

CHAPTER 6 PROCUREMENT AND SUPPLY OF PHARMACEUTICAL PRODUCTS IN THE PUBLIC AND PRIVATE MEDICAL SECTORS

Overview

6.1 This chapter sets out the Review Committee's findings and recommendations on procurement and supply of pharmaceutical products in the public medical sector including DH and the Hospital Authority (HA), after detailed examination of their existing procurement system. The Review Committee makes recommendations to further ensure the safety of drugs supplied by DH and HA.

6.2 This chapter also sets out (a) a set of guiding principles being practised in private hospitals and (b) the current practices of solo or joint private medical practitioners, in the procurement and supply of pharmaceutical products. It then presents the Review Committee's findings and recommendations on areas for improvement to the drug procurement system in the private medical sector.

The Existing Procurement and Supply System

Procurement System of DH

6.3 DH follows a strict set of procurement procedures which are in accordance with the Supplies and Procurement Regulations (SPR) promulgated by the Government Logistics Department.

6.4 There are two routes for procurement, namely by supplies contracts and by direct purchase, and are determined based on the total value of the purchase. In accordance with SPR, purchase value of over HK\$50,000 procurement is by tendering procedures. Drugs the consumption of which does not exceed \$50,000 per year are procured by direct purchase and DH would invite quotations from a list of potential suppliers of the drug.

Procurement System of HA

6.5 The Hospital Authority prescribes a wide spectrum of pharmaceutical products for patients in its hospitals and clinics. The procurement system is in compliance with the requirements of the Government Procurement Agreement of the World Trade Organization.

6.6 There are three levels of procurement procedures. Purchase exceeding \$1 million per year are purchased through tendering procedures. Purchase between \$50,000 and \$1 million per year are purchased using standing quotations. Standing quotations are arranged through tendering procedures, but without quantity commitment; and more than one standing quotations can be set up for the same item. Purchase which does not exceed \$50,000 per year, procurement is conducted by direct purchase. HA headquarters maintain item-specific list of approved suppliers, from which hospitals and clinics can make direct purchase of individual items.

Quality Requirements

6.7 Whichever procurement procedures are used, the drug must satisfy the quality requirements required by DH and HA. Suppliers are required to provide documentation evidence to support the quality of the drug on the areas of manufacturing and quality control; product characteristics including, where applicable, comparative clinical data either in the form of bioequivalence study reports or clinical trial reports; and sales data. These documents may include GMP certificate of the manufacturer; registration status, composition and certificate of analysis of a batch of the drug.

Storage and Inventory Monitoring System

6.8 DH has a computer system to monitor drug inventory, stock levels and expiry dates of drugs and to handle requisitions for drugs by clinic dispensaries. After the drugs are procured in accordance with SPR, suppliers will deliver the drugs to the dispensaries. Upon delivery, the clinic dispensers will examine the drugs against the orders in accordance with the procedures in the Good Dispensing Practice Manual issued by DH.

6.9 HA has a set of guidelines on the storage of pharmaceutical products in respect of the corresponding storage conditions required by individual products. Goods are stored in a way to facilitate the implementation of the “first in first out” practice.

6.10 HA requests the Government Laboratory to undertake the testing for the first introduction of a generic drug purchased from a supplier. Regarding auditing of inventory, samples of contract items are tested by the School of Pharmacy of the Chinese University of Hong Kong once in each contract cycle, which is usually for two years.

Findings

6.11 The Review Committee finds that the drug procurement system of both DH and HA follows a strict set of procedures which are in line with international standards.

6.12 Both procurement systems are determined based on the total value of the purchase. Whichever route of procurement is used, the Review Committee finds that quality of drug, which is the most important element is ensured via the quality requirements set out in details by both DH and HA.

6.13 The Review Committee further finds that both DH and HA utilize a computer system to monitor the drug inventory, stock levels and expiry dates of drugs and to handle requisitions for drugs by different clinic dispensaries and hospitals. In DH, dispensing of drugs and stock management are guided by the Good Dispensing Practice Manual available since 1999.

Recommendations

6.14 The Review Committee finds that there are rooms for improvement in the receipt and the handling of drugs after delivery. The Review Committee makes the following recommendations –

- (a) The Review Committee **recommends** that both DH and HA conduct post-delivery surveillance including microbiological and chemical testing to ensure drug quality. This is to be conducted regularly in accordance with standard operating procedures for transparency.
- (b) The Review Committee **recommends** that both DH and HA require the suppliers to provide additional information, such as pack size and registration number, etc. in the delivery documents to enable more effective physical checking and verification of drugs received.
- (c) The Review Committee **recommends** that both DH and HA provide additional training to staff and monitor the workflow in the repacking activities in drug dispensing to minimize errors.
- (d) The Review Committee **recommends** that DH imposes new requirement on suppliers to keep samples of each batch of drugs that are still within the expiration period to facilitate investigation when needed.
- (e) The Review Committee **recommends** that DH upgrades its central

inventory monitoring computer system to enhance the traceability of drugs.

- (f) The Review Committee **recommends** that DH works with the trade associations to enrich the database of registered pharmaceutical products so as to provide more detailed information to the public on registration details of products, e.g. pack-size, labelling, legal classification, etc.
- (g) The Review Committee **recommends** that HA requires suppliers to provide evidence that their products are either registered or are exempted from registration under the law.
- (h) The Review Committee **recommends** that HA requires suppliers to provide microbiological test results for high risk drug items and batch release certificates on all drugs supplied to HA to ensure safety and quality.
- (i) The Review Committee **recommends** that HA uses multiple sources for the supply of high risk products with high usage volume to ensure continuity of supply in case problems arise with one supplier.
- (j) The Review Committee **recommends** that HA establishes a Drug Quality Assurance Office to enhance quality monitoring of products, performance management of manufacturers and suppliers and quality incident management as well as to monitor the implementation of all improvement initiatives.
- (k) The Review Committee **recommends** that HA enhances the current electronic system, such as exploring the use of RFID, bar coding, wireless data transmission, etc. to enable product traceability and effective stores management.
- (l) The Review Committee **recommends** that HA requires suppliers to provide drugs in suitable pack sizes as far as possible to reduce the need for repacking.

Guiding Principles for Drug handling in Private Hospitals

6.15 There are currently 13 private hospitals in Hong Kong, each with its own drug procurement and supply system. After consulting among themselves and making reference to relevant guidelines drawn up by DH and HA, as well

as international hospital management and accreditation practices, the private hospitals have put in place the following set of guiding principles for compliance. The principles encompass the selection, procurement, delivery and receipt, storage and repacking of drugs. Staff training and auditing are also important elements during the drug handling process.

Selection of Drugs

6.16 A drug formulary should be set up which enables members of the healthcare team to focus on a limited choice of carefully selected drugs for specific medical conditions rather than on all the available drugs in the market. It helps prevent medication errors. Drug selection and formulary management is usually carried out through the professional expertise of the pharmacists of individual institutions. Some private hospitals also involve a multi-disciplinary committee of medical and administrative personnel to ensure that the safest, most efficacious and least costly medications are stocked.

6.17 Drugs selected include both patent and generic drugs. The purchase pattern follows such sequence: patent drug, generic drug registered in developed countries, generic drugs from other sources. Selected drugs must fulfill all the quality requirements. For generic drugs, bioequivalence and bioavailability data shall be submitted to prove their equivalence with patent drugs. Drugs similar in appearance are avoided in order to minimize dispensing errors. Blister packaging of drugs are preferred over loose tablets as blister packs are more convenient to dispense and offer assurance of product integrity. Oral liquid medicines with smaller pack sizes are preferred over bulk bottles to minimize errors resulting from the repacking process.

Procurement of Drugs

6.18 Procurement of drugs should be done in a timely manner and in reasonable quantity in order to minimize interruption in supply while at the same time to avoid overstocking. All procurement activities should be performed by qualified staff under the supervision of pharmacists.

Receipt of Drugs

6.19 Drugs should only be received and handled by staff with relevant training. During the receipt process, all essential information such as brand name and chemical name, strength, dosage form, Hong Kong registration number, etc. of the drug should be checked against the purchase order. The expiry date, pack size, product appearance and storage condition of drug should also be audited. Should there be any non-conformity in product appearance,

pack size, volume, etc. of the delivered product, it should be quarantined pending clarification from the supplier.

Storage of Drugs

6.20 All drugs should be stored according to conditions described on the package/label with respect to temperature, humidity, light, etc. Temperatures of drug storage areas should be properly controlled and monitored by keeping temperature log. The principle of “First-in First-Out” should be properly followed. Stock rotation is vital to use stocks with shorter shelf lives first and to facilitate the identification of soon-to-expire or expired products. Regular check on expiry date should be conducted for all storage locations to ensure timely removal and replacement of near expiry or expired products. A disposal record of expired products should be maintained.

Repacking of Drugs

6.21 Ready-for-use drugs should be used whenever possible to minimize the need for repacking or compounding. To facilitate dispensing, repacking of bulk purchase drugs into smaller packs is commonly practised. All staff engaged in repacking must be adequately trained and must follow a set of standard repacking procedures, including environmental control measures.

Staff Training

6.22 All staff involved in procurement and stock management should be well qualified and well trained, and should have the knowledge in all pertinent principles and guidelines.

Auditing

6.23 Internal audits on compliance of established procedures and guidelines relating to procurement, inventory receipt, storage and repacking should be conducted periodically to identify areas that need reinforcement or improvement.

Drug Handling by Solo or Joint Private Medical Practitioners

6.24 Private medical practitioners are subject to the code of professional conduct promulgated by the Hong Kong Medical Council, the registration body of medical practitioners in Hong Kong. The code states that doctors are advised

to observe the provisions of the Good Dispensing Practice Manual issued by the Hong Kong Medical Association.

6.25 Private medical practitioners can work in solo or joint practices. In the case of the former, the medical practitioner concerned will be solely responsible for the procurement and supply of drugs. In the case of the latter, one of the medical practitioners in the joint practice will be responsible for all the drugs handled in the clinic.

Findings and Recommendations

6.26 The Review Committee considers the guiding principles on drug handling as practised by private hospitals in order and serves as a useful reference for the private medical sector. Many guiding principles can be equally applied to the settings of Managed Care Organizations (MCOs) and private medical practitioners in solo or joint practices in spite of the difference in scale of operation.

6.27 The Review Committee **recommends** that DH issues a set of guiding principles as set out in paragraphs 6.16 to 6.23 above for the private medical sector and encourage private hospitals, MCOs and private medical practitioners in solo or joint practices to follow the set of guiding principles as far as practicable.

6.28 The Review Committee also considers it desirable for private hospitals to widen the use of information technology in drug handling to enhance efficiency and reduce the chance of human errors.

6.29 The Review Committee **recommends** that DH encourages private hospitals to develop an automated inventory management system and bar-coding system for pharmaceutical products. Private hospitals can devise a computer system for better control on the inventory and drug dispensing, while the use of bar-coding can also be integrated in the drug dispensing and administration activities within the hospital to ensure that the correct drug is being given to the patient. Furthermore, in designing the automated inventory management system, private hospitals can introduce a bar-coding system coding individual product with information on (a) the manufacturer (including repacker or relabeller), (b) the specific strength, dosage form and formulation, and (c) the packaging configuration (pack size and type). If all products are coded in a structured manner, problematic drugs, manufacturers or suppliers can be traced more easily when necessary.