廉政公署 ICAC

CPAS 防貪諮詢服務 Corruption Prevention Advisory Service

CORRUPTION PREVENTION GUIDE

PROCUREMENT OF DRUGS

FOR PRIVATE HOSPITALS

CONTENTS

FROM THE EDITORIAL BOARD

Descriptions and explanation of legal requirements under the Prevention of Bribery Ordinance (Cap. 201) and other relevant ordinances/laws in this publication are necessarily general and abbreviated for ease of understanding. Users of this publication are advised to refer to the original text of the relevant ordinances/laws or seek legal advice on particular issues where necessary. The Independent Commission Against Corruption (ICAC) will not accept any responsibility, legal or otherwise, for any loss occasioned to any person acting or refraining from action as a result of any material in this publication.

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Throughout this publication, the male pronoun is used to cover references to both the male and female genders. No gender preference is intended.

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FOREWORD

The prudent procurement of drugs is essential to the effective operation of every hospital. At the same time, the risks of corruption, manipulation and other malpractice inherent in almost all procurement processes are also found in drug procurement. Private hospitals are not immune from such risks. For example, hospital staff may accept advantages from drug suppliers in return for placing orders with them. Hospital staff may also collude with other parties to purchase drugs in the name of the hospital, and resell them elsewhere for personal financial gains. The occurrence of such incidents would damage the reputation of the hospitals concerned. More importantly, any impropriety in drug procurement may result in the use of drugs of a poor quality and pose threats to the patients' health and safety. To ensure that their drug procurement practices are free from corruption and other abuse, it is important that all private hospitals put in place adequate safeguards in the related system.

This Corruption Prevention Guide aims at providing a list of recommended safeguards to help private hospitals strengthen their governance and system controls, with a view to preventing corruption and other malpractice in relation to drug procurement.

The Corruption Prevention Advisory Service (CPAS) of the Corruption Prevention Department of ICAC stands ready to provide free, confidential, and tailor made corruption prevention advice and services to private companies, organisations and individuals, including the ways to implement the recommended practices in this Guide. For further information, please contact CPAS at telephone no. 2526 6363 or fax no. 2522 0505 or email address at cpas@cpd.icac.org.hk.

1 INTEGRITY MANAGEMENT

All systems, procedures and safeguards can only be as good as the integrity of the people implementing them. Staff and other parties involved in drug procurement in a hospital are easily exposed to integrity risks such as conflict of interest, and corruption risks such as offering of advantages by suppliers. Given that the conduct of staff would affect the quality of services, the confidence of patients and the reputation of the hospital, it is important for hospitals to adopt sound integrity management practices to uphold the integrity of drug procurement staff.

1.1 The Prevention of Bribery Ordinance

Section 9 of the Prevention of Bribery Ordinance governs corruption in the private sector and helps to maintain fair play in the sector and uphold market integrity. Directors, staff and agents[1] (for simplicity, they are all referred to as "staff" hereafter unless otherwise specified) of the hospital should have a basic understanding of the relevant provisions of the Prevention of Bribery Ordinance (Cap. 201, Laws of Hong Kong). The following is a gist of the relevant section (Section 9) of the Ordinance[2], its key elements and some examples relating to a hospital's environment.

i. Section 9 – Corrupt Transactions with Agents

- Section 9 (1) - It is an offence for an agent to solicit or accept an advantage as an inducement to, or reward for, his doing or forbearing to do any act, or showing or forbearing to show favour or disfavour to any person, in relation to his principal's affairs.
- Section 9 (2) - Any person who offers an advantage to an agent for the above purpose also commits an offence.
- Section 9 (3) - Any agent who, with an intent to deceive his principal, uses any receipt, account or other document which contains any statement which is misleading or false or defective in any material particular and in respect of which the principal is interested, is guilty of an offence.

ii. Principal

- The principal is the employer or any authorised person of the employer.

[1] *Hospitals may seek legal advice on whether the mode of co-operation between the hospital and its honorary / associate doctors constitutes a principal / agent relationship.*

[2] *The full text can be accessed through the Department of Justice's e-Legislation website at www.elegislation.gov.hk.*

iii. Agent

- An agent is a person acting for the principal. If a hospital appoints another person to act for it in business, that person becomes the agent whether the appointment is full-time or part-time, and whether or not the agent receives a fixed salary or a fee from the hospital. Any employee acting for the hospital is an agent of the hospital.

iv. Advantage

- An advantage includes money, gift, discount, commission, offer of employment, free service, etc.
- Entertainment, defined as food or drink provided for consumption on the occasion and other entertainment provided at the same time, is not an advantage under the Ordinance.

v. Principal's Permission

- An agent may accept an advantage in his official capacity if his principal so permits.

vi. Custom Constitutes No Defence

- It is not a defence upon prosecution to claim that an advantage accepted or offered is customary in any profession, trade, vocation or calling.

vii. Penalty

- A person convicted of an offence under Section 9 of the Prevention of Bribery Ordinance is subject to a maximum penalty of seven years' imprisonment and a fine of HK$500,000.

An extract of the Prevention of Bribery Ordinance is at **Appendix 1**.

1.2 Other Legal Concerns

Apart from the Prevention of Bribery Ordinance, all staff should pay attention to other ordinances that may apply to the procurement and handling of drugs in a hospital, such as the Pharmacy and Poisons Ordinance (Cap. 138), the Personal Data (Privacy) Ordinance (Cap. 486), etc.[3]

1.3 Clean Business Culture

To enhance the integrity of staff, and prevent corrupt or fraudulent practices, a hospital should promote and foster a clean business and law-abiding culture in the hospital. Actions that should be taken include: explicit commitment to clean business practices and staff integrity, promulgation of a Code of Conduct for staff covering relevant legal, professional and integrity requirements, etc., provision of corruption prevention training to staff, and effective enforcement of the Code of Conduct issued.

[3] *The full text can be accessed through the Department of Justice's e-Legislation website at www.elegislation.gov.hk.*

1.4 Code of Conduct for Directors, Staff and Agents

The first step to promote clean business culture and to demonstrate that the hospital is committed to anti-corruption practices is to set out in a Code of Conduct[4] the standards of behaviour the hospital expected of its staff (including both full-time and part-time staff).

It is presumed that hospitals have already adopted or planned to adopt a Code of Conduct. Where necessary, the following reminders or further guidelines, among others, should be provided to those involved in procuring drugs.

i. Relations with Patients

- Remind the staff concerned to take responsibility for the quality, safety and efficacy of the drugs they procured/handled, and give the best protection to the safety and health of patients at all times.
- Where practicable, develop a good partnership with patients, encouraging them to contribute positively towards their treatment, rehabilitation and health promotion.

ii. Relations with Suppliers and Contractors

- As a general principle, promote fair competition through established procurement policies and procedures (i.e. where applicable, the selection of goods is based on the principle of value for money in terms of price, quality, delivery time, after-sales service, etc.).
- Abide by the spirit, intent and content of the hospital's contractual agreement with all suppliers and contractors.
- Procure goods and services in a professional manner in line with the required integrity standards to ensure proper use of the hospital's money and uphold the continued confidence of suppliers and contractors in their business dealings with the hospital.
- Avoid accepting benefits or favours (e.g. entertainment) from suppliers and contractors if they are too generous, excessive or frequent, or may make the recipient feel obliged to the offeror or may bring the recipient or the hospital into disrepute.
- Avoid engaging in games of chance with suppliers and contractors.
- Avoid accepting advantages, gifts or entertainment from suppliers and contractors which could compromise one's position in any way.
- Ensure that suppliers and contractors understand and follow the hospital's procurement policies and procedures (e.g. the staff authorised to place drug orders, methods of payment, etc.).
- Make transparent to the suppliers and contractors, as far as practicable and where considered appropriate, the hospital's probity requirements for staff, in particular those concerning acceptance of advantages and entertainment by staff.

[4] *A sample Code of Conduct can be accessed through the CPAS website at cpas.icac.hk.*

iii. Avoidance and Declaration of Conflict of Interest[5]

- Provide examples applicable to procurement/handling of drugs in the hospital environment to help staff assess whether they have conflict of interest. Some examples are:
  - A pharmacist involved in drug procurement is a relative or close friend of the drug supplier.
  - A doctor has investment in, or has a relative operating, a drug company which supplies some of the drugs used by the hospital.

iv. Mechanism to Manage Conflict of Interest

- Adopt a "three-step mechanism" in managing conflict of interest:
  - Avoid - All staff should remain alert to and avoid any actual, potential or perceived conflict of interest situation;
  - Declare - If the conflict is unavoidable, the staff should report it to the designated approving authority once he becomes aware of the conflict (e.g. require staff to declare to the Board/Council or senior management, as appropriate); and
  - Mitigate - The designated approving authority, after assessing the impact of the conflict and the risk of impropriety, should take appropriate mitigating measure as early as possible (e.g. require any staff having a conflict of interest to abstain from the related deliberation and decision-making process).
- The mitigating measure to be taken would depend on the circumstances of individual cases and the level of mitigation should commensurate with the severity of the conflict.
- Maintain proper documentation of the declaration, the rationale for the decisions made and the course of mitigating measure taken. A sample form for making the declaration, recording the decision made and the mitigating measure taken is at **Appendix 2** for reference.
- Designate an office/a staff member of appropriate rank to keep the precedent cases in managing declared conflict of interest so as to enhance consistency and facilitate sound decisions in managing declared conflict in future.

v. Positive Declaration

- Depending on the operational needs and circumstances, the hospital may require a staff member who participates in projects/exercises involving sensitive issues/information, or with great public concerns to declare if they have or do not have any conflict of interest (i.e. positive declaration) on the matter in order to protect the public interest and the interest of the hospital.

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[5] *A conflict of interest situation arises when the "private interests" of a staff member compete or conflict with the interests of the hospital or his official duties. Private interests include financial and other interests of the staff member himself; his family and other relations; his personal friends; the clubs and associations to which he belongs; any other groups of people with whom he has personal or social ties; or any person to whom he owes a favour or to whom he may be obligated in any way.*

vi. Handling Reports of Corruption and Violations

- State the hospital's anti-corruption policy and provide suitable channels for reporting corruption and violations of the policy.
- Require all personnel of the hospital to report promptly any corruption to the ICAC or through the reporting channels provided as appropriate.
- Encourage business partners (e.g. suppliers, contractors) to report corruption or corruption attempts by any of the hospital's personnel.
- Provide assurance of confidentiality, prompt handling and non-retaliation to the staff who make a report in good faith.
- Reiterate the zero-tolerance policy towards any corrupt behaviour detected, which will result in reporting to the relevant law enforcement agency and disciplinary action such as termination of employment (in the case of staff) or termination of contract and exclusion from future bidding (in the case of suppliers/contractors).
- Inform the Board regularly on the report received (e.g. number, type, handling of complaints).

1.5 Professional Code(s) of Practice and Other Relevant Guidelines

Apart from the Code of Conduct, staff involved in procurement/handling of drugs should also ensure that their services and performance comply with the code(s) of practice of their own profession, observe relevant guidelines issued by the regulatory authorities and industry associations, and make reference to industry's good practices as well as international hospital management practices. Some of the examples are listed below:

(a) Chapter 28 of the "Code of Practice for Private Hospitals" issued by the Department of Health;

(b) the "Good Dispensing Practice Manual" issued by the Hong Kong Medical Association and "Code of Ethics" by the Society of Hospital Pharmacists of Hong Kong; and

(c) the "Benchmarking Study on Management Practices of Hong Kong Private Hospitals – Report Summary" published by the Hong Kong Private Hospitals Association on good practices of private hospitals.

2 MANAGEMENT OF SPONSORSHIP

Sponsorship usually refers to a commercial arrangement whereby a sponsor provides a contribution in money or in-kind to support an activity in return for some kind of benefits (e.g. building relationships or good will, or enhancing image). It is common for doctors to receive sponsorship from pharmaceutical companies to conduct medical researches or attend overseas conferences. While such sponsorship may bring benefits to the hospital or individual staff of the hospital, it can also increase the risks of conflict of interest as the hospital staff receiving the sponsorship may feel obliged towards the sponsor and make official decisions that favour the sponsor (e.g. use the drugs supplied by the sponsor). To address this concern, hospitals should put in place appropriate policies and procedures to process applications for accepting sponsorship.

2.1 Clear Policy, Guidelines and Procedures

Well established policies and procedures could help prevent malpractices by letting staff have a clear understanding of the principles, values and practices they are required to follow, and allowing management to hold the staff concerned accountable for any non-compliance. It is therefore necessary for hospitals to lay down clear policy, guidelines and procedures for managing sponsorship, covering the following key elements, among others:

- The objectives of the policy and guidelines (e.g. to ensure proper receipt and handling of sponsorship by staff and parties concerned, to avoid any disrepute to the hospital);
- The scope of the policy (e.g. to whom the policy applies);
- The staff/division responsible for enforcing the policy;
- Possible sanctions for non-compliance with the policy and procedures;
- Guiding principles and procedures for implementing and evaluating the policy; and
- Management of the information collected/disseminated as a result of the policy.

2.2 Guiding Principles

For consistent and systematic application and compliance, hospitals should consider laying down some guiding principles for acceptance of sponsorship as follows:

- The sponsorship should benefit the hospital, patients or the professional development of doctors, and not compromise the quality and fairness of any service or business of the hospital.
- Any products, services or benefits provided by the sponsor as part of the sponsorship should be consistent with the hospital's objectives and values.
- Sponsorship engagements/agreements should not impose or imply conditions that may limit, or appear to limit, the hospital's ability to carry out its functions fully and impartially (i.e. should not place the hospital in an obligatory position to the sponsor/any related party, and give, or be perceived to give, the sponsor/any related party an unfair edge over others in obtaining services from or business dealings with the hospital).
- Acceptance of the sponsorship will not cause actual or perceived disrepute to the hospital.

- The recipient should not be obliged to do something in return for the offeror.
- Any sponsorship offered should in principle not include direct personal benefits to the recipient such as grant of honorarium, consultancies, unconditional gifts, donations, etc. (where direct personal benefits are involved, the case should be processed in a manner different from sponsorship, e.g. requiring the applicant to seek approval for undertaking outside work in accordance with the hospital's outside work policy).

2.3 Examples of Sponsorship

Since sponsorship can take many forms, hospitals should provide some common examples of sponsorship that may be considered for acceptance:

- Participation with input at local or overseas conferences (e.g. participation with paper presentation or as an invited speaker, panel chairman, or member of organising committee);
- Clinical trials or research (e.g. attending investigators' meetings or conferences); and/or
- Attendance at seminars and other health promotion activities.

2.4 Criteria for Approving Sponsorship

Hospitals should formulate clear and pre-determined criteria for approving sponsorship, and make them known to all potential recipients and sponsors. These criteria may include the following, among others:

- The sponsorship arrangement should be consistent with the guiding principles (***Clause 2.2***) adopted by the hospital.
- Potential recipients should be required to seek prior approval from the hospital as far as practicable for accepting any sponsorship. Where an application is submitted after acceptance, full justifications should be provided by the recipient.
- If the sponsorship is for training, equity in training opportunities among staff should be considered.
- The sponsorship should not be excessive in value and in frequency, and should be governed by the hospital's policy on the maximum number of sponsored activities (e.g. overseas conference trips) that can be accepted by a staff member within a specified period.
- Acceptance of the sponsorship should not give rise to actual or perceived conflict of interest related to operations of the hospital. In case it is unavoidable for the recipient to be involved in any business dealing or decision involving the sponsor, he should be required to declare his interest and refrain from taking part in the business dealing or decision–making process for a reasonable period of time.
- Suitability of the sponsor should be carefully assessed (e.g. whether the sponsor is reputable, conducts business consistent with the values and objectives of the hospital, and has a satisfactory sponsorship record with the hospital and/or other hospitals/business associates).

2.5 Processing Procedures

To facilitate fair and systematic processing of applications for accepting sponsorship, hospitals should put in place the following control measures:

- Require applicants to ascertain with the sponsor details of the sponsorship before they submit the application.
- For any clinical trial or research participation which involves considerable commitment of the recipient, require applicants to work out in consultation with their supervisors the expected total commitment during and outside normal working hours prior to the application, to ensure that service delivery will not be unduly affected.
- Devise an application form, specifying all the information required including the sponsored items, the applicant's interest, etc.
- Assess the application against the maximum number of sponsorship (e.g. sponsored trips for overseas conferences) that can be accepted by a staff member in a year.
- Assess the application against the applicant's terms of employment, e.g. his leave entitlement.
- Specify the appropriate authorities for approving different sponsorship applications.
- Require the applicant, processing staff and approving authorities to declare conflict of interest with the sponsor as necessary.
- Maintain an electronic register of sponsorships received by all staff to facilitate monitoring by management.

2.6 Effective Enforcement and Monitoring

For effective enforcement and monitoring, hospitals should consider adopting the following safeguards:

- Where practicable, designate a central office to process all applications for accepting sponsorship.
- Include sponsorship policy in the hospital's Code of Conduct for compliance by all staff and parties concerned.
- Regularly remind the staff and parties concerned to comply with the policy and procedures for accepting sponsorship (e.g. via the hospital's intranet).
- Review the policy and procedures periodically to meet operational changes upon consultation with the staff and parties concerned.
- Subject sponsorship cases to the hospital's internal audit and risk management processes.
- Where necessary and resources permit, computerise the processing procedures and announce all the sponsorships accepted, to facilitate internal/external monitoring and enhance transparency.

3 MANAGEMENT OF DRUG FORMULARY

A hospital would normally maintain a drug formulary listing all the drugs used by the hospital for prescription to patients. The maintenance of a formulary is conducive to prudent selection of drugs to prevent medication errors, and operational efficiency by focusing on a limited choice of carefully selected drugs for specific medical conditions. The following are the basic internal control framework recommended for effective management of a hospital's drug formulary.

3.1 Clear Policy, Guidelines and Procedures

Hospitals should formulate and lay down clear policy, guidelines and procedures for the proper management of drug formularies, covering the following aspects:

- Requirement for adherence to the drug formulary as far as practicable (i.e. in principle, the hospital should only purchase drugs on its drug formulary for use).
- Circumstances under which drugs not listed on the drug formulary may be used and the approving authorities required as appropriate.
- The choice between proprietary drugs and generic drugs.
- Drug inclusion criteria (e.g. service need of the hospital, medical outcome/safety, fulfilment of quality and regulatory requirements).
- Drug deletion criteria (e.g. the drug is no longer produced, there is no stock movement for a specified period, a more effective drug is available).
- Requirement for periodic review of the drug formulary.
- Drug inclusion and deletion procedures (e.g. the parties who may propose inclusion/deletion of drugs, the justifications and clinical assessment by qualified personnel required, the designated approving authorities).
- The roles and responsibilities of different levels of staff in the drug formulary management process.

3.2 Expertise Required, Supervision and Integrity Management

To ensure that the most efficacious and safe drugs are selected, dispensed and stocked, hospitals should ensure that the staff involved in the management of the drug formulary are well qualified and adequately supervised to discharge their duties. The recommended measures are listed below:

- Assign suitably qualified persons (e.g. pharmacist and/or medical practitioner) to take charge of drug selection and formulary management, including the supervision of other personnel involved.

- Where practicable and resources permit, task an internal multi-disciplinary committee of medical and administrative personnel to oversee drug formulary management, covering the approval of admission/deletion of drugs onto/from the drug formulary, conduct of periodic review, etc.
- Subject all staff and parties involved in drug formulary management to stringent requirements on declaration of conflict of interest as follows:
  - Require the staff and parties concerned to make positive declaration to the senior management/Board on whether or not they have any conflict of interest (actual/perceived, personal/financial, etc.) before taking up the related duties, and update the declarations thereafter on a regular basis.
  - As acceptance of sponsorship is a common cause for conflict of interest, explicitly require the staff and parties concerned to declare if they have accepted any sponsorship from the suppliers/drug companies the drugs of which are under consideration for inclusion onto the drug formulary.
  - Require proper documentation of any declared conflict and the mitigating measure taken by the senior management/Board (e.g. the staff concerned should within a specified period from the receipt of a sponsorship refrain from making any decision concerning the interest of the sponsor).
  - Remind all staff and parties concerned to declare conflict of interest as and when it arises or comes to their knowledge.

3.3 Drug Admission and Deletion Process

From time to time, hospitals may find it necessary to select new drugs for use. Upon successful trial, these drugs will be admitted to the drug formulary for regular use by the hospital. Drugs on the drug formulary are also subject to deletion for various reasons (e.g. the drug is no longer produced). To ensure that the drug formulary is updated properly, hospitals may adopt the following recommended measures as appropriate:

- Upon a suggestion for using a new drug, require the staff in-charge (normally the pharmacist in-charge) to conduct an evaluation on the drug proposed (including the relevant clinical papers on drug efficacy and evidence, unit cost, estimated annual consumption, etc.).
- Require the senior management (or delegated authorities) or a specific committee (if any set up for the purpose) to consider the evaluation and recommendation, and endorse the admission of the drug to the drug formulary as appropriate.
- For drugs fulfilling the criteria for deletion from the drug formulary, seek the senior management (or delegated authorities) or the specific committee's approval for the formal deletion of a drug.
- Require all the deliberations to be properly recorded.

3.4 Overall Monitoring

To ensure effective monitoring, hospitals should consider adopting the following recommended safeguards:

- If a specific committee is tasked to oversee the drug formulary management, uphold its governance to ensure effective and fair conduct of business, including selection of suitable members for the committee, specifying the meeting quorum, laying down the guiding principles for making decisions, and stipulating the requirement for positive declaration of conflict of interest before the deliberation of important matters (e.g. the inclusion of drugs onto the drug formulary).
- Where a specific committee is not available for the purpose, engage the senior management (or its delegated authorities) to oversee the matter, in particular the approval for admission/deletion of drugs onto/from the drug formulary.
- Provide the senior management (or its delegated authorities) or the specific committee (if any set up for the purpose) with periodic management or exception reports to facilitate their monitoring of the activities and trends.
- Make transparent through various means including the hospital's intranet, the drug formulary management policy and procedures to all the users as far as appropriate.
- Review the policy, guidelines and procedures periodically to meet operational needs and market changes, and designate the staff responsible for the review.
- Carry out regular audit on the related activities to ensure that the established policies and procedures are complied with.
- Where necessary and resources permit, computerise drug formulary management to enhance monitoring and safeguard the integrity of the important information.

4 PROCUREMENT SAFEGUARDS

Unlike the procurement of general goods and services, drug procurement in private hospitals has its unique features. Firstly, dispensing of drugs generates revenue to the hospital as patients would eventually bear all the cost. Secondly, price may not always be the major consideration as the hospitals and patients may be more concerned about the quality and efficacy of the drugs. For these reasons, doctors of private hospitals in general prefer proprietary drugs to generic drugs, and this may make open competitive sourcing (e.g. tender or quotation) less common in private hospitals, especially when drug prices are quite transparent in the market and the quantity ordered by a private hospital is relatively small when compared with public hospitals. That said, any procurement system is prone to corruption in view of the money transactions involved. Private hospitals should therefore consider putting in place the following safeguards[6] in their drug procurement system while endeavouring to satisfy the operational and customer needs.

4.1 Clear Policy, Guidelines and Procedures

In setting the policy, guidelines and procedures for procuring drugs, hospitals may take into account the following elements:

- Adherence to the drug formulary (Chapter 3) as far as practicable.
- Requirement for procuring drugs in a timely manner and in appropriate quantities in order to reduce interruption in supply while at the same time avoid overstocking.
- Discharge of drug procurement activities by qualified staff (e.g. dispensers and supplies staff) under supervision of pharmacists.
- Basic requirements (quality, safety and efficacy, registration requirements) and specific requirements (e.g. country of origin, product presentation and labelling requirements) where applicable.
- Guiding principles for approving a purchase, including quality requirements, price consideration where applicable, and for stocking drugs (e.g. the acceptable stock level prior to replenishment).
- The roles and responsibilities of different levels of staff in drug procurement.
- Where necessary and applicable, the procurement methods for drugs of different values and the corresponding levels of approving authority, as follows:
    - Restrictive quotation (normally adopted where price is the major consideration and the number of suppliers in the market is not limited, e.g. procurement of generic drugs) – Purchases above a specified amount require quotations from a specified number of

[6] *For other common procurement safeguards, hospitals may also make reference to the "Corruption Prevention Guide: Procurement" compiled by the Corruption Prevention Department, ICAC, which can be accessed through the CPAS website at cpas.icac.hk.*

suppliers sourced from an approved list or the market, and/or nominated by users. The approving authority should be at the managerial/supervisory level.

- Verbal order – In the situation of sole supplier (e.g. for proprietary drugs) or replenishment of current stock or urgent and ad hoc purchases (e.g. ad hoc prescription of a new drug not listed on the drug formulary by a doctor for a particular patient), verbal order may be adopted with orders placed with the suppliers/retailers direct by authorised staff.
- Irrespective of which procurement method is adopted, the authorities for approving different values of purchases should be specified.

- Where necessary, the requirement for a two-envelope bidding system (i.e. for high value purchases where price is not the only consideration, bidders are required to submit their technical and price offers in two separately sealed envelopes, and the price offer is opened for assessment only after assessment of the technical offer is completed).
- Requirement for all staff and parties involved in the procurement process to declare any perceived or actual conflict of interest and for management to take steps to resolve the conflict (if any) by, say, assigning other staff/parties to take over the job or requiring supervisors to closely monitor the process.
- Reminding the staff and parties involved in the procurement process to avoid accepting entertainment from suppliers or over-socialising with them.

4.2 Drug Selection

Hospitals normally engage their pharmacist in–charge to take control of drug procurement. He is usually assisted by other supporting staff such as dispensers and supplies staff who are responsible for routinely placing orders to replenish the drug stock. All the items to be purchased and replenished are in general governed by the established drug formulary. The pharmacist may be required to identify alternative drugs should he find that a drug will soon become not available in the market or its supply is unsteady or there are problems with the drug/supplier. To prevent impropriety in the drug selection process, it is important for hospitals to put in place the following recommended safeguards:

- Closely monitor the supply situation of all drugs in use.
- Require adequate lead time for the replacement.
- Document the justifications for replacement of a drug together with the necessary evidence (e.g. proof of unsteady supply or cessation of supply) and seek prior approval from the relevant authority (Clause 3.3).
- Where applicable, consult the doctors concerned for alternative drug recommendations.
- Shortlist and select the new drug based on established criteria/specifications, for example:
  - Selection priority (e.g. the hospital may follow this order of priority: patent drugs, generic drugs registered in developed countries, generic drugs from other sources).
  - Fulfilment of quality and registration requirements (e.g. registration of the drug and supplier with the Department of Health, supplier's proof of the generic drugs' equivalence with patent drugs, Good Manufacturing Practices (GMP) certification)

- Product presentation and labelling requirements (e.g. drugs similar in appearance are avoided to reduce dispensing errors, blister packaging of drugs are preferable to loose tablets as the former offers dispensing convenience and assurance of product integrity, oral liquid medicines with smaller pack size are preferable to bulk bottles to reduce errors resulting from repackaging).

- Recommend the selected drug together with the evaluation and justifications to the approving authority for endorsement of inclusion onto the drug formulary prior to actual purchase and use by the hospital (Chapter 3).
- In cases where the established policies/requirements cannot be complied with, follow the stipulated procedures and seek approval from the relevant authorities.

4.3 Ad Hoc Purchase Requests

On some occasions, a hospital doctor may consider it necessary to prescribe for a particular patient a new drug which is not on the drug formulary. To respect clinical judgment and satisfy patients' needs, the hospital would normally accept these ad hoc requests. Thus, the pharmacist in-charge may resort to various means to procure the drugs required, including direct purchases from "drug retailers". Listed below are some recommended measures to enhance the integrity of the process:

- Ascertain the actual need for the purchase (i.e. efficacy of the drug in relation to the comparable ones in stock) upon clarification with the doctor concerned as necessary.
- Lay down the procurement approaches that can be adopted for entertaining these ad hoc requests and the circumstances applicable to each approach.
- Document the outcome of the approach adopted.
- Where shortlisting of suppliers for ad hoc purchases is required (e.g. for generic drugs), source suppliers according to the pre-determined criteria endorsed by the hospital, and proceed with the purchase by quotation.
- Ensure that the "drug retailer" is properly engaged based on pre-determined criteria (e.g. range of drugs supplied and service commitment) or competitive sourcing where practicable, and subject it to periodic performance evaluation (e.g. price and delivery).
- Where the "drug retailer" is engaged on a term basis, subject it to price and service commitment, and review the engagement upon expiry of the term agreement.
- Monitor the consumption of the new drug, and consider whether it should be recommended for inclusion in the drug formulary based on the pre-determined inclusion criteria and procedures (Chapter 3).

4.4 Quotation Invitation and Evaluation

As proprietary drugs are generally used, it may not be common for hospitals to resort to open competitive sourcing in drug procurement. That said, in procuring some types of drugs (e.g. long established generic drugs) where price is the major consideration, large quantity of orders is placed, and more suppliers are available in the market, hospitals may still make the purchases by restrictive quotation. Listed below are some recommended measures to enhance the control of such procurement activities:

- Draw up clear specifications for the drug before invitation.
- Invite the stipulated number of suppliers on the approved suppliers' list (if any) to submit quotations or compile a shortlist based on pre-determined criteria endorsed by the approving authority if necessary.
- Include additional suppliers nominated by doctors as appropriate.
- Specify the method (e.g. by fax or email) and deadline of submission of quotations.
- Invite quotations formally and include the following in the invitation documents:
  - clear specifications of the drug required;
  - the selection criteria and their weightings in assessment, if price is not the only consideration; and
  - a warning against corrupt offers to the hospital's staff and collusion with other bidders, and that the hospital may terminate the contract and claim damages from the supplier/bidder if bribery or collusion is involved in obtaining the contract.
- Lay down the safeguards against tampering with quotations, for example, using a secure electronic system for receiving quotations, refusing the acceptance of any quotation after the deadline.
- Where verbal quotation is acceptable, record all such quotations in writing immediately upon receipt.
- Properly record all quotations received (e.g. the supplier's name, price quoted) for easy comparison and future audit.
- Where applicable, make duplicate copies of the quotations for custody of a designated staff member so that they may be referred to in the future if necessary (e.g. in the investigation of complaints).
- Require the quotations to be evaluated by more than one staff at the appropriate level.
- Check compliance with the specifications, and select the conforming bid with the best price offer, or evaluate the quotations based on pre-determined selection criteria if price is not the only consideration.
- Recommend the selected supplier for approval by the designated authority, together with the purchase requisition form (showing the drug specifications), the quotation invitation, the comparison summary of the quotations and copies of all the quotations received.
- Give justifications if the lowest conforming bid is not selected where price is the major consideration.

4.5 Negotiation with Suppliers

Sometimes, hospitals may need to conduct negotiation with the selected supplier, say, when the price offered has room for adjustment. Since any negotiation process is prone to corruption and other malpractices, hospitals are recommended to adopt the following safeguards when conducting negotiations for high value purchases:

- Lay down the criteria and approving authorities for the conduct of negotiation.
- Require procurement staff to seek the management's endorsement of the negotiation strategy (e.g. the hospital's bottom line) or to inform the management the negotiation strategy prior to the conduct of negotiation.

- Require the negotiation team to comprise at least two staff at the appropriate level (e.g. the pharmacist in-charge).
- Require the negotiation team to record the salient points of discussion and the negotiation result for management's information and/or audit checks.
- Prohibit the negotiation team from disclosing the suppliers' offers during or after the negotiation.
- Require the supplier to submit the "best and final offer" in writing after negotiation.
- Require approval from the appropriate authority for acceptance of the "best and final offer" by the procurement staff.

4.6 Placing Drug Orders

It is common for hospitals to place verbal orders for replenishing the current stock of drugs used. This practice is prone to abuse and errors for various reasons (e.g. the specifications of the drug required could be mistaken and there may be no proper record of the order placed). It is therefore necessary for hospitals to adopt the following recommended safeguards to ensure that all drug orders are properly placed:

- Designate staff at the appropriate level for ordering drugs in accordance with the purchase values where practicable.
- Require the staff to keep proper written records of drug orders (e.g. purchase orders must show the drug's details). Where necessary and resources permit, adopt electronic recording for efficiency and effective monitoring.
- Subject the orders to periodic audit checks to detect any irregularities (e.g. a substantial increase in the ordered quantity contrary to the usual pattern).

4.7 Receipt of Drugs

To prevent impropriety or errors during the delivery and receipt of drugs, hospitals should adopt the following recommended measures as appropriate:

- Ensure that drugs are only received and handled by staff with relevant experience and training.
- Assign a staff member, preferably one not participating in selecting the supplier or placing the order, to inspect the drugs delivered against the specifications shown on the purchase order to ensure that the correct quantity and product are delivered.
- For high-value purchases, assign a supervisor (e.g. the pharmacist in-charge) to monitor and counter-sign the receipt of goods.
- Check the expiry date, pack size, product appearance and storage condition of the drug to detect if there is any irregularity.
- Should there be any irregularity of the delivered products, quarantine the drug pending clarification from the supplier.
- Monitor the delivery performance of suppliers and draw the attention of the pharmacist in-charge/management to repeated cases of unsatisfactory delivery performance (e.g. frequent delays).

4.8 Storage and Inventory of Drugs

The storage of drugs and management of inventory are important to a hospital not only because the safety and efficacy of the drugs are at stake, but also because there may be risks of misappropriation of the drugs in store. Hospitals should consider adopting the following recommended measures where applicable to reduce such risks:

- Store drugs in a manner that would facilitate the implementation of the "first in first out" principle.
- Keep dangerous drugs in accordance with the Dangerous Drugs Ordinance (Cap. 134) and the Pharmacy and Poisons Ordinance (Cap. 138).
- Keep drugs according to their storage conditions (e.g. temperature, humidity).
- Conduct regular checks on the expiry date of all drugs to ensure timely disposal and replacement of the expiring or expired products.
- Maintain a disposal record of expired products.
- Conduct regular stock-takes and prepare management reports (e.g. the closing stock, details of the expiring/expired drugs, the consumption pattern of each drug) for the management's review.
- Where necessary and resources permit, develop an automatic inventory management system (e.g. with bar-coding) to monitor drug inventory and the expiry dates of drugs, and to handle dispensing of drugs.
- Where repackaging of bulk purchase drugs into smaller packs is necessary, provide adequate training to the staff discharging the duties, and require them to comply with a set of standard procedures.

4.9 Handling Drug Samples

It is not uncommon for drug suppliers to provide the "users" (e.g. doctors) and "buyers" (e.g. pharmacy staff) with drug samples for trial use or under a procurement incentive scheme of the suppliers. Hospitals may have different policies and procedures for handling the samples offered. To prevent impropriety in the process, and to facilitate tracking of the disposal of the drug samples, it is necessary for hospitals to put in place adequate safeguards. Listed below are some recommended measures:

- Establish clear policy and procedures for handling the drug samples received, covering the retention and dispensing authorities, etc.
- Where practicable, require the samples to be maintained and handled centrally (e.g. by the pharmacist in-charge), to facilitate control and enhance accountability.
- Keep a register of drug samples received with information on the date of receipt, name of offeror, handover record (e.g. from doctor to pharmacy staff), transaction details, and periodic stock-take.
- Make suppliers aware of the hospital's policy and procedures on sample handling, and require their compliance as one of the terms of the purchase contract/order.

4.10 Processing Payments

After the delivery of goods, suppliers are generally concerned about the time when payments are received as this will significantly affect their cash flow. Anxious suppliers may attempt to offer advantages or entertainment to the hospital staff concerned in return for expedition of the payment process. To prevent any corruption or malpractice in this respect, hospitals should adopt the following recommended safeguards as appropriate:

- Lay down the policy on adopting different payment methods (e.g. payment by cash is normally not adopted) and the proper procedures for each method (e.g. require all payments to be processed by the Accounts Department).
- Make suppliers aware of the established policies and procedures, and encourage them to report to the hospital management any suspicious act by hospital staff (e.g. payment is made by individual staff direct, in cash or by cheques not in the name of the hospital).
- Make payment for drugs against duly certified invoices, purchase orders and/or delivery notes.
- Specify the time limits for effecting payment for drugs received, make them known to the suppliers, and require staff to record the reasons for cases where late payments are made.
- Keep proper records of the payments made and all the supporting documents to facilitate management monitoring and internal/external audits.

4.11 Supervision and Audit Checks

While the day-to-day procurement of drugs is normally entrusted to the pharmacy, hospitals should ensure adequate supervisory and audit checks over the process to detect and deter malpractice:

- Put in place an internal audit function to independently evaluate the effectiveness of risk management, control and governance processes.
- Ensure that the internal audit function –
  - is independent from the operation under audit, sufficiently staffed by staff of appropriate qualification and training, has unfettered access to all records, assets, personnel and premises, and to obtain such information and explanations as and when considered necessary;
  - develops an audit programme setting out the auditing assignments to be performed and conducts regular review to the programme taking into account the risk of key business processes; and
  - reports directly to the Audit Committee, if established, or the senior management and draws their immediate attention to any significant irregularities detected in the course of audit review.
- Give due consideration to the opinions and findings of the internal audit function and take timely actions in response to its recommendations/findings.
- Require procurement staff to vigorously monitor the storage, inventory, and consumption of drugs and drug samples.

- Require Accounts Department to conduct surprise checks on the stock level of drugs at specified intervals against the computer/manual inventory records to ensure consistency, and report irregularities found to the management/Internal Audit (if any).
- Require management or Internal Audit (if any) to conduct surprise audit checks on drug procurement activities, covering the replenishment of inventory, selection of drugs, placing of drug orders, etc., to ensure compliance with laid down policies and procedures, and investigate into any discrepancy or irregularity detected (e.g. purchase of an unusually large quantity of particular drugs, drug orders made by unauthorised persons).
- Ensure the confidentiality of all the surprise checks and disclose the related information to relevant staff only on a "need-to-know" basis.
- Require the managers/audit staff to select pharmacy/supplies staff for interview during the checks to collect information/feedback on drug procurement and dispensing activities.
- Subject the payment and accounting records to periodic audit checks to ensure that all payments are properly made for the authorised purchases, and that the established policies and procedures are compiled with (e.g. whether the stipulated payment method is used for a particular purchase).
- Where necessary and practicable, provide a checklist for the conduct of the various checks to properly record the findings on the spot and to ensure no omission of the items to be checked.
- Make all staff aware of the hospital's practice of conducting surprise checks to deter malpractice.
- If resources allow, engage an external auditor to conduct periodic procedural/financial audits on procurement activities, or an external accreditation agency for quality assurance checks.

4.12 Other Management Controls

To build up a monitoring system so that irregularities can be detected at an early stage, hospitals should consider implementing the following recommended control measures as appropriate over the drug procurement system:

- Review the procurement policies and guidelines periodically, taking into account the operational needs and changing business environment.
- Where necessary and resources permit, more widely use information technology in the procurement and handling of drugs to enhance efficiency and monitoring, and to reduce errors (e.g. devising a computer system for drug formulary management, inventory control, drug prescription and dispensing, sample handling, and other administrative activities such as processing sponsorship applications).
- Require the pharmacist in-charge and the Accounts Department to produce periodic management or exception reports (e.g. on repeated orders of the same drug over a short period) to facilitate monitoring and review by the management.
- Establish an internal communication channel for staff to give views and report non-compliance with the regulations and procedures (e.g. unauthorised retention/dispensing of drug samples).
- Provide an effective channel to collect feedback from patients/customers and suppliers.

- Establish a mechanism to investigate complaints and suspected irregularities (including the staff responsible for investigation, the investigation and reporting procedures, the authority for approving follow-up actions and case closure).
- Through various means including the hospital's website, make known to the suppliers, where appropriate, information about the hospital's probity requirements for staff and suppliers and its procurement policy.
- Periodically remind the suppliers of the hospital's probity requirements expected of staff and suppliers, and its procurement policies, and collect their feedback to detect any irregularities.
- Require/encourage staff to attend internal and external training to enhance their awareness of integrity management, and knowledge and skills in carrying out their drug procurement or formulary management duties.

APPENDIX 1
Extracts of the Prevention of Bribery Ordinance (Chapter 201 of Hong Kong Laws)

Section 9 – Corrupt transactions with agents

(1) Any agent who, without lawful authority or reasonable excuse, solicits or accepts any advantage as an inducement to or reward for or otherwise on account of his –

(a) doing or forbearing to do, or having done or forborne to do, any act in relation to his principal's affairs or business; or
(b) showing or forbearing to show, or having shown or forborne to show, favour or disfavor to any person in relation to his principal's affairs or business,

shall be guilty of an offence.

(2) Any person, who, without lawful authority or reasonable excuse, offers any advantage to any agent as an inducement to or reward for or otherwise on account of the agent's –

(a) doing or forbearing to do, or having done or forborne to do, any act in relation to his principal's affairs or business; or
(b) showing or forbearing to show, or having shown or forborne to show, favour or disfavor to any person in relation to his principal's affairs or business,

shall be guilty of an offence.

(3) Any agent who, with intent to deceive his principal, uses any receipt, account or other document –

(a) in respect of which the principal is interested; and
(b) which contains any statement which is false or erroneous or defective in any material particular; and
(c) which to his knowledge is intended to mislead the principal,

shall be guilty of an offence.

(4) If an agent solicits or accepts an advantage with the permission of his principal, being permission which complies with subsection (5), neither he nor the person who offered the advantage shall be guilty of an offence under subsection (1) or (2).

(5) For the purposes of subsection (4) permission shall –

(a) be given before the advantage is offered, solicited or accepted; or
(b) in any case where an advantage has been offered or accepted without prior permission, be applied for and given as soon as reasonably possible after such offer or acceptance,

and for such permission to be effective for the purposes of subsection (4), the principal shall, before giving such permission, have regard to the circumstances in which it is sought.

Section 4 – Bribery

(1) Any person who, whether in Hong Kong or elsewhere, without lawful authority or reasonable excuse, offers any advantage to a public servant as an inducement to or reward for or otherwise on account of that public servant's –

(a) performing or abstaining from performing, or having performed or abstained from performing, any act in his capacity as a public servant;
(b) expediting, delaying, hindering or preventing, or having expedited, delayed, hindered or prevented, the performance of an act, whether by that public servant or by any other public servant in his or that other public servant's capacity as a public servant; or

(c) assisting, favouring, hindering or delaying, or having assisted, favoured, hindered or delayed, any person in the transaction of any business with a public body,

shall be guilty of an offence.

(3) If a public servant other than a prescribed officer solicits or accepts an advantage with the permission of the public body of which he is an employee being permission which complies with subsection (4), neither he nor the person who offered the advantage shall be guilty of an offence under this section.

Section 8 – Bribery of public servants by persons having dealings with public bodies

(1) Any person who, without lawful authority or reasonable excuse, while having dealings of any kind with the Government through any department, office or establishment of the Government, offers any advantage to any prescribed officer employed in that department, office or establishment of the Government, shall be guilty of an offence.

(2) Any person who, without lawful authority or reasonable excuse, while having dealings of any kind with any other public body, offers any advantage to any public servant employed by that public body, shall be guilty of an offence.

Section 2 – Interpretation

"Advantage" means –

(a) any gift, loan, fee, reward or commission consisting of money or of any valuable security or of other property or interest in property of any description;

(b) any office, employment or contract;

(c) any payment, release, discharge or liquidation of any loan, obligation or other liability, whether in whole or in part;

(d) any other service, or favour (other than entertainment), including protection from any penalty or disability incurred or apprehended or from any action or proceedings of a disciplinary, civil or criminal nature, whether or not already instituted;

(e) the exercise or forbearance from the exercise of any right or any power or duty; and

(f) any offer, undertaking or promise, whether conditional or unconditional, of any advantage within the meaning of any of the preceding paragraphs (a), (b), (c), (d) and (e), but does not include an election donation within the meaning of the Elections (Corrupt and Illegal Conduct) Ordinance (Cap. 554), particulars of which are included in an election return in accordance with that Ordinance.

"Entertainment" means the provision of food or drink, for consumption on the occasion when it is provided, and of any other entertainment connected with, or provided at the same time as, such provisions.

Section 19 – Custom not to be a defence

In any proceedings for an offence under this Ordinance, it shall not be a defence to show that any such advantage as is mentioned in this Ordinance is customary in any profession, trade, vocation or calling.

APPENDIX 2
Sample Form for Declaration of Conflict of Interest

(Name of the hospital)

Declaration of Conflict of Interest

Part A – Declaration (To be completed by the Declarer)

To : (Approving Authority)

☐ I have no conflict of interest, whether actual or potential, in discharging my official duties in relation to [insert the name of the project / exercise requiring positive declaration by the hospital], and undertake to declare any such conflict immediately when I become aware of it.#
(# For use only when there is a requirement for positive declaration)

☐ I would like to report the following actual/potential* conflict of interest situation arising during the discharge of my official duties:

Person(s)/organisation(s) with whom/which I have official dealings and/or private interest
My relationship with the person(s)/organisation(s) (e.g. relative)
My contact with the person(s)/organisation(s) (Please state the frequency of contact and the usual occasions of contact, etc.)
Relationship of the person(s)/organisation(s) with the hospital (e.g. supplier)
Brief description of my duties which involved the person(s)/organisation(s) (e.g. handling of tender exercise)
File reference, if any, of the mentioned duties

(Name of the Declarer)

(Date)

(Title)

Part B – Approval (To be completed by Approving Authority)

To : (Declarer)

Part B(i) – In respect of the declaration in Part A of this form, it has been decided that:

☐ The declaration as described in Part A is noted. You are allowed to continue handling the work as described in Part A, provided that there is no change in the information declared above.

☐ You are restricted in the work as described in Part A (e.g. prohibit from handling the specific part/duty that you have conflict, withdraw from discussion on a specific issue/case).
Details : _____
_____

☐ You may continue to handle the work as described in Part A, but an independent person would be recruited to participate in, oversee or review part or all of the decision-making process (e.g. task another staff with the required expertise to provide objective assessment on the matter).
Details : _____
_____

☐ You are relieved of your duty as described in Part A, which will be taken up by another person (e.g. staff, expert) through redeployment.
Details : _____
_____

☐ You should relinquish the personal/private interest (e.g. cease to be a member of a club/association, divest the investments until the conflict situation described in Part A no longer exists).
Details : _____
_____

☐ Others (please specify) (e.g. you should not contact the person(s)/organisation(s) concerned until the conflict situation described in Part A no longer exists):
Details : _____
_____

Part B(ii) – The justification(s) for the measure(s) as described in Part B(i) above is/are:
(Factors of consideration including the materiality of the conflict, link between the conflict and the matter in question, and any possible negative public perception over the conflict/incident.)

In all cases, please be reminded that you should not disclose any privileged/internal information of the subject matter to the person(s)/organisation(s) concerned and should further report if there are changes in circumstances necessitating reporting.

(Name of the Approving Authority)

(Date) (Title)

Part C – Keeping of Records (To be completed by the Declarer)

To : (Designated office/staff for keeping the completed declaration form)
Via: (Approving Authority)

I noted the decision in Part B. The completed form is for your retention please.

(Name of the Declarer)

(Date) (Title)

*Potential conflict of interest refers to situation that may be developed into an actual conflict in the future.