Submissions.

12. DESTRUCTION OF UNSUCCESSFUL TENDERS

Those unsuccessful tender submissions falling within the purview of the WTO GPA shall be destroyed 3 years after the date of the Memorandum of Acceptance. Where a tender is cancelled (whether or not such tender is within the purview of WTO GPA), all tender submissions under that tender can be destroyed any time after cancellation.

13. ENVIRONMENTALLY FRIENDLY MEASURES

(a) The Authority is sensitive to the environmental impact of its purchasing decisions and takes account of legitimate environmental concerns while it is committed to achieving best value for money in its purchasing functions.

(b) The following environmentally friendly measures are recommended in the preparation of the Tender Submissions:

(i) all documents should preferably be printed on both sides and on recycled paper. Paper exceeding 80 gsm is not recommended as a general rule;

(ii) 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; and

(iii) single line spacing should be used and excessive white space around the borders and in between the paragraphs should be avoided.

14. PERFORMANCE MONITORING

(a) As from the date these performance monitoring provisions were introduced, the Authority monitors performance under contracts it awards ("**Awarded Contracts**") including, for example:

(i) the quality of the contractor's performance and compliance with the terms of each Awarded Contract (e.g. supply of goods, compliance with the UI Requirements (as defined in Clause 1.2 of Part II (The Goods)), etc.);

(ii) the quality and availability of the goods contracted to be supplied, and whether such can on balance be attributed to the contractor and/or the manufacturer.

(b) In any case, sanctions may be imposed in respect of any future tender, quotation or request for proposal ("**Future Offer**") at the Authority's absolute discretion, including, for example:

(i) the disqualification of the tenderer which is the contractor of an Awarded Contract and/or its Related Parties;

(ii) the disqualification of any good which has previously been supplied under an Awarded Contract; and/or

(iii) the disqualification of any good and its manufacturer when the good has previously been supplied under an Awarded Contract.

(c) If, based on the Tenderer's performance record, the Authority has a reasonable concern about the Tenderer's legal and financial capabilities and the commercial and technical abilities to undertake the relevant procurement, the Authority may in its

absolute discretion (i) take into consideration the Tenderer's performance record, whether or not the type(s) of goods concerned in its performance record is of the same type of goods under evaluation and/or (ii) exclude that Tenderer and/or its Related Parties from participation in tendering, for such period as the Authority may in its entire discretion consider appropriate. The Authority shall have the right to publicize or disclose, whenever it considers appropriate or upon request (verbal or written) by any third party, information of the contractor/tenderer who has been excluded from participation in tendering by the Authority, such as the name of the contractor and duration, without reference to or consent from the contractor/tenderer. Tenders from the tenderer who has been excluded from participation in tendering by the Authority shall be rejected.

(d) Please note that these performance monitoring provisions shall not in any way affect or limit the Authority's rights and powers under the Contract, or the ability of the Authority to reject any Future Offer or to disqualify/suspend any tenderer or goods or manufacturer from any Future Offer for such period of time as the Authority may in its absolute discretion deem appropriate.

(e) "**Related Parties**" means:

(i) each subsidiary and holding company of that tenderer, and any subsidiary of that tenderer's holding company, whether direct or indirect (each an "**Affiliate**");

(ii) each controlling person, which means in relation to a tenderer any person who either individually or as part of a group of persons acting together owns an interest (whether beneficial or legal, directly or indirectly) in a tenderer or a holding company of the tenderer, that gives that person, or the group acting together, significant influence or control over that tenderer ("**Controlling Person**");

(iii) each family member, which means spouse, parent, child or siblings of that tenderer (if an individual) ("**Family Member**");

(iv) any entity, and any subsidiary of such entity, that is controlled (or has been controlled), directly or indirectly, together or individually, by any (or any combination of) Affiliate, Controlling Person and/or Family Member of that tenderer.

(f) The Tenderer must confirm in the relevant Tenderer's Schedule that it has provided the manufacturer of the Goods to be offered under this Tender these performance monitoring provisions relating to it and its goods.

(g) If a Tenderer is, or reasonably believes that it is, a Related Party of any contractor or ex-contractor of the Authority, it shall disclose in its Tender Submission details of such relationship failing which the Authority may disqualify the Tenderer from participating in that Tender.

15. OFFERING GRATUITIES

(a) The Tenderer must not, and must procure that its employees, agents and sub-contractors do not, offer, solicit or accept an advantage as defined in the Prevention of Bribery Ordinance (Cap. 201 of the Laws of Hong Kong) in connection with the tendering and execution of the Contract.

(b) Failure to so procure or any act of offering, soliciting or accepting advantage referred to in (a) above committed by the Tenderer or by an employee, agent or sub-contractor of the Tenderer shall, without affecting the Tenderer's liability for such failure and act, result in its Tender Submission being invalidated.

16. CONFLICT OF INTEREST

(a) Without limiting the Authority's right and the Contractor's obligations under Clause 22 of Terms and Conditions, Tenderers must declare in Tenderer's Schedule A11 of Part III whether any actual, apparent, potential or perceived conflict of interest will, or might, arise in the performance of their obligations under the Contract and the details of any such conflict. If at any time after submitting the Tender Submission and prior to entering into the Contract with the Authority, any actual, apparent, potential or perceived conflict of interest arises or may arise for or becomes known to any Tenderer which is inconsistent with the declaration in Tenderer's Schedule A11 of Part III, such Tenderer should immediately notify the Authority in writing.

(b) The Authority reserves the right to reject any Tender Submission or take any other action it considers appropriate if, in the Authority's opinion, any conflict of interest will or might arise in respect of any Tenderer. However, identification of a potential or actual conflict of interest does not necessarily preclude a Tender Submission from consideration. The Authority will carefully consider the circumstances surrounding the conflict of interest to determine whether the Tender Submission should be rejected on this basis.

17. THE SALE OF GOODS (UNITED NATIONS CONVENTION) ORDINANCE (CAP. 641)

The provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Tender and a Tender Submission submitted by a Tenderer in response to this Tender.

18. NATIONAL SECURITY

Notwithstanding anything to the contrary in this Tender, the Authority reserves the right to disqualify a Tenderer on the grounds that the Tenderer has engaged, is engaging, or is reasonably believed to have engaged or be engaging in acts or activities that are likely to cause or constitute the occurrence of offences endangering national security or otherwise the

exclusion is necessary in the interest of national security, or is necessary to protect the public interest of Hong Kong, public morals, public order or public safety. The Tenderers shall in Tenderer's Schedule A13 confirm and warrant that they have not engaged, are not engaging and will not engage in the aforesaid acts or activities. Failure to observe the requirement shall render all related submissions null and void and any such submission shall not be considered.

19. GENERAL

(a) The Authority reserves the right in its absolute discretion to cancel this Tender at any time, to award the Tender to a panel of up to two Contractors for each Good or to Contractors in whole or in part, or to accept all or part of any Tender Submission.

(b) The Authority intends to award contracts based on Tender Prices and level of compliance with the Tender. The Authority is not bound to accept any conforming Tender Submission or the lowest Tender Price. The Authority reserves the right to negotiate with any Tenderer on the terms of the offer.

(c) The Authority will not be responsible for or liable to any Tenderer for any cost or expense incurred in relation to (i) the preparation or submission of the Tender Submission; or (ii) any communication between the Tenderer and the Authority in relation to the Tender, under any circumstances (including the cancellation of this Tender by the Authority).

(d) The Tenderer acknowledges and agrees that the Authority is not responsible for the accuracy of any information provided in this Tender, and the Tenderer has made its own independent evaluation of the business potential of the Goods and it has submitted its Tender Submission based solely on the result of such independent evaluation.

Dated this 23rd December 2026.

Dr Libby LEE, Chief Executive, HA
Authority Representative

PART II

THE GOODS

1. TERM

1.1 The term of the Contract shall be for an initial term of up to 36 months after the start date ("**initial term**") unless the Authority in its absolute discretion extends the term for an additional period of up to 24 months by notice in writing to the Contractor given at any time prior to the expiry of the initial term. The initial term of the Contract and its start date shall be notified by the Authority in writing.

1.2 Unless otherwise determined by the Authority in its absolute discretion, the successful Tenderer will be awarded Contract with initial term as follows:

(a) if the successful Tenderer can demonstrate by way of its Tender Submission (including the samples submitted) to the Authority's satisfaction that all of the Goods to be awarded to it will meet the Authority's requirements on UI (the "**UI Requirements**") at the commencement of the Contract, it will be awarded the Contract covering all such Goods for the initial term of 36 months;

(b) if the successful Tenderer cannot demonstrate that all of the Goods to be awarded to it comply with the UI Requirements as set out in Clause 1.2(a) above but it has, insofar as those Goods which cannot meet the UI Requirements are concerned, indicated in its Tender Submission its commitment to meet the UI Requirements within nine (9) months after the commencement of the Contract ("**UI Commitment**"), it will be awarded the Contract covering all the Goods awarded to it for 24 months first, which will be further extended for another 12 months on the same terms (including as to Price and Supply Plan) on condition that it can demonstrate to the Authority's satisfaction that all of the Goods have met the UI Requirements within nine (9) months after the commencement of the Contract and the Top-up Deposit (as defined in Clause 3.2(e) below) is paid, and in such case the initial term of the Contract will be 36 months; and

(c) if the successful Tenderer cannot demonstrate that all of the Goods to be awarded to it will comply with the UI Requirements as set out in Clause 1.2(a) above and does not give UI Commitment in respect of all of those Goods which cannot meet the UI Requirements, it will be awarded the Contract covering all the Goods awarded to it for the initial term of 24 months only, save that if the successful Tenderer has given UI Commitment in respect of some (but not all) of those Goods, the Authority may, in its absolute discretion, award two separate Contracts to the successful Tenderer, namely:

(i) a Contract covering Goods awarded which the successful Tenderer can demonstrate compliance of the UI Requirements at the commencement of the Contract and those for which it has given UI Commitment, with an initial term of 24 months first which will be further extended for another 12 months on the same terms (including as to Price and Supply Plan) subject to the conditions as mentioned in Clause 1.2(b) above; and

(ii) a Contract covering Goods awarded for which the successful Tenderer cannot demonstrate compliance with the UI Requirements at the commencement of the Contract nor give any UI Commitment, with an initial term of 24 months only.

For the avoidance of doubt, the Goods are considered to have met the UI Requirements if Clause 7 below and the specifications as set out in **Appendix 6** to Part III have been fully complied with.

1.3 Any extension beyond the initial term will be on the same terms, subject to the parties' agreement as to the Price and Supply Plan. The word "**Term**" in the Contract shall apply to the initial term and any extension of the initial term.

2. SUPPLY OF GOODS

2.1 Supply Requirements

(a) Subject to sub-paragraphs (d) and (e) below, "**The Authority's Supply Requirements**" in Part III sets out the Authority's requirements applicable to each Good and points to note on evaluation. Tenderers must submit a proposal on each Good based on the estimated requirements as set out in "**The Authority's Supply Requirements**" including its Tender Price under the relevant Tenderer's Schedule. The minimum quantity and estimated requirement of a Good specified in "**The Authority's Supply Requirements**" are arrived at based on a contract term of 36 months, and as such the minimum quantity and estimated requirement stated therein shall be adjusted downwards by one third accordingly if the Contract is only awarded to the successful Tenderer for an initial term of 24 months. Whilst the Authority shall purchase the minimum quantity of a Good, the estimated requirement of a Good (including the breakdown thereof) is only an estimate of the Authority's requirement and shall not be considered as a guaranteed requirement or commitment.

(b) It is of paramount importance for the Authority to ensure continuity and availability of supplies of the Goods, and the Authority may in its absolute discretion award the Contract:

(i) based on an overall assessment of all Goods or individual Goods; or

(ii) to a Contractor or a panel of up to two Contractors for each Good in such quantities as the Authority may decide (including a Tenderer whose Goods have previously been supplied under Bulk Supplies Contracts).

(c) Subject to sub-paragraphs (d) and (e) below,

(i) where there is only one Contractor for a Good, the Contractor may be required to supply to the Authority such Good up to 130% of the aggregate Price of the estimated requirements of such Good as set out in "**The Authority's Supply Requirements**" (or up to 130% of the aggregate Price of such estimated requirement as adjusted in accordance with sub-paragraph (a) above) on a full quantity basis but without regard to the breakdown of the estimated requirements of such Good; or

(ii) where there are two Contractors for a Good, each Contractor may be required to supply to the Authority such Good up to 130% of the aggregate Price of half of the estimated requirements of such Good as set out in "**The Authority's Supply Requirements**" (or up to 130% of the aggregate Price of half of such estimated requirement as adjusted in accordance with sub-paragraph (a) above) (i.e. up to 130% of the aggregate Price of the estimated requirements of such Good on a half quantity basis but without regard to the breakdown of the estimated requirements of such Good, as adjusted in accordance with sub-paragraph (a) above if applicable).

The aggregate of the values calculated in respect of the Contractor or a Contractor under subparagraph (i) and (ii) above shall be the "**Total Contract Value**" for the contract awarded to such Contractor under this Tender whether in respect of a Good or more than one Good, and for the avoidance of doubt, the Total Contract Value is equivalent to 130% of the Estimated Contract Value. Where a Contractor is awarded for more than one Good under this Tender, such Contractor may be required to supply to the Authority one of the awarded Goods or a mixture of the awarded Goods as determined by the Authority up to the Total Contract Value for such Contractor.

The Total Contract Value is not a guaranteed requirement of the Authority.

(d) The relevant Glaucoma PPP Goods supplied by the relevant Glaucoma PPP Contractor to the relevant Glaucoma PPP Doctors shall not count towards the Total Contract Value or any minimum quantity or estimated requirement of any Good under this Contract.

(e) The Goods to be delivered to Community Pharmacies under Community Pharmacy Programme, Family Doctors under specified Government primary healthcare programme(s), and GOPC PPP Doctors under GOPC PPP Programme shall count towards the minimum quantity and overall estimated requirement of Goods under this Contract.

2.2 Buffer Stock

(a) The Contractor must hold buffer stock for each Good in Hong Kong, in such quantity as may have been agreed with the Authority in writing from time to time. In the absence of any such agreement, the quantity required shall be the amount required to cover the lead time necessary for the manufacturer to supply against the Contractor's order for supply of Goods to the Authority. For example, if it takes 2 months from the date of the Contractor's order for any Good to arrive in Hong Kong, then the quantity of buffer stock must be 2 months' supply of that Good based on the Authority's estimated requirement.

(b) The Contractor must notify the Authority immediately if the buffer stock of any Good is less than the required quantity and there is a reasonably foreseeable supply gap.

(c) The Authority may at any time, in writing, waive or reduce the Contractor's obligation to keep the buffer stock for a specific duration.

2.3 Supply Plan

(a) Each Tenderer must propose a supply plan under the relevant Tenderer's Schedule for the Goods to be supplied to the Authority (subject to the Authority's final approval, after such approval "**Supply Plan**" which the Contractor must comply with):

(i) indicating its lead time to have adequate stocks of Goods to commence supply if awarded the Contract. The Authority may not consider a lead time in excess of 12 weeks;

(ii) proposing the arrival schedule of each Good based on the Authority's estimated requirement of that Good as set out in "**The Authority's Supply Requirements**";

(iii) indicating its buffer stock for each Good based on manufacturer's lead time to supply against Tenderer's order.

(b) The Authority may issue purchase orders for the Goods in accordance with its requirements. Around mid-Term of the Contract or if earlier when 50% of the estimated requirement of any Good has been drawn, the Authority may provide a revised monthly estimated requirement and review the Supply Plan with the Contractor. If the Authority does not provide a revised monthly estimated requirement, or if the parties cannot agree on the revised plan, the Supply Plan shall apply for the remaining balance of the Term. No later than 3 months before the end of the Term, the Authority may notify the Contractor of an indicative quantity of each Good that it anticipates it will purchase before expiry of the Term.

(c) The Contractor must cooperate fully and comply with all reasonable requests from the Authority near the end of the Term to ensure a smooth transition to any new supplier of equivalent items.

2.4 Product Presentation

(a) The Authority's requirements on product presentation (its packing and, if applicable, the marking on the Good to identify the Good) and product labelling of the Goods ("**Product Presentation**") are set out in the "**Product Presentation Requirements**" in Part III. For the avoidance of doubt, the Product Presentation Requirements are mandatory specifications of the Goods and the UI Requirements shall not be considered as Product Presentation Requirements.

(b) The Authority will review the samples provided and request changes to meet its requirements. The Tenderer agrees to make such changes within the time frame specified (including registration with the Department of Health), failing which the Memorandum of Acceptance will lapse and the Contract will be void unless the Authority agrees otherwise.

(c) The Contractor must comply with changes to Product Presentation of the Goods requested by the Authority during the Term.

2.5 Samples Requirements

(a) For Tender evaluation, Tenderers must submit:

(i) one sample of each Good in its original sales pack that is currently registered with the Pharmacy and Poisons Board of Hong Kong; and

(ii) one mock up sample of each Good demonstrating the product presentation of such Goods, except where a Tenderer reasonably believes that a Good in its original sales pack complies with the Authority's "**Product Presentation Requirements**" as set out in **Appendix 2 to Part III** (and if the Tenderer has specified that such Good will meet the UI Requirements at the commencement of the Contract, the UI Requirements as set out in **Clause 7** below and **Appendix 6** to Part III), in which case, the Tenderer does not need to provide a mock up sample of such Good and the Authority will evaluate the product presentation (and where applicable, the compliance of the UI Requirements) of the original sales pack sample of such Good submitted in sub-paragraph (i) above.

Tenderers should note that all samples must be submitted in accordance with the sample submission requirements as set out in paragraph A7 of Part III.

(b) Where Tenderers have specified that the Goods will meet the UI Requirements at the commencement of the Contract in the relevant Tenderer's Schedule, the samples to be submitted under Clause 2.5(a) above shall also demonstrate the compliance of the UI Requirements of the Goods as set out in **Clause 7** below and **Appendix 6** to Part III.

(c) The Tenderer/Contractor must provide free samples of Goods upon the Authority's request. If the Authority draws Goods from its own stocks during the Term, the Contractor must either replenish or give the Authority credit for the Goods drawn in terms of free Goods.

2.6 Change Control Process

(a) If the Contractor wishes to make any changes to the Goods during the Term then the Authority will, without any commitment, consider such changes provided that the Contractor supplies the Authority with all relevant information and justifications regarding the changes at least 3 months before the date when the Contractor wishes the changes to take effect. The Authority is not obligated to consider any proposed changes that do not comply with this change control process.

2.7 Supply of PPP Goods

(a) The PPP Programmes are public-private partnership programmes of the Authority whereby PPP Doctors provide services to participating patients of the Authority.

(b) PPP Doctors assume primary responsibility for, and attend to their patients under the PPP Programmes as an extension of the services of the Authority. HA patients participating in the PPP Programmes will from time to time be prescribed with drugs.

(c) If the Authority has identified a Good as a PPP Good in the Attachment to **Appendix 1** in Part III and

(i) where there is only one Contractor for such Good, the Contractor, or

(ii) where there are two Contractors for such Good, the Contractor with the lowest Price,

shall be selected as the relevant PPP Contractor for such PPP Good and shall participate in the relevant PPP Programme by supplying such PPP Good at the relevant PPP Price and delivering it to the relevant PPP Doctors during the Term pursuant to the relevant terms and conditions set out in the Contract, including the relevant part of **Appendix 5.1 and Appendix 5.2** to Part III. If the Prices offered by the two Contractors for such Good are the same, both Contractors shall be selected as the relevant PPP Contractors for such PPP Good to participate in the relevant PPP Programme, one for the first half of the initial term and the other for the remaining period of the initial term and any extension of the initial term, and the Authority will select randomly which Contractor to first participate as the relevant PPP Contractor for such PPP Good (or in case the initial terms of the two Contractors are different, the Contractor whose initial term is shorter will be the relevant PPP Contractor for the first half of the longer initial term and the other Contractor will be the relevant PPP Contractor for the remaining period of the longer initial term and any extension thereof). The Contractor(s) in subparagraph (i) or (ii) above shall be notified in the Memorandum of Acceptance whether it is selected as the relevant PPP Contractor for such PPP Good or not, and if applicable, the period of its/their participation.

(d) If the Authority has identified a Good as a PPP Good in the Attachment to **Appendix 1** in Part III,

(i) Tenderers are required to complete and provide the statement in Tenderer's Schedule A10 in relation to each and every PPP Good so identified; and

(ii) Tender Submissions which do not provide the statement in Tenderer's Schedule A10 in relation to each and every PPP Good so identified shall be rejected.

3. INSURANCE, DEPOSIT AND STATEMENT OF COMPLIANCE

3.1 Product Liability Insurance

(a) The Contractor must put in place adequate and appropriate product liability insurance policy written by a reputable insurance company authorised to do insurance business in Hong Kong to cover claims in connection with or arising out of the Tenderer's supply of the Goods, whether due to manufacture, handling, repackaging, storage, logistics, supplies or otherwise up to a minimum indemnity limit of US$10M per occurrence with the Authority named as a vendor ("**Product Liability Insurance**").

(b) The Contractor must within 14 days of the date of the Memorandum of Acceptance supply the Authority with a copy of the Product Liability Insurance certificate and annually within 14 days of the renewal an updated certificate for the following period. The Memorandum of Acceptance shall be conditional on the provision of a copy of the Product Liability Insurance certificate within 14 days of the date of the Memorandum of Acceptance, failing which the Memorandum of Acceptance will lapse and the Contract will be void unless the Authority agrees otherwise. The Tenderer must provide information on the product liability insurance arrangements under the relevant Tenderer's Schedule.

3.2 Deposit

(a) The Contractor must place and maintain during the Term and until the date falling 3 months after the end of the Term or the date on which all obligations and liabilities of the Contractor under the Contract have been duly carried out, completed and discharged, whichever is the later, a deposit ("**Deposit**") in an amount equivalent to:

(i) subject to sub-paragraph (ii) below, where the Contractor is a Tenderer which, in the opinion of the Authority, has passed the financial assessment referred to in paragraph 8 of Part I, 2 % of the Estimated Contract Value in respect of the Contractor; or

(ii) if required by the Authority, where the Contractor is a Tenderer which, in the opinion of the Authority, fails in the financial assessment referred to in paragraph 8 of Part I or fails to provide accurate and adequate information requested by the Authority for the financial assessment, 5% of the Estimated Contract Value in respect of the Contractor,

as security for the performance of all the Contractor's warranties, undertakings and obligations under the Contract, either by cheque or a duly executed and valid irrevocable banker's guarantee issued by a bank licensed in Hong Kong under the Banking Ordinance (Cap. 155 of the laws of Hong Kong) in a form as set out in **Appendix 3 to Part III**. Tenderers must provide details of their deposit under the relevant Tenderer's Schedule.

For the purpose of determining the amount of Deposit which is required to be placed or maintained by the Contractor under the Contract, "**Estimated Contract Value**" shall mean the sum of the aggregate Price of the estimated requirements on full quantity basis as set out in "**The Authority's Supply Requirements**" of all Goods which are awarded to the Contractor under this Tender, provided that when there are two Contractors in respect of a particular Good, only the aggregate Price of half of the estimated requirements of such Good will be taken into account in calculating the part of the Estimated Contract Value attributable to such Good for each Contractor. For the avoidance of doubt, the Estimated Contract Value applicable to a Contractor shall be adjusted downwards by one third accordingly if the Contract is only awarded to the Contractor for an initial term of 24 months.

(b) The Tenderer shall elect in the relevant Tenderer's Schedule which method it prefers to pay the Deposit and, in the case of a banker's guarantee, details of the same including the issuing bank. In the event that the Tenderer fails to elect which method of providing the Deposit it prefers, it will be deemed that the Tenderer has agreed to pay the Deposit by cheque to the Authority.

(c) On award of the Contract, the Contractor must place the Deposit with the Authority (i) within 30 days from the date of Memorandum of Acceptance or (ii) before the commencement of the Contract, whichever is the later.

(d) Should the successful Tenderer fail to place the Deposit with the Authority by the due date aforesaid, the Authority may in its absolute discretion terminate the Contract by notice in writing to the successful Tenderer.

(e) Notwithstanding the foregoing, if the Contractor falls under Clause 1.2(b) or Clause 1.2(c)(i) above under which it is initially awarded the Contract for 24 months which will potentially be extended for another 12 months, the Contractor shall pay the Deposit in the following manner:

(i) an amount equivalent to 2% or 5%* of the 24-month Estimated Contract Value ("**Initial Deposit**") shall be paid by the due date as specified in Clause 3.2 (c) above, failing which Clause 3.2(d) above shall apply; and

(ii) a top-up amount ("**Top-up Deposit**") shall be paid within 30 days from the Authority's notification to the Contractor about the proposed extension of the initial term of the Contract such that the amount of Deposit that will be held by the Authority shall be equivalent to 2% or 5%* of the 36-month Estimated Contract Value, failing which the Authority's notification about the proposed extension of the initial term shall be invalid and the initial term of the Contract shall remain as 24 months,

where:

"**24-month Estimated Contract Value**" = the Estimated Contract Value applicable to the Contractor on the basis that the Contract is awarded to the Contractor for an initial term of 24 months

"**36-month Estimated Contract Value**" = the Estimated Contract Value applicable to the Contractor on the basis that the Contract is awarded to the Contractor for an initial term of 36 months

** Subject to the Authority's financial assessment as set out in Clause 3.2(a) above*

3.3 Statement of Compliance with this Tender/Statement of Compliance with Goods supplied under any previous Bulk Supplies Contract

Tenderers are required to provide the statement of compliance with this Tender and statement of compliance with goods supplied under any previous Bulk Supplies Contract in the relevant Tenderer's Schedule.

4. SPECIFICATIONS OF GOODS, THEIR QUALITY AND SAFETY

4.1 Mandatory Specifications

In addition to the specification set out in "**The Authority's Supply Requirements**", the mandatory specification of each Good shall include:

(a) its "**Technical and Registration Requirements**" in Part III;

(b) if the Good is a proprietary product, the manufacturer's product specifications; and

(c) if the Good is a generic product, the product specifications of the Good that must comply with any one of the following:

(i) the Pharmacopoeia of the People's Republic of China product monograph;
(ii) the BP product monograph;
(iii) the Ph. Eur. active ingredient monograph;
(iv) the Ph. Eur. product monograph;
(v) the Ph. Int. product monograph;
(vi) the JP product monograph; or
(vii) the USP product monograph,

where a relevant monograph is published in any of the Pharmacopoeia. If no such monograph is published in any of the Pharmacopoeia, the manufacturer's product specifications must be specified and complied with.

4.2 Technical and Registration Requirements

Tenderers must provide information on each Good under the relevant Tenderer's Schedule in accordance with the "**Technical and Registration Requirements**" in Part III.

4.3 Quality Assurance Tests

(a) The Authority is extremely concerned about the quality (including safety and efficacy) of the Goods and may require the Tenderer/Contractor at its own costs to commission a Laboratory to perform any quality assurance tests required by the Authority ("**Quality Assurance Tests**") during Tender evaluation and the Term. Either the Tenderer/Contractor may, or the Authority may at the cost of the Tenderer/Contractor, commission the Laboratory to undertake such Quality Assurance Tests. The Authority may also specify the contents/formats of the test reports and require the

Tenderer/Contractor to provide relevant documents and analytical reference standard to HA and/or the Laboratory for reference, testing or other related purposes. All Quality Assurance Tests reports must be provided to the satisfaction of the Authority. Routine Quality Assurance Tests are:

(i) chemical analysis tests to ensure compliance with specifications;

(ii) microbiological tests to ensure compliance to acceptance criteria specified in USP, BP, Ph. Eur. or JP (if and where applicable); and

(iii) such sterility tests to ensure compliance to the relevant standard as accepted by the relevant regulatory body (if applicable).

(b) (i) To facilitate microbiological tests and save cost, Tenderer/Contractor may under the relevant Tenderer's Schedule submit a microbial examination validation report in respect of the Good which complies with USP, BP, Ph. Eur. or JP.

(ii) Tenderer must under the relevant Tenderer's Schedule specify if any Good contains natural raw materials of animal, vegetable or mineral origin for which antimicrobial pre-treatment is not feasible.

(c) Notwithstanding the foregoing, for Goods selected for Tender evaluation, the Authority shall pay for chemical analysis tests and may accept microbiological tests report prepared by the in-house laboratory of the manufacturer of the Goods.

(d) Tenderers are to refer to **Appendix 4 to Part III** on the estimates of samples of Goods required and the testing frequency for Quality Assurance Tests during the Term. If the Authority commissions the Laboratory to undertake any Quality Assurance Test with samples drawn from the Goods supplied to the Authority or any HA Hospital during the Term, then in addition to reimbursing the Authority for the cost of the Quality Assurance Test, the Contractor shall also make an additional delivery to the Authority or the HA Hospital concerned in an amount equivalent to the amount of Goods drawn for the Quality Assurance Test free of charge.

4.4 Manufacturer of the Goods

The Tenderer must provide under the relevant Tenderer's Schedule information in respect of each manufacturer of the Goods (if applicable).

4.5 Product Safety Alert and Product Recall

(a) Tenderers must have in place an appropriate and adequate product safety alert system and product recall system covering the Goods to the Authority for their shelf life or the Term (whichever is longer).

(b) Each Tenderer's product safety alert notice ("**Safety Alert Notice**") must comply with industry practice and contain at least the following information:

(i) the manufacturer and the batch(es) of the relevant Goods;

(ii) the safety issue in question;

(iii) when and how the safety issue was discovered;

(iv) the manufacturer's recommendation in respect of patients who may have used the batch(es) of the relevant Goods and other action that needs to be taken.

(c) Tenderer's product recall notice ("**Product Recall Notice**") must comply with industry practice and contain at least the following information:

(i) the manufacturer and the batch(es) of the relevant Goods;

(ii) the safety issue in question;

(iii) when and how the safety issue was discovered;

(iv) the distribution list of affected batch(es) of the relevant Goods delivered to the Authority;

(v) the anticipated duration of the product recall exercise;

(vi) whether the product recall is at hospital level or on patient level;

(vii) the manufacturer's recommendation in respect of patients who may have used the batch(es) of the relevant Goods and other action that needs to be taken;

(viii) whether the Department of Health has been alerted.

(d) Tenderers must under the relevant Tenderer's Schedule provide the Tenderer's product recall system in respect of the Goods to the Authority ("**Product Recall System**") (if applicable).

(e) Tenderers must note that after receipt of a Product Recall Notice, the Authority may request the Contractor to supply and arrange for delivery of Goods available to the Contractor and unaffected by the Product Recall Notice in such quantity as the Authority may request within 24 hours after the Authority's request or such later time as the Authority may agree and the Contractor shall comply with the same.

5. 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 analysis, finished product specifications) of the Goods, 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 is 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 as set out in this paragraph 5 shall not apply or shall cease to apply in respect of any of the Items of Information to the extent that such 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 HKG 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 5(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 "**Instructions to Third Parties**" at **Annexure 2**. On notification, the Authority's sole obligation is discharged and the third party has thereby undertaken the confidentiality obligation to the Tenderer. The Authority shall not be responsible for any breach of the confidentiality obligation on the part of such third party.

6. HA'S REQUIREMENTS

6.1 Freedom to Operate

A Tenderer if and when required to do so, must demonstrate to the satisfaction of the Authority that the Goods are free from any patent or potential patent infringement or patent-related supply issues, whether such Goods are offered by or on behalf of the party originally developing or owning the proprietary rights therefor ("**Innovator**"); or by or on behalf of a non-Innovator. In particular, the Goods supplied by the Tenderer and the use thereof must not infringe any granted patents or fall within the claims of any pending patent applications in Hong Kong, and the Goods supplied must not infringe any granted patent or fall within the claims of any pending patent applications in their country/place of origin.

6.2 Innovator Version of the Goods

Without limiting paragraph 6.1 above, each Tenderer offering an Innovator version of the Goods, must in the relevant Tenderer's Schedule, confirm that each such Good is proprietary in that the relevant drug patent/patent applications in respect of that Good exist and are valid and in force.

6.3 Non-Innovator Version of the Goods – Patent and Related Information

(a) Without limiting paragraph 6.1 above, any Tenderer offering a non-Innovator version of the Goods (to include generic versions and derivative versions of the drugs and/or follow on or subsequent versions of any biological products) must at its sole expense and within 45 days of being required to do so by the Authority, submit a formal written opinion (including a search report upon which the opinion is based) ("**Search Report**") from an independent patent agent or patent attorney registered in the United Kingdom, Australia or New Zealand ("**Tenderer's Patent Attorney**") to confirm the conclusion of no patent infringement in respect of the importation, sale, supply and use of the Goods in Hong Kong ("**Formal Written Opinion**"). This Formal Written Opinion must be addressed to the Authority and must include for the relevant Goods a full, complete and exhaustive analysis and consideration of at least the following aspects:

(i) all active pharmaceutical ingredients and their relevant forms;

(ii) all formulations of the Goods (including strength and concentration, and product format including tablet, capsule, extended-release, sustained-release, injection, aerosol or the like);

(iii) the process of preparation of all active pharmaceutical ingredients and all formulations (and if the Tenderer's Patent Attorney's Formal Written Opinion is based on a study of the process, it must be expressly confirmed by him);

(iv) all licensed indications of the Goods as registered with the Department of Health in Hong Kong, and all indications and uses (including but not limited to therapeutic indications and usages) of the Goods as set out in the package insert, if available, or original sales pack;

(v) any other relevant aspects including delivery form of the Goods, excipients and additives utilised, combination or adjuvant therapy, if any; and

(vi) any patents or patent applications in Hong Kong corresponding to or associated with any "Designated Patent" in the US "Orange Book" in respect of the proprietary product as listed by the United States Food and Drug Administration.

(b) The Search Report must be based upon at least all patents and patent applications in Hong Kong, all Patent Cooperation Treaty ("**PCT**") patent applications, all patents and patent applications in Chinese Mainland, the European Patent Office and the United Kingdom, all of which should be searched and analysed if they could become potential Hong Kong patent applications or patents, and must include:

(i) a list of the granted patents/patent applications studied and analysed (with reasoned comments on their relevance to the Goods under the Tender), and their status;

(ii) a description of the search strategy utilised, including search terms and databases used in the search upon which the Search Report is based;

(iii) a list of jurisdictions searched, including at least Hong Kong, Chinese Mainland, the European Patent Office and the United Kingdom; and

(iv) the years searched, including for the People's Republic of China, patent applications and/or granted patents published from and including 27 December 1996 up to the date of this Tender; and for all other jurisdictions, patent applications and/or granted patents published in the 21 years preceding the date of this Tender.

(c) The Authority reserves the right in its absolute discretion to reject any Formal Written Opinion it deems insufficient, incomplete, non-compliant with the requirements as set out in paragraph 6.3(a)(i) - (vi) and 6.3(b)(i) – (iv) above or otherwise not to the satisfaction of the Authority, and request the Tenderer to submit a new Formal Written Opinion prepared by another Tenderer's Patent Attorney (as approved by the Authority) within 30 days (or within the timeline as specified by the Authority) at the Tenderer's sole expense.

(d) In lieu of or before requiring the Formal Written Opinion (but without limiting its right to require the Formal Written Opinion), the Authority may at its absolute discretion:

(i) require the Tenderer to provide any clarifications/confirmations required by the Authority to it, including:

- where the Goods offered have previously been supplied under Bulk Supplies Contracts, provide such confirmations on behalf of the manufacturer as may be required by the Authority;

- where the Goods offered have not been previously supplied by the Tenderer, but other Goods have been purchased by the Authority under Bulk Supplies Contracts, provide such confirmations on behalf of the manufacturer and/or from the Tenderer's Patent Attorney as may be required by the Authority. Where the Goods offered have not been previously supplied by the Tenderer, that Tenderer should normally expect the Authority to require confirmation from its Patent Attorney; or

(ii) on its own volition or at the Tenderer's written application, waive the Tenderer's requirement to submit the Formal Written Opinion or the extent of such Formal Written Opinion. Any such waiver granted will be subject to any restrictions or conditions imposed by the Authority in its absolute discretion, and in addition (whether specifically stated in the waiver or not) will be subject to the conditions that the Authority may revoke the waiver at any time prior to the award of the

Contract and that the waiver does not constitute in any respect a waiver or modification of the terms of the Tender or the Contract if awarded.

Each Tenderer acknowledges the conditionality of the above and must make arrangements to be able to supply the Formal Written Opinion in time if the waiver is revoked.

6.4 Non-Innovator Version of the Goods – Wholesale or Infringement Information

Each Tenderer offering a non-Innovator version of the Goods must:

(i) if and when required by the Authority, provide under the relevant Tenderer's Schedule wholesale information in respect of non-Innovator version of each Good to assist the Authority to understand the situation in Hong Kong and elsewhere;

(ii) provide to the Authority under the relevant Tenderer's Schedule and in accordance with the requirements in Part III, "**Confirmation of No Infringement/No Litigation and Claims**" on its own behalf and on behalf of the manufacturer of all non-Innovator versions of the Goods. The "**Confirmation of No Infringement/No Litigation and Claims**" relate to the aspects of the Goods as set out in paragraph 6.3(a)(i) to (vi) above.

6.5 General

(a) The Tenderer acknowledges the Authority's unilateral rights to seek information/advice from third parties (including professional advisors or the manufacturer) in respect of any matter under paragraphs 6.1, 6.2, 6.3 and 6.4, and where appropriate, the Tenderer hereby authorises such third parties to directly respond to the Authority.

(b) The Tenderer agrees that information/advice provided by third parties under paragraph 6.5(a) and the information/clarifications/confirmations provided to the Authority under paragraphs 6.1, 6.2, 6.3 and 6.4 will not modify, reduce, or otherwise affect any representations given by the Tenderer/Contractor (express or implied) under this Tender, or reduce or negate the Authority's reliance on information provided by the Tenderer, including the Formal Written Opinion.

(c) The Tenderer/Contractor shall promptly and within such time required by the Authority provide further information (or procure the Tenderer's Patent Attorney to do so) in response to the Authority's request in relation to patent matters under this paragraph 6 during the Tender Validity Period and for the duration of the shelf life of the last batch of Goods supplied under the Contract.

7. HA'S REQUIREMENTS ON UI

7.1 The Authority has promoted the application of UI on the actual sales pack of pharmaceutical products over recent years to facilitate electronic identification and verification and has now formulated the UI Requirements. The UI Requirements are set out in the specifications in **Appendix 6** to Part III. They are not mandatory specifications of the Goods but the Authority

has the absolute discretion to determine the initial term of the Contract that may be awarded to the successful Tenderer depending on its compliance with the UI Requirements.

7.2 Tenderers must under the relevant Tenderer's Schedule specify (1) if the Goods will meet the UI Requirements at the commencement of the Contract and (2) if the Goods do not comply with the UI Requirements as at the commencement of the Contract, whether the Tenderer gives UI Commitment in respect of those Goods.

7.3 (a) For Goods falling within situation (1) as stipulated in Clause 7.2 above, the Tenderer shall provide samples demonstrating compliance with the UI Requirements for such Goods as required under Clause 2.5 above and the samples provided by Tenderer(s) which may be awarded the Contract will be evaluated in considering the compliance of the UI Requirements of the Goods for the purpose of determining the initial term of the Contract.

(b) For Goods falling within situation (2) as stipulated in Clause 7.2 above and which the Tenderer has given UI Commitment , the Tenderer, if awarded the Contract in respect of those Goods, shall submit the application for stand-alone change of registered particulars of the Goods involving UI additions to the Department of Health followed by an application for change in particulars of the Contract for such UI additions with samples or mock up samples to the Authority within three (3) months after the commencement of the Contract and use its best endeavours to complete the change and implement the UI Requirements within nine (9) months after the commencement of the Contract. Upon completion of the change and implementation of the UI Requirements, the Contractor shall promptly submit to the Authority all necessary documents, including the letter issued by the Department of Health acknowledging the UI additions, and samples of the Goods demonstrating compliance of the UI Requirements (if only mock up samples are previously submitted) for the Authority to conduct evaluation and consider whether the Goods comply with the UI Requirements.

7.4 The Tenderer/ Contractor shall promptly and within such time required by the Authority provide all further information and/or samples in response to the Authority's request in relation to its compliance with the UI Requirements during the Tender Validity Period and for the duration of the Term. HA's determination as to compliance of the UI Requirements and the initial term of the Contract (or the extension thereof) shall be final and conclusive except in case of manifest error.

PART III

SPECIFIC REQUIREMENTS (INCLUDING THE APPENDICES) AND TENDERER'S SCHEDULES

Notes:

(1) Tenderers may provide information required under each item by completing the relevant Tenderer's Schedule. All information/Supporting Documents provided must bear the relevant number of the Tenderer's Schedule (e.g. Tenderer's Schedule A1) and be inserted into the appropriate folder (e.g. Folder A) in sequential order for ease of evaluation.

(2) Tenderers may apply for a waiver in the relevant Tenderer's Schedule from provision of information/Supporting Documents under an item (e.g. A1) supported by a written justification (e.g. based on any previous Bulk Supplies Contract). In certain cases, a waiver application must be based on offer of Goods which are proprietary, identical (to products, manufacturer and manufacturing site) or materially the same as supplied previously under Bulk Supplies Contract, in which case the Bulk Supplies Contract or tender number must be provided. The Authority may in its absolute discretion decide whether or not a contract qualifies as a Bulk Supplies Contract for the purpose of this Tender.

(3) Tenderers must also read the appendices to these Specific Requirements carefully.

Folder A

A1. Company/Business Organisation Status (Tenderer's Schedule A1)
(Please refer to Part I)

Tenderers must provide the following information by completing the pro-forma **Tenderer's Schedule A1**:

1. Name and address of the Tenderer.

2. Length and nature of business experience including experience in the performance and/or supply of the Goods.

3. Shareholders/partners/owners of the Tenderer.

4. Names and addresses of bankers who are prepared to provide references.

5. A copy of the Tenderer's Articles of Association or other documents evidencing its business and legal status.

6. Copies of the Tenderer's Certificate of Incorporation with the companies registry (if incorporated), its current business registration certificate and its application form for registration of business.

7. Copies of all current Permits issued in favour of the Tenderer by the relevant authorities that are required to legally perform the Contract and/or supply the Goods (if applicable).

8. Documentary evidence of any agency relationships that the Tenderer claims to have in relation to the performance of the Contract or the Goods, whether on a sole or exclusive basis or otherwise.

A2. Accounts Information (Tenderer's Schedule A2)
(Please refer to Part I)

Tenderers must also provide to the Authority the following information on its accounts under pro-forma **Tenderer's Schedule A2**:

1. Audited accounts/financial statements of the Tenderer for the past three years. The latest audited accounts/financial statements must be for the period ended no more than 18 months before the date stated in Part V (Offer to be Bound). The audited accounts/financial statements must include Director's report, Auditor's report, profit and loss statement/statement of comprehensive income, balance sheet/statement of financial position, statement of cash flow and notes to the accounts/financial statements. The accounts/financial statements shall be prepared on the same basis for each year in accordance with accounting principles generally accepted in Hong Kong and the disclosure requirements of the Companies Ordinance, Cap. 32/Cap. 622 (as applicable) of the laws of Hong Kong, or for overseas company the equivalent requirements of the local laws; and

2. Projected profit and loss accounts/statement of comprehensive income and cash flow statements for the Term, showing the revenue, operating expenses, capital expenditure and the sources of finance such as upfront investment and/or debt financing. For the purpose of this requirement, information shall be provided on the assumption that the initial term is 36 months.

A3. Certificate of Non-Collusion and Code of Conduct (Tenderer's Schedule A3)
(Please refer to Part I)

Tenderer must sign and return the Certificate of Non-Collusion and submit a proposal of their code of conduct applicable to their staff by reference to the "Sample Code of Conduct for NGO" or "Sample Code of Conduct for private sector" by completing the pro-forma **Tenderer's Schedule A3**.

A4. Performance Monitoring (Tenderer's Schedule A4)
(Please refer to Part I)

Tenderers must provide confirmation in respect of the "**Performance Monitoring**" provisions in this Tender by completing the pro-forma **Tenderer's Schedule A4**.

A5. The Authority's Supply Requirements (Tenderer's Schedule A5)
(Please refer to Part II)

The Authority's Supply Requirements under this Tender are set out in the Attachment to **Appendix 1** in Part III. Tenderers must submit a proposal for the Goods by completing the pro-forma proposal at **Tenderer's Schedule A5**.

A6. Tenderer's Proposed Supply Plan (Tenderer's Schedule A6)
(Please refer to Part II)

Tenderers must submit a proposed supply plan of the Goods to the Authority by completing the pro-forma supply plan at **Tenderer's Schedule A6**.

A7. Samples of Goods (Tenderer's Schedule A7)
(Please refer to Part II)

The Authority's "**Product Presentation Requirements**" are at **Appendix 2**. Tenderers must submit information on samples of Goods to be provided to the Authority by completing the pro-forma **Tenderer's Schedule A7** on Samples of Goods.

In addition, Tenderers must submit the following samples:

1. one sample of each Good in its original sales pack that is currently registered with the Pharmacy and Poisons Board of Hong Kong; and

2. one mock up sample of each Good demonstrating the product presentation of such Goods, except where a Tenderer reasonably believes that a Good in its original sales pack complies with the Authority's "**Product Presentation Requirements**" as set out in **Appendix 2** to Part III (and if the Tenderer has specified that such Good will meet the UI Requirements at the commencement of the Contract, the **UI Requirements** as set out in **Clause 7 of Part II** and **Appendix 6 to Part III**), in which case, the Tenderer does not need to provide a mock up sample of such Good and the Authority will evaluate the product presentation (and where applicable, the compliance of the UI Requirements) of the original sales pack sample of such Good submitted in sub-paragraph (1) above.

Where Tenderers have specified that the Goods will meet the **UI Requirements** at the commencement of the Contract in **Tenderer's Schedule A12**, the samples to be submitted shall also demonstrate the compliance of the UI Requirements of the Goods as set out in **Clause 7** of Part II and **Appendix 6** to Part III.

All samples must be submitted in accordance with the following sample submission requirements:

(a) All samples must be sent to the Authority at the following address during the working hours on any working day on or before the Tender Closing Time on the Tender Closing

Date. In case of typhoon or rainstorm, the Tender Closing Time and the Tender Closing Date may be extended pursuant to the arrangements as set out in "**Lodging of Tender**":

Hospital Authority Head Office
Procurement (Pharmaceutical Supplies)
7th Floor, Multicentre Block A, Pamela Youde Nethersole Eastern Hospital,
3 Lok Man Road, Chai Wan, Hong Kong
(Attn: Mr. Kenny TAM, Sample Unit in-charge)

(Working hours: 9:00 a.m. to 12:30p.m., 2:00p.m. to 5:30 p.m.)

(b) All samples must be sealed 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 breaking the seal. Samples may be rejected if they are not properly sealed in the manner required.

(c) A label bearing the following information must be attached to each sample:
- (a) Tender reference number;
- (b) Company chop;
- (c) Brief description of the Good;
- (d) An item number which is identical to the number assigned to the Good in **The Authority's Supply Requirements**;
- (e) Quantity of the Good;
- (f) Tender Closing Date; and
- (g) whether it is a sample of original sales pack or a mock up sample.

(d) For chemicals and dangerous goods, Tenderers must submit a Material Safety Data Sheet ("**MSDS**") together with the samples. MSDS must 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.

(e) A receipt for samples duly signed by the Sample Unit in-charge should be obtained as proof of delivery.

(f) Samples submitted may not be returned.

TENDERERS ARE REMINDED THAT, SUBJECT TO CLAUSES 4 AND 5 OF PART I, THEIR OFFERS MAY BE JEOPARDISED IF SAMPLES HAVE NOT BEEN SUBMITTED IN ACCORDANCE WITH THE ABOVE REQUIREMENTS.

A8. Insurance (Tenderer's Schedule A8)
(Please refer to Part II)

Tenderers must complete the pro-forma **Tenderer's Schedule A8** on Product Liability Insurance.

A9. Deposit (Tenderer's Schedule A9)
(Please refer to Part II)

The Authority requires a Deposit in an amount as required under paragraph 3.2 of Part II. Tenderers undertake to place and maintain the Deposit during the Term and until the date falling 3 months after the end of the Term or the date on which all obligations and liabilities of the Contractor under the Contract have been duly carried out, completed and discharged, whichever is the later, by completing the pro-forma **Tenderer's Schedule A9**. A form of the banker's guarantee approved by the Authority is at **Appendix 3**.

A10. Statement of Compliance with this Tender/Statement of Compliance with Goods supplied under any previous Bulk Supplies Contract (Tenderer's Schedule A10)
(Please refer to Part II)

Tenderer must provide the above by completing the pro-forma **Tenderer's Schedule A10**.

A11. Conflict of Interest (Tenderer's Schedule A11)
(Please refer to Part I)

Tenderers must complete the pro-forma **Tenderer's Schedule A11**.

A12. UI Requirements (Tenderer's Schedule A12)
(Please refer to Part II)

Tenderers must complete the pro-forma **Tenderer's Schedule A12**.

A13. National Security Undertaking (Tenderer's Schedule A13)
(Please refer to Part I)

Tenderers must complete the pro-forma **Tenderer's Schedule A13**.

Folder B

For each Good, the following Technical and Registration Requirements must be complied with.

B1. Technical and Registration Requirements

1. Tenderers must provide the following information on each Good, if available, by completing the pro-forma **Tenderer's Schedule B1(a)**:

   (a) Brand name of the Good.
   (b) Registered pack size(s) of the Good in Hong Kong.
   (c) Hong Kong product registration number(s) by registered pack size(s).
   (d) Hong Kong product registration expiry date.
   (e) Licensed indications of the Good as registered with Department of Health in Hong Kong.
   (f) All indications and uses (including but not limited to therapeutic indications and usages) of the Good as set out in the relevant package insert, if available, or original sales pack

2. Tenderers must provide the following information on each Good by completing the pro-forma **Tenderer's Schedule B1(a)**:

   (g) Description of Good.
   (h) Country/place of origin (manufacture).
   (i) Name of manufacturer.
   (j) Address of manufacturer.
   (k) Shelf-life of Good from date of manufacture.
   (l) The product registration status of the Good in the country/place of origin and information on the product registration status of the Good in overseas countries/places whose regulatory authorities are participating authorities of the Pharmaceutical Inspection Co-operation Scheme ("**PIC/S**"). (Note: Such a participating authority is called "**PIC/S Participating Authority**" and a list of PIC/S Participating Authorities can be found at www.picscheme.org)
   (m) A copy of the Certificate of Drug/Product Registration of the Good issued by the Pharmacy and Poisons Board of Hong Kong.
   (n) Where the Good is manufactured outside Hong Kong:
      (i) a certified true copy of its marketing authorisation ("**Marketing Authorisation**") issued by the regulatory authority in the overseas country / place which has to be a PIC/S Participating Authority, or where the Good is registered for export only, a certified true copy of an export certificate ("**Export Certificate**") issued by the regulatory authority in the overseas country / place from which the Good is exported which has to be a PIC/S Participating Authority, or in the case of the Good registered under the "1+" Mechanism, the "1+" Mechanism reference country/ place; or

(ii) if the Good will be supplied from an Established Source, a certified true copy of the Marketing Authorisation or Export Certificate from the regulatory authority in the country / place of origin.

(o) A copy of the complete master formula of the Good in English as currently registered with the Pharmacy and Poisons Board of Hong Kong.

(p) A copy of the method of analysis of the Good.

(q) A copy of the finished product specifications of the Good in English as currently registered with the Pharmacy and Poisons Board of Hong Kong.

(r) Stability data of the Good supporting the shelf-life and storage condition as currently registered with the Pharmacy and Poisons Board of Hong Kong.

(s) If the Good requires reconstitution or dilution, its post-reconstitution or post-dilution stability data (as the case may be) with recommended shelf-life and storage condition.

(t) A copy of the certificate of analysis of a representative batch of that Good.

(u) A copy of the bioequivalence studies report of the Good as compared with the following brand or a brand that has been used by the Authority through Bulk Supplies Contracts. The bioequivalence studies must be conducted in accordance with the World Health Organization guidelines.

Brand: VIMPAT

(v) Proof of compliance of the Good with the monograph as published in the applicable Pharmacopoeia.

3. As part of the Tender Submission, each Tenderer must as per the requirements in **Tenderer's Schedule B1(b)**, provide a declaration regarding the active pharmaceutical ingredients and excipients used and compliance with manufacturing related regulatory and quality guidelines.

B2. Quality Assurance (Tenderer's Schedule B2)
(Please refer to Part II)

Tenderers are to note the estimates of samples of Goods required and the testing frequency for Quality Assurance Tests are at **Appendix 4**. Tenderers must provide the following quality assurance information on each Good by completing the pro-forma **Tenderer's Schedule B2**:

1. Non-Sterile Products

(a) Tenderers must provide a report on the microbiological tests performed on each Good specified in USP/BP/Ph. Eur./JP. The report can be from the manufacturer's in-house laboratory or a Laboratory (either arranged by the Tenderer or commissioned by the Authority, each at the Tenderer's own costs).

(b) Tenderers may provide a microbial examination validation report in respect of each Good which complies with USP/BP/Ph. Eur./JP, if available.

(c) For each Good, Tenderers must specify if the Good contains raw materials of natural (animal, vegetable or mineral) origin for which antimicrobial pre-treatment is not feasible.

2. Sterile Products

Tenderers must provide for each Good, either:

(a) evidence of sterility tests performed on batch release of the Good as specified in its certificate of analysis as specified under paragraph B1(2)(t) above; OR

(b) a document demonstrating parametric batch release.

B3. Manufacturer of the Goods (Tenderer's Schedule B3)

Not applicable.

B4. Supply of the Goods (Tenderer's Schedule B4)
(Please refer to Part II)

Tenderers must provide the following in respect of the Tenderer's supply of the Goods by completing the pro-forma **Tenderer's Schedule B4**:

1. A copy of the relevant registrations/licences, such as the Wholesale Dealer Licence, Antibiotics Permit, Wholesale Dealer's Licence to supply Dangerous Drugs.

Folder C

For each Good, Tenderers must provide the following information:

C1. Patent Information in respect of Innovator Versions of the Goods

Tenderer offering Innovator versions of the Goods must in **Tenderer's Schedule C1** confirm that each such Good is proprietary and that the relevant drug patents/patent applications in respect of that Good exist and are still valid and in force.

C2. Non-Innovator Version of the Goods – Wholesale Information

For each Good, Tenderers should provide upon request the names, addresses and telephone numbers (for contact by the Authority) of their top 5 wholesale purchasers for the past 3 years and specify whether they are commercial entities, national/international organisation or government/supra-government organisation **(Tenderer's Schedule C2)**.

C3. Non-Innovator Version of the Goods – Confirmation of No Infringement/No Litigation and Claims

As part of the Tender Submission, each Tenderer must as per the requirements in **Tenderer's Schedule C3**, provide confirmations on its own behalf and on behalf of the manufacturer that the Goods offered have not been subject to any infringement litigation/claim or any threat thereof, and that the supply and use thereof in Hong Kong will not infringe any granted patent or fall within the claims of any pending patent applications etc.

C4. Non-Innovator Version of the Goods – Confirmation from the Tenderer's Patent Attorney

Tenderers must provide the confirmation from its Patent Attorney by completing the pro-forma **Tenderer's Schedule C4**.

Appendix 1 to Part III

The Authority's Supply Requirements

1. Points to note on evaluation are set out below:

In the context of the Authority's Supply Requirements under any tender:

(a) If the good is to be evaluated on an individual basis:

(i) a non-compliant good will not affect other compliant goods in a tender submission;

(ii) the tender price of a good will be its offer price per unit if divisible e.g. a tablet or a capsule, or per unit pack for compliant pack size if indivisible e.g. liquid, cream or gel, regardless of the actual pack size offered, unless the Authority specifies that the unit offer price should be per ml/litre.

(b) If the goods are to be evaluated on an overall basis:

(i) a tender submission will be disqualified if it fails to offer all goods or offers a non-compliant good;

(ii) the tender price of a good will be its offer price per unit or per unit pack × the estimated requirement of that good; and the aggregate tender prices of all goods will be the overall tender price for that tender submission.

(c) (i) The Authority may specify "strip pack", "range pack" and "special requirements" for a good. If both "strip pack" and "range pack" are specified, the tenderer may offer both for that good, but each will be treated as an individual item and evaluated separately.

(ii) Each good will be placed in one of the following groups with descending order of priority for evaluation, with group 1 accorded the highest priority. The same order of priority applies where one or two of the above requirements are specified:

Group 1 Compliance with "strip pack" and "special requirements" (but not "range pack").

Group 2 Compliance with "range pack" and "special requirements" (but not "strip pack").

Group 3 Compliance with "special requirements" (but not "strip pack" or "range pack").

Group 4 Compliance with "strip pack" (but not "special requirements" or "range pack").

Group 5 Compliance with "range pack" (but not "special requirements" or "strip pack").

Group 6 Non-compliance with all three requirements.

(d) The Authority may specify any quantity requirement of a good. The Authority may award the contract to a panel of up to two contractors for each good or to contractors in whole or in part, or to accept all or part of any tender submission. Tenderers are to note that where in respect of any good, half quantity is specified in the table in the

Attachment to this Appendix 1 and in the table in Tenderer's Schedules A5 of Part III under the columns for minimum quantity of a good and/or for estimated requirement of a good, it is mandatory for a Tenderer in its tender submission to complete all parts of all these tables for the Authority's half quantity requirement. It is optional for Tenderers in their tender submissions to complete or not complete all these tables in respect of the Authority's full quantity requirement. Those who fail to comply with this mandatory requirement will be rejected. Tenderers are to further note that notwithstanding this mandatory requirement, the Authority may elect to award its full quantity requirement solely to a contractor. Further, the Authority is not obliged to only consider the lowest tender prices.

2. The following sets out the steps that the Authority may take in evaluating tender submissions under a tender:

Step 1 All tender submissions will be ranked (and placed in different groups, if applicable) in ascending order of tender prices.

Step 2 (a) The Authority may in its absolute discretion choose a number of tender submissions so ranked and grouped and consider whether they comply with paragraph 4.1 (Part II). Those considered not to be in full compliance may be rejected.

(b) The Authority may then choose one or more of the remaining tender submissions for evaluation under paragraph 6 (Part II), if applicable. The Authority reserves the right to require any tenderer to provide patent information on any good under offer in tenders without paragraph 6 (Part II) requirements.

Step 3 The Authority may choose one or more tender submissions not rejected after Step 2 for final consideration in ascending order of tender prices. Contract award will be based principally on overall compliance with the tender, tender prices and past performance.

Step 4 Once the Authority has decided to award the contract, it is not obliged to evaluate other tender submissions, including those under concurrent evaluation. If the Contract is not awarded, the Authority may repeat the above steps for some, but not all, of the remaining compliant tender submissions.

Notes:

(i) The Authority may at any time conclude any tender submission to be incomplete and reject it if the tenderer has failed to provide any information, documents or clarification within the stipulated time frame or to the Authority's satisfaction.

(ii) The consideration by the Authority under Step 2 (with or without independent investigation) shall not affect or limit the tenderer's obligations under the contract (including without limitation, intellectual property warranties and indemnities). However, the Authority reserves the right to stipulate as part of its acceptance such further conditions (whether such pertains to the tenderer or the manufacturer of the goods) as it thinks fit.

3. The Authority's Supply Requirements under this Tender are set out in the Attachment to this **Appendix 1**.

Attachment to Appendix 1

The Authority's Supply Requirements

Item No.	Name of Good	Specification*	Minimum Quantity of a Good** *(Note (1) & (2))*	Estimated Requirement of a Good** *(Note (1) & (2))*	Breakdown of Estimated Requirement of a Good *(Note (1) & (2))*				Strip Pack	Range Pack	Special Requirements	Remarks	PPP Good (Yes/No)***
					HA	CPP	CDF	GOPC PPP					
1.	Lacosamide Tablet 50mg	Lacosamide Tablet 50mg with licensed indications of monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy and adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalized epilepsy, in blister or strip pack	1,680,000 tablets	2,400,000 tablets	2,280,000 tablets	120,000 tablets	0	0	-	-	-	-	No

2.	Lacosamide Tablet 100mg	Lacosamide Tablet 100mg with licensed indications of monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy and adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalized epilepsy, in blister or strip pack.	2,170,000 tablets	3,100,000 tablets	2,945,000 tablets	155,000 tablets	0	0	-	-	-	-	No

* If the Good is a generic product, the product specifications of the Good must comply with any one of the following:

(i) the Pharmacopoeia of the People's Republic of China product monograph;
(ii) the BP product monograph;
(iii) the Ph. Eur. active ingredient monograph;
(iv) the Ph. Eur. product monograph;
(v) the Ph. Int. product monograph;
(vi) the JP product monograph; or
(vii) the USP product monograph,

where a relevant monograph is published in any of the Pharmacopoeia.

** Supply of the relevant Glaucoma PPP Goods by the relevant Glaucoma PPP Contractor(s) to the relevant Glaucoma PPP Doctors shall not count towards any minimum quantity or the estimated requirement.

*** If the Authority has identified an item of Good as a PPP Good in the Attachment to Appendix 1, the relevant PPP Contractor(s) shall comply with all the requirements in the Tender in relation to such PPP Good in every respect including paragraph 2.7(c) of Part II. Whilst GOPC PPP Goods will be ordered by the Authority for delivery to the GOPC PPP Doctors, the Glaucoma PPP Goods will be ordered by the Glaucoma PPP Doctors directly on the designated electronic drug ordering platform provided by the Authority.

Note (1): The minimum quantity and estimated requirement of a Good specified herein are arrived at based on a contract term of 36 months, and as such the minimum quantity and estimated requirement shall be adjusted downwards by one third accordingly if the Contract is only awarded to the successful Tenderer for an initial term of 24 months.

Note (2): The Goods to be delivered to Community Pharmacies under Community Pharmacy Programme, Family Doctors under specified Government primary healthcare programme(s), and GOPC PPP Doctors under GOPC PPP Programme shall count towards the minimum quantity and overall estimated requirement of Good under this Contract. For the avoidance of doubt, the item "CPP" in the breakdown of estimated requirement refers to the estimated requirement for HA patients collecting drugs in Community Pharmacy, the item "CDF" in the breakdown of estimated requirement refers to the estimated requirement for patients receiving care under specified Government primary healthcare programme(s) who have the choice to obtain their medications of the Community Drug Formulary either from Family Doctors or Community Pharmacies, and the item "GOPC PPP" in the breakdown of estimated requirement refers to the estimated requirement for patients receiving care under the GOPC PPP Programme.

Tenderers are to note that evaluation of Goods under this Tender is on:

☐ an overall basis.

☑ an individual basis.

Appendix 2 to Part III

The Authority's Product Presentation Requirements

a. (For all products) Immediate container and all levels of packaging of the actual sales pack must include an English translation.

b. (For all products) The expiration date must be expressed in English and/or Arabic numerals in a clear and comprehensible format.

c. (For generic products) The generic name must be prominently displayed on the product label in a clear and conspicuous manner.

For generic product having a brand name which is displayed on the product labelling, at least one of the following conditions must be met:

1. the generic name must be displayed with the brand name, where the generic name must be at least as large as the brand name unless the generic name itself is in 12- point size or greater;

2. a brand name made up solely of the generic name plus the company name/logo/trademark/etc. could be considered acceptable.

d. (For generic products in the form of tablets and capsules in loose pack) Each tablet or capsule must have a unique marking that will enable the product to be identifiable on its own.

e. (For generic products in the form of tablets and capsules in strip pack) Each strip pack must be packaged and labelled with generic name in a way that the product could be identified when the strip pack is cut into individual units.

(For generic products in the form of tablets or capsules that do not bear unique marking and in strip pack) Each strip pack must be labelled in a way that the generic name is displayed with each pocket.

Appendix 3 to Part III

HA's Pre-approved Form of Banker's Guarantee for the Performance of a Contract

THIS GUARANTEE is made the day of 20XX.

By [name of bank]_____

of [address of registered office / principal place of business in HK] , a bank within the meaning of the Banking Ordinance (Chapter 155 of the Laws of Hong Kong) (hereinafter called the "Guarantor")

In favour of

The Hospital Authority (hereinafter called the "Hospital Authority") of the other part.

WHEREAS:

(A) By a contract (hereinafter called the "**Contract**") dated the made between _____ (hereinafter called the "**Contractor**") of the one part and the Hospital Authority of the other part (designated as Hospital Authority Contract No.), the Contractor agreed to perform all its obligations under the Contract for _____ (Contract Description).

(B) The Guarantor has agreed to guarantee in the manner hereinafter appearing, the due and faithful performance of the Contract by the Contractor.

Now the Guarantor HEREBY AGREES with the Hospital Authority as follows:

(1) Where applicable, words and expressions used in this Guarantee shall have the meaning assigned to them under the Contract.

(2) In consideration of the Hospital Authority entering into the Contract with the Contractor:

(a) The Guarantor hereby irrevocably and unconditionally guarantees the due and punctual performance and discharge by the Contractor of all of his, her and their obligations and liabilities under the Contract and the Guarantor shall pay to the Hospital Authority on demand and without cavil or argument all monies and liabilities which are now or at any time hereafter shall become due or owing by the Contractor to or in favor of the Hospital Authority under or in connection with the Contract together with all costs, charges and expenses on a full indemnity basis which may be incurred by the Hospital Authority by reason or in consequence of any default on the part of the Contractor in fulfilling, performing or observing any of the obligations terms conditions stipulations or provisions of the Contract.

(b) The Guarantor, as a principal obligor and as a separate and independent obligation and liability from its obligations and liabilities under sub-clause (a) above, irrevocably and unconditionally agrees to indemnify or keep indemnified the Hospital Authority against and shall pay to the Hospital Authority on demand and without cavil or

argument all losses, damages, costs, charges and expenses on a full indemnity basis suffered or incurred by the Hospital Authority arising from or in connection with the failure of the Contractor to perform fully or promptly any of his, her or their obligations terms conditions stipulations or provisions of the Contract.

(c) Subject to Clause 8, the Guarantor further agrees that all dividends, compositions and payments which the Hospital Authority may at any time receive from the Contractor or from his, her or their estate or estates, whether in liquidation, bankruptcy or otherwise, in respect of such all losses damages costs charges expenses shall be taken and applied by the Hospital Authority as payments in gross, and that this Guarantee shall stand good in respect of the full amount stipulated in Clause 15.

(3) This Guarantee shall not be affected by any change of name or status in the company, firm or individual described as "the Contractor" or where "the Contractor" is a partnership, any change in the partners.

(4) The Guarantor shall not be discharged or released from this Guarantee by any compromise, settlement or arrangement made between the Hospital Authority and the Contractor or by any alteration in the obligations imposed upon the Contractor by the Contract or by any waiver, forbearance or suspension granted by the Hospital Authority to the Contractor as to payment, time, performance or otherwise whether or not such compromise, settlement, arrangement, alteration, waiver or forbearance may have been or is made or granted with or without knowledge or assent of the Guarantor.

(5) Without prejudice to Clause 4 above, the obligations of the Guarantor under this Guarantee shall remain in full force and effect and shall not be affected or discharged in any way by, and the Guarantor hereby waives notice of:

(a) any suspension of, variation to or amendment of the Contract (including without limitation extension of time for performance of any obligations under the Contract or extension of the duration of the Contract) or any concession or waiver by the Hospital Authority, in whole or in part, in respect of the Contractor's obligations under the Contract;

(b) any provision of the Contract being or becoming illegal, invalid, void, voidable, severed, severable or unenforceable;

(c) the termination of the Contract (whether for reason of breach of any party or otherwise) or of the engagement of the Contractor under the Contract for any reason;

(d) any forbearance or waiver of any right of action or remedy that the Hospital Authority may have against the Contractor and/or the negligence, failure, omission, indulgence or delay by the Hospital Authority in enforcing any right, power, privilege to or remedy available to the Hospital Authority in relation to the obligations of the Contractor set out in the Contract;

(e) the voluntary or involuntary liquidation, bankruptcy, dissolution, sale of assets, receivership, general assignment for benefit of creditors, insolvency, reorganisation arrangement, composition, or other proceedings of or affecting the Contractor or its assets, or any change in the constitution of the Contractor;

(f) any assignment or sub-contracting by the Contractor of any or all of its obligations set out in the Contract, whether or not such assignment or sub-contracting has been consented to by the Hospital Authority or the Guarantor;

(g) without prejudice to the generality of the foregoing, any fact or event (whether similar to any of the foregoing or not) which in the absence of this provision would or might constitute or afford a legal or equitable discharge or release of or defence to the Guarantor, other than the express release by the Hospital Authority of the Guarantor's obligations.

(6) This Guarantee shall extend to any variation of or amendment to the Contract and to any agreement supplemental thereto agreed between the Hospital Authority and the Contractor and for the avoidance of doubt, the Guarantor hereby authorises the Hospital Authority and the Contractor to make any such amendment, variation or supplemental agreement.

(7) This Guarantee shall have immediate effect upon execution and is a continuing security. This Guarantee shall cover all of the obligations and liabilities of the Contractor under the Contract and shall remain in full force and effect and irrevocable until-

(a) the date falling three months after the expiry of the Contract; or

(b) the date on which all the obligations and liabilities of the Contractor under the Contract have been duly carried out, completed and discharged in accordance with the Contract,

whichever is the later. Notwithstanding the foregoing, if prior to the date of expiry of this Guarantee as aforesaid, there shall be any claim, litigation or threatened litigation concerning or arising out of the Contractor's possible breach of Contract, the Guarantor agrees that this Guarantee shall, upon notice of the Hospital Authority of such claim, litigation or threatened litigation, be automatically extended for a period until three months following the final conclusion of such claim, litigation or threatened litigation. For the avoidance of doubt, this Guarantee shall be further extended if there shall be any appeal proceedings until three months after a final decision which is non-appealable is delivered.

(8) This Guarantee is in addition to and shall not merge with or otherwise prejudice or affect any contractual or other right or remedy or any guarantee, indemnity, lien, pledge, bill, note, charge or any other security which the Hospital Authority may at any time hold (collectively "Other Security") and this Guarantee may be enforced by the Hospital Authority without first having recourse to any of the Other Security or taking any steps or proceedings against the Contractor, and notwithstanding any release, waiver or invalidity of the Other Security.

(9) Any demand, notification or certificate given by the Hospital Authority specifying amounts due and payable under or in connection with any of the provisions of this Guarantee shall be conclusive and binding on the Guarantor.

(10) The obligations expressed to be undertaken by the Guarantor under this Guarantee are those of primary obligor and not as a surety.

(11) This Guarantee shall be governed by and construed according to the laws for the time being in force in the Hong Kong Special Administrative Region ("**Hong Kong**") and the Guarantor agrees to submit to the exclusive jurisdiction of the Courts of Hong Kong.

(12) The application of the Contracts (Rights of Third Parties) Ordinance is expressly excluded and no person who is not a party to this Guarantee shall be entitled to enforce any right or term of this Guarantee pursuant to the Contracts (Rights of Third Parties) Ordinance.

(13) All documents arising out of or in connection with this Guarantee shall be served:

(a) upon the Hospital Authority, at the Room 310N, 3/F., Hospital Authority Building, 147B Argyle Street, Kowloon, Hong Kong, facsimile number (852) 2515 9046;

(b) upon the Guarantor, at _____.
Hong Kong, marked for the attention of _____.
facsimile number _____.

(14) Documents to be served under this Guarantee shall be deemed to have been duly served by one party if sent by letter or fax addressed to the other party at the address stated above or to the facsimile number set out above. The documents so served shall be effective (a) on the date of delivery if hand-delivered; (b) on the date of transmission if sent by facsimile; and (c) if dispatched by mail (whether registered or not), on the day on which they are tendered for delivery by the postal authority in Hong Kong.

(15) The aggregate amount of the Guarantor's liability under this Guarantee shall not exceed .

IN WITNESS whereof the said Guarantor ……. has caused its Common Seal to be hereunto affixed the day and year first above written.

The Common Seal of the said)
Guarantor was hereunto affixed)
in the presence of)
…….)

@ Signed Sealed and Delivered)
for and on behalf of and as)
lawful attorney of the Guarantor)
under power of attorney dated)
……..… and deed of delegation)
dated ……)
by ……)
and in the presence of ……..)
……..)

@ See Powers of Attorney Ordinance Cap. 31

Note: When Banker's Guarantees are executed under power of attorney, a photocopy of the power of attorney, certified on each page by a Hong Kong solicitor that it is a true and complete copy of the original, should be submitted.

Appendix 4 to Part III

Estimates of Samples Required and Testing Frequency for Quality Assurance Tests

Item No. (Note 1)	Item Description	Estimate of Chemical Analysis Test Frequency	Quantity per Chemical Analysis Test (Note 2)	Estimate of Microbiological Test Frequency	Quantity per Microbiological Test (Note 2-4)	Quantity for Validation Test (Note 2-5)
1.	Lacosamide Tablet 50mg	Once per year	1 pack where each pack contains no less than 60 tablets	Once per year	20 – 30g	20 – 30g
2.	Lacosamide Tablet 100mg	Once per year	1 pack where each pack contains no less than 60 tablets	Once per year	20 – 30g	20 – 30g

Notes:

1. Item no. must correspond to the number assigned to the Good in the Attachment to **Appendix 1** in Part III.
2. All quantities quoted are subject to final confirmation with the laboratories.
3. The quantities quoted reflect the number of smallest pack required or the total weight of the dosage units required including both the active and inactive ingredients.
4. A quantity of 30g is required for oral dosage forms containing raw materials of natural (animal, vegetable or mineral) origin for which antimicrobial pretreatment is not feasible.
5. Samples for validation test are required when validation reports cannot be provided.

Appendix 5.1 to Part III

Terms and Conditions for the Supply of GOPC PPP Goods by the GOPC PPP Contractor(s) for Delivery to GOPC PPP Doctors during the Term under the General Outpatient Clinic Public-Private Partnership Programme ("GOPC PPP Programme")

1. The GOPC PPP Programme is a public-private partnership programme of the Authority whereby GOPC PPP Doctors in designated geographical areas provide outpatient services to participating patients of the Authority.

2. GOPC PPP Doctors assume primary responsibility for, and attend to their patients in respect of designated chronic diseases under the GOPC PPP Programme as an extension of the services of the Authority's General Outpatient Clinic services. HA patients participating in the GOPC PPP Programme will from time to time be prescribed with drugs.

3. The PPP Contractor as selected to participate in the GOPC PPP Programme by supplying Goods during the Term, and notified as such in the Memorandum of Acceptance ("**GOPC PPP Contractor**") agrees that during the Term:

3.1 to enable the GOPC PPP Programme to proceed, the GOPC PPP Contractor shall deliver to GOPC PPP Doctors the GOPC PPP Goods that the Authority may order;

3.2 the price at which the GOPC PPP Contractor shall supply GOPC PPP Goods for delivery to GOPC PPP Doctors under the GOPC PPP Programme during the Term ("**GOPC PPP Price**") shall be the same as the Price;

3.3 Goods to be delivered to GOPC PPP Doctors shall count towards the minimum quantity and overall estimated requirement of Goods under this Contract;

3.4 The ordering mechanism of GOPC PPP Goods shall follow the ordering mechanism of items of Goods listed in Community Drug Formulary as set out in Appendix 5.2, including the following arrangement:

3.4.1 The order and delivery requirements in the Annexure to Terms and Conditions for Supply of Goods to Community Pharmacies and Family Doctors in Appendix 5.2 to Part III shall apply mutatus mutandis to the supply of the GOPC PPP Goods by the GOPC PPP Contractor and delivery of such goods to the GOPC PPP Doctors;

3.4.2 The Authority shall pay to the GOPC PPP Contractor a commitment fee for the provision of logistics and administrative support to the GOPC PPP Programme in the amount and in such manner, mutatus mutandis, set out in the Annexure to Terms and Conditions for Supply of Goods to Community Pharmacies and Family Doctors in Appendix 5.2 to Part III in respect

of delivery to Family Doctors;

3.5 The GOPC PPP Contractor and GOPC PPP Doctors shall contact each other directly in case of any issue, including delivery error or drug recall, late delivery, shelf-life or dispute regarding GOPC PPP Goods delivered by the GOPC PPP Contractor and endeavour to resolve such issue or dispute in good faith.

Terms and Conditions for the Supply of Glaucoma PPP Goods by the Glaucoma PPP Contractor(s) to Glaucoma PPP Doctors during the Term under the Glaucoma Public-Private Partnership Programme ("Glaucoma PPP Programme") ("Glaucoma PPP Goods Terms and Conditions")

1. The Glaucoma PPP Programme is a public-private partnership programme of the Authority whereby private doctors participating in the Glaucoma PPP Programme ("**Glaucoma PPP Doctors**") provide outpatient services to participating patients from designated clusters of the Authority.

2. Glaucoma PPP Doctors assume primary responsibility for, and attend to their patients on their glaucoma condition under the Glaucoma PPP Programme as an extension of the services of the Authority's Specialist Outpatient Clinic services. HA patients participating in the Glaucoma PPP Programme will from time to time be prescribed with drugs.

3. The PPP Contractor as selected to participate in the Glaucoma PPP Programme by supplying Goods to Glaucoma PPP Doctors during the Term, and notified as such in the Memorandum of Acceptance ("**Glaucoma PPP Contractor**") agrees that during the Term:

3.1 to enable the Glaucoma PPP Programme to proceed, the Glaucoma PPP Contractor shall supply to Glaucoma PPP Doctors the Glaucoma PPP Goods they ordered on the designated electronic drug ordering platform provided by the Authority ("**Ordering Platform**") subject to and in accordance with the ordering requirements set out in the **Annexure** hereto;

3.2 the price at which the Authority shall pay the Glaucoma PPP Contractor for the Glaucoma PPP Goods delivered to Glaucoma PPP Doctors under the Glaucoma PPP Programme during the Term ("**Glaucoma PPP Price**") shall be the Price, unless the Glaucoma PPP Contractor has agreed under the Contract to supply free unit(s) of such Good to the Authority whenever a minimum quantity of units of such Good is ordered by the Authority under the Contract ("**Bonus Term Arrangement**") in which case, the Glaucoma PPP Price per unit shall be adjusted down to the net price calculated according to the formula below ("**Discounted Glaucoma PPP Price**"):

$$\frac{\text{Price per unit x M}}{\text{M + F}}$$

Where:

"**M**" is the minimum quantity of units of such Good that the Authority has to order to qualify for the Bonus Term Arrangement under the Contract; and
"**F**" is the number of free unit(s) of such Good to be supplied to the Authority under the Bonus Term Arrangement whenever M is ordered.

The Discounted Glaucoma PPP Price shall apply irrespective of the volume of the Confirmed Orders (defined in paragraph 3.3 below) placed by Glaucoma PPP Doctors. If the Discounted Glaucoma PPP Price is not a whole number, it shall be rounded down to two decimal places;

3.3 the Glaucoma PPP Contractor shall, subject to the terms and conditions of use of the Ordering Platform as may be notified by the Authority from time to time, utilise the Ordering Platform

to receive and fulfil orders for the Glaucoma PPP Goods placed by Glaucoma PPP Doctors under paragraph 3.1 above and confirmed by the Authority on the Ordering Platform ("**Confirmed Orders**");

3.4 the Glaucoma PPP Contractor shall supply directly to Glaucoma PPP Doctors, rather than the Authority, Glaucoma PPP Goods under Confirmed Orders and all contractual and legal relations relating to such supply of Glaucoma PPP Goods will be between the Glaucoma PPP Contractor and Glaucoma PPP Doctors save and except that payment of Glaucoma PPP Goods supplied shall be in accordance with paragraph 3.5 below. Glaucoma PPP Doctors and the Glaucoma PPP Contractor shall contact each other directly in case of any issue, including delivery error or drug recall, late delivery, shelf-life or dispute regarding the Glaucoma PPP Goods delivered and endeavor to resolve such issue or dispute in good faith;

3.5 After delivery of the Glaucoma PPP Goods, the Glaucoma PPP Contractor shall submit to the Authority its delivery notes with recipient's signature or clinic chop acknowledging receipt of the Glaucoma PPP Goods delivered by uploading such delivery notes to the Ordering Platform. The Authority's payment of the Glaucoma PPP Goods delivered calculated by reference to the Glaucoma PPP Price is conditional upon the Authority's receipt of the Glaucoma PPP Contractor's delivery notes via their uploading to the Ordering Platform;

3.6 Glaucoma PPP Goods supplied by the Glaucoma PPP Contractor to Glaucoma PPP Doctors under Confirmed Orders shall not count as drugs purchased by the Authority under the Contract or count towards any minimum or maximum volumes of Glaucoma PPP Goods the Glaucoma PPP Contractor agreed to supply to the Authority under the Contract. All the Glaucoma PPP Contractor's and the Authority's obligations under the Contract shall remain unchanged;

3.7 The Authority shall pay to the Glaucoma PPP Contractor a commitment fee ("**Commitment Fee**") for the provision of logistics and administrative support to the Glaucoma PPP Programme in the amount and in such manner set out in the **Annexure** to the Glaucoma PPP Goods Terms and Conditions.

Annexure to the Glaucoma PPP Goods Terms and Conditions

Order and Delivery Requirements

(1) There is no minimum quantity or value of Glaucoma PPP Goods that a Glaucoma PPP Doctor must order.

(2) A Glaucoma PPP Doctor can start to order a Glaucoma PPP Good under the Glaucoma PPP Programme from the Glaucoma PPP Contractor from the commencement of the next quarter immediately after the date the Glaucoma PPP Doctor first supplied such Glaucoma PPP Good to a patient enrolled under his/her care under the Glaucoma PPP Programme. In this Appendix, a quarter denotes a 3-month period from 1 April to 30 June, 1 July to 30 September, 1 October to 31 December or 1 January to 31 March.

(3) In each quarter, a Glaucoma PPP Doctor can only place 1 Confirmed Order with the same Glaucoma PPP Contractor (regardless of the delivery date).

(4) The Glaucoma PPP Contractor shall deliver Glaucoma PPP Goods within 7 working days of the receipt by the Glaucoma PPP Contractor of a Confirmed Order or such other date as otherwise agreed by the Glaucoma PPP Contractor and the Glaucoma PPP Doctor. Other than the Commitment Fee, the Glaucoma PPP Contractor shall not charge a Glaucoma PPP Doctor for delivery of the Glaucoma PPP Goods.

(5) All Glaucoma PPP Goods supplied shall have an expiry date of at least 18 months from the date of delivery (unless otherwise agreed by HA) or such shorter period as agreed between the Glaucoma PPP Contractor and the Glaucoma PPP Doctor.

(6) A Glaucoma PPP Doctor can only order not more than a maximum quantity specified by the Authority as shown on the Ordering Platform whenever an order is placed for a Glaucoma PPP Good on the Ordering Platform.

Commitment Fee

(1) The Authority shall pay to the Glaucoma PPP a Commitment Fee every 12 months from 1 April to 31 March ("**Relevant Year**") except that the first Relevant Year shall be from the start date of the Contract to the next 31 March.

(2) The Commitment Fee payable to the Glaucoma PPP Contractor in a Relevant Year shall be the sum total for each quarter in such year of all the amounts calculated below for each Glaucoma PPP Doctor who has placed a Confirmed Order with the Glaucoma PPP Contractor in that quarter (regardless of the delivery date):

(a) The amount shall be HKD100 per quarter if on the last day of such quarter the Glaucoma PPP Contractor is supplying 10 or more items of Glaucoma PPP Goods to Glaucoma PPP Doctors for the Glaucoma PPP Programme under the Contract; and

(b) The amount shall be HKD50 per quarter if on the last day of such quarter the Glaucoma PPP Contractor is supplying less than 10 items of Glaucoma PPP Goods to Glaucoma PPP Doctors for the Glaucoma PPP Programme under the Contract.

The Glaucoma PPP Contractor is not entitled to a separate Commitment Fee for each type of Glaucoma PPP Goods it supplies to Glaucoma PPP Doctors under the Contract.

(3) A Confirmed Order shall not be taken into account under paragraph (2) if by the time of payment of the Commitment Fee delivery for such Confirmed Order is not completed by the Glaucoma PPP Contractor. The Authority shall be entitled to conduct checking from time to time to ascertain whether deliveries have been made by the Glaucoma PPP Contractor to the Glaucoma PPP Doctors and the Glaucoma PPP Contractor shall promptly provide all relevant documentary proof to show the same upon request by the Authority.

Appendix 5.2 to Part III

Terms and Conditions for the Supply of Goods to Community Pharmacies under Community Pharmacy Programme and Family Doctors under specified Government primary healthcare programme(s) ("Terms and Conditions for Supply of Goods to Community Pharmacies and Family Doctors")

1. The Community Pharmacy Programme (CPP) is launched by the Health Bureau (HHB) to strengthen the primary healthcare system in Hong Kong. It expands the role of community pharmacies and pharmacists in line with the Primary Healthcare Blueprint. The CPP aims to alleviate the burden on the public healthcare system by engaging community pharmacies to provide more frequent dispensing services, thereby expanding the clinical roles of community pharmacists and enhancing their involvement in patient care. The CPP operates under two service models:

   CPP (Community): Focuses on providing services that covers dispensing of refills and prescriptions, including medication counselling, for HA patients and participants in specified Government primary healthcare programme(s).

   CPP (RCH): Tailored for HA patients residing in Residential Care Homes (RCHs), this model involves streamlined drug dispensing, medication reconciliation, and multi-dose medication packaging, as well as IT-enabled drug administration systems to improve medication safety and operational efficiency at RCHs.

2. As a government initiative, the Community Drug Formulary (CDF) aimed at enhancing access to affordable drugs within Hong Kong's primary healthcare system. It provides a list of drugs that supports specified Government primary healthcare programme(s) and enables the acquisition of listed drugs at affordable prices while ensuring high standards of safety, efficacy, quality, and cost-effectiveness. Patients receiving care under specified Government primary healthcare programme(s) have the choice to obtain their medications either from participating doctors (i.e. Family Doctors) or community pharmacies (i.e. Community Pharmacies). (Note: details of Community Drug Formulary can be found at https://www.healthbureau.gov.hk/phcc/files/community_drug_formulary.pdf)

3. When Goods are listed in the CPP Drug List and/or CDF, the Contractor is required to deliver the Goods to the Community Pharmacies and/or the Family Doctors, in addition to the HA Hospitals. While the Goods to be delivered to the Community Pharmacies may include (1) any drug items listed in the CPP Drug List for dispensing to HA patients and (2) any drug items listed in the CDF for dispensing to patients participating in specified Government primary healthcare

programme(s), only drug items listed in the CDF will be delivered to the Family Doctors for prescribing and dispensing to patients participating in specified Government primary healthcare programme(s).

4. Unless specified in this Appendix, all the requirements set out in this Tender also apply to the Goods to be delivered to Community Pharmacies and Family Doctors.

5. Separate quantities of estimated requirements are provided in the **Attachment to Appendix 1 in Part III** for Goods that are covered by the Community Pharmacy Programme or the Community Drug Formulary for specified Government primary healthcare programme(s) on issuance of tender. If separate quantities of estimated requirements are not provided on issuance of tender but delivery of Goods to Community Pharmacies or Family Doctors are required during the Term of the Contract, the Authority shall provide written notice to the Contractor with relevant estimated quantity and proposed start date for Contractor's confirmation on readiness before commencing ordering and delivery to Community Pharmacies and Family Doctors.

6. The Goods to be delivered to Community Pharmacies under Community Pharmacy Programme and Family Doctors under specified Government primary healthcare programme(s) shall count towards the minimum quantity and overall estimated requirement of Goods under this Contract.

7. The Contractor shall deliver Goods to Community Pharmacies and Family Doctors in accordance with the order and delivery requirements in the **Annexure to Terms and Conditions for Supply of Goods to Community Pharmacies and Family Doctors**.

8. The Contractor and Community Pharmacies or Family Doctors shall contact each other directly in case of any issue, including delivery error or drug recall, late delivery, shelf-life or dispute regarding Goods delivered by the Contractor and endeavour to resolve such issue or dispute in good faith.

9. The Authority shall pay to the Contractor a commitment fee ("**Commitment Fee**") for the provision of logistics and administrative support to the Community Pharmacies and Family Doctors in the amount and in such manner set out in the **Annexure to Terms and Conditions for Supply of Goods to Community Pharmacies and Family Doctors**.

Annexure to Terms and Conditions for Supply of Goods to Community Pharmacies and Family Doctors

Order and Delivery Requirements

(1) To enable the delivery of Goods to Community Pharmacies under Community Pharmacy Programme and Family Doctors under specified Government primary healthcare programme(s), the Authority shall place orders specifying the Community Pharmacies and the Family Doctors as delivery points.

(2) The Goods shall be delivered directly to Community Pharmacies and Family Doctors in accordance with the instruction of the purchase orders issued by the Authority. The Contractor shall ensure acknowledgement of receipt (if in paper form, with recipient's signature and pharmacy or clinic chop) is obtained upon delivery.

(3) All Goods ordered by the Authority shall be delivered within 7 days of the receipt of order by the Contractor or such other delivery date as otherwise specified on the purchase order.

(4) After the delivery of Goods, the Contractor shall submit relevant invoices to the Authority for payment. Documentary proof of the delivery shall be provided by the Contractor upon request by the Authority.

(5) There shall be free delivery for 1 order out of all orders placed to the Contractor for delivery to the Community Pharmacy or the Family Doctor in any 1 month (regardless of the delivery date). For the avoidance of doubt, a doctor who participates in both the specified Government primary healthcare programme(s) and the GOPC PPP Programme is only entitled to free delivery of one purchase order with the same Contractor per calendar month in total; a Community Pharmacy that participates in both the CPP (Community) and CPP (RCH) is only entitled to free delivery of one purchase order with the same Contractor per calendar month in total. For each additional order placed within the same month, the Contractor can charge a Community Pharmacy or a Family Doctor HKD100 delivery charge. Any delivery fee incurred for the additional delivery(ies) shall be settled directly between the Community Pharmacy or Family Doctor and the Contractor. The Authority shall have no liability in respect of any delivery fees or any dispute arising between Community Pharmacy or Family Doctor and the Contractor.

Commitment Fee

(1) The Authority shall pay to the Contractor a Commitment Fee every 6 months from 1 April to 30 September, 1 October to 31 March ("**Relevant Periods**") except that the first Relevant Period shall start from the start date of the Term of the Contract.

(2) Where the Authority has ordered any Goods for delivery to a Community Pharmacy in a month (regardless of the delivery date), the Contractor will get a monthly amount for that month as calculated below in respect of that Community Pharmacy:

(a) The monthly amount shall be HKD100 if on the last day of the month there are 10 or more items of Goods available for supply by the Contractor under the relevant model of Community Pharmacy Programme; and

(b) The monthly amount shall be HKD50 if on the last day of month there are less than 10 items of Goods available for supply by the Contractor under the relevant model of Community Pharmacy Programme.

For the avoidance of doubt, if the Contractor has supplied item(s) of Goods under the relevant model of Community Pharmacy Programme but all the relevant Contract(s) have ended before the last day of a month, the number of items that are available for supply by the Contractor under the relevant model of Community Pharmacy Programme is regarded as one for that particular month.

Subject to paragraph (4) below, the Commitment Fee payable to the Contractor for delivery to each Community Pharmacy for a Relevant Period shall be the sum total of all the monthly amounts calculated above.

The Contractor however is not entitled to a separate Commitment Fee for each item of Goods it supplies to the Community Pharmacies. The Contractor is also not entitled to a separate Commitment Fee in the case where the Contractor is supplying drug items to the same Community Pharmacy participating in both the CPP (Community) and CPP (RCH). If the Community Pharmacy participates in both the CPP (Community) and CPP (RCH), the larger number of available items of Goods between the two models shall be adopted for purposes of (a) and (b) above.

(3) Where the Authority has ordered any Goods for delivery to a Family Doctor in a month (regardless of the delivery date), the Contractor will get a monthly amount for that month as calculated below in respect of that Family Doctor:

(a) The monthly amount shall be HKD100 if on the last day of the month there are 10 or more items of Goods available for supply by the Contractor and listed in the Community Drug Formulary; and

(b) The monthly amount shall be HKD50 if on the last day of the month there are less than 10 items of Goods available for supply by the Contractor and listed in the Community Drug Formulary.

For the avoidance of doubt, if the Contractor has supplied item(s) of Goods under the Community Drug Formulary but all the relevant Contract(s) have ended before the last day of a month, the number of items that are available for supply by the Contractor and listed in the Community Drug Formulary is regarded as one for that particular month.

Subject to paragraph (4) below, the Commitment Fee payable to the Contractor for delivery to each Family Doctor for a Relevant Period shall be the sum total of all the monthly amounts calculated above.

The Contractor however is not entitled to a separate Commitment Fee for each item of Goods it supplies to the Family Doctors. The Contractor is also not entitled to a separate Commitment Fee in the case where the Contractor is supplying drug items to the same Family Doctor / GOPC PPP Doctor participating in both the specified Government primary healthcare programme(s) and the GOPC PPP Programme.

(4) An order for Goods shall not be taken into account under paragraphs (2) and (3) if by the time of payment of the Commitment Fee delivery for such order is not completed by the Contractor. The Authority shall be entitled to conduct sample checking from time to time to ascertain whether deliveries have been made by the Contractor to the Community Pharmacies and Family Doctors and the Contractor shall promptly provide documentary proof to show the same upon request by the Authority.

Appendix 6 to Part III

The Authority's UI Requirements

(a) The GS1 2D DataMatrix and its affiliated components including the product GTIN, Expiration date and Batch number are present on the actual sales pack of the offered goods and pass the Authority's UI verification process, and otherwise meet the Authority's requirements imposed from time to time.

(b) The format of the GS1 2D DataMatrix and its affiliated components shall follow and adhere to the standards specified in "The Authority's Guideline for Identification and Labelling of Pharmaceutical Products" as set out in the Annexure to Appendix 6 of Part III, which may be updated by the Authority from time to time.

(c) The data encoded within the GS1 2D DataMatrix shall be accurately represented in the corresponding printed presentation.

Annexure to Appendix 6 of Part III

THE AUTHORITY'S GUIDELINE FOR IDENTIFICATION AND LABELLING OF PHARMACEUTIAL PRODUCTS

June 2024

Chief Pharmacist's Office

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Revision History

Author	Month - Year	Comments
The Hospital Authority Hong Kong	June 2024	First Draft

1.Introduction

The Guideline for Identification and Labelling of Pharmaceutical Products document outlines implementation requirements for those stakeholders in scope for meeting the UI requirements described in tender for the supply of pharmaceutical products to the Hospital Authority, Hong Kong.

1.1 Rationale

By leveraging existing global standards for the labelling and packaging of pharmaceutical products, the Authority hopes to create efficiencies in the public health supply chains through standardised identification and automated data capture, thus facilitating pharmaceutical traceability.

1.2 Purpose

This document is intended to provide suppliers with further information on how to implement the 2D DataMatrix on pharmaceutical products supplied to the Hospital Authority, Hong Kong.

DISCLAIMER:

The views expressed in this publication refer solely to the Hospital Authority, Hong Kong and do not necessarily represent the views of any other body.

2. Product Identification and Labelling Requirements for Pharmaceuticals

All secondary packaging items or sales pack as defined by the Authority, should include a GS1 2D DataMatrix encoded with the following information, printed adjacent to the data carrier, in addition to generating a successful scan and fulfilling the Authority's UI verification checks, with reference to the UI Requirements.

	Information
1	GTIN
2	Expiration Date
3	Batch Number

Example	
	GTIN 10857674002017 EXP 251231 BATCH NYFUL01

Encoded in the data carrier, this example will take on the following format:

FNC Opening character	AI	GTIN	AI	Expiration Date	AI	Batch
FNC1	01	10857674002017	17	251231	10	NYFUL01

Function 1 Symbol Character (FNC1, codeword 232[1]) must be in the first position of the data encoded for the GS1 2D DataMatrix. Upon correct creation, the ISO/IEC Symbology Identifier "]d2" will be transmitted upon reading and scanning by a barcode reader or imager.

When read through a barcode reader or imager, this example will take on the following format:

]d201108576740020171725123110NYFUL01

[1] GS1 AISBL, GS1 DataMatrix Guideline (Release 2.5.1., Ratified, Jan 2018) 15, s 2.2.1

2.1 Description of Packaging Levels[2]

2.1.1 Secondary Packaging

Secondary packaging is a level of packaging that may contain one or more primary packages, or a group of primary packages containing a single item.[3] The secondary packaging level usually refers to the sales pack, unless the supplier is providing items in “carton-less packaging” i.e., without a secondary packaging level. This packaging level is marked with a GS1 DataMatrix, either printed on the packaging itself or on a label affixed to the packaging.

Examples of secondary packaging include, but are not limited to:



2.1.2 Primary Packaging

Primary packaging is the first level of packaging that is in direct contact with the item.[4] Examples of primary packaging include, but are not limited to:



[2] The Glossary of Terms is referenced directly from the Global Standards Technical Implementation Guideline for Global Health Commodities

[3] For more information, see GS1 AIDC Healthcare Implementation Guidelines, Section 3.5.3, Secondary Package.

[4] For more information, see GS1 AIDC Healthcare Implementation Guidelines, Section 3.5.2, Primary Package.

3. Overview of Relevant Global Standards[5]

A summary of the GS1 standards relevant to the Authority are described in this section. This document is based on the use of the *GS1 General Specifications*[6] as the primary reference document for technical specifications to implement in accordance with GS1 global standards. Since changes are regular, the latest version of the *GS1 General Specifications* should always be considered.

3.1. Identify

The GS1 application identifiers (AIs) referenced in this section are used for identifying items and locations.

3.1.1 AI (01) Global Trade Item Number[7]

The GS1 AI (01) indicates that the data field contains a GTIN. The GTIN is the globally unique GS1 identification number used to identify trade items GTINs are assigned by the brand owner of the item and are used to identify items as they move through the global supply chain to the hospital or ultimate end user.

The GTIN contained within the 2D DataMatrix should be 14 digits in length. The format of the GTIN-14 is as follows:

GS1 Application Identifier (AI)	Global Trade Item Number (GTIN)													
	GS1-8 Prefix or GS1 Company Prefix →							← Item Reference						Check Digit
01	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11	N12	N13	N14

If your original GTIN has only 13 digits, a leading zero should be placed before the GTIN for the sake of barcode creation only. Where multiple barcode types are present on the same secondary packaging, they need to be encoded **with the same GTIN**.

[5] Annex A is referenced directly from the Global Standards Technical Implementation Guideline for Global Health Commodities.

[6] For more information, see GS1 General Specifications

[7] For more information, see GS1 General Specifications, Section 3.3.2, Identification of a trade item (GTIN): AI (01)

3.1.2 AI (10) Batch Number[8]

The GS1 AI (10) indicates that the data field contains a batch number. This number field is alphanumeric.

The format of the batch number is as follows:

GS1 Application Identifier (AI)	Batch Number
10	X1 ⟶ Variable Length ⟵ X20

3.1.3 AI (17) Expiration Date[9]

The GS1 AI (17) indicates that the data field contains an expiration date. The structure of the expiration date should be as follows:

- Year (YY): the tens and units of the year (e.g., 2003 = 03)
- Month (MM): the number of the month (e.g., January = 01)
- Day (DD): the number of the day of the relevant month (e.g., second day = 02);

The format of the expiration date is as follows:

GS1 Application Identifier (AI)	Expiration Date					
	Year		Month		Day	
17	N1	N2	N3	N4	N5	N6

To avoid diverse interpretation by different systems and persons of expiration date with only month and year along the supply chain, all of the day, month and year in the barcode shall be indicated on packaging, whenever possible. In the case that only month and year are practical, one must encode two zeros “00” in the day field of the barcode.

3.2 Capture

All secondary packages are required to be labelled in accordance with the specified barcode requirement, encoded with relevant GS1 Application Identifiers, with printing of the corresponding data in a clear and comprehensible format

[8] For more information, see GS1 General Specifications, Section 3.4.1, Batch or Lot Number: AI (10).

[9] For more information, see GS1 General Specifications, Section 3.4.7, Expiration Date: AI (17).

3.2.1 GS1 DataMatrix[10]

A GS1 DataMatrix is a 2D matrix symbology made up of square modules arranged within a perimeter finder pattern that is required on all pharmaceutical products. It is not a QR code or generic DataMatrix. Barcode readers or imagers can read DataMatrix symbols.

Example of a GS1 DataMatrix



GTIN 10857674002017
EXP 251231
BATCH NYFUL01

3.2.2 Printed Information

The purpose is to facilitate data entry in the event the barcode symbol cannot be scanned.
It is defined as the printed information below, beside, or above a barcode that is encoded within the 2D DataMatrix, and represents the same characters as those carried in the barcode.



GTIN 04012345678901
EXP 230420 (YYMMDD)
BATCH ABC123

Extra labelling or printing may be required to avoid misinterpretation of the printed expiry date. Without the printed (YYMMDD) near the expiry date, the same set of values could also be interpreted as (DDMMYY). Organisations utilising the GS1 standards for data carrier implementation are expected to fully conform to the *GS1 General Specifications*, with the exception of applicable regulatory requirements which shall take precedence in all situations.[11]

3.2.3 Information in the DataMatrix

The encoded and printed data (i.e. GTIN, Batch number and Expiration date) shall represent the same data, despite the fact that the format of the printed expiration date may vary from the format used to encode the data into the bar code.

[10] For more information, see GS1 General Specifications, Section 5.7, Two-dimensional barcodes—GS1 DataMatrix symbology.

[11] GS1 AISBL, GS1 DataMatrix Guideline (Release 2.5.1., Ratified, Jan 2023) 15, s 4 .14

3.2.3.1 Descriptive Data Titles

The Authority recommends the use of descriptive text as data titles on secondary packaging. Full descriptive words or their commonly used abbreviations should be used which are deemed acceptable by the Regulatory.

The table below are examples of commonly used terms and is not an exhaustive list.

Information	Examples of Descriptive Data Titles
GTIN	GTIN, Product Code, PC
Expiration Date	Expiry Date, Expiry, EXP
Batch Number	BATCH

3.2.3.2 Additional Data

There may be additional data in the same barcode which should be encoded under the correct GS1 Application Identifier where such information should be mutually agreed between trading partners. The GS1 AI (90) can be used to encode the HK registration number for use within the Authority only. Where your product is traded through various channels, the interpretation of AI (90) may differ and should be removed.

GS1 Application Identifier (AI)	Agreed Additional Data
90	X1 ⟶ Variable Length ⟵ X30

3.2.3.3 Encoded Data Sequence

This guideline does not mandate the sequence in which data are encoded into the data carrier. However, for the most efficient encoding, it is recommended that fixed-length data elements precede variable-length elements.

Common practice of data sequence is:

Sequence	GS1 Application Identifier (AI)	Required Encoded Data	AI Type	Format
1	01	GTIN	Fixed Length	14 Numerical Digits
2	17	Expiration Date	Fixed Length	6 Numerical Digits
3	10	Batch Number	Variable Length	Alphanumeric up to 20 Characters

Glossary of Terms

Term	Definition
2D	Two Dimensional
Barcode	A symbol that encodes data into a machine-readable pattern of adjacent, varying width; parallel, rectangular dark bars; and pale spaces
Batch	The batch number that associates an item with production information that the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it. The batch number can be up to 20 alphanumeric characters in length.
Brand Owner	The organisation that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for the management of the Global Trade Item Number (GTIN)
DataMatrix	A standalone, 2D matrix symbology that is made up of square modules arranged within a perimeter finder pattern. DataMatrix symbols are read by 2D imaging scanners or vision systems.
Expiration Date	The date up until which the drug manufacturer can guarantee that the medicine is fully potent and safe to take based on scientifically sound product testing.
Function 1 Symbol Character (FNC1)	A separator used as a barrier in between different data entry components that do not have a fixed character count. (e.g., AI (17) Batch, AI (21) Serial Number)
Global Trade Item Number (GTIN)	The GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference, and check digit.
GS1	A neutral, not-for-profit, global organisation that develops and maintains the most widely used supply chain data standards in the world.
GS1 Application Identifier (AI)	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
ISO/IEC Symbology Identifier,]d2[12]	The symbology concept provides a standardised way for a device receiving data from a reader to differentiate between the data carriers.
Unique Identifier	A numeric or alphanumeric string captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is associated with a single product or product group.

[12] ISO/IEC 115424:2008 Information Technology – Automatic Identification and data capture techniques – Data Carrier Identifiers (including Symbology Identifiers.)

Tenderer's Schedule A1

Company/Business Organisation Status

	Tenderer's Waiver Application (please tick as appropriate)
1. Name and address of the Tenderer: _____ _____ _____	☐ **item 2**, based on: previous tender no.: _____
2. Length and nature of business experience including experience in the performance and/or supply of the Goods: _____ _____ _____ _____	☐ **item 3**, based on: previous tender no.: _____ ☐ **item 4**, based on: previous tender no.: _____
3. Shareholders/partners/owners of the Tenderer: _____ _____ _____ _____	☐ **item 5**, based on: previous tender no.: _____
4. Names and addresses of bankers who are prepared to provide references: _____ _____ _____ _____	☐ **item 6**, based on: previous tender no.: _____ ☐ **item 7**, based on: previous tender no.: _____
5. A copy of Tenderer's Articles of Association or other documents evidencing its business and legal status.	
6. Copies of the Tenderer's Certificate of Incorporation with the companies registry (if incorporated), its current business registration certificate and its application form for registration of business.	☐ **item 8**, based on: previous tender no.: _____
7. Copies of all current Permits issued in favour of the Tenderer by the relevant authorities that are required to legally perform the Contract and/or supply the Goods (if applicable).	
8. Documentary evidence of any agency relationship that the Tenderer claims to have in relation to the performance of the Contract or the Goods, whether on a sole or exclusive basis or otherwise.	

Tenderer's Schedule A2

Accounts Information

	Tenderer's Waiver Application (please tick as appropriate)
1. Audited accounts/financial statements of the Tenderer for the past three years. The latest audited accounts/financial statements must be for the period ended no more than 18 months before the date stated in Part V (Offer To Be Bound). The audited accounts/financial statements must include Director's report, Auditor's report, profit and loss statement/statement of comprehensive income, balance sheet/statement of financial position, statement of cash flow and notes to the accounts/financial statements. The accounts/financial statements shall be prepared on the same basis for each year in accordance with accounting principles generally accepted in Hong Kong and the disclosure requirements of the Companies Ordinance, Cap. 32/Cap. 622 (as applicable) of the laws of Hong Kong, or for overseas company the equivalent requirements of the local laws. 2. Projected profit and loss accounts/statement of comprehensive income and cash flow statements for the Term, showing the revenue, operating expenses, capital expenditure and the sources of finance such as upfront investment and/or debt financing. Information shall be provided on the assumption that the initial term is 36 months.	☐ **item 1**, based on: previous tender no.: _____ _____ ☐ **item 2**, based on: previous tender no.: _____ _____

Tenderer's Schedule A3

Certificate of Non-Collusion

We, the Tenderer named below, certify that this is a bona fide Tender Submission, and that we have not fixed or adjusted our Tender Prices by or under or in accordance with any agreement or arrangements with any other person. We also certify that we have not done and we undertake that we will not do at any time before the date of Memorandum of Acceptance of our Tender Submission any of the following acts:

(a) Communicate to any person other than the person calling for this Tender 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 our Tender Submission;

(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.

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

(i) disqualify our Tender Submission from consideration;

(ii) withdraw any confirmation of award of tender already made, without penalty or liability;

(iii) disqualify 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 us to the government or regulatory authorities in Hong Kong or elsewhere, as the Authority considers appropriate.

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Contractor's Code of Conduct

(Note: The "Sample Code of Conduct for NGO" or "Sample Code of Conduct for Private Sector" which can be accessed via the following link in the Authority's website under "Tender Notice":
http://www.ha.org.hk/visitor/ha_visitor_index.asp?Content_ID=2001&Lang=ENG&Dimension=100
or such other applicable website of the Authority.)

	Tenderer's Waiver Application (please tick as appropriate)
We, the Tenderer named below, submit a proposal of its code of conduct applicable to its staff, as follows (or on a separate sheet with heading "Contractor's Code of Conduct"): Name of Tenderer: _____ Signature & Name of Person authorised on behalf of the Tenderer: _____ Affix Company Chop	☐ the information has been provided under previous tender no.: _____ _____

Tenderer's Schedule A4

Performance Monitoring Provisions

We, the Tenderer named below, confirm that we have provided "**Performance Monitoring**" provisions as set out in Part I of this Tender to the manufacturer of the Goods.

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule A5

Tenderer's proposal in response to the Authority's Supply Requirements

1. Goods to be supplied

Item No.*	Name of Good	Specification**	Estimated Requirement of a Good*** #	Breakdown of Estimated Requirement of a Good ##				Strip Pack (please specify Yes, No or N/A)	Range Pack (i.e. Unit Packaging, e.g. 100 capsules per bottle)	Special Requirements (please specify Yes, No or N/A)	Tender Price (per unit)	Tender Unit	Total Tender Price***
				HA	CPP	CDF	GOPC PPP						
1.	Lacosamide Tablet 50mg	Lacosamide Tablet 50mg with licensed indications of monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy and adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalized epilepsy, in blister or strip pack	2,400,000 tablets	2,280,000 tablets	120,000 tablets	0	0	-	-	-			

2.	Lacosamide Tablet 100mg	Lacosamide Tablet 100mg with licensed indications of monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy and adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalized epilepsy, in blister or strip pack.	3,100,000 tablets	2,945,000 tablets	155,000 tablets	0	0	-	-	-			

* Item no. must correspond to the number assigned to the Good in the Attachment to **Appendix 1** in Part III.

** If the Good is a generic product, the product specifications of the Good must comply with any one of the following:

(i) the Pharmacopoeia of the People's Republic of China product monograph;
(ii) the BP product monograph;
(iii) the Ph. Eur. active ingredient monograph;
(iv) the Ph. Eur. product monograph;
(v) the Ph. Int. product monograph;
(vi) the JP product monograph; or
(vii) the USP product monograph,

where a relevant monograph is published in any of the Pharmacopoeia.

*** Supply of the relevant Glaucoma PPP Goods by the relevant Glaucoma PPP Contractor(s) to the relevant Glaucoma PPP Doctors shall not count towards the estimated requirement nor be included in the total tender price.

Please submit a proposal on each Good based on the estimated requirements as set out in "The Authority's Supply Requirements" in the Attachment to **Appendix 1** in Part III.

The Goods to be delivered to Community Pharmacies under Community Pharmacy Programme, Family Doctors under specified Government primary healthcare programme(s),and GOPC PPP Doctors under GOPC PPP Programme shall count towards the minimum quantity and overall estimated requirement of Goods under this Contract. For the avoidance of doubt, the item "CPP" in the breakdown of estimated requirement refers to the estimated requirement for HA patients collecting drugs in Community Pharmacy, the item "CDF" in the breakdown of estimated requirement refers to the estimated requirement for patients receiving care under specified Government primary healthcare programme(s) who have the choice to obtain their medications of the Community Drug Formulary either from Family Doctors or Community Pharmacies, and the item "GOPC PPP" in the breakdown of estimated requirement refers to the estimated requirement for patients receiving care under the GOPC PPP Programme.

Notes:

(1) For each Good, Tenderer must provide the information in (a). For the information in (b), Tenderer which is enabled under "Electronic Data Interchange" or has specified that the Goods will meet the UI Requirements at the commencement of the Contract in **Tenderer's Schedule A12** must provide such information. In other cases, Tenderer must also use its best endeavours to provide the information in (b):

(a) Ordering unit: _____

(b) Global Trade Item No. (GTIN) corresponding to the ordering unit: _____.

(2) On Contract award, the Contractor which is enabled under "Electronic Data Interchange" must supply GTIN of each Good within the time frame specified by the Authority, if "Electronic Data Interchange" was not enabled at the time of Tender Submission and GTIN has not been provided under the Tender Submission.

2. Payment Discount

Tenderer must indicate the discount offered on Tender Prices if payment is made within 14 clear working days of the Authority's acknowledgement of receipt of the invoice: _____% discount.

Name of Tenderer: _____

Signature & Name of Person authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule A6
Tenderer's proposed supply plan
(Note: The Tenderer's proposed supply plan below shall apply to Goods excluding GOPC PPP Goods)

1. Duration of the Contract: 36 months.

2. Tenderer's lead time to have adequate stock to commence supply on Contract award is: _____ weeks.
(Note: The Authority may not consider a lead time in excess of 12 weeks.)

3. Tenderer's proposal on the stock arrival schedule of each Good based on the Authority's estimated requirement of each Good as set out in the "The Authority's Supply Requirements" in the Attachment to **Appendix 1** in Part III is:

Item No*.	Name of Good	Estimated Requirement of a Good	Stock Arrival Schedule (quantity of each Good including its buffer stock)																																								
			Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13	Month 14	Month 15	Month 16	Month 17	Month 18	Month 19	Month 20	Month 21	Month 22	Month 23	Month 24	Month 25	Month 26	Month 27	Month 28	Month 29	Month 30	Month 31	Month 32	Month 33	Month 34	Month 35	Month 36	Total
1	Lacosamide Tablets 50mg	2,400,000 tablets																																								
2	Lacosamide Tablets 100mg	3,100,000 tablets																																								

4. Tenderer's proposal on buffer stock based on the manufacturer's lead time to supply against order is:

Item No.*	Name of Good	Manufacturer's Lead Time	Proposed Buffer Stock Quantity	Remarks
1	Lacosamide Tablets 50mg			
2	Lacosamide Tablets 100mg			

Notes: (1) Item no. marked with an asterisk (*) must correspond to the number assigned to the Good Item no. marked with an asterisk (*) must correspond to the number assigned to the Good in the Attachment to **Appendix 1 in Part III**.
(2) The quantity of buffer stock required for each Good depends on the lead time for the manufacturer to supply against the Tenderer's order.

We, the Tenderer, undertake to notify the Authority immediately if the buffer stock of any Good is less than the required quantity and there is a reasonably foreseeable supply gap.

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule A7

Samples of Goods

We, the Tenderer named below, confirm that we have submitted the following samples of the Goods in accordance with the sample submission requirements as set out in Part III of this Tender for demonstrating the product presentation (and if the Tenderer has specified that the Goods will meet the UI Requirements at the commencement of the Contract, the compliance of the UI Requirements) of the Goods:

Name of Good	**Samples of Good** (please tick as appropriate)	
	(1) Original sales pack sample (Mandatory) (Note: The original sales pack sample is in the form currently registered with the Pharmacy and Poisons Board of Hong Kong)	**(2) Mock up sample (if applicable)** (Note: if a Tenderer reasonably believes that a Good in its original sales pack complies with the Authority's "**Product Presentation Requirements**" as set out in **Appendix 2 to Part III** (and if the Tenderer has specified that such Good will meet the UI Requirements at the commencement of the Contract, the **UI Requirements** as set out in **Clause 7 of Part II** and **Appendix 6 to Part III**), the Tenderer does not need to provide a mock up sample of such Good and the Authority will evaluate the product presentation (and where applicable, the compliance of the UI Requirements) of the original sales pack sample of such Good submitted in (1))
Lacosamide Tablet 50mg		
Lacosamide Tablet 100mg		

Name of Tenderer: _____

Signature & Name of Person authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule A8

Insurance

1. Where the Tenderer is the distributor of the Goods (please tick as appropriate)

   ☐ We, the Tenderer named below, confirm that we are the distributor of the Goods and undertake to put in place appropriate Product Liability Insurance (which carries the minimum indemnity limit of US$10M per occurrence) with the Authority named as a vendor.

   ☐ We confirm that the manufacturer has put in place product liability arrangements in respect of the Goods which cover the minimum indemnity limit of US$10M per occurrence.

      ☐ The manufacturer's insurance company is:

      _____

      ☐ The manufacturer is self-insured.

2. Where the Tenderer is both the manufacturer and distributor of the Goods (please tick as appropriate)

   ☐ We, the Tenderer named below, confirm that we are the manufacturer and distributor of the Goods and undertake to put in place appropriate Product Liability Insurance (which carries the minimum indemnity limit of US$10M per occurrence) with the Authority named as a vendor.

3. Where a Product Liability Insurance in not in place (please tick as appropriate)

   ☐ We, the Tenderer named below, undertake to acquire the Product Liability Insurance policy in respect of the Goods in accordance with the requirements specified in Part II.

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule A9

Deposit

We, the Tenderer named below, undertake to place and maintain the Deposit during the Term and until the date falling 3 months after the end of the Term or the date on which all obligations and liabilities of the Contractor under the Contract have been duly carried out, completed and discharged, whichever is the later, in an amount as required under paragraph 3.2 of Part II of the Tender, which will be (please tick as appropriate):

☐ paid by company cheque.

☐ by way of banker's guarantee in the form set out in **Appendix 3** to Part III of the Tender from the following bank:

Name of Bank: _____

(name of bank must be provided)

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule A10

Statement of Compliance with this Tender/ Statement of Compliance with Goods supplied under any previous Bulk Supplies Contract

1. Statement of Compliance with this Tender

We, the Tenderer named below,

(a) confirm all Goods on offer under this Tender comply with this Tender (including the Terms and Conditions for Supply of Goods to Community Pharmacies and Family Doctors set out in Appendix 5.2 to Part III where the Goods are ordered for delivery to Community Pharmacies under Community Pharmacy Programme and Family Doctors under specified Government primary healthcare programme(s)); and

(b) agree and confirm that if Goods include any relevant PPP Goods identified as such in the Attachment to Appendix 1 in Part III, and if we are selected as the relevant PPP Contractor, we shall comply with all the requirements in this Tender in relation to the relevant PPP Goods in every respect including paragraph 2.7(c) of Part II.

2. Statement of Compliance with Goods supplied under any previous Bulk Supplies Contract

We, the Tenderer named below, confirm all Goods on offer under this Tender (please tick as appropriate):

☐ are identical as to products, manufacturer and manufacturing site to those previously supplied under Bulk Supplies Contract No. _____.

☐ differ from those previously supplied under Bulk Supplies Contract No. _____ in the following aspects:

_____

_____

_____

_____

_____

_____

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule A11

Declaration of Conflict of Interest by Tenderer

The Tenderer, hereby declares and represents that, having made all reasonable enquiries, either:-

(a) none of the Tenderer and the Related Persons (as defined below) have any known actual, apparent, potential or perceived conflicts of interest that will, or might, arise in respect of the Tender, the Tender Submission, the provision of the Services or the performance of the obligations under the Contract (if awarded to the Tenderer); or

(b) the Tenderer has in this Declaration declared all such actual, apparent, potential or perceived conflicts to the Authority.

The Tender represents that, having made all reasonable enquiries, the following represents all of its actual, apparent, potential or perceived conflicts of interest in respect of the Tender, the Tender Submission, the provision of the Services or the performance of the obligations under the Contract (if awarded to the Tenderer):-

(List any conflict details or state "Nil Conflicts")

The Tender undertakes to advise the Authority in writing and keep the Authority advised of any actual, apparent, potential or perceived conflict of interest which the Tenderer or any Related Persons may have in respect of the Tender, the Tender Submission, the provision of the Services or the performance of the obligations under the Contract (if awarded to the Tenderer) (including all or any facts which may reasonably be considered to give rise to conflict of interest) immediately upon becoming aware of the same.

"Related Persons" means:-

(a) the directors, employees, agents and sub-contractors of the Tenderer (and if the Tenderer is a partnership, any of the members/partners of that partnership) who are or will be involved in the Tender, the Tender Submission, the provision of the Services or the performance of the obligations under the Contract (if awarded to the Tenderer); and

(b) any person or entity (i) which has control, directly or indirectly, over the Tenderer; (ii) which is controlled, directly or indirectly, by the Tenderer; or (iii) which is controlled by, or has controlled over, a person/entity referred to in paragraphs (i) or (ii). For the purposes of this Declaration, "control" means:

(aa) the possession by one person, directly or indirectly (through one or more intermediaries) of the power (whether holding office as director or otherwise) to affect, secure, direct and/or cause the direction of the management, affairs or policies

of another person;

(bb) with respect to a corporation, partnership or other body corporate, such power in (aa) may be evidenced by (but is not limited to) that person: (i) holding shares or interests or possessing voting power in or in relation to that or any other person such as, but not limited to, the right to exercise, directly or indirectly, more than fifty percent (50%) of the other body corporate; and / or (ii) having powers conferred on that person by any constitution, memorandum or articles of association, partnership, agreement or arrangement (whether legally enforceable or not); and

(c) (i) any member of a partnership in which the Tenderer is a member or (ii) any company one or more of whose Directors is in common with one or more of the Directors of the Tenderer.

"Conflicts of interest" shall include (but are not limited to) (a) any situation where the personal, financial, commercial or other interest of the Tenderer or any of its Related Persons, conflict or compete, or may be expected to conflict or compete, with the Tenderer's duties to the Authority under the Contract; and (b) any situation where the Tenderer or any of its Related Persons may have any personal, financial, commercial or other interests in any potential service, advice, proposals or recommendations made or which may be made by the Tenderer under the Contract.

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule A12

UI Requirements

We, the Tenderer named below, confirm that:

(a) the following Goods will meet the UI Requirements at the commencement of the Contract and the samples of the Goods submitted under Tenderers' Schedule A7 can demonstrate the compliance of the UI Requirements of such Goods:

Item No.	Name of Good

(b) we will commit to meet the UI Requirements for the following Goods within nine (9) months after the commencement of the Contract and we will submit the application for stand-alone change of registered particulars of the Goods involving UI additions to the Department of Health and an application for change in particulars of the Contract for such UI additions with samples or mock up samples to the Authority within three (3) months after the commencement of the Contract.

Item No.	Name of Good

(c) we will not commit to meet the UI Requirements for the following Goods within nine (9) months after the commencement of the Contract.

Item No.	Name of Good

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule A13

National Security Undertaking

(a) I/We confirm that, before I/we sign this undertaking, I/we have read and fully understand this undertaking, Clause 18 of Part I, and Clause 26 of Part IV on "National Security".

(b) I/We, represent and warrant that I/we have not engaged, am/are not engaging and will not engage in acts or activities that are likely to constitute or cause the occurrence of offences endangering national security or which would otherwise be contrary to the interest of national security.

(c) I/We shall indemnify and keep indemnified the Authority against all losses, damages, costs or expenses arising out of or in relation to any breach of any of the representations and/or warranties above, including but not limited to damages for delay, costs and expenses of re-tendering and other costs incurred.

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule B1(a)

Technical and Registration Requirements

Tenderers must provide a completed Tenderer's Schedule B1(a) for each Good offered under this Tender. Please tick as appropriate and provide Supporting Documents for each Good. For the soft copy version of each Supporting Document, it must be saved as a separate file with a file name in the format of "B1_[item no.]_[document name]", e.g. "B1_n_Marketing Authorisation". For the hard copy version of each Supporting Document, it must be clearly labeled with the same file name as that is used in the soft copy version.

	Tenderer's Waiver Application
Name of Good: _____ If available, the following information on the above Good must be provided: (a) Brand name of the Good: _____ (b) Registered pack size(s) of the Good in Hong Kong: _____ (c) HK product registration number(s) by registered pack size(s): _____ (d) HK product registration expiry date: _____ (e) Licensed indications of the Good as registered with Department of Health: _____ _____ _____ (f) All indications and uses (including but not limited to therapeutic indications and usages) of the Good as set out in the relevant package insert, if available, or original sales pack: _____ _____ The following information on the above Good must be provided: (g) Description of Good: _____ (h) Country/Place of origin (manufacture): _____ (i) Name of manufacturer: _____	

	Tenderer's Waiver Application

(j) Address of manufacturer: _____

_____

(k) Shelf-life of Good from date of manufacture: _____

If shelf-life of Good is less than or equal to 18 months from the date of manufacture, please specify:

(i) the guaranteed shelf life upon delivery:_____

(ii) Replacement and exchange of expired Good is offered:

YES / NO

If YES, please provide details:_____

_____

(l) (i) Product registration of the above Good in the country/place of origin:

(Note: The requirement for product registration in the country / place of origin shall be complied with unless the Good is manufactured for export only)

☐ Yes ☐ No

(ii) Product registration of the above Good in overseas countries/places whose regulatory authorities are PIC/S Participating Authorities. Tenderers shall provide information on product registration in all such PIC/S Participating Authorities where they have obtained product registration for the above Good. A list of PIC/S Participating Authorities can be found at www.picscheme.org:

☐ Yes, in the following country/countries: ☐ No

☐ Argentina	☐ Iceland	☐ Poland
☐ Australia	☐ Indonesia	☐ Portugal
☐ Austria	☐ Iran	☐ Romania
☐ Belgium	☐ Ireland	☐ Saudi Arabia
☐ Brazil	☐ Israel	☐ Singapore
☐ Bulgaria	☐ Italy	☐ Slovak Republic
☐ Canada	☐ Japan	☐ Slovenia
☐ Chinese Taipei	☐ Jordan	☐ South Africa

				Tenderer's Waiver Application
	☐ Croatia	☐ Korea (Republic of)	☐ Spain	
	☐ Cyprus	☐ Latvia	☐ Sweden	
	☐ Czech Republic	☐ Liechtenstein	☐ Switzerland	
	☐ Denmark	☐ Lithuania	☐ Thailand	
	☐ Estonia	☐ Malaysia	☐ Turkey	
	☐ Finland	☐ Malta	☐ Ukraine	
	☐ France	☐ Mexico	☐ United Kingdom	
	☐ Germany	☐ Netherlands	☐ U.S.A	
	☐ Greece	☐ New Zealand		
	☐ Hungary	☐ Norway		

☐ Other country / countries whose regulatory authority / authorities is/are PIC/S Participating Authorities and is / are not listed above (please specify):

_____

_____

_____

(m) A copy of the Certificate of Drug/Product Registration of the Good issued by the Pharmacy and Poisons Board of Hong Kong.

(n) Where the Good is manufactured outside Hong Kong:

(i) a certified true copy of its marketing authorisation ("**Marketing Authorisation**") issued by the regulatory authority in the overseas country / place which has to be a PIC/S Participating Authority, or where the Good is registered for export only, a certified true copy of an export certificate ("**Export Certificate**") issued by the regulatory authority in the overseas country / place from which the Good is exported which has to be a PIC/S Participating Authority, or in the case of the Good registered under the "1+" Mechanism, the "1+" Mechanism reference country/ place; or

	Tenderer's Waiver Application
(ii) if the Good will be supplied from an Established Source, a certified true copy of the Marketing Authorisation or Export Certificate from the regulatory authority in the country / place of origin: Name of Good: _____ Bulk Supplies Contract No.: _____	☐ **item (s)**, based on: ☐ the information is available in the package insert of the Good (package insert must be provided). ☐ not applicable for the dosage form of the Good.
(o) A copy of the complete master formula of the Good in English as currently registered with the Pharmacy and Poisons Board of Hong Kong. (p) A copy of the method of analysis of the Good. (q) A copy of the finished product specifications of the Good in English as currently registered with the Pharmacy and Poisons Board of Hong Kong. (r) Stability data of the Good supporting the shelf-life and storage condition as currently registered with the Pharmacy and Poisons Board of Hong Kong. (s) If the Good requires reconstitution or dilution, its post-reconstitution or post-dilution stability data (as the case may be) with recommended shelf-life and storage condition. (t) A copy of the certificate of analysis of a representative batch of that Good. (u) A copy of the bioequivalence studies report of the Good as compared with the brand specified in Part III or a brand that has been used by the Authority through Bulk Supplies Contracts.	☐ **item (u)**, based on: ☐ the Good has previously been supplied by an Established Source: Bulk Supplies Contract No.: _____ _____ ☐ only applicable when the bioequivalence studies report of the Good has been submitted to Department of Health of Hong Kong for the purpose of pharmaceutical product registration according to the Drug Office's Guidance Notes on Registration of Pharmaceutical Products/Substances
(v) Proof of compliance of the Good with the monograph as published in the applicable Pharmacopoeia: The Good complies with the following monograph of the applicable Pharmacopoeia: ☐ Pharmacopoeia of the People's Republic of China product monograph. ☐ BP product monograph.	☐ **item (v)**, based on: ☐ it is not applicable as the Good is a proprietary product. ☐ it is not applicable as no such monograph is published in any of the Pharmacopoeia.

	Tenderer's Waiver Application
☐ Ph. Eur. active ingredient monograph. ☐ Ph. Eur. product monograph. ☐ Ph. Int. product monograph. ☐ JP product monograph. ☐ USP product monograph. Proof of compliance with the above monograph as published in the applicable Pharmacopoeia: ☐ Document of compliance issued by a PIC/S Participating Authority. Specify name of the document of compliance supplied: _____ ☐ Test report from a Laboratory. ☐ Test report from a Laboratory is under preparation, the expected date of submission of the test report is _____ (date). (Note: Tenderers must note that the test report under preparation should be submitted within 4 weeks of the Tender Closing Date.)	

Tenderer's Schedule B1(b)

Declaration Regarding the Active Pharmaceutical Ingredients and Excipients used and Compliance with Manufacturing Related Regulatory and Quality Guidelines

(Note: To be provided on Tender Submission.)

We, the Tenderer, declare that:

(a) The active pharmaceutical ingredients and the sources used in the manufacture of the Goods are the same in every respect as that used in the Goods as supplied to and registered (if required) in Hong Kong and all overseas countries/places as indicated in Tenderer's Schedule B1(a) item (l)(ii);

(b) The Goods are manufactured in accordance with the latest version of all relevant and applicable regulatory and quality guidelines; and

(c) The active pharmaceutical ingredients and all excipients used in the manufacture of the Goods have not had/not been subject to any import licence restrictions nor any GMP licence revocations by any regulatory authorities.

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

(i) disqualify our Tender Submission from consideration;

(ii) withdraw any confirmation of award of tender already made, without penalty or liability.

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule B2
Quality Assurance

Tenderers must provide a completed Tenderer's Schedule B2 for each Good (non-sterile/sterile product) offered under this Tender. Please tick as appropriate and provide Supporting Documents for each Good. For the soft copy version of each Supporting Document, it must be saved as a separate file with a file name in the format of "B2_[document name]", e.g. "B2_ Microbiological Test Report". For the hard copy version of each Supporting Document, it must be clearly labeled with the same file name as that is used in the soft copy version.

	Tenderer's Waiver Application
Name of Good (non-sterile product): _____ 1. ☐ The above Good is a non-sterile product: ☐ Microbiological tests on the above Good have been conducted by a Laboratory in accordance with the testing methodology and acceptance criteria specified in USP, BP, Ph. Eur. or JP. (Note: Test report must be provided. Certificate of accreditation of the Laboratory must be provided upon request.) ☐ Microbiological tests on the above Good have been conducted by the in-house laboratory of the manufacturer in accordance with the testing methodology and acceptance criteria specified in USP, BP, Ph. Eur. or JP. (Note: Test report must be provided.) ☐ The microbiological tests on the above Good to be conducted by a Laboratory commissioned by the Authority at the Tenderer's costs. 2. ☐ A microbial examination validation report of the above Good which complies with USP, BP, Ph. Eur. or JP: ☐ is attached. ☐ is not available. 3. The Tenderer must specify below if the Good contains raw materials of natural (animal, vegetable or mineral) origin for which antimicrobial pre-treatment is not feasible. "Nil" must be specified if the Good does not contain raw materials of natural (animal, vegetable or mineral) origin. _____ _____	☐ **item 1**, based on: the Good will be supplied from an Established Source under the following Bulk Supplies Contract and Quality Assurance Tests reports have been accepted thereunder: Bulk Supplies Contract No.: _____ _____

Tenderers must provide a completed Tenderer's Schedule B2 for each Good (non-sterile/sterile product) offered under this Tender. Please tick as appropriate and provide clearly labeled Supporting Documents for each Good, such as for sterile product, evidence of sterility tests performed on batch release of the Good as specified in its certificate of analysis or a document demonstrating parametric batch release.

	Tenderer's Waiver Application
Name of Good (sterile product): _____ ☐ Evidence of sterility tests performed on batch release of the Good as specified in its certificate of analysis. ☐ A document demonstrating parametric batch release.	

Tenderer's Schedule B3
Manufacturer of the Goods

Not applicable.

Tenderer's Schedule B4

Supply of the Goods

Tenderers must provide a completed Tenderer's Schedule B4 in respect of their supply of Goods offered under this Tender and provide Supporting Documents for each Good. For the soft copy version of each Supporting Document, it must be saved as a separate file with a file name in the format of "B4_[item no.]_[document name]", e.g. "B4_2_Product Recall System". For the hard copy version of each Supporting Document, it must be clearly labeled with the same file name as that is used in the soft copy version.

1. A copy of the relevant registrations/licences applicable to the Goods in question, e.g. the Wholesale Dealer Licence, Antibiotics Permit, Wholesale Dealer's Licence to supply Dangerous Drugs.

Tenderer's Schedule C1

Patent Information in respect of Innovator Versions of the Goods

The Tenderer hereby confirms, on its own behalf and on behalf of the manufacturer of Innovator versions of the Goods, that each such Good is proprietary and that the following drug patents/patent applications (as shown on copies of all registration certificates annexed hereto) in respect of that Good exist and are still valid and in force.

Item No.*	Name of Good	Name(s) of patent holder(s) or patent applicant(s)	Patent number or application number assigned by Hong Kong Patents Registry	Date of grant or filing of application	Expiry date
1.	Lacosamide Tablet 50mg				
2.	Lacosamide Tablet 100mg				

Note: Item no. marked with an asterisk (*) must correspond to the number assigned to the Good in the Attachment to **Appendix 1** in Part III.

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule C2

Non-Innovator Version of the Goods – Wholesale Information

Note: To be provided within 45 days when notified by the Authority.

For each Good, the Tenderer is required to provide the names, addresses and telephone numbers of its top 5 wholesale purchasers for the supply and use in UK, Australia, Canada and New Zealand (or other countries if there is no wholesale information in these countries) of the past 3 years for contact by the Authority, and specify whether they are a commercial entity, a national/international organisation or a government/supra-government organisation (please tick as appropriate):

Year	Top 5 Wholesale Purchasers
____	1. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 2. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 3. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 4. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 5. The Good has been supplied to and used in (country name): _____

Year	Top 5 Wholesale Purchasers
	Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation
____	1. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 2. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 3. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 4. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 5. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____

Year	Top 5 Wholesale Purchasers
	☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation
____	1. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 2. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 3. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 4. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation 5. The Good has been supplied to and used in (country name): _____ Name of wholesale purchaser: _____ Contact person & tel. no.: _____ Address: _____ ☐ commercial entity ☐ national/international organisation ☐ government/supra-government organisation

Tenderer's Schedule C3

Non-Innovator Version of the Goods – Confirmation of No Infringement/No Litigation and Claims

(Note: To be provided on Tender Submission.)

Note: The Tenderer must on its own behalf and on behalf of the manufacturer of all Goods, provide the confirmation/clarification required under this Tenderer's Schedule C3 on the following aspects of the Goods (as per Part II, paragraph 6.3(a)(i) to (vi) of the Tender):

(i) all active pharmaceutical ingredients and their relevant forms;

(ii) all formulations;

(iii) the process of preparation of all active pharmaceutical ingredients and all formulations;

(iv) all licensed indications of the Goods as registered with the Department of Health of Hong Kong, and all indications and uses (including but not limited to therapeutic indications and usages) of the Goods as set out in the package insert, if available, or original sales pack;

(v) any other relevant aspects including delivery form of the Goods, excipients and additives utilised, combination or adjuvant therapy, if any; and

(vi) any patents or patent applications in Hong Kong corresponding to or associated with any "Designated Patent" in the US "Orange Book" in respect of the proprietary product as listed by the United States Food and Drug Administration.

1. Tenderer's confirmation (please tick as appropriate):

We, the Tenderer named below, confirm that after having made all due and appropriate enquiries:

☐ all Goods to be supplied to the Authority (including those to be delivered to Community Pharmacies and Family Doctors) and/or PPP Doctors and the use thereof in Hong Kong do not infringe any granted patent or fall within the claims of any pending patent applications in Hong Kong;

☐ no third party has formally or informally notified us or alleged to us, that any of the Goods or the use thereof in Hong Kong infringes any granted patent or fall within the claims of any pending patent applications in Hong Kong; and

☐ neither we, the Tenderer, in respect of the Goods, nor any of the Goods have been the subject of any litigation in Hong Kong.

We, the Tenderer, undertake that upon the requirement of the Authority, that we will at our sole expense submit a formal opinion from an independent patent agent or patent attorney registered in the country/place of origin of the Goods to confirm the conclusion of no patent infringement in respect of the manufacture in and export from the country/place of origin of all Goods.

2. <u>Tenderer's confirmation on behalf of the manufacturer of all Goods</u> (please tick as appropriate):

We, the Tenderer named below, confirm on behalf of the manufacturer of all Goods that:

☐ all Goods (including their active pharmaceutical ingredients) and the manufacture thereof do not infringe any granted patent or fall within the claims of any pending patent applications in the country/place of origin of the Goods;

☐ all Goods or the use thereof are not and have not been subject to any infringement litigation claim or threat thereof, anywhere in the world ("**Infringement Claims**").

3. <u>Tenderer's clarification (if any of the above confirmations at item 1 and item 2 cannot be given)</u>:

Where we, the Tenderer named below, cannot provide the above confirmations for all of items 1 and 2 on our own behalf or on behalf of the manufacturer, we must provide the following information (please tick as appropriate):

☐ The following Goods or use thereof, namely:

_____

_____

may infringe the following patents or fall within the claims of the following pending patent applications:

☐ in Hong Kong (please provide the patent/patent application number and the details):

_____

_____

☐ in the country/place of origin (please provide the patent/patent application number and the details):

_____

_____

☐ The following Goods, namely:

_____

_____

are/have been subject to Infringement Claims or threats of Infringement Claims, in which case the following must be provided:

(a) details of the Infringement Claim or threat thereof including the relevant jurisdiction, the date(s) the threat or claim was made, the content of the threat or claim, the patent(s) under dispute, copies of any warning letter/interlocutory injunction, and how it is to be or has been dealt with by the Tenderer or the manufacturer;

(b) 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;

(c) if a court decision has been delivered, a copy of the decision, and advice as to whether or not the time for appeal has expired;

(d) explanation as to the relevance and impact upon the supply and use of the Goods in Hong Kong in respect of any Infringement Claim; and

(e) if any settlement agreement has been reached in relation to any Infringement Claim, whether any conditions of settlement would be contravened by any supply of the Goods or the use thereof in Hong Kong.

Name of Tenderer: _____

Signature & Name of Person
authorised on behalf of the Tenderer: _____

Affix Company Chop

Tenderer's Schedule C4

Non-Innovator Version of the Goods – Confirmation from the Tenderer's Patent Attorney

(Note: This confirmation must be provided on Tender Submission. Tenderers must note that under paragraph 6.3 of Part II, a Tenderer must at its sole expense and within 45 days when required to do so by the Authority, submit the Formal Written Opinion.)

To: (Name of Tenderer) _____

From: (Name of Patent Attorney) _____

(Note: Tenderer's Patent Attorney must be patent agent or patent attorney registered in the United Kingdom, Australia or New Zealand.)

(Jurisdiction of Registration): ☐ UK ☐ Australia ☐ New Zealand

I am writing to confirm that I will provide a Formal Written Opinion in accordance with paragraph 6.3(a) of Part II of the Tender requirement.

Signature of Tenderer's Patent Attorney: _____ Date: _____

PART IV

TERMS AND CONDITIONS

1. Terms of Supply

These T&Cs shall apply to the supply of the Goods by the Contractor (and if applicable, the supply of the relevant PPP Goods by the relevant PPP Contractor) under the Contract.

2. Supply of Goods

2.1 The Contractor shall be liable, and agrees to, to provide the Authority the Goods:

(a) in accordance and in full compliance with their specifications; and

(b) for the Price.

2.2 The Goods shall be supplied during the Term to the Authority as determined by the Authority and upon issue of one or more purchase orders.

2.3 The minimum quantity in respect of any item of Goods represents the minimum quantity of such item of Goods that the Authority shall order during the Term, and which the Contractor shall supply, under the Contract. Subject to the minimum quantity in respect of each item of Goods, the Authority may require, and the Contractor shall supply any single item of the Goods or a mixture of items of the Goods up to the Total Contract Value.

2.4 The relevant PPP Contractor shall be liable, and agrees to, supply the relevant PPP Goods and deliver them to the relevant PPP Doctors:

(a) in accordance and in full compliance with the specifications of the relevant Goods; and

(b) for the relevant PPP Price.

2.5 If the price of the Goods shall have come down during the Term of the Contract, the Contractor shall promptly reflect such price benefit to the Authority by a corresponding reduction in the Price and, where the Contractor is the relevant PPP Contractor, the relevant PPP Price.

3. Specifications and Quality Assurance Requirements

3.1 All Goods supplied under the Contract shall comply in full in all respects with their specifications, shall be of merchantable quality, fit for their purposes and have an expiry date of at least 18 months from the date of delivery.

3.2 The Authority may in its absolute discretion and without the need to assign any reasons, waive in part or shorten the requirement of the 18-month expiry date on a case by case basis for the Goods to be delivered under the Contract.

3.3 The Contractor shall prior to delivery of each batch of Goods under the Contract, provide to the Chief Pharmacist's Office of the Authority the corresponding Certificate of Analysis. The Contractor shall also, on request of the Authority, provide with each batch of Goods such appropriate certificates/documentations confirming that the Goods are in full compliance with their specifications.

4. Permits and Inspection of Facilities

4.1 (a) The Contractor shall obtain and maintain the Permits. The Contractor shall notify the Authority in writing immediately upon any withdrawal, cancellation, suspension or modification of any Permit.

(b) In the event of a withdrawal, cancellation, suspension or modification of any Permit, the Authority shall be immediately entitled to terminate the Contract without liability. The Contractor shall indemnify the Authority for any claim, liability, loss, damage, cost and expense of any nature (including legal expenses) which may be incurred or suffered by the Authority as a result of any disruption in the supply of the Goods or termination of the Contract, including, without limitation, all costs and expenses ("**Alternate Supplies Cost**") in obtaining products to substitute for the Goods which, but for the termination of the Contract, were to be supplied under the Contract ("**Alternate Supplies**").

4.2 (a) The Contractor shall upon request of the Authority permit or, if the Contractor is not the manufacturer, procure the manufacturer(s) of the Goods to permit Authority Representatives to inspect and/or examine the manufacturing facilities and process (including storage) in respect of the Goods.

(b) The Contractor shall upon request of the Authority permit Authority Representatives to inspect and/or examine warehouse(s) or distribution operation (including, without limitation, logistics, manpower, facilities or transportation arrangements) in respect of the Goods.

(c) The Contractor shall take or procure to be taken all reasonable action to rectify any reasonable concerns raised by the Authority following inspection and/or examination under this Clause 4.2. The Contractor shall also furnish the Authority with a report satisfactory to the Authority on the action taken, within such time frame as may reasonably be requested by the Authority.

5. Delivery

5.1 (a) Prior to delivery to the Authority, the Community Pharmacies or the Family Doctors, the Contractor shall conduct appropriate checks and take all other necessary steps to ensure that all Goods are properly packaged and packed in accordance with the Authority's requirements; and have been properly stored in accordance with the manufacturer(s)' recommendations.

(b) Prior to delivery to the relevant PPP Doctors, the relevant PPP Contractor shall conduct appropriate checks and take all other necessary steps to ensure that all relevant PPP Goods are properly packaged and packed in accordance with the Authority's requirements and have been properly stored in accordance with the manufacturer(s)' recommendations.

5.2 (a) The Contractor shall, on receipt of a purchase order issued by the Authority Representative or any person duly authorised by him, supply and deliver at its own expense to the destination named in such order (which could be HA Hospitals, Community Pharmacies, Family Doctors or GOPC PPP Doctors), the quantities of Goods therein specified within the time or times specified in such order, or if no time is specified, then within 7 days of such order and for this purpose, time shall be of the essence of the Contract.

(b) Each delivery to the Authority, Community Pharmacies, Family Doctors or PPP Doctors shall be accompanied by a delivery note with details as specified in Annexure 3. No price information should be displayed on the delivery note to Community Pharmacies, Family Doctors and PPP Doctors. The Contractor shall ensure that it obtains a receipt, but such receipts shall not constitute an acknowledgement that the Goods therein mentioned are acceptable or satisfactory.

(c) The Contractor shall issue an invoice to the Authority with details as specified in Annexure 3.

(d) The Authority may change any delivery schedule by prior notice to the Contractor (whether such change relates to the Goods or the delivery date(s) for all or part of such Goods, or both).

5.3 Purchase orders for Goods (including PPP Goods) placed before the expiration of the Term shall remain in force until fulfilled in accordance with the terms of the Contract notwithstanding the intervening expiration of the Contract by effluxion of time.

6. Cancellation, Inspection, Acceptance and Rejection

6.1 The Authority may cancel any purchase order wholly or in part by notice to the Contractor at any time after the issue of the purchase order but before delivery of the Goods.

6.2 The Authority, Community Pharmacies, Family Doctors and GOPC PPP Doctors may, but are not obliged to, inspect the Goods upon delivery. By taking time to inspect the

Goods or not inspecting the Goods at all, the Authority shall not be taken to have accepted the Goods and the rights of the Authority provided under the Contract (including, but not limited to, the right to reject the Goods or any part thereof) shall not in any way be prejudiced.

6.3 If the Authority becomes aware of any shortfall in the Goods delivered, the Authority may at any time thereafter notify the Contractor and, upon being so notified, the Contractor shall at the Authority's option, either:

(a) make an immediate additional delivery to make up the deficiency; or

(b) issue a credit note for the shortfall.

6.4 In addition to the Quality Assurance Tests, the Authority may require other tests to be conducted by the Contractor on samples of Goods drawn from any HA Hospital and the test reports must be provided to the Authority promptly after completion of these other tests.

6.5 (a) If the Goods delivered to the Authority, Community Pharmacies, Family Doctors or GOPC PPP Doctors (or any part thereof) is not in accordance with the Contract, or does not comply in full with the specifications, or fails to pass any tests (including any Quality Assurance Tests), or is not of merchantable quality, or is not fit for its purposes, or does not comply with the UI Requirements as agreed or committed by the Contractor or is suspected to have infringed or have the risks of infringing any third party proprietary rights (including Intellectual Property Rights), the Authority may, without prejudice to its other rights (including right of termination) and remedies, provided under the Contract or otherwise according to law, reject the Goods or any part thereof ("**Rejected Batches**"), whereupon:

(i) the Contractor shall, on demand by the Authority, repay to the Authority the Price of the Rejected Batches; and/or

(ii) the Authority may accept products offered by the Contractor to replace the Rejected Batches; and/or

(iii) the Authority may purchase from other sources Alternate Supplies to substitute for the Rejected Batches and the Contractor shall, on demand by the Authority, pay to the Authority the Alternate Supplies Cost.

(b) For the avoidance of doubt, the Price repaid by the Contractor under Clause 6.5(a)(i) above shall be according to the quantity of the Rejected Batches returned by the Authority in accordance with Clause 6.5(c) below, and the estimate of such quantity by the Authority shall be accepted as accurate by the Contractor, in the absence of manifest error.

(c) Upon receipt of notice from the Authority of the rejection of the Goods or any part thereof, the Contractor shall at its own cost remove the Rejected Batches within the time frame specified by the Authority. If the Contractor fails to remove the Rejected Batches within such time frame, the Authority may dispose of the

Rejected Batches as it sees fit and no liability shall attach to the Authority in respect of such disposal. The Contractor acknowledges and accepts that the Authority bears no responsibility whatsoever for the Rejected Batches as from the time they are rejected by the Authority.

6.6 In the event of any failure on the part of the Contractor to deliver the Goods on time, any shortfall in the supply of the Goods or any rejection of the Goods, the Authority may, without prejudice to its other rights and remedies, obtain Alternate Supplies (whether equivalent or otherwise) from any third party supplier. In such event, the Contractor shall accept the Authority's decision and be responsible for any price difference above the Price herein and all the related freight and delivery charges.

7. Safety Alert and Product Recall

7.1 The Contractor shall maintain:

(a) the safety alert system; and

(b) the Product Recall System

covering the Goods to be supplied to the Authority under the Contract throughout the Term.

7.2 (a) Without prejudice to any other provisions of the Contract, where a Safety Alert Notice or a Product Recall Notice is to be issued by the Contractor in respect of the Goods supplied or to be supplied to the Authority under the Contract, the Contractor is required to issue the Safety Alert Notice or the Product Recall Notice to the Authority simultaneously by telephone (at telephone numbers (852) 3912 2478) and fax (at fax numbers (852) 3523 1533) and email (at address cpo.qa.team@ha.org.hk) (or such other numbers or email addresses as may be notified by the Authority to the Contractor in writing from time to time), and, in the case of a Safety Alert Notice, within 24 hours after the Contractor becomes aware of the safety issue concerning the Goods. A Safety Alert Notice or a Product Recall Notice may be in English or Chinese. For the avoidance of doubt:

(i) the Goods subject to a Product Recall Notice shall be referred to as "**Recalled Goods**"; and

(ii) a Safety Alert Notice should be issued even if the safety issue concerning the Goods is not yet confirmed, or the legal liability for it is not yet ascertained, or the remedial actions required are not yet established.

(b) The Contractor shall fully co-operate with the Authority and keep the Authority fully informed of all developments following the issue of a Safety Alert Notice or a Product Recall Notice. The Contractor shall promptly advise the Authority of any remedial actions it proposes and, subject to the agreement of the Authority, at its own cost and expense carry out such remedial actions within the time stipulated by the Authority.

7.3 After receipt of a Safety Alert Notice, the Authority may, without prejudice to other rights and remedies of the Authority under the Contract, reject the Goods delivered to the Authority, Community Pharmacies, Family Doctors or GOPC PPP Doctors (or any part thereof), whereupon the Authority shall have the options set out in Clause 6.5 in these T&Cs and may:

(a) suspend the performance of the Contract (including cessation of any use or distribution of the Goods) until the safety issue is addressed to the satisfaction of the Authority; or

(b) terminate the Contract whereupon Clause 15.4 in these T&Cs shall apply.

7.4 (a) After receipt of a Product Recall Notice, without prejudice to other rights and remedies of the Authority under the Contract:

(i) the Contractor shall, on demand by the Authority, repay to the Authority the Price of the Recalled Goods; and/or

(ii) the Contractor shall, on demand by the Authority, supply and arrange for delivery of Goods available to the Contractor and which are unaffected by the Product Recall Notice in such quantity as the Authority may request within 24 hours after the Authority's request or such later time as the Authority may agree; and/or

(iii) the Authority may accept products offered by the Contractor to replace the Recalled Goods; and/or

(iv) the Authority may purchase from other sources Alternate Supplies to substitute for the Recalled Goods and the Contractor shall, on demand by the Authority, pay to the Authority the Alternate Supplies Cost.

(b) Additionally, the Authority may

(i) suspend the performance of the Contract (including cessation of any use or distribution of the Goods) until the problem underlying the Product Recall Notice is rectified; or

(ii) terminate the Contract, whereupon Clause 15.4 in these T&Cs shall apply.

7.5 Where the Authority suspends the performance of the Contract pursuant to Clause 7.3 or Clause 7.4 in these T&Cs, or the Contractor suspends supply of the Goods under the Contract, the Authority may purchase from other sources Alternate Supplies to cover Goods which the Authority may further order under the Contract and the Contractor shall, on demand by the Authority, pay to the Authority the Alternate Supplies Cost.

7.6 Where, as a result of a Safety Alert Notice or a Product Recall Notice, the Authority has to:

(a) require its staff to work overtime in getting together the Goods, which are subject to the Safety Alert Notice, or the Recalled Goods, maintaining the continuity of supplies (such as sourcing Alternate Supplies), stock-taking its inventory, compiling a list of patients who may be affected and contacting them, and providing follow up consultations and treatment that may be required, and has thereby incurred staff overtime cost ("**Staff Overtime Cost**"); and/or

(b) provide the affected patients with such medication (including Alternate Supplies) and such medical examination (including tests, radiological examinations) as may be necessary, and has thereby incurred expenses ("**Additional Expense**"); and/or

(c) incur other expenses ("**Other Expense**");

the Contractor shall on demand by the Authority pay to the Authority the Staff Overtime Cost, the Additional Expense, and the Other Expense.

7.7 The Contractor shall indemnify the Authority in full against:

(a) any loss, damage, liability, cost and expense of any nature (including legal expenses) which may be incurred or suffered by the Authority; and

(b) any demand, claim and action against the Authority

arising out of or in connection with a Safety Alert Notice, a Product Recall Notice or where the Contractor suspends supply of the Goods under the Contract.

7.8 For the avoidance of doubt, the Authority may act in accordance with Clauses 7.3, 7.4, 7.5 and 7.6 of these T&Cs without incurring any liability to the Contractor even if the Goods, which are subject to the Safety Alert Notice, and/or the Recalled Goods are later confirmed by any laboratory analysis, health or regulatory authority or by a court of law (whether or not in Hong Kong) to have complied fully with the relevant provisions of the Contract.

8. Title and Risk

8.1 Subject to other terms and conditions of the Contract, (including, without limitation, the Authority's right to reject under Clause 6 and the provisions in relation to Safety Alert Notice and Product Recall Notice under Clause 7), title to and risk in the Goods supplied by the Contractor to the Authority shall pass to the Authority with the receipt provided under Clause 5.2(b).

8.2 The Authority will not be responsible for any Goods delivered to the Authority otherwise than in accordance with the terms of the Contract and pursuant to a valid purchase order.

9. Payment

9.1 Upon acknowledgment of receipt of the Goods by the Authority (or, where applicable, the Community Pharmacy, the Family Doctor or GOPC PPP Doctors) and where there is no dispute regarding the Goods delivered, payment by the Authority shall be made within 30 days of the date of receipt of the Contractor's Invoice. For the avoidance of doubt, payment for the Goods does not prejudice or compromise the Authority's rights to reject any Goods or to dispute any aspect of the delivery for which payment has been made.

9.2 The Contractor shall not be entitled to any increase in the Price by reason of foreign exchange fluctuation.

9.3 The Authority shall be entitled to set off against the Price or any payment due to the Contractor any sums owed to the Authority by the Contractor under any contract (including the Contract) between the Authority and the Contractor. The Authority shall also be entitled to withhold any sums under dispute.

10. Warranties, Undertakings and Liability

10.1 The Contractor represents, warrants and undertakes to the Authority that:

(a) the Contractor has all necessary title to the Goods and full right and authority to transfer title of the Goods to the Authority, Community Pharmacies and Family Doctors, or where the Contractor is the relevant PPP Contractor, to the relevant PPP Doctors;

(b) the possession, administration, use, distribution, supply, dealing in or with and/or exploitation of the Goods by the Authority, the HA Hospitals, Community Pharmacies or Family Doctors, or where the Contractor is the relevant PPP Contractor, by the relevant PPP Doctors shall not infringe any third party proprietary rights, including Intellectual Property Rights;

(c) the Goods shall be delivered free from any security interest or other lien or encumbrance;

(d) the Goods will be of merchantable quality and fit for the purpose for which they are intended or required;

(e) the Goods will be free from defects in formulation, process and material;

(f) the Goods shall be in conformity with the descriptions and requirements stated in the Contract (including the UI Requirements as agreed or committed by the Contractor) and will correspond in all respects with their specifications and all manufacturers specifications;

(g) the manufacturer of the Goods will, in relation to the manufacture thereof, comply with all enactments, orders, regulations or other instruments issued by the government or other competent authority in the place of manufacture of the Goods;

(h) the Goods will only be manufactured in the jurisdiction/country/place of origin as specified and/or as otherwise expressly agreed in writing by the Authority during the Term;

(i) the Goods will comply with all applicable laws, regulations, statutory requirements and requirements of any competent authority (including those relating to health, safety, import and registration) in both the country/place of origin and in Hong Kong;

(j) the Goods shall have the required expiry date after they have been delivered to the Authority, Community Pharmacies and Family Doctors, or where the Contractor is the relevant PPP Contractor, to the relevant PPP Doctors;

(k) it has taken out and shall maintain with a reputable insurer during the Term Product Liability Insurance in respect of the Goods to be supplied under the Contract up to the minimum indemnity limit to cover all liabilities that may arise in connection with or arising out of death or personal injury;

(l) if applicable (where the Contractor is the distributor of the Goods), the manufacturer of the Goods has appropriate and adequate arrangements in place (including product liability insurance) in respect of the Goods to cover all liability that may arise in connection with or arising out of death or personal injury;

(m) if any declaration made by the Contractor becomes incorrect during the Term, the Contractor shall immediately notify the Authority; and

(n) if there is any change to the Goods (in particular changes in formulations or indications and usages), the Contractor shall notify the Authority in accordance with the change control process as stated in Clause 2.6 of Part II.

10.2 The Contractor acknowledges that the Goods to be supplied to the Authority are intended to be distributed to the public hospitals, the Community Pharmacies, the Family Doctors or GOPC PPP Doctors for use by, administration on, consumption, possession by and supply to patients of HA Hospitals or participants of specified Government primary healthcare programme(s) under Primary Healthcare Commission or participants of GOPC PPP Programme. Notwithstanding Clauses 10.1(k) and 10.1(l) above, the Contractor shall be fully responsible for and shall indemnify the Authority on demand in full against any claim made by anyone in respect of the Goods (including death or personal injury) resulting directly or indirectly from or in connection with the failure by the Contractor to comply with any term of the Contract.

11. Indemnity

11.1 Notwithstanding the Product Liability Insurance and without prejudice to any other indemnity provisions in the Contract, the Contractor shall indemnify the Authority, its officers, employees and agents on demand in full against any claim, demand, action, liability, loss, damage, cost and expense of any nature (including legal expenses) demanded, claimed and/or awarded against and/or incurred, paid and/or suffered by the Authority (or its directors, officers, employees, representatives and/ or agents) (collectively, "HA Parties") directly or indirectly as a result of, arising from or in connection with:

(a) actual or alleged breach of any warranty given by the Contractor;

(b) any actual or alleged loss or damage (including death or personal injury) suffered by any person in respect of or arising from the storage, handling or use of the Goods;

(c) any actual or alleged breach by the Contractor of the terms of the Contract (including without limitation any actual or alleged breach and/or violation of the laws or regulations by or in relation to the Goods sold, supplied and/or provided to the Authority for its use in accordance with the specifications);

(d) any Rejected Batches, any Recalled Goods, any Safety Alert Notice or Product Recall Notice;

(e) any act or omission of the Contractor or its directors, officers, employees, representatives, agents or sub-contractors (if any), affiliates, sub-manufacturers and/or distributors; and

(f) any damage to Authority's property that may be caused by the Contractor or its directors, officers, employees, representatives, agents or sub-contractors (if any), affiliates, sub-manufacturers and/or distributors including without limitation any interference caused.

11.2 For the avoidance of doubt, the benefit of any indemnity by the Contractor to the Authority under any provision of the Contract shall be extended to the Authority, any committee established by the Authority including but not limited to the Regional Advisory Committees and the Hospital Governing Committees, the chairman or any member of the Authority or of its committee, any public hospitals or any of its employee, officer and agents. The Authority shall hold the benefit of such indemnities on trust for such persons to the extent necessary to give effect to this provision.

12. Intellectual Property Warranty and Indemnity

12.1 The Contractor represents and warrants to the Authority that:

(a) the Goods supplied by the Contractor to the Authority, the HA Hospitals, Community Pharmacies or Family Doctors, and where the Contractor is the

relevant PPP Contractor, the relevant PPP Goods supplied by the relevant PPP Contractor to the relevant PPP Doctors under the Contract do not infringe any Intellectual Property Rights of a third party (whether in Hong Kong or elsewhere);

(b) where appropriate, the Contractor has procured or ascertained and confirmed the current and valid registration of all Intellectual Property Rights in respect of the Goods provided; and

(c) the possession, administration, use, distribution, supply, dealing in or with and/or exploitation of the Goods by the Authority, the HA Hospitals, Community Pharmacies or Family Doctors, or where the Contractor is the relevant PPP Contractor, by the relevant PPP Doctors do not infringe any rights, including Intellectual Property Rights, of a third party.

The Contractor shall at its own cost, and without prejudice to its representations and warranties, upon the Authority's request and within the time stipulated, provide the Authority with such information or documentation (including third party opinions) as the Authority may require to assess the Intellectual Property Rights position of the Goods at any time during the Term, and whether or not any allegation or claim in respect of their validity or infringement of third party rights has been made or threatened.

12.2 Without prejudice to Clause 11, the Contractor shall indemnify the Authority and/or any of the HA Parties against any claim, demand, action, liability, loss, damage, cost and expense of any nature (including legal expenses) which may be demanded, claimed and/or awarded against and/or incurred, paid and/or suffered by the Authority or any HA Parties as a result of, arising from or in connection with any misrepresentation and/or actual or alleged breach by the Contractor of any representation or warranty in Clause 12.1 (including without limitation any actual or alleged infringement of third party Intellectual Property Rights in relation to the Goods sold, supplied and/or provided to the Authority for its use in accordance with the specifications).

12.3 (a) If at any time any allegation or claim is made against the Contractor or the manufacturer in respect of or in connection with the Goods, and/or any Intellectual Property Rights in relation to the Goods (whether in respect of infringement of third party Intellectual Property Rights, invalidity or any Intellectual Property Rights in relation to the Goods or otherwise, and whether made in Hong Kong or in the jurisdiction where the Goods are manufactured, supplied or sold, or anywhere in the world), or in the Contractor's reasonable opinion is likely to be made, the Contractor shall forthwith notify the Authority. The Contractor shall thereafter promptly inform the Authority of all developments in connection therewith. Subject to all the arrangements being agreed with the Authority and provided that:

(i) the specifications shall be fully met;

(ii) the purity and potency expected or required of the Goods being pharmaceutical products are not compromised; and

(iii) there shall be no delay or disruption with the administration of treatment to the patients,

the Contractor may at its expense replace the Goods with a non-infringing alternative so as to avoid the risk of infringement. All costs and expenses including delivery, removal, and recall of products, administrative and labour costs, overtime charges, incidental to or occasioned by the replacement (including those of the Authority, the HA Parties, the Community Pharmacies, the Family Doctors and the PPP Doctors) shall be borne solely by the Contractor.

(b) If any claim or allegation is made by a third party against the Authority, any of HA Parties, the Community Pharmacies and/or the Family Doctors and/or the PPP Doctors under this Clause 12, or of a nature which, if substantiated, would give rise to such a claim, without prejudice to any right to indemnity of the Authority or HA Parties above, the Authority will:

(i) give the Contractor notice in writing of any such claim being made or action threatened or brought against the Authority, the HA Parties, the Community Pharmacies, the Family Doctors and the PPP Doctors;

(ii) subject to the Contractor providing such security against costs and damages as the Authority may require, permit the Contractor at the Contractor's expense to conduct any litigation which may ensue and all negotiations for a settlement of the claim; and

(iii) give the Contractor all reasonable assistance, subject to reimbursement from the Contractor of its reasonable costs.

The costs incurred or recovered by the Contractor in such negotiations and litigation will be for the Contractor's account.

(c) The Authority Representative may also, at his election, without prejudice to other rights and remedies of the Authority:

(i) forthwith terminate the Contract in respect of the Goods not yet received by the Authority;

(ii) suspend the performance of the Contract until the claim in question is resolved to the satisfaction of the Authority without prejudice to the Authority's right to terminate the Contract any time after such election;

(iii) obtain Alternate Supplies from any third party supplier; and/or

(iv) without prejudice to the Contractor's liability under this Clause 12, require the manufacturer of the Goods to enter into an intellectual property warranty and indemnity in favour of the Authority substantially

in the form of this Clause 12 (with the manufacturer being substituted for the Contractor) as a pre-condition and requirement for the Authority not to terminate the Contract, or otherwise cease to continue to purchase the Goods from the Contractor.

12.4 The Authority shall not be liable to the Contractor for any loss, cost or expense incurred by the Contractor or any third party arising from, or as a result of, the exercise by the Authority of any right or remedy available to it under Clause 12.3, whether or not the allegation or claim in relation to which such right or remedy is exercised is later found by a court of law to have been validly made. The Contractor irrevocably and unconditionally waives any right to make any claim for compensation arising therefrom, and to the extent the Authority has any liability arising from its exercise of such rights and remedies hereby releases and discharges the Authority from the same.

13. Authority's Liability

13.1 The Authority shall not be liable for or in respect of any damages or compensation under the Fatal Accidents Ordinance (Cap. 22 of the laws of Hong Kong), the Employees' Compensation Ordinance (Cap. 282 of the laws of Hong Kong), the Occupiers Liability Ordinance (Cap. 314 of the laws of Hong Kong) or at common law by or in consequence of any accident or injury to any workman or other person whether in the employ of the Contractor or in the performance of the Contractor's obligations under the Contract (save and except liability for death or personal injury resulting directly from negligence of the Authority) and the Contractor shall indemnify and keep indemnified the Authority against all claims, demands, proceedings, costs, charges and expenses whatsoever in respect of or in relation thereto.

13.2 In the event that any workman or other person in the employ of the Contractor or engaged on any work done in pursuance of the Contract suffers any personal injury and whether there be a claim for compensation or not, the Contractor shall within 7 days give notice in writing of such personal injury to the Authority.

13.3 The Contractor acknowledges and accepts that except for the liability for death or personal injury resulting directly from negligence of the Authority as set out in Clause 13.1 above, all other liabilities, potential or actual, of the Authority are excluded to the maximum extent permitted by law.

14. Confidentiality

14.1 The Contractor undertakes that the Contractor and its servants, agents or sub-contractors (if any) will keep in confidence and not disclose to any third party without the Authority's prior written consent any information or data (whether of a commercial or technical nature or otherwise) acquired from the Authority in connection with the Contract (including but not limited to any oral or written information which they obtain under the Contract or accidentally overhear or encounter when carrying out any work in the Authority premises) other than disclosure to those persons to whom it is necessary

to supply such information to enable performance of the Contract. The Contractor shall not use the expertise evident therein in any manner detrimental to the interests of the Authority.

14.2 Nothing contained above shall apply to prevent the Contractor from disclosing any information:

(a) in its possession (with full right to disclose) prior to receiving it from the Authority;

(b) which is or later becomes public knowledge other than by breach of this Clause; or

(c) which it may independently develop or receive from a third party (with full right to disclose).

14.3 Upon the completion, expiry or termination of the Contract, the Contractor shall return to the Authority and shall not retain any copy of any confidential documents and materials which have been supplied by the Authority to the Contractor to enable performance of the Contract.

15. Termination

15.1 The Contract will expire automatically, without notice being necessary, on expiry of the Term upon satisfactory fulfilment by the Contractor of its contractual obligations in accordance with this Contract.

15.2 Without prejudice to any other right of termination of the Authority under the Contract, the Authority may at any time by notice in writing terminate the Contract immediately, without entitling the Contractor to compensation, if:

(a) the Contractor, being an individual or a partnership, at any time receives a bankruptcy notice or petition or be adjudged bankrupt, or has a receiving order or order for administration of his estate made against him, or takes or suffers any proceedings for liquidation or composition under any Bankruptcy Ordinance (Cap. 6 of the laws of Hong Kong) for the time being in force or distress or any form of execution against him or make any conveyance or assignment of his effects or composition or arrangement for the benefit of his creditors or purports so to do;

(b) the Contractor, being a company, becomes insolvent or enters into any composition or arrangement with its creditors or passes a resolution for winding up (other than for the purpose of amalgamation or reconstruction) or receives a winding up notice or petition or a court makes an order for the liquidation of its assets or a Receiver or Manager shall be appointed on behalf of the debenture holders over the whole or part of its assets, or circumstances arise which entitle the court or debenture holders to appoint a Receiver or Manager, or suffers distress or any form of execution against it;

(c) the Contractor or any employee or agent of the Contractor or its sub-contractor (if any) is found to have committed an offence under the Prevention of Bribery Ordinance (Cap. 201 of the laws of Hong Kong), the Crimes Ordinance (Cap. 200 of the laws of Hong Kong), the Personal Data (Privacy) Ordinance (Cap. 486 of the laws of Hong Kong) or any subsidiary legislation made thereunder or under any law of a similar nature in relation to the Contract or any other contract with the Authority;

(d) the Contractor ceases, or threatens to cease, to carry on business;

(e) in the absolute discretion of the Authority the Goods fail to comply with the specifications, any test or other requirements of the Contract (including the supply of PPP Goods to support PPP Programmes, supply of Goods to support Community Pharmacy Programme and specified Government primary healthcare programme(s), and the UI Requirements as agreed or committed by the Contractor) in any respect;

(f) the Goods are subject to a Safety Alert Notice or a Product Recall Notice;

(g) the Contractor, its agent or sub-contractor (if any) fails to pay its staff or fails to pay its debts as they fall due;

(h) the Permit (if any) which authorises the Contractor and/or its staff to perform its obligations under the Contract is withdrawn, cancelled, suspended or modified;

(i) the Marketing Authorisation or Export Certificate (if any) for the Goods issued by the relevant regulatory authority and submitted by the Contractor in compliance with requirements set out in **B1. Technical and Registration Requirements** and **Tenderer's Schedule B1(a)** in **Part III**, is withdrawn, cancelled or suspended;

(j) the Contractor is in breach of any term of the Contract, the Authority notifies the Contractor of such breach in writing, and the Contractor fails to rectify such breach within such time period as the Authority shall stipulate

(k) the Contractor is in breach of any term of this Contract and such breach is incapable of rectification;

(l) there is a change in direct or indirect control of the management or ownership of the Contractor or any of its associated companies (as that term is defined in Clause 22) which in the reasonable opinion of the Authority adversely impacts the Contractor's ability to provide the Goods;

(m) the Contractor assigns its rights or novates its obligations (or purports to do so) otherwise than in accordance with this Contract;

(n) the Contractor is found to have provided any incomplete, false or incorrect statement or information or document during the tendering process or from time to time during the Term; or

(o) any failure on the part of the Contractor to comply with any applicable laws and regulations, in particular relevant legislation in Hong Kong, whether in the performance of this Contract, any contracts or arrangements with third parties, in its operation or otherwise,

provided always that such termination shall not prejudice or affect any right or action or remedy which shall have accrued or shall accrue thereafter to the Authority.

15.3 The Authority may also at any time during the Term by not less than 30 days' prior written notice terminate the Contract.

15.4 Where the Contract is terminated by the Authority other than pursuant to Clause 15.3, without prejudice to the remedies to which the Authority is entitled under other provisions in the Contract or otherwise under the law, the Authority may purchase from other sources Alternate Supplies to substitute for the Goods which, but for the termination of the Contract, would be supplied by the Contractor to the Authority under the Contract, and the Contractor shall, on demand by the Authority, pay to the Authority the Alternate Supplies Cost and, if required by the Authority, consent to assign, novate or transfer its rights and obligations under this Contract to the replacement contractor or contractors.

15.5 The Contractor agrees and acknowledges that if the Authority terminates the Contract in accordance with any clause of the Contract, the Authority has no liability to the Contractor arising from such termination other than paying the Contractor for the Goods delivered and accepted up to the date of termination, provided that any such Goods have been delivered by the Contractor and have been endorsed and accepted. Upon termination of the Contract, any licence (actual or implied) granted by the Authority to the Contractor shall immediately terminate.

15.6 Those clauses of the Contract which by their nature should survive the termination of the Contract shall survive. Such clauses shall include without limitation this Clause 15.6 and Clauses 4.1(b), 6, 7, 10, 11, 12, 13, 14, 19, 21,23 and 26.

16. Force Majeure

16.1 Neither the Contractor nor the Authority shall be liable to the other, or be deemed to be in breach of its obligations under this Contract, by reason of any delay in performing, or any failure to perform, any of its obligations hereunder if and to the extent the delay or failure was due to an event of force majeure of which it has notified the other party in accordance with Clause 16.3.

16.2 "An event of force majeure" means act of God, explosion, flood, tempest, fire, accident, war or threat of war, sabotage, insurrection or civil disturbance which the affected party proves was beyond its control and without the fault or negligence of the party affected and which by the exercise of reasonable diligence the party affected was unable to prevent.

16.3 Any party affected by an event of force majeure shall notify the other in writing forthwith giving full particulars of the nature and extent of the circumstances in question, their effect on its ability to perform and the likely duration of such effect, and that party shall use its

reasonable efforts to remove or mitigate the effect of the event of force majeure upon its performance of the Contract. To the extent that the performance of obligations by the party affected is prevented by an event of force majeure, its performance of such obligations will, subject to this Clause, be suspended, and the Contractor shall not be entitled to any cost, fee, charge or payment of the Price in respect of the suspended obligations.

16.4 Upon completion or termination of an event of force majeure, the party affected must forthwith notify the other and as soon as reasonably practicable resume performance of its obligations under the Contract. In the event that such event of force majeure continues for 1 month or more, then the party not affected by such event may terminate the Contract, without liability to the non-terminating party.

17. Personal Data

17.1 The Authority may, to permit performance of the Contract, require that certain personal data or information of the Contractor, its staff, agents and sub-contractors (if any) be provided by the Contractor.

17.2 Any such personal data will be used for purposes relating to the Contract. If insufficient or incorrect information is provided, the Authority may terminate the Contract for breach in accordance with Clause 15.

17.3 The personal data provided by the Contractor may be disclosed to the HKG, regulatory authorities, the parties responsible for overseeing the Contract or evaluating the Contractor in relation to the Contract, and to comply with legal obligations of the Authority.

18. Corrupt Gifts

If the Contractor or any employee or agent of the Contractor or its sub-contractor (if any) shall be found to have committed an offence under the Prevention of Bribery Ordinance (Cap. 201 of the laws of Hong Kong) for the time being in force or any subsidiary legislation made thereafter or under any law of a similar nature in relation to the Contract, the Authority Representative may, on behalf of the Authority, terminate the Contract, without entitling the Contractor to any compensation therefor and the Contractor shall indemnify the Authority against any claim, liability, loss, damage, cost and expense of any nature (including legal expenses) which may be incurred or suffered as a result by the Authority, including those provided under Clause 15.

19. Publicity

The Contractor shall submit to the Authority and/or the HA Hospitals all advertising or other publicity material relating to the Contract or the Goods supplied or other work done in connection with the Contract wherein the name of the Authority or the HA

Hospitals is mentioned or from which a connection with the HA Hospitals or the Authority can reasonably be inferred or implied. The Contractor shall not publish or use any advertising or other publicity material relating to the Authority and/or the HA Hospitals or otherwise use or mention the name of the Authority and/or the HA Hospitals for any promotion or marketing purposes without the prior written consent of the Authority and/or the HA Hospitals. Nothing in the Contract expressly or impliedly constitutes an endorsement of any goods or services and each party agrees not to conduct itself in such a way as to imply or express any such approval or endorsement.

20. Compliance with Law

20.1 The Contractor shall comply with all applicable international and local laws, rules and regulations pertinent to its obligations under the Contract.

20.2 The Contractor shall indemnify the Authority against any penalty, loss or cost arising as a result of the Contractor's failure to comply with any of the said enactments, orders, regulations, or other instruments and in addition, the Authority reserves the right to claim full compensation in the event of the whole or any part of the Contract not being completed as a result of such failure to comply.

21. Deposit

21.1 The Contractor is required to place and maintain the Deposit with the Authority as security for the due performance of all the Contractor's warranties, undertakings and obligations under the Contract. The Contractor must maintain the full amount of the Deposit throughout the Term of the Contract and until the date falling 3 months after the end of the Term or the date on which all obligations and liabilities of the Contractor under the Contract have been duly carried out, completed and discharged, whichever is the later.

21.2 The Contractor hereby irrevocably agrees and allows the Authority to, at any time prior to the expiry of the duration as set out in Clause 21.1, withdraw, deduct or set-off from the Deposit any amount which the Authority may recover from the Contractor under the Contract. If the Authority shall make any withdrawal, deduction or set-off thereby reducing the Deposit, the Contractor must, within 7 days from notice of the Authority, top up the Deposit to maintain it at the level required in Clause 21.1.

21.3 Upon expiry of the duration as set out in Clause 21.1, the Authority shall return to the Contractor without interest the Deposit after any withdrawal, deduction or set-off as allowed under Clause 21.2. The return of the Deposit in full or in part does not prejudice the Authority's right to pursue any claim for loss, damage or liability under the Contract.

22. Conflict of Interest

22.1 The Contractor shall on appointment and during the Term and for six (6) months thereafter:

(a) immediately declare any actual, apparent, potential or perceived Conflict of Interest

that will, or might, arise in respect of the provision of the Services or the performance of its obligations under the Contract, including but not limited to any interest or association, the Contractor, its Associated Persons may have with any contractors, suppliers or sub-contractors related to this Contract, directly or indirectly; and

(b) forthwith notify the Authority in writing and keep the Authority notified of all or any facts which may reasonably be considered to give rise to a Conflict of Interest.

22.2 The Contractor shall render its advice or recommendations pursuant to this Contract to the Authority on an impartial basis without giving favour to any particular service, equipment or product in which the Contractor has a direct or indirect commercial interest. The Contractor shall obtain from each and every one of its Directors, employees, agents and sub-contractors who are involved in this Contract a written undertaking to observe this sub-clause and sub-clause 22.3 below.

22.3 The Contractor shall require its Directors, employees, agents and sub-contractors involved in this Contract to declare in writing to the Authority and keep the Authority informed regularly of any actual, apparent, potential or perceived Conflict of Interest, including but not limited to all or any facts which may reasonably be considered to give rise to a Conflict of Interest. In the event that any Conflict of Interest becomes known to the Contractor or any of its Directors, employees, agents and sub-contractors involved in this Contract and / or is disclosed in a declaration, the Contractor shall forthwith take such measures as are necessary to mitigate as far as possible or to remove the Conflict of Interest so disclosed.

22.4 The Contractor shall prohibit its Directors and employees who are involved in this Contract from engaging in any work or employment other than in the performance of this Contract, with or without remuneration, which could give rise to any actual, apparent, potential or perceived Conflict of Interest. The Contractor shall procure that its agents and sub-contractors impose similar restrictions on their Directors and employees by way of a contractual provision.

22.5 The Contractor shall take all necessary measures (including by way of contractual provisions where appropriate) to ensure that its Directors, employees, agents and sub-contractors who are involved in this Contract are aware of the provisions under Sub-clause 22.2 to the Sub-clause 22.4 above. Where the Contractor has obtained the Authority's written approval to appoint sub-contractors to undertake any part of the Services, the Contractor shall take all necessary steps to procure and ensure that the same covenants in this Clause are imposed on the sub-contractors and shall take all necessary steps to enforce such covenants.

22.6 In this Clause 22:

(a) "Associated Company" in relation to the Contractor means any company which is the holding company or subsidiary company or sister company of the Contractor. A 'sister company' means a company which belongs to the same holding company as the Contractor's;

(b) "Associate Person" or "Related Person" means:

- the Directors, employees, agents and sub-contractors of the Tenderer / Contractor (and if the Tenderer / Contractor is a partnership, any of the members/partners of that partnership) who are or will be involved in the Tender, the Tender Submission, the provision of the Services or the performance of the Contractor's obligations under the Contract;

- any person or entity (i) which has Control, directly or indirectly, over the Tenderer / Contractor; (ii) which is Controlled, directly or indirectly, by the Tenderer / Contractor; or (iii) which is Controlled by, or has Control over, a person/entity referred to in (i) or (ii); and

- (i) any member of a partnership in which of the Tenderer / Contractor is a member or (ii) any company one or more of whose Directors is in common with one or more of the Directors of the Tenderer / Contractor.

(c) "Control" or Controlled" means

- the possession by one person, directly or indirectly (through one or more intermediaries) of the power (whether holding office as Director or otherwise) to affect, secure, direct and / or cause the direction of the management, affairs or policies of another person;

- with respect to a corporation, partnership or other body corporate, such power in (a) above may be evidenced by (but is not limited to) that person: (i) holding shares or interests or possessing voting power in or in relation to that or any other person such as, but not limited to, the right to exercise, directly or indirectly, more than fifty percent (50%) of the voting rights attributable to the shares of or interest in such corporation, partnership or other body corporate; and / or (ii) having powers conferred on that person by any constitution, memorandum or articles of association, partnership, agreement or arrangement (whether legally enforceable or not);

(d) "Conflict(s) of Interest" shall include (but are not limited to) (a) any situation where the personal, financial, commercial or other interest of the Tenderer / Contractor or any of its Related Persons, conflict or compete, or may be expected to conflict or compete, with the Tenderer's / Contractor's duties to the Authority under the Contract; and (b) any situation where the Contractor or any of its Related Persons may have any person, financial, commercial or other interests in any potential service, advice, proposals or recommendations made or which may be made by the Tenderer / Contractor under the Contract;

(e) "Director" means any person occupying the position of director by whatever name called and without limitation a de facto or shadow director;

22.7 Notwithstanding any provisions in this Clause, the restrictions in this Clause shall not prohibit the holding (directly or through nominees) of investments in companies which

investments are listed on any stock exchange provided that such investments do not exceed 5 per cent of the issued shares of any one company.

23. General

23.1 The Contract is personal to the Contractor and the Contractor shall not assign, transfer, sub-contract or purport to assign, transfer or sub-contract to any other person any of its rights, or sub-contract any of its obligations, under the Contract.

23.2 The Contract and all the rights and obligations under it may be assigned or transferred by the Authority.

23.3 The Contractor shall be an independent contractor and nothing herein shall be taken to constitute a partnership between the parties or the appointment of one of the parties as agent or employee of the other.

23.4 Any notice or document to be given under the Contract shall be in writing and shall be left at or sent by prepaid post or facsimile transmission to such address and such facsimile number as may have been last notified in writing by such party to the other party. All notice or document to be sent to the Authority shall be marked for the attention of the Authority Representative.

23.5 Any such notice or document shall be deemed to have been duly given at the time of delivery (if given by hand) or on the third day after posting (if given by prepaid post) or immediately upon transmission with confirmatory answerback (if given by facsimile).

23.6 No waiver by the Authority of any breach of the Contract by the Contractor shall be considered as a waiver of any subsequent breach of the same or any other provision.

23.7 Any variation to the Contract shall be binding only if it is recorded in a document signed by both parties.

23.8 If any provision of the Contract is held by any court or competent authority to be invalid or unenforceable in whole or in part, the validity of the other provisions of the Contract and the remainder of the provision in question shall not be affected thereby.

23.9 The rights of the parties under the Contract are cumulative and do not exclude or restrict any other rights (except as otherwise provided in the Contract).

23.10 The application of the Contracts (Rights of Third Parties) Ordinance is expressly excluded and no person who is not a party to the Contract shall be entitled to enforce any right or term of the Contract pursuant to the Contracts (Rights of Third Parties) Ordinance.

23.11 The Contract shall be governed by and construed in accordance with the laws of Hong Kong.

24. Admission of Contractor Personnel to HA Premises

24.1 Upon request from time to time by the Authority, the Contractor shall provide to the Authority a list of the names, posts, staff identity card numbers, addresses and telephone numbers of all Contractor's employees, agents, sub-contractors and those employees and agents of the aforementioned sub-contractors (collectively "Relevant Personnel") who may at any time require admission on behalf of the Contractor to any premises owned, managed, controlled or occupied by the Authority ("HA premises") for the purposes of the Contract if so required by the Authority Representative, and in that event such list shall specify the capacities in which those persons are employed by or connected with the Contractor and shall contain such other particulars as the Authority Representative may reasonably require.

24.2 The Contractor shall ensure that while any of the Relevant Personnel is on HA premises, they shall observe the Authority's rules, regulations, guidelines and code of practice which are from time to time applicable to the Contractor's execution of all or any part of the services at the HA premises.

24.3 The Contractor shall obtain from all Relevant Personnel consent to disclose and/or submit to the Authority their personal data for the purposes of the provisions of this Clause 24 and other provisions of the Contract.

24.4 The Authority Representative reserves the right to refuse to admit to the HA premises, or the right to evict from the HA premises, any person, whose admission would be, in the reasonable opinion of the Authority Representative, undesirable.

24.5 In the event that the Contractor fails to comply with this Clause 24 and it is determined that such failure is prejudicial to the interests of the Authority, the Authority's/Authority Representative may thereupon terminate the Contract.

24.6 Without prejudice to any other provision of the Contract, the Contractor shall indemnify and keep indemnified the Authority against all losses, claims, costs, demands and expenses that may arise out of or in consequence of any breach of this Clause 24.

24.7 The Contractor acknowledges and agrees that:

(a) the Authority may at any time vary unilaterally the entry requirements (including any vaccination and/or testing requirements) to any HA premises;

(b) it will comply with the guidelines and/or directions issued by the Authority from time to time on entry requirements (including any vaccination and/or testing requirements) to the HA premises.

25. The Sale of Goods (United Nations Convention) Ordinance (Cap. 641)

The Authority and the Contractor agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Contract.

26. National Security

26.1 The Contractor shall not engage in acts or activities that are likely to constitute or cause the occurrence of offences endangering national security or which would otherwise be contrary to the interest of national security.

26.2 The Authority may immediately terminate the Contract upon the occurrence of any of the following events:

(a) the Contractor has engaged or is engaging in acts or activities that are likely to constitute or cause the occurrence of offences endangering national security or which would otherwise be contrary to the interest of national security;
(b) the continued engagement of the Contractor or the continued performance of the Contract is contrary to the interest of national security; or
(c) the Authority reasonably believes that any of the events mentioned above is about to occur.

26.3 In the event that the Contract is terminated in accordance with Clause 26.2 above, the Contractor shall be liable for and shall indemnify and keep indemnified the Authority against, all losses, damage, costs and expenses incurred by the Authority arising out of or in relation to the termination.

26.4 In the event that the Contract is terminated in accordance with Clause 26.2 above, the Authority shall not be responsible for any claim, legal proceeding, liability, loss (including any direct or indirect loss, any loss of revenue, profit, business, contract or anticipated saving), damages (including any direct, special, indirect or consequential damages of whatsoever nature) or any cost or expense, suffered or incurred by the Contractor arising out of or in relation to the termination.

PART V

OFFER TO BE BOUND

If the Tenderer is a firm (that is, it operates either as a sole proprietorship or a partnership and holds a business registration certificate issued by the Business Registration Office), please complete and sign Part A below:

Part A

1. The Tenderer hereinafter mentioned hereby agrees to supply the Goods to the Authority subject to and in accordance with the Tender.

2. The Tenderer certifies that the following particulars are correct:

   (a) The number of the Tenderer's Business Registration Certificate is _____.

   (b) The date of expiry of the Tenderer's Business Registration Certificate is _____.

3. [If the Tenderer is a partnership] The undersigned is/are partner(s) in the Tenderer and is/are duly authorised to bind the Tenderer and the partners therein for the time being by his/their signature(s).

4. [If the Tenderer is a partnership] This Tender is submitted on behalf of the undersigned and the Tenderer and the other partners thereof; namely (state names and residential addresses of all other partners):

   _____

5. In the event of any queries relating to the Tenderer's offer please contact the Tenderer as follows:

   Tel. No.: _____ Fax No.: _____

   Contact Person: _____

   Name of Tenderer: _____

   Business Address: _____

   Signature(s): _____

   (Name)
   (Address)

   _____

   (Name)
   (Address)

   Date: _____

If the Tenderer is a limited company (that is, it holds a business registration certificate issued by the Business Registration Office and a certificate of incorporation issued by the Companies Registry), please complete and sign Part B below:

Part B

1. The Tenderer hereinafter mentioned hereby agrees to supply the Goods to the Authority subject to and in accordance with the Tender.

2. The Tenderer certifies that the following particulars are correct:

   (a) The number of the Tenderer's Business Registration Certificate is _____.
   (b) The date of expiry of the Tenderer's Business Registration Certificate is _____.
   (c) The number of the Tenderer's Certificate of Incorporation is _____.
   (d) The date of incorporation of the Tenderer is _____.
   (e) The place of incorporation of the Tenderer (if not Hong Kong) is _____.

3. The undersigned director(s) is/are duly authorised to bind the Tenderer by his/their signature(s).

4. This Tender is submitted with the full authority of and on behalf of the Tenderer.

5. In the event of any queries relating to the Tenderer's offer, please contact the Tenderer as follows:

   Tel. No.: _____ Fax No.: _____

   Contact Person: _____

   Name of Tenderer: _____

   Business Address: _____

   Signature(s): _____
   (Name)
   (Address)

   _____
   (Name)
   (Address)

   Date: _____

PART VI

MEMORANDUM OF ACCEPTANCE

On behalf of the Authority, I accept your Tender Submission in respect of:

☐ the Goods.

☐ the following Goods:

_____

_____

_____

_____

on and subject to the terms and conditions set out in the Contract.

Please note that the Contract will commence on a date notified by the Authority in writing (**Commencement Date**).

Please note that when the Goods are listed in the CPP Drug List and/or CDF, the Contractor is required to deliver the Goods to the Community Pharmacies and/or the Family Doctors, in addition to the HA Hospitals. For details, please refer to Attachment to Appendix 1 in Part III and Appendix 5.2 to Part III.

Please note that this Memorandum of Acceptance is conditional on the Authority receiving the Deposit (or where applicable, the Initial Deposit) (i) within 30 days from the date of this Memorandum of Acceptance or (ii) before the Commencement Date, whichever is the later. Should the successful Tenderer fail to place the Deposit (or where applicable, the Initial Deposit) with the Authority by the due date aforesaid, the Authority may in its absolute discretion terminate the Contract by notice in writing to the successful Tenderer.

Signed by the Authority Representative:

_____

Name: .....
Rank (designation): .....
Date: .....

Annexure 1

Notice for Tender Submissions

Please read this notice before you provide any Personal Data to us.

The Hospital Authority (HA) is a statutory body which manages public hospitals. Our staff member may ask you to provide your Personal Data for purposes related to evaluation of your tender/offer of tender contract.

When you provide Personal Data to us, please make sure that the data are accurate and complete. If you fail to provide us with information required or if the information provided is inaccurate or incomplete, our evaluation of your tender/offer to tender contract will be affected.

Please also note that your Personal Data may be made available to:

- Appropriate persons in the HA;
- Any other relevant parties who require them for matters related to evaluation of your tender/offer of tender contract; or
- Any relevant government departments/appropriate authorities when the HA is required to provide them under the relevant legislation for use for the purposes of that legislation.

In addition to the above, we will only use, disclose or transfer the Personal Data you provided to us:

- For those purposes relating to evaluation of your tender/offer of tender contract or directly related purposes; or
- Where permitted by law.

We will obtain your consent before using your Personal Data for any other purposes.

If you wish to require access to and/or correction of your Personal Data, you may do so under Personal Data (Privacy) Ordinance. For request(s) relating to Hospital Authority Head Office, please contact the relevant Data Controller during office hours at:

Address: 147B Argyle Street, Kowloon, Hong Kong

Annexure 2

Instructions to Third Parties

To: [Third Parties]

Re: Tender for the supply of: Lacosamide Tablets 50mg and 100mg ("**Goods**")
Tender Reference: HAHO(S)/T/26-D113
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 Goods (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. By accepting the Items of Information, you confirm to HA and the Tenderer/Contractor that you shall use them only to the extent necessary and appropriate for the purposes required by HA. You confirm that you will 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 as set out in this notice shall not apply or shall cease to apply in respect of any of the Items of Information to the extent that such Items of Information:

1. have become part of the public domain or are obvious or trivial;

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, provided that in such event the HA shall have given you prior notice of such requirement.

Annexure 3

Invoice and Delivery Note Information

(A) The Contractor shall issue an invoice to the Authority containing such information required by the Authority from time to time, the current requirements are:

1. Contractor's name
2. Authority's Purchase Order number
3. Authority's Purchase Order date
4. Delivery location
5. Goods description
6. Dosage form
7. Strength / concentration
8. Pack size
9. Quantity
10. Price
11. Batch number
12. Goods expiry date
13. Name of manufacturer
14. Place of manufacture
15. Hong Kong registration number (if any)
16. Classification of product under the laws of Hong Kong

(B) The Contractor shall provide a delivery note on delivery of the Goods to the Authority (and if applicable, Community Pharmacies, Family Doctors and PPP Doctors) containing such information required by the Authority from time to time, the current requirements are:

1. Product name
2. Dosage form
3. Strength / Concentration

4. Pack size / Unit of measure (UOM)

5. Quantity

6. Supplier

7. Manufacturer

8. Country/Place of origin

9. Hong Kong registration number (applicable to registered products in Hong Kong only)

10. Legal classification

11. Unit price (for delivery to HA Hospitals only)*

*** No price information should be displayed on the delivery note to Community Pharmacies, Family Doctors and PPP Doctors.**

Annexure 4

Review Body on Bid Challenges

This Tender is covered by the Agreement on Government Procurement of the World Trade Organisation ("**WTO GPA**") and the provisions of the WTO GPA will apply to this Tender. Tenderers are requested to note that a Review Body on Bid Challenges (under WTO GPA) ("**the Review Body**") has been set up by the Government to deal with challenges made against alleged breaches of the WTO GPA and the relevant procedures for handling bid challenges are set out in the Rules of Operation of the Review Body ("**the Rules**") which are available for inspection at the Secretariat of the Review Body located at the Trade and Industry Department or which may be downloaded from the website http://www.info.gov.hk/reviewbody-gpa. In the event that a Tenderer believes that a breach of the WTO GPA has occurred, the Tenderer may, within ten (10) working days after he/she knew or reasonably should have known the basis of the challenge, lodge a challenge to the Review Body on the alleged breaches of the WTO GPA. Nevertheless, the Tenderer is encouraged to seek resolution of its complaint in consultation with the Authority before lodging a complaint to the Review Body. In such instances, the Authority shall accord impartial and timely consideration to any such complaint, in a manner that is not prejudicial to obtaining corrective measures through the Review Body.

Tenderers are also to note that the Review Body may receive and consider a late challenge, if satisfied that reasonable cause for the delay has been shown, but a challenge shall not be considered if it is filed later than thirty (30) days after the basis of the challenge is known or reasonably should have been known.