For discussion
on 19 December 2016

LC Paper No. CB(2)386/16-17(03)

Legislative Council Panel on Health Services

Drug Management of the Hospital Authority

Purpose

This paper briefs Members on the drug management system of the Hospital Authority (HA) and HA's action plan to further enhance the system in light of the findings of the value-for-money audit conducted by the Audit Commission on HA's drug management recently.

Background

2. In Hong Kong, public healthcare services are heavily subsidised by the Government. It is the Government's public healthcare policy to ensure that no one is denied adequate medical treatment due to lack of means. As a publicly-funded healthcare services provider, HA strives to provide optimal care for all patients, and drug treatment is an integral part of healthcare services. In 2015-16, the total cost of drugs used by HA patients amounted to $5.71 billion, representing about 10% of HA's total expenditure. The effective management of drugs is therefore of paramount importance in ensuring that public fund is used rationally and efficiently to achieve value for money.

3. The Audit Commission has recently conducted a value for money audit on HA's drug management. Fieldwork was conducted in the HA Head Office and selected public hospitals between February and August 2016. The Director of Audit tabled the Report No. 67 (Audit Report) in the Legislative Council on 23 November 2016. Chapter 5 of the Audit Report (attached at

Annex I) sets out detailed observations and recommendations of the Director of Audit with respect to drug management in HA on the following major areas:

(a) Management of the HA Drug Formulary (HADF)

(b) Procurement of Drugs

(c) Dispensing and Handling of Drugs

(d) Monitoring the Quality of Drugs

(e) Administration of Financial Assistance Programmes for Purchasing Self-financed Drugs

Drug Management in HA

4. The drug management system of HA consists of several major components, namely the management of the HADF, the procurement and quality assurance for drugs as well as the administration of safety net for the provision of financial assistance for needy patients on the use of specific self-financed drugs to meet the clinical needs of patients. Manuals and operation guidelines are in place to elucidate the policies and principles, and to provide guidance on operational practice in drug management across HA institutions.

Management of HADF

5. HA implements the HADF since July 2005 with the aim of ensuring equitable access by patients to cost effective drugs of proven safety and efficacy through standardisation of drug policy and utilisation in all public hospitals and clinics. Its development was underpinned by core values including

evidence-based medical practice, rational use of public resources, targeted subsidy, opportunity cost consideration and facilitation of patients' choice. HADF evolves with regular appraisal of new drugs and review of the prevailing drug list under the established mechanism. The review process follows an evidence-based approach, having regard to the principles of safety, efficacy and cost-effectiveness and taking into account relevant factors, including international recommendations and practices, advance in technology, disease state, patient compliance, quality of life, actual experience in the use of drugs as well as the views of relevant professionals and patient groups.

6. HA has put in place a defined structure to govern the management of HADF. The Drug Management Committee takes charge of overall formulary management with the support of various functional committees at the corporate and cluster levels so as to ensure consistency in policy formulation and implementation across HA and clear accountability for drug management at all levels.

7. To enhance the transparency and communication with stakeholders on HADF management, HA published the HADF Management Manual which is accessible to the public on HA's website and revamped the website on HADF management in July 2015. The Manual gives an explicit account of the overall governance of drug management in HA, elucidates the principles and operational processes of listing new drugs and regular review of the HADF, and describes the consultation, engagement and participation of different stakeholders, including patient groups, in managing the HADF. It serves as a consistent tool for further discussion among stakeholders to improve the management of HADF in future.

8. Over the past decade, HA has been expanding the coverage of HADF in accordance with established mechanism in order to benefit more patients in the use of safe and efficacious drugs at standard fees and charges in public hospitals and clinics. There are currently around 1 300 drugs in the HADF, including 866 General drugs, 352 Special drugs, 69 self-financed drugs without safety net, 26 self-financed drugs covered by Samaritan Fund (SF) and 13 self-financed drugs covered by the Community Care Fund (CCF) Medical Assistance Programme.

Drug Procurement and Quality Assurance

9. HA has an established mechanism for procurement of pharmaceutical products. The HA Procurement and Materials Management Manual, first issued in December 1995 and now in its third edition since July 2015, lays down detailed procedural guidelines on the roles, responsibilities and processes over a wide spectrum of procurement and materials management functions across all HA institutions.

10. To ensure the safety, quality and continuity of supplies of drugs used in public hospitals and clinics, HA has further enhanced various quality assurance measures in a risk-based approach by phases since 2010. These measures include, for example, sample testing of drugs, performance management of pharmaceutical manufacturers and suppliers as well as the enhancement of the drug product quality complaint handling mechanism. Detailed operational procedures have been disseminated to guide frontline reporting and handling of quality and service problems related to pharmaceutical products with due follow-up at the corporate level.

Administering Safety Net for the Use of Self-financed Drugs

11. As a publicly-funded healthcare organisation, HA has to ensure rational use of public resources so as to protect public health and patients' interest. Guided by the principles of evidence-based medical practice, targeted subsidy, opportunity cost consideration and facilitation of patients' choice, self-financed drugs in the HADF are non-standard provisions in HA. For self-financed drugs that are proven to be of significant benefits but extremely expensive for HA to provide as part of its subsidised services or have been rapidly accumulating medical scientific evidence and with relatively higher efficacy, HA provides financial assistance for needy patients through SF and the CCF Medical Assistance Programme. On the other hand, self-financed drugs without safety net are those drugs that have preliminary medical evidence only, drugs with marginal benefits over available alternatives but at significantly higher cost, or lifestyle drugs (e.g. anti-obesity drugs). The therapeutic objectives of these drugs fall outside the scope of highly subsidised public medical services. The provision of self-financed drugs without safety net provides patients with the additional choice of using such drugs at their own expense while continuing their treatment in the highly subsidised public healthcare system.

12. HA has an established mechanism to consider the inclusion of specific self-financed drugs under the coverage of SF and the CCF Medical Assistance Programme regularly. In recent years, in response to patients' opinions and feedback, HA has relaxed the financial assessment criteria for granting financial assistance through re-defining the basis for calculating disposable income and allowable deductions, and expanding the coverage of both SF and the CCF Medical Assistance Programme in order to benefit more patients. Since August 2016, 26 and 13 self-financed drugs have been supported under SF and

the CCF Medical Assistance Programme respectively.

13. Besides, the Government has made several one-off injections, amounting to $11.5 billion in total, in order to meet the rising demand for financial assistance under SF. The amount of financial assistance granted under SF and the CCF Medical Assistance Programme increased from $174.9 million and $10.3 million in 2011-12 to $317.5 million and $156.8 million respectively in 2015-16.

14. In addition, HA has a risk-based system in place to conduct post-approval checks on approved cases with financial assistance granted under SF and the CCF Medical Assistance Programme. The primary objective is to prevent and deter fraud in the use of public fund. With the rollout of various measures including patient education and publicity since 2010, the number of cases involving under-reporting of financial conditions and overpayment of financial assistance had dropped from 27% to 1% in 2015 while the amount of overpayment was reduced from $0.82 million to $0.03 million for those cases with checking completed in the same period.

Support for Patients with Uncommon Disorders

15. There is no common definition of rare diseases worldwide. Drug treatments for uncommon disorders can be extremely expensive, and their efficacy varies among patients under different clinical conditions. In considering whether individual drugs are suitable for listing on the HADF for corporate-wide use benefitting the entire local population, HA follows the core values including evidence-based medical practice, rational use of public resources, targeted subsidy and opportunity cost consideration. The safety, efficacy and cost-effectiveness of drugs would be carefully considered,

alongside other relevant factors, including international recommendations and practices, views of the relevant professionals and patient groups, etc.

16. To ensure optimal and rational use of public resources, HA has put in place an independent expert panel mechanism to formulate treatment protocols for specific uncommon disorders and evaluate the benefits of individualised treatments. Additional annual recurrent funding amounting to $75 million in total has also been allocated by the Government in phases to meet the increasing demand for ultra-expensive drug treatments for uncommon disorders in HA. Currently, the ultra-expensive drug treatments for six types of lysosomol storage disorders (namely, Pompe, Gaucher, Fabry and Mucopolysaccharidosis Types I, II and VI) are provided to individual patients at standard fees and charges if the treatments are proven to be of significant clinical benefits to them.

17. Apart from drug treatments, HA provides other treatments for patients with uncommon disorders, including rehabilitative care, pain alleviation, surgical treatment and bone marrow transplant, irrespective of the number of patients with such uncommon disorders.

18. HA will keep abreast of international researches and development of health policies in other economies in respect of uncommon disorders with a view to enhancing the HADF and optimising the support for local patients. HA is open to suggestions of offering sustainable financial assistance to patients with uncommon disorders and will continue to collaborate with drug companies in providing affordable, sustainable and appropriate support for these patients in the long term.

The Audit Report and HA's Action Plan

19. The Audit Commission has made 33 recommendations which seek to

further enhance HA's current drug management system and practices in its Audit Report at Annex I. HA accepts and welcomes the Audit Report and will continue to further enhance its established drug management system.

20. In response to the recommendations made in the Audit Report, HA has drawn up a list of action items (attached at Annex II) for implementation in phases. The major recommendations and measures are highlighted in the ensuing paragraphs.

Use of Non-HADF Drugs

21. Drugs in the HADF are intended for corporate-wide use benefiting the entire local population. However, there are occasions where the use of non-HADF drugs is required to cater for the clinical needs of individual patients in exceptional circumstances and in emergency or life-threatening situations. The use of non-HADF drugs is an integral part of medical care, and the HADF Management Manual has stipulated the procedures for the handling of non-HADF drugs in public hospitals.

22. The Audit Report recommends that HA should draw up a detailed manual for managing the use of non-HADF drugs and issue comprehensive guidelines on the charging of non-HADF drugs covering different situations. HA will formulate a comprehensive guideline to align the application, approval, documentation and monitoring of the use of non-HADF drugs. In addition, HA will further elaborate the charging principles for use of non-HADF drugs in order to guide decision making in individual clinical situations.

Bulk Contract Arrangement

23. It is HA's established procurement practice to centrally arrange bulk

contracts for suitable drug items so as to save procurement cost and achieve economies of scale. There were progressive annual increases in the number of drug items procured under supply contracts of bulk contract arrangement between 2013-14 and 2015-16, representing an overall increase by 16% in these three years.

24. The Audit Report recommends that HA should review the direct purchase method for items not covered by bulk contracts so as to consider consolidating the demands of individual hospitals for establishing bulk contracts. In line with the current drug procurement strategies, HA will continue to increase bulk contract arrangements for suitable drug items with consumption of over $1.5 million.

Addressing Drug Wastage

25. The growing demand for public healthcare services and the long waiting time for specialist outpatient appointments have brought about lengthened drug supply duration over the years. Patients, especially the elderly and those with multiple drug prescriptions, are exposed to higher medication risks and potential drug wastage due to changes in medical conditions and unplanned re-admissions. Over the years, HA has been exploring different options to minimise potential drug wastage, taking into account patients' acceptability, practicality, technology and resource requirements.

26. The Audit Report recommends that HA should regularly assess the extent and tackle the problem of drug wastage among patients. To address the above-said issues, HA will implement drug refill services by phases to split long-duration prescriptions and provide drug counselling for targeted patients between refills so as to help estimate and reduce the extent of drug wastage and

improve patient care.

Coverage of Safety Net for Use of Self-financed Drugs

27. HA has established mechanism in place for listing new drugs, reviewing the HADF and including specific expensive self-financed drugs under the coverage of the safety net. Over the years, HA has expanded the safety net to cover more self-financed drugs and repositioned certain self-financed drugs with safety net as Special drugs in the HADF which are provided at standard fees and charges in public hospitals.

28. The Audit Report recommends that HA should continue to include appropriate new self-financed drugs under the scope of the safety net. In accordance with the established mechanism, HA will continue to include suitable self-financed drugs in the safety net in light of safety, efficacy and cost-effectiveness considerations and other relevant factors as described in the HADF Management Manual.

Advice Sought

29. Members are invited to note the observations and recommendations made in the Audit Report and HA's action plan as elaborated in the preceding paragraphs.

Food and Health Bureau
Hospital Authority
December 2016

CHAPTER 5

Hospital Authority

Hospital Authority's drug management

Audit Commission
Hong Kong
28 October 2016

This audit review was carried out under a set of guidelines tabled in the Provisional Legislative Council by the Chairman of the Public Accounts Committee on 11 February 1998. The guidelines were agreed between the Public Accounts Committee and the Director of Audit and accepted by the Government of the Hong Kong Special Administrative Region.

Report No. 67 of the Director of Audit contains 10 Chapters which are available on our website at http://www.aud.gov.hk

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HOSPITAL AUTHORITY'S DRUG MANAGEMENT

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HOSPITAL AUTHORITY'S DRUG MANAGEMENT

Executive Summary

1. The Hospital Authority (HA) manages public hospital services in Hong Kong, which are heavily subsidised by the Government. In 2015-16, the HA's total expenditure was $59 billion, mostly funded by subvention from the Government of $52 billion. The provision of drug treatments to patients in accordance with their clinical needs is an integral part of the services of public hospitals and clinics. In 2015-16, the costs of drugs used by HA patients totalled $5,710 million, representing about 10% of HA expenditure. The Audit Commission (Audit) has recently conducted a review of the HA's drug management.

Management of the HA Drug Formulary

2. Each year, the HA dispenses a huge quantity of drugs to patients. Drugs supplied must comply with the HA's standards of product quality, safety and efficacy. Since 2005, the HA has implemented the HA Drug Formulary (HADF) to standardise drug policy and drug utilisation in all public hospitals and clinics, thereby ensuring equitable access by patients to cost-effective drugs of proven safety and efficacy. As at April 2016, the HADF consisted of 1,295 drugs, involving 2,708 drug items. (A drug may be available in different dosage forms, such as in tablet or syrup form of different dosages. Each form is known as a drug item.) The 1,295 drugs comprised 1,218 general or special drugs provided to patients at standard fees and charges, and 77 self-financed drugs that had to be purchased by patients at their own expense. Self-financed drugs are drugs that are of significant or marginal clinical benefits but very costly, drugs that only show preliminary medical evidence on their clinical benefits, safety or efficacy, or lifestyle drugs (such as anti-obesity drugs). Under the HADF mechanism, the HA's Drug Advisory Committee is responsible for evaluating applications for listing new drugs on the HADF, with principal considerations being safety, efficacy and cost-effectiveness. To suit its specific needs, each hospital may select drugs from the HADF to draw up its own formulary, which describes the scope of drugs used in the hospital. A hospital may acquire a new drug not listed on the HADF (non-HADF drug) in emergency/life-threatening situations or specific circumstances.

If it is intended to include the new drug in the HADF, the concerned hospital should follow the normal procedure and submit an application to the Drug Advisory Committee (paras. 1.8, 2.2, 2.4, 2.5, 2.7, 2.8 and 4.3).

3. ***Need to better manage the use of non-HADF drugs.*** According to the HA, while HADF drugs were intended for corporate-wide use benefiting the entire local population, non-HADF drugs were to cater for the clinical needs of individual patients in exceptional situations. In 2015-16, the expenditure on non-HADF drugs totalled $249 million, representing 4.4% of the total drug expenditure of the HA. In 2015-16, 362 non-HADF drug items were used by public hospitals and clinics, up 25% from 290 items in 2013-14. The 362 items comprised 95 items which had been registered in Hong Kong and 267 unregistered ones. Audit noted the following issues: (a) the 362 drug items were not listed on the HADF and may not be made available to patients attending different public hospitals and clinics having the relevant clinical needs; (b) the 95 non-HADF registered drug items involved 73 drugs. For 45 drugs, applications for listing on the HADF had not been made (see para. 5 below). For the other 28 drugs, the Drug Advisory Committee had rejected their applications for listing on the HADF for reasons including insufficient evidence on clinical benefits, efficacy, safety or cost-effectiveness; (c) as the Drug Advisory Committee does not accept applications for listing unregistered drugs on the HADF, the clinical benefits, efficacy, safety and cost-effectiveness of the 267 non-HADF unregistered drug items had not been evaluated by the Committee; and (d) the HA had not provided clear written guidelines for managing the use of non-HADF drugs. Audit visits to hospitals revealed different practices in the approval procedures for the prescription of non-HADF drugs by doctors (paras. 2.10 to 2.19).

4. ***Need to issue guidelines on charging of non-HADF drugs.*** The HA has not laid down any policy or guideline on the charging of non-HADF drugs. Audit visits to hospitals revealed differences in charging practices. In 2015-16, a total of 171,200 prescriptions were issued on the 362 non-HADF drug items. For 5,966 (3.5%) prescriptions, in addition to paying standard fees and charges, the patients were charged for the drugs at cost. For the remaining 165,234 (96.5%) prescriptions, the drugs were covered by standard fees and charges (e.g. included in the standard fee of $45 for general outpatient services) (paras. 2.3 and 2.20 to 2.23).

5. ***Need to encourage and facilitate applications for new drug listing.*** The HA's practice is that applications for new drug listing on the HADF should be initiated by HA clinicians. During 2013-14 to 2015-16, a total of 51 drugs were added to the HADF. Audit noted that only a few HA hospitals and clinics, mainly the leading hospitals, had regularly applied for new drug listing. During the audit visit to a medium-sized hospital, Audit was informed that the hospital had never applied for new drug listing. Audit also noted that no applications for listing on the HADF had been made for 45 non-HADF registered drugs used by public hospitals and clinics in 2015-16 (see para. 3(b) above), although some were in regular demand (paras. 2.30 to 2.33).

Procurement of drugs

6. ***Room for establishing more bulk contracts to achieve better economies of scale.*** The HA Head Office is responsible for establishing bulk contracts for drug items to save procurement costs and achieve economies of scale, including supply contracts established by tender (normally with a three-year term and for drug items with an average annual purchase amount exceeding $500,000). For drug items not covered by bulk contracts, hospitals purchase them directly from suppliers. In 2015-16, of the 2,491 drug items purchased by the HA, 1,472 (59%) were purchased using bulk contracts and 1,019 (41%) were purchased directly by hospitals. Audit analysis of the 1,019 drug items revealed room for procuring 193 drug items (involving $328 million in aggregate) through bulk supply contracts by tender to achieve better value for money (paras. 3.3, 3.4, 3.7, 3.8 and 3.10).

7. ***Room for better managing the risk of supply interruption.*** The HA procures drugs from many suppliers, including Supplier A which accounted for 37% of the amount of procurement in 2015-16. During 2013-14 to 2015-16, the number of complaints about late delivery of drugs by Supplier A increased by 183% from 65 to 184. According to its internal procedure, the HA may convene a Performance Review Group meeting to review a drug supplier's performance in detail for necessary follow-up. However, no such meeting had been held in respect of Supplier A. Audit also noted room for enhancing multi-source procurement of drug items. In 2012, the HA set a guideline that drug items used for the treatment of chronic diseases by more than 100,000 patients annually should be procured from multiple sources. As at July 2016, 13 drug items met the criteria. However, multi-source procurement had been adopted for only 7 of the 13 drug items.

Moreover, although some commonly-used drug items did not meet the current criteria for multi-source procurement, including 34 drug items each used by more than 50,000 patients, the HA should consider the need to implement multi-source procurement for them (paras. 3.14 to 3.20).

Dispensing and handling of drugs

8. ***Need to assess the extent of drug wastage.*** Each year, the HA dispenses a huge quantity of drugs to patients. HA records showed that, in general, the average period of time covered by a prescription (average prescription length) had been increasing. For example, during 2011-12 to 2015-16, the average prescription length for specialist out-patients increased by 7.8 days (10.2%), from 76.4 to 84.2 days. Overseas experience indicated that prescribing large quantities of drugs for a long period of time could lead to drugs being unused and wasted. Audit noted that the HA had not taken steps to assess the extent of drug wastage among patients for taking appropriate measures to tackle the problem (paras. 4.3 to 4.6).

9. ***Need to improve the handling of dangerous drugs.*** Dangerous drugs are drugs or substances specified in the Dangerous Drugs Ordinance (Cap. 134). The Ordinance sets out the rules for controlling the manufacture, supply, possession and administration of dangerous drugs. The number of incidents of missing dangerous drugs in the HA increased from 3 in 2011-12 to 10 in 2015-16, totalling 32 incidents for the 5 years. For each incident, the responsible hospital conducted investigations. However, the direct causes in 27 (84%) incidents could not be identified. Of the 27 incidents, 4 incidents occurred in the same hospital, suggesting that effective improvement measures had not been taken after each incident. Pursuant to the Dangerous Drugs Ordinance, the hospital shall forthwith notify the Department of Health of an incident of missing dangerous drugs. However, of the 32 incidents, Audit found that 5 (16%) had not been reported after a lapse of 425 to 1,494 days since the drugs were found missing. For 5 of the remaining 27 incidents, more than 14 days had been taken to report the incidents (paras. 4.10 and 4.13 to 4.16).

Monitoring the quality of drugs

10. ***Scope for improving sample testing of drugs.*** The HA has commissioned local laboratories to conduct microbiological testing and chemical testing on drugs procured by it. Drugs in general are tested under a sampling programme. During 2013-14 to 2015-16, the amount of drugs procured by the HA increased by 15.4%, from $5,421 million to $6,256 million. However, excluding drugs related to safety alerts or drug quality complaints (tests on them were ad hoc and the number of tests might fluctuate from year to year), the total number of drugs selected for testing decreased by 6.1%, from 773 to 726. The HA had not laid down the drug testing strategy and detailed sampling methodology to justify the scale of drug testing. For testing performed in 2014-15, 41% of the laboratories' reports on testing results were not submitted to the HA within the required time. Late reporting of testing results will cause delay in taking necessary action to mitigate the risk of sub-standard drug items (paras. 5.3 to 5.6).

11. ***Scope for improving investigation of complaints about drug quality.*** The Chief Pharmacist's Office of the HA is responsible for reviewing and following up drug quality complaints received from frontline hospitals and clinics. It will request suppliers to investigate the issue and propose improvement measures where necessary. Audit analysis of 240 complaint cases in 2015-16 revealed that in 24 cases, the HA took more than 6 months to complete the investigations. Audit noted that many suppliers had failed to provide investigation reports to the HA within the required time frame of one month, which could be a factor causing the long time taken to complete some investigations by the HA. The HA needs to ensure that investigations of drug quality complaints are completed as soon as possible, with a view to taking timely remedial action where necessary (paras. 5.14 to 5.16).

Administering financial assistance programmes for purchasing self-financed drugs

12. ***Expanding coverage of drugs.*** The HA is responsible for administering two financial assistance programmes (funded by the Samaritan Fund and the Community Care Fund respectively) to provide subsidies to needy patients for purchasing self-financed drugs covered by the programmes. As at April 2016, of the 77 self-financed drugs listed on the HADF (see para. 2 above), 30 were covered by the programmes (referred to as self-financed drugs with safety net) and 47 were not (referred to as self-financed drugs without safety net). Audit noted that many

patients needed self-financed drugs without safety net for treatment (e.g. a total of 589,000 items were prescribed to HA out-patients in 2014-15). From time to time, there have been requests from patients and patient groups for expanding the coverage of the safety net to benefit more patients (e.g. drugs for treatment of certain cancers). The HA should continue its efforts to prioritise new drugs to be included under the scope of the safety net (paras. 6.3, 6.4 and 6.7 to 6.9).

13. ***Enhancing post-approval checks.*** The subsidies under the financial assistance programmes are provided only for needy patients. To prevent and detect fraud and abuse and to take appropriate action against suspect who commits deception related offence, the HA conducts sample checks on approved financial assistance cases. During 2010-11 to 2015-16, of the 1,369 cases with checks completed, under-reporting of income and/or assets had been found in 591 (43%) cases, involving overpayments of $5.4 million in subsidies. Audit examination revealed inadequacies in the conduct of checking (e.g. limited scope of checking), which might have affected the checking results (paras. 6.13 to 6.22).

Audit recommendations

14. **Audit recommendations are made in the respective sections of this Audit Report. Only the key ones are highlighted in this Executive Summary. Audit has *recommended* that the Chief Executive, HA should:**

Management of the HADF

(a) **review what measures need to be implemented to ensure that patients attending different public hospitals and clinics have equitable access to non-HADF drugs when they have the relevant clinical needs (para. 2.28(a));**

(b) **consider drawing up a detailed manual for managing the use of non-HADF drugs and ensure compliance (para. 2.28(c));**

(c) **issue comprehensive guidelines on the charging of non-HADF drugs covering different situations and ensure compliance (para. 2.28(d));**

(d) **encourage and facilitate more HA hospitals and clinics to apply for new drug listing on the HADF (para. 2.35(b));**

Procurement of drugs

(e) **set up an effective mechanism for regularly analysing hospitals' demand for drug items not covered by bulk contracts to determine whether bulk contracts should be used to achieve the best value for money (para. 3.12(c));**

(f) **closely monitor the performance of drug suppliers in complying with delivery schedules and take effective follow-up action on delivery complaints received from hospitals (para. 3.25(a));**

(g) **assess the risk and impact of supply disruption for commonly-used drug items to determine whether multi-source procurement should be implemented for them (para. 3.25(c) and (d));**

Dispensing and handling of drugs

(h) **regularly assess the extent of drug wastage among patients of the HA, and take appropriate measures to tackle the problem (para. 4.8);**

(i) **conduct a comprehensive review of the handling and custody of dangerous drugs where necessary, issue guidelines on the investigation of incidents of missing dangerous drugs and ensure that such incidents are forthwith reported to the Department of Health (para. 4.17(a), (c) and (d));**

Monitoring the quality of drugs

(j) **formulate a strategy for sample testing of drugs and lay down clearly the sampling methodology for implementing the strategy (para. 5.7(a) and (b));**

(k) **ensure that contractors submit reports on drug testing according to the time frame set out in the contracts (para. 5.7(c));**

(l) **ensure that investigations of complaints about drug quality are completed as soon as possible (para. 5.17);**

Administering financial assistance programmes for purchasing self-financed drugs

(m) **continue to include appropriate new self-financed drugs under the scope of the safety net (para. 6.10); and**

(n) **explore expanding the scope of post-approval checks on financial assistance cases and take improvement measures on the long time taken to follow up some significant cases of under-reporting of income and/or assets (para. 6.23(b) and (d)).**

Response from the Hospital Authority

15. The Chief Executive, HA has said that the HA agrees with the audit recommendations.

PART 1: INTRODUCTION

1.1 This PART describes the background to the audit and outlines the audit objectives and scope.

1.2 In Hong Kong, services at public hospitals and clinics are heavily subsidised by the Government. It is the Government's public healthcare policy to ensure that no one is prevented from obtaining adequate medical treatment because of the lack of means.

Hospital Authority

1.3 The Hospital Authority (HA) is a statutory body established under the Hospital Authority Ordinance (Cap. 113). The HA Board consists of 28 members, comprising 24 non-official members (including the Chairman), three public officers (i.e. Permanent Secretary for Food and Health (Health), Director of Health and Deputy Secretary for Financial Services and the Treasury (Treasury)) and one principal officer (i.e. the HA Chief Executive). Since December 1990, the HA has been managing public hospital services in Hong Kong (Note 1). In 2015-16, the expenditure of the HA totalled $59 billion, mostly funded by subvention from the Government of $52 billion. The Food and Health Bureau, which is responsible for formulating overall health policies for Hong Kong, subvents the HA to provide the services.

Note 1: *The HA's functions include:*

(a) managing and controlling public hospitals;

(b) advising the Government of the needs of the public for hospital services and of the resources required to meet those needs;

(c) managing and developing the public hospital system; and

(d) recommending to the Government appropriate policies on fees for the use of hospital services by the public.

1.4 As at June 2016, the HA managed 41 public hospitals and institutions (collectively referred to as "hospitals" hereinafter). The hospitals were organised into seven clusters, serving different catchment areas over the territory:

(a) ***Hong Kong.*** The 2 clusters were Hong Kong East (7 hospitals) and Hong Kong West (7 hospitals);

(b) ***Kowloon.*** The 3 clusters were Kowloon East (3 hospitals), Kowloon Central (5 hospitals) and Kowloon West (8 hospitals); and

(c) ***New Territories.*** The 2 clusters were New Territories East (7 hospitals) and New Territories West (4 hospitals).

Operating in the clusters were also 73 general out-patient clinics providing community-based primary care services, and 47 specialist clinics providing specialist consultation, treatment and investigation services. A total of about 71,000 HA staff were working at the HA headquarters (HA Head Office) and the seven clusters.

HA Drug Formulary

1.5 The provision of drug treatments to patients in accordance with their clinical needs is an essential part of patient care. This is also an integral part of the services of public hospitals and clinics.

1.6 The World Health Organisation has been actively promoting the concept of "essential medicine". It recommends that health authorities around the world establish their own mechanisms for systematic selection of drugs to promote availability, accessibility, affordability, quality and rational use of medicines. The HA embarked on the development of the HA Drug Formulary (HADF) in 2003, based on the guiding principle that public resources should be used to maximise the effects of healthcare and provide equitable access for all patients.

1.7 Since July 2005, the HA has implemented the HADF in all public hospitals and clinics. The objectives are to standardise drug policy and drug utilisation in all public hospitals and clinics, thereby ensuring equitable access by patients to cost-effective drugs of proven safety and efficacy. As at April 2016, 1,295 drugs were listed on the HADF.

Drug procurement

1.8 Drugs supplied to the HA must comply with its quality requirements, in particular:

(a) drugs supplied to the HA should meet product registration requirements according to the laws of Hong Kong (Note 2);

(b) the manufacturing sites of drug manufacturers should meet the Good Manufacturing Practices (Note 3) requirements; and

(c) complete product specific information (Note 4) should be provided to the HA for evaluation of product quality, safety and efficacy for HA operation.

Note 2: *In Hong Kong, it is a legal requirement that drugs must be registered by specified persons (e.g. licensed manufacturer or licensed wholesale dealer) with the Pharmacy and Poisons Board established under the Pharmacy and Poisons Ordinance (Cap. 138). As at 31 December 2015, there were 19,489 drug items registered in Hong Kong.*

Note 3: *The Good Manufacturing Practices is a system of manufacturing practices for ensuring that pharmaceutical products are consistently produced and controlled according to quality standards appropriate to their intended use as required by the product specifications.*

Note 4: *The required product specific information includes product master formula, finished product specifications and stability data, and bioequivalence data for generic drugs demonstrating comparable efficacy as the proprietary drugs.*

1.9 The Chief Pharmacist's Office of the HA oversees pharmaceutical service deliveries in the HA including drug procurement. In collaboration with the pharmaceutical supplies team of the Procurement and Materials Management Section, bulk contracts are established for the procurement of drugs, and safety and quality of drugs as well as the performance of drug suppliers are monitored. In 2015-16, the relevant staff cost of the Chief Pharmacist's Office in overall drug management was about $55 million, and that for the pharmaceutical supplies team was about $8.8 million. The total amount of drugs procured in 2015-16 was $6,256 million. Appendix A shows the specific offices and sections of the HA Head Office which are involved in drug management (including drug quality management and procurement). PART 2 and Appendix B provide an overview of the HA's drug management.

Drug consumption

1.10 Pharmacies of HA hospitals and clinics provide pharmaceutical care services, including dispensing of drugs. As at 31 March 2016, there were 2,208 staff working in the hospital and clinic pharmacies. The related staff cost in 2015-16 was $1,193 million. In 2015-16, the costs of drugs used by HA patients totalled $5,710 million, around 10% of the total expenditure of the HA.

Audit review

1.11 In January 2016, the Audit Commission (Audit) commenced a review of the HA's drug management. In the review, Audit has examined the work performed by the HA Head Office and visited four of the 41 HA hospitals. The four hospitals comprised Hospital A located in Hong Kong, Hospitals B and C located in Kowloon and Hospital D located in the New Territories, involving four of the seven hospital clusters. The review has focused on the following areas:

(a) management of the HADF (PART 2);

(b) procurement of drugs (PART 3);

(c) dispensing and handling of drugs (PART 4);

(d) monitoring the quality of drugs (PART 5); and

(e) administering financial assistance programmes for purchasing self-financed drugs (PART 6).

Audit has found room for improvement in the above areas and has made a number of recommendations to address the issues.

General response from the Hospital Authority

1.12 The Chief Executive, HA has said that the HA agrees with the audit recommendations. He has also said that the HA expresses sincere gratitude for Audit's efforts and positive recommendations for enhancing the drug management in the HA.

Acknowledgement

1.13 Audit would like to acknowledge with gratitude the assistance and full cooperation of the staff of the HA during the course of the audit review.

PART 2: MANAGEMENT OF THE HOSPITAL AUTHORITY DRUG FORMULARY

2.1 This PART examines the management of the HADF. Audit has found room for improvement in the following areas:

(a) managing the use of drugs not listed on the HADF (paras. 2.10 to 2.29);

(b) listing new drugs (paras. 2.30 to 2.36); and

(c) deleting obsolete drugs (paras. 2.37 to 2.40).

HADF

2.2 The HADF was first implemented in 2005, then consisting of 1,370 drugs. Over the years, new drugs have been listed and obsolete drugs deleted from the HADF. As at April 2016, the HADF consisted of 1,295 drugs grouped into four categories (Note 5). Table 1 shows the nature and the HA's charging policy for each drug category.

Note 5: *A drug may be available in different dosage forms (e.g. in tablet or syrup form of different dosages). Each form is known as a "drug item". As at April 2016, the HADF consisted of 1,295 drugs. In terms of drug items, it consisted of 2,708 drug items.*

Table 1

Drugs listed on the HADF
(April 2016)

Category	Nature and charging policy	No. of drugs
General drugs	• available for general use as indicated by patients with relevant clinical indications • provided at standard fees and charges in public hospitals and clinics (see para. 2.3)	879
Special drugs	• used under specific clinical conditions with specific specialist authorisation • provided at standard fees and charges in public hospitals and clinics (see para. 2.3)	339
Self-financed drugs with safety net (Note)	• not covered by the standard fees and charges in public hospitals and clinics • patients who require these drugs have to purchase them at their own expense • a safety net is provided through two Government funds (see para. 6.3) to subsidise the drug expenses of needy patients	30
Self-financed drugs without safety net (Note)	• not covered by the standard fees and charges in public hospitals and clinics • patients who require these drugs have to purchase them at their own expense • no safety net is provided	47
	Total	1,295

Source: HA records

Note: According to the HA, self-financed drugs include: (a) drugs that are of significant clinical benefits but extremely expensive for the HA to provide as part of its standard services; (b) drugs with preliminary medical evidence only; (c) drugs with marginal benefits over available alternatives but at significant higher costs; and (d) lifestyle drugs (e.g. anti-obesity drugs). As at April 2016, of the 77 self-financed drugs (i.e. 30 plus 47), 37 were drugs for treatment of certain cancers.

Drug charges

2.3 HA standard services rendered in the context of public services are covered by fixed package rates (e.g. included in the standard attendance fee of $45 for general outpatient services for eligible persons — Note 6). The package rates are set on a highly subsidised basis for eligible persons and on a full cost recovery basis for non-eligible persons. General drugs and special drugs on the HADF are covered by the fixed package rates, except that eligible persons attending specialist clinics for public services are also charged $10 for each drug item (up to 16 weeks) on the prescription. Self-financed drugs purchased from public hospitals and clinics (Note 7) are charged at the HA's purchase cost. For other self-financed drugs, patients need to purchase them from the market.

Objectives of implementing the HADF

2.4 The objectives of implementing the HADF are to standardise drug policy and drug utilisation in all public hospitals and clinics, thereby ensuring equitable access by patients to cost-effective drugs of proven safety and efficacy.

Governance of the HADF

2.5 ***Drug Management Committee.*** The Drug Management Committee, which reports to the HA's Directors' Meeting, is responsible for overall drug management in the HA, including the management of the HADF (Note 8). It is supported by the following 2 functional committees and 21 panels (see Appendix B):

Note 6: *Eligible persons include holders of Hong Kong Identity Card, and children who are Hong Kong residents and under 11 years of age.*

Note 7: *The HA supplies some self-financed drugs at cost for purchase by patients, including those with safety net, supplied for operational reasons (e.g. used by inpatients and day patients) or not easily accessible in community pharmacies.*

Note 8: *The Drug Management Committee is chaired by the Director (Cluster Services) of the HA. Committee members include Chairmen of functional committees, HA staff and academics from local universities.*

(a) ***Drug Advisory Committee.*** The Committee is responsible for evaluating applications for listing new drugs/indications on the HADF (Note 9). The principal considerations for listing new drugs include safety, efficacy and cost-effectiveness. For drugs evaluated with positive recommendations, the Committee will also decide on the category of the drugs for listing as general drugs, special drugs or self-financed drugs on the HADF. The Committee meets once every three months;

(b) ***Drug Formulary Committee.*** The Committee is responsible for conducting biennial comprehensive review of the existing drug list and prescribing indications in the HADF (Note 10). It may propose changes such as repositioning of drugs across categories, relaxation of prescribing indications for special drugs and deletion of drugs; and

(c) ***Expert Panels.*** Expert Panels provide specialist advice on selection of drugs and furnish professional views for review of existing drugs in related speciality areas (see (a) and (b) above). As at May 2016, there were 21 Expert Panels dealing with different specialty areas (e.g. dermatology, oncology and surgery) (Note 11).

Headed by the Chief Pharmacist who reports to the Director (Cluster Services), the Chief Pharmacist's Office at the HA Head Office provides professional and secretariat support for the Drug Management Committee and its functional committees and panels.

Note 9: *The Drug Advisory Committee is chaired by a senior management executive of the HA. Committee members include members from Expert Panels, HA staff and academics from local universities.*

Note 10: *The Drug Formulary Committee is chaired by one of the chairmen of the cluster Drug and Therapeutics Committees (see para. 2.6). Committee members include the remaining chairmen of the cluster Drug and Therapeutics Committees and HA staff.*

Note 11: *Expert Panels are convened by the Chairman of the Drug Formulary Committee and the Chief Pharmacist of the HA. Panel members include specialist representatives of HA clusters.*

2.6 ***Drug and Therapeutics Committees (DTCs).*** For each of the seven clusters (see para. 1.4), a Drug and Therapeutics Committee (cluster DTC) is established. DTCs are also established in some hospitals (hospital DTCs). The cluster and hospital DTCs (Note 12) play an essential supportive role in the management of the HADF, including:

(a) implementing policies/guidelines of the Drug Management Committee;

(b) endorsing cluster/hospital applications for new drug listing before submission to the Drug Advisory Committee; and

(c) managing hospital formulary (see para. 2.7) and regularly reviewing the need for non-HADF drugs (see para. 2.8).

2.7 ***Hospital formulary.*** New drugs are listed on the HADF after evaluation by the Drug Advisory Committee as cost-effective drugs of proven safety and efficacy. Under the HADF mechanism, to suit its specific needs, each hospital may select drugs from the HADF to draw up its own formulary, which describes the scope of drugs used in the hospital.

2.8 ***Non-HADF drugs.*** A hospital may, at its discretion, acquire a new drug not listed on the HADF that is required in emergency/life-threatening situations or specific circumstances through urgent request. Examples of these situations are as follows:

(a) drugs that await the Drug Advisory Committee's evaluation but are required for urgent use;

(b) drugs that are required for urgent use but for which an application is yet to be submitted for the Drug Advisory Committee's evaluation; and

(c) drugs that are required for one-off use in urgent situations.

Note 12: *A cluster DTC is chaired by the Chief Executive or his/her delegate of the cluster, while a hospital DTC is chaired by the Chief Executive or his/her delegate of the hospital. Members of the cluster and hospital DTCs are HA staff.*

If it is intended to include the new drug in the HADF, the concerned cluster/hospital should follow the normal procedure and submit an application to the Drug Advisory Committee.

2.9 ***Unregistered drugs.*** The Drug Advisory Committee does not accept applications for listing drugs which are not registered in Hong Kong (see Note 2 to para. 1.8(a)) on the HADF. If an unregistered drug is required for use on certain named patients (i.e. names of patients must be provided), the concerned clinician must obtain prior endorsement from the respective Cluster/Hospital DTC via the Chief of Service of related specialties. The clinician should inform the concerned patients on the use of unregistered products and that adverse effects of drug use would be monitored and reported. Upon enquiry, the Department of Health informed Audit in September 2016 that:

(a) according to the Pharmacy and Poisons Regulations (Cap. 138A), all pharmaceutical products had to be registered with the Pharmacy and Poisons Board before they could be sold, offered for sale or distributed or possessed for the purposes of sale, distribution or other use in Hong Kong. However, the above requirement did not apply in the case of possession or use where the pharmaceutical product was possessed or was to be used for the purpose of treatment of a particular patient by a registered medical practitioner;

(b) importation of pharmaceutical products into Hong Kong, whether they were registered or unregistered, had to be accompanied by import licences issued by the Department of Health; and

(c) for importation of an unregistered pharmaceutical product, supporting documents, such as letter of a registered doctor stating the drug's name, required quantity and patient's information, certificate of analysis of the drug issued by the manufacturer, product information, proof of registration of the drug in overseas, etc., were required for consideration by the Department. If the unregistered drug was used by the HA, additional documents (i.e. endorsement by hospital management on the use of the unregistered drug, and acknowledgement from hospital pharmacy on the use of unregistered drug) were required.

Managing the use of drugs not listed on the Hospital Authority Drug Formulary

Increasing use of non-HADF drugs in public hospitals and clinics

2.10 As mentioned in paragraph 2.4, one of the objectives of implementing the HADF is to standardise drug utilisation in all public hospitals and clinics. This ensures that patients attending different public hospitals and clinics have equitable access to cost-effective drugs of proven safety and efficacy as listed on the HADF. However, Audit analysis of HA records revealed that, in the past three years (2013-14 to 2015-16), there had been an increasing use of non-HADF drugs by public hospitals and clinics (see Table 2). Compared to 2013-14, the expenditure on non-HADF drugs increased by 180% to $249 million and represented 4.4% of the total drug expenditure of the HA. Upon enquiry, the HA informed Audit in September 2016 that:

(a) the increase in use of non-HADF drugs was due to the advancement in technologies with more new drugs coming into the market and these were usually very expensive. The efficacy, safety and cost-effectiveness of these drugs varied. These drugs might not be registered drugs or might not fulfil the criteria for incorporation into the HADF. However, their use on individual basis based on clinical needs was still justifiable; and

(b) HADF drugs were intended for corporate-wide use benefiting the entire local population while non-HADF drugs were to cater for the clinical needs of individual patients in exceptional situations. The inclusion of non-HADF drugs in the HA drug policy was to bridge the gap between the population and individual needs and to manage urgent situations to ensure patients were provided with appropriate clinical care. The use of non-HADF drugs was an integral part of medical care, accounting for 0.3% of the total number of drug items dispensed in the HA in 2015-16.

Table 2

Non-HADF drug items used by public hospitals and clinics (2013-14 to 2015-16)

	2013-14	2014-15	2015-16	Increase from 2013-14 to 2015-16
No. of non-HADF drug items used				
Registered drug items	71	86	95	24 (34%)
Unregistered drug items	219	260	267	48 (22%)
Overall	290	346	362	72 (25%)
HA expenditure on non-HADF drug items used ($ million)				
Registered drug items	45	103	180	135 (300%)
Unregistered drug items	44	57	69	25 (57%)
Overall	89	160	249	160 (180%)
Total HA drug expenditure ($ million)	4,941	5,328	5,710	
Expenditure on non-HADF drug items as a percentage of total drug expenditure	1.8%	3.0%	4.4%	

Source: Audit analysis of HA records

Need to ensure that non-HADF drugs are accessible to patients with relevant clinical needs

2.11 Under the HADF mechanism, non-HADF drugs are used in emergency/life-threatening situations or specific circumstances through urgent request, and where appropriate, actions should be taken to list them on the HADF (see para. 2.8). For drugs listed on the HADF, patients with the same clinical needs could have access to the drugs in all public hospitals and clinics, and would be subject to the same charging policy for the drugs as determined by the category in which they are listed (see Table 1 in para. 2.2). Audit analysis of the 362 non-HADF drug items used in 2015-16 revealed that:

(a) for 57 (16%) registered drug items (involving 45 drugs), applications for new drug listing on the HADF had not been made (see para. 2.33);

(b) for 38 (10%) registered drug items (involving 28 drugs), applications for new drug listing on the HADF had not been successful (see para. 2.12); and

(c) for the remaining 267 (74%) items (involving 222 drugs), they were unregistered drugs and no applications for listing them on the HADF would be accepted by the Drug Advisory Committee (see para. 2.17).

The HA needs to implement measures to ensure that individual patients attending different public hospitals and clinics have equitable access to non-HADF drugs when they have the relevant clinical needs.

Some non-HADF drugs used by public hospitals and clinics had failed new drug evaluation by Drug Advisory Committee

2.12 The 95 non-HADF registered drug items used in 2015-16 (see Table 2) involved 73 drugs (see para. 2.11(a) and (b)). For 28 of these 73 drugs, applications for listing on the HADF had been made during the seven-year period January 2009 to January 2016 one to four times. However, all the 28 drugs had failed the Drug Advisory Committee's new drug evaluation, including 12 drugs which had failed more than one time (see Table 3).

Table 3

28 non-HADF drugs had failed new drug evaluation by Drug Advisory Committee (January 2009 to January 2016)

No. of times applications had been submitted and rejected	No. of drugs	
1	16	
2	7	12
3	4	
4	1	
Total	28	

Source: Audit analysis of HA records

2.13 Audit noted that the Drug Advisory Committee had stated the following reasons for rejecting the applications:

(a) for 10 drugs, alternative drugs were available on the HADF with comparable benefits;

(b) for 13 drugs, there was insufficient evidence to demonstrate the clinical benefits, efficacy or safety of the drugs; and

(c) for 17 drugs, there was insufficient justification of the treatment cost in relation to the benefits.

2.14 Upon enquiry, the HA informed Audit in September 2016 that the Drug Advisory Committee approved HADF drugs that were intended for corporate-wide use for the benefit of the general patient population (see para. 2.10(b)). However, drugs rejected by the Drug Advisory Committee might be necessary for the clinical benefits of individual patients. The number of patients using non-HADF drugs was very small. For example, for the 10 drugs mentioned in paragraph 2.13(a), the number of patients involved ranged from 9 to 198.

2.15 In the visits to the four hospitals (see para. 1.11) during May and June 2016, Audit noted different practices for approving the prescription of non-HADF drugs by doctors. For three hospitals, the relevant doctors had to obtain written approval (e.g. from the Chief of Service) for using a non-HADF drug. For the remaining hospital, its guidelines only specified that written approval was required for acquiring a new drug for one-off use in urgent situation.

2.16 In Audit's view, the continual use of the 28 non-HADF drugs that had failed the Drug Advisory Committee's new drug evaluation should be reviewed regularly because, according to the Committee's comments, comparable drugs on the HADF could have been used instead (see para. 2.13(a)), or there was insufficient evidence on their clinical benefits, efficacy, safety or cost-effectiveness (see para. 2.13(b) and (c)).

Prior endorsement for the use of some non-HADF unregistered drugs not sought or documented

2.17 The non-HADF drug items used in 2015-16 included 267 unregistered drug items (see Table 2 in para. 2.10). The Drug Advisory Committee does not accept applications for listing unregistered drugs on the HADF. As a result, unlike drugs listed on the HADF, the clinical benefits, efficacy, safety and cost-effectiveness of these drugs had not been evaluated by the Committee. Upon enquiry, the HA informed Audit in May and September 2016 that:

(a) the use of unregistered drugs was allowed for certain individual patients who demonstrated a clinical need. They were normally used on a named-patient basis (see para. 2.9) when no registered drugs could provide an alternative to the treatment. The use of unregistered drugs would need to bring about clinical benefits to specific patients;

(b) the prescribing doctor was required to obtain prior endorsement from the respective Cluster/Hospital DTC via the Chief of Service (see para. 2.9); and

(c) approval of the Department of Health would be obtained on a case-by-case basis for importing the unregistered drugs from places outside Hong Kong.

2.18 For 13 unregistered drug items (about 5% of the 267 unregistered drug items used in 2015-16), Audit examined the 44 prescriptions issued in 2015-16 on them (involving eight hospitals) and noted the following issues:

(a) ***Prior endorsement not sought.*** In 19 (43%) cases, the requirement of seeking prior endorsement for using unregistered drugs (see para. 2.17(b)) had not been met, as follows:

  (i) ***Endorsement not sought.*** In 16 (36%) cases, there were no records of endorsement for using the unregistered drugs; and

  (ii) ***Only covering endorsement sought.*** In 3 (7%) cases, endorsement for using the unregistered drugs was sought only after the drugs had been prescribed; and

(b) ***Prior endorsement sought.*** In the remaining 25 (57%) cases, prior endorsement for using the unregistered drugs had been sought.

Moreover, the HA could not provide Audit with records of approval by the Department of Health (see para. 2.17(c)) for 30 (68%) of the 44 cases.

2.19 Audit notes that while the HA has issued a detailed HADF Management Manual to give an account of the governance structure and elucidate the principles and operational procedures for managing the HADF (Note 13), there is no similar detailed manual for non-HADF drugs (registered or unregistered drugs). In Audit's view, such manual is useful for managing the use of non-HADF drugs properly.

Note 13: *The HADF Management Manual contains a section on handling of non-HADF drugs by local hospitals (see para. 2.8).*

Patients prescribed with non-HADF drugs in public hospitals and clinics might be charged differently

2.20 The HA's drug charging policies/guidelines are summarised as follows:

Immediate life-threatening emergency situations

(a) the HA has issued a guideline on the charging principle for use of drugs in all immediate life-threatening emergency situations. The guideline states that a drug given under immediate life-threatening emergency situation deemed necessary by the clinician should not be charged outside the standard fees and charges. The guideline applies to all drugs; and

Other situations

(b) for cases other than immediate life-threatening emergency situations, the HA's drug charging policies/guidelines are as follows:

(i) ***Drugs listed on the HADF.*** As mentioned in paragraph 2.3, general drugs and special drugs are provided to patients at standard fees and charges, and self-financed drugs (with or without safety net) provided to patients are charged at cost; and

(ii) ***Non-HADF drugs.*** The HA has not laid down a policy or guidelines on the charging of non-HADF drugs.

2.21 In 2015-16, 362 non-HADF drug items were used by HA hospitals and clinics (see Table 2 in para. 2.10), involving a total of 171,200 prescriptions. For 5,966 (3.5%) prescriptions, in addition to paying standard fees and charges (i.e. fixed package rates — see para. 2.3), the patients were charged for the drugs at cost (i.e. similar to self-financed drugs). For the remaining 165,234 (96.5%) prescriptions, the drugs were covered by standard fees and charges (i.e. similar to general drugs and special drugs). Table 4 shows the details.

Table 4

Charging of non-HADF drugs
(2015-16)

Drug item	No. of prescriptions		
	Issued	With non-HADF drugs charged at cost	With non-HADF drugs covered by standard fees and charges
95 non-HADF registered drug items	47,378 (100%)	4,364 (9.2%)	43,014 (90.8%)
267 non-HADF unregistered drug items	123,822 (100%)	1,602 (1.3%)	122,220 (98.7%)
362 non-HADF drug items	171,200 (100%)	5,966 (3.5%)	165,234 (96.5%)

Source: HA records

2.22 Upon enquiry, the HA informed Audit in September 2016 that doctors could propose and recommend whether or not non-HADF drugs were to be charged at cost. The application would be decided and approved by the local DTC depending on the necessity for use.

2.23 As mentioned in paragraph 2.15, in the visits to the four hospitals, Audit noted different practices for approving the prescription of non-HADF drugs. Regarding charging of the drugs, Audit also noted different practices. For two hospitals, the application form for seeking approval for prescribing non-HADF drugs required the relevant doctors to propose whether or not to charge the patient for the drugs in a similar way as self-financed drugs. For the other two hospitals, the application form did not require the relevant doctors to make such proposal.

2.24 In the absence of any policy or guideline on the charging of non-HADF drugs for cases other than immediate life-threatening emergency situations, patients with the same clinical conditions, in the same hospital or in different hospitals, may or may not be required to pay for the cost of a non-HADF drug.

Different versions of hospital formularies

2.25 Drugs listed on the HADF are grouped under four categories with different charging policies (see para. 2.2). In the visits to the four hospitals, at Audit's request, the hospitals provided a copy of their hospital formularies for audit examination. Audit noted that, for Hospitals B, C and D, the categories of some drug items in the formularies provided to Audit were different from those specified in the HADF. Examples are as follows:

(a) "***Special drugs" misclassified as "general drugs".*** 3 drug items specified as "special drugs" in the HADF were misclassified as "general drugs" in Hospital C formulary;

(b) ***"Self-financed drugs without safety net" misclassified as "special drugs".*** 6 drug items specified as "self-financed drugs without safety net" in the HADF were misclassified as "special drugs" in Hospital B formulary; and

(c) ***Items of non-HADF drugs misclassified as "general drugs".*** In Hospital C formulary, 5 non-HADF drug items were misclassified as "general drugs".

2.26 Upon enquiry, the HA informed Audit in September 2016 of the following:

(a) ***Hospital formularies for communication purpose.*** The hospital formularies provided to Audit were used by the hospitals for internal communication. They showed hospital clinical staff which drugs were enlisted in the hospitals for service provision. Hospitals prepared such formularies manually, thus leading to the observed variances; and

(b) ***Hospital formularies for operation purpose.*** The hospital formularies used for daily operation (e.g. for dispensing drugs and charging patients) were incorporated in the local computer system, which was linked up to the central computer system of the HA. Both systems were synchronised without any discrepancies.

2.27 The hospital formulary describes the scope of drugs used in a hospital (see para. 2.7). The HA needs to ensure that the categories of drugs are correctly shown on the hospital formulary for communication purpose.

Audit recommendations

2.28 **Audit has *recommended* that the Chief Executive, HA should:**

(a) **review what measures need to be implemented to ensure that patients attending different public hospitals and clinics have equitable access to non-HADF drugs when they have the relevant clinical needs;**

(b) **regularly review the need for the continued use of non-HADF drugs which had failed the Drug Advisory Committee's new drug evaluation;**

(c) **consider drawing up a detailed manual for managing the use of non-HADF drugs, and ensure compliance with the relevant provisions including the approval procedure for prescribing non-HADF drugs;**

(d) **issue comprehensive guidelines on the charging of non-HADF drugs covering different situations, and ensure compliance with the guidelines; and**

(e) **ensure that the drug classifications in hospital formularies for communication uses by clinical staff tally with those specified in the HADF.**

Response from the Hospital Authority

2.29 The Chief Executive, HA has said that the HA agrees with the audit recommendations. He has also said that the HA will:

(a) share information among hospitals to facilitate cross referencing in the use of non-HADF drugs;

(b) set up a mechanism to monitor and analyse the use of non-HADF drugs, and evaluate the need for continual use;

(c) formulate a guideline on the use of non-HADF drugs to align their application, approval, documentation and monitoring. The existing section on non-HADF drugs in the HADF Management Manual will be expanded into a new chapter in the next revised version;

(d) explicitly define the charging principles through expanding the existing guideline on the use of immediate life-threatening emergency drugs to cover non-HADF drugs as well, taking into consideration whether it is clinical need or patient's choice; and

(e) develop a system function for auto-generation of the communication document on hospital drug formulary containing real-time information in a standard format.

Listing new drugs

2.30 As a publicly-funded healthcare service provider, the HA considers that the coverage of the HADF should be driven by service needs, and applications for new drug listing should be initiated by HA clinicians and submitted to the Drug Advisory Committee for consideration via the cluster/hospital DTC. The Committee does not accept new drug applications submitted by pharmaceutical companies.

Few hospitals regularly applied for new drug listing

2.31 Audit noted that a large number of new drugs were registered in Hong Kong each year (Note 14). While the HA's practice is that applications for new drug listing on the HADF should be initiated by HA clinicians, Audit examination revealed that few HA hospitals and clinics had regularly applied for new drug listing. Those that applied were mainly the leading hospitals. For example, during the visit to Hospital C which was a medium-sized hospital, Audit was informed that the Hospital had never applied for new drug listing. During 2013-14 to 2015-16, a total of 51 drugs were added to the HADF. The applications for listing these 51 drugs came from 12 hospitals (i.e. Hospitals A, B and D to M) (see Table 5 — Note 15). Of the 12 hospitals, 4 submitted applications for 29 (57%) drugs. These 4 hospitals (namely Hospitals A, B, D and E) were leading hospitals.

Note 14: *As at 31 December 2015, there were 19,489 drug items registered in Hong Kong. Between 2013 and 2015, there were on average 850 new drug items registered each year.*

Note 15: *The HA had a total of 161 hospitals and clinics (i.e. 41 public hospitals, 73 general out-patient clinics and 47 specialist clinics).*

Table 5

Analysis of 51 new drugs listed on the HADF
(2013-14 to 2015-16)

Hospitals which applied for new drug listing	No. of new drugs	
Hospital A	12 (23%)	29 (57%)
Hospital D	9 (18%)	
Hospital B	5 (10%)	
Hospital E	3 (6%)	
Hospital F	2 (4%)	
Hospitals G, H, I and J	4 (8%)	
Hospitals K, L and M in collaboration with other hospitals (Note)	16 (31%)	
Total	51 (100%)	

Source: *Audit analysis of HA records*

Note: *The other hospitals comprised Hospitals A, B, D, E, F, G, H and J.*

Remarks: *For the 51 new drugs listed, there were 81 drug items.*

2.32 Upon enquiry, the HA informed Audit in September 2016 that:

(a) all hospital DTCs could submit new drug applications. Cluster DTCs usually covered the need for new drug applications for their affiliated hospitals/clinics;

(b) applications for listing new drugs were clinical service driven. New technologies generally targeted advanced and complex clinical cases which were predominantly treated in hospitals with teaching and quaternary services. Hospitals A, D and B provided teaching and quaternary services while Hospital E was a centre for infectious diseases.

Once a new drug application had been submitted, it was not necessary for other DTCs to submit an application for the same drug; and

(c) new drug applications were initiated by clinicians who were aware of international practices and market availabilities of new drugs relevant to their services. Among the new product registrations every year, the majority were related to new sources or formulations of existing drugs.

In Audit's view, the HA needs to review the adequacy of its mechanism in encouraging and facilitating more HA hospitals and clinics to apply for new drug listing on the HADF.

Applications for new drug listing not made for many non-HADF drugs in regular demand

2.33 Of the 95 non-HADF registered drug items (involving 73 drugs) used in 2015-16, applications for new drug listing had not been made for 57 items (involving 45 drugs — see para. 2.11(a)). Audit noted that 12 of these 57 drug items, being in regular demand, had been acquired through bulk contracts (standing offer agreements) with drug suppliers over a one-year period (see para. 3.5).

2.34 In Audit's view, for non-HADF drugs intended to be used for an extended duration, the due process for putting up the drugs for listing on the HADF should be followed. The listing of cost-effective drugs of proven safety and efficacy on the HADF helps ensure that patients attending different public hospitals and clinics have equitable access to the drugs (see para. 2.28 for the audit recommendations on non-HADF drugs).

Audit recommendations

2.35 **Audit has *recommended* that the Chief Executive, HA should:**

(a) **given that few hospitals had applied for new drug listing, review the adequacy of the HA mechanism for listing new drugs on the HADF, taking account of the numerous new drugs emerging over time, and the benefits for considering their potential inclusion in the HADF in a timely manner; and**

(b) **take measures to encourage and facilitate more HA hospitals and clinics to apply for new drug listing on the HADF.**

Response from the Hospital Authority

2.36 The Chief Executive, HA has said that he agrees with the audit recommendations. He has also said that the HA will:

(a) request cluster and hospital DTCs to set a standing agenda item on new drug applications in their meetings; and

(b) share the link to the Department of Health's webpage on newly registered medicines in Hong Kong.

Deleting obsolete drugs

2.37 The Drug Formulary Committee is responsible for regular review of the existing drug list in the HA (see para. 2.5(b)). For obsolete drugs including those discontinued by manufacturers or no longer used in the HA due to change in practice, the supporting Expert Panels may make recommendations to delete the drugs from the HADF, for consideration by the Drug Formulary Committee and final endorsement by the Drug Management Committee. Between 2013 and 2015, 327 drug items were deleted from the HADF.

2.38 Audit analysis of HA records revealed that 47 drugs currently listed on the HADF had no consumption records during 2013-14 to 2015-16. The HA needs to review whether any of them should be deleted from the HADF.

Audit recommendation

2.39 **Audit has *recommended* that the Chief Executive, HA should review the 47 drugs with no consumption records during 2013-14 to 2015-16 to ascertain the need for deleting any of them from the HADF.**

Response from the Hospital Authority

2.40 The Chief Executive, HA has said that the HA agrees with the audit recommendations. He has also said that:

(a) the biennial HADF review (see para. 2.5(b)) includes deletion of obsolete drugs. The 47 drugs include 5 drugs which had been missed in the screening for drugs with no consumption by the computer system in the last exercise. The remaining 42 drugs, which include standby drugs (e.g. antidotes) and drugs for prescribing as self-financed drugs for purchase at community pharmacies, are retained for operational need; and

(b) the HA will review and refine the screening methodology of the computer system to ensure that all potentially obsolete drugs are identified for assessment.

PART 3: PROCUREMENT OF DRUGS

3.1 This PART examines the HA's procurement of drugs. Audit has found room for improvement in the following areas:

(a) establishing bulk contracts (paras. 3.7 to 3.13); and

(b) managing the risk of supply interruption (paras. 3.14 to 3.26).

Procurement and Materials Management Manual

3.2 ***Procurement methods.*** The HA's Procurement and Materials Management Manual states that the objective of procurement is to obtain the best value-for-money supplies (including drugs) and services through an efficient and speedy system that is seen to be fair and competitive, and is accountable. Table 6 summarises the requirements on procurement methods for achieving this objective.

Table 6

Procurement methods for different purchasing limits

Value of purchase	Procurement method
$3,000 or less	No requirements on obtaining quotations
Over $3,000 to $50,000	At least 2 quotations should be obtained
Over $50,000 to $100,000	At least 2 written quotations should be obtained
Over $100,000 to $1,500,000	At least 5 written quotations should be obtained
Over $1,500,000	Purchase should be conducted by tender

Source: *HA records*

Remarks: *The lowest conforming offer should normally be accepted.*

3.3 ***Bulk contracts.*** According to the HA's Procurement and Materials Management Manual, any particular item/service likely to be acquired repeatedly in quantities should be purchased through an established supply term contract. The HA Head Office is responsible for establishing bulk contracts for supplies and

services. In order to save procurement costs, standardise the purchase of supplies and services, and achieve economies of scale, it is mandatory for HA staff to acquire the supplies or services concerned from such bulk contracts.

Drug procurement practices

3.4 The HA's drug procurement practices are as follows:

(a) ***Direct purchases by hospitals.*** Hospitals are given authority to make direct purchases of drug items with a value not exceeding $1.5 million by quotation if the drug items are not covered by bulk contracts established by the HA Head Office. As a procurement practice for drugs, hospitals would request the HA Head Office to conduct quotation process for direct purchases with a value exceeding $100,000; and

(b) ***Purchases under bulk contracts established by HA Head Office.*** For drug items covered by bulk contracts established by the HA Head Office, hospitals issue purchase orders to the contractors to purchase the drug items at prices stated in the contracts.

3.5 ***Two types of bulk contracts.*** The bulk contracts established by the HA Head Office for procuring drug items comprise supply contracts and standing offer agreements. Supply contracts, generally with a value exceeding $1.5 million, are established by tender (Note 16). Standing offer agreements are established by quotation for drug items with estimated annual purchase amounts exceeding $100,000. Table 7 summarises the general characteristics of the two types of bulk contracts.

Note 16: *There are four types of tender for procurement of drugs:*

(a) single tender (for proprietary drugs protected by patents);

(b) restricted tender (e.g. for particular brands of drug products recommended by expert groups due to clinical reasons);

(c) open (new generic) tender (for drugs with proprietary patents that require clearance); and

(d) open (established generic) tender (for drugs with no known proprietary patents that require clearance).

Table 7

Bulk contracts for procuring drug items established by the HA Head Office

Type of contract	Purchase amount	Procedures for establishing the contract and making purchases	Contract period
Supply contract	Over $1,500,000 in the contract period	• HA Head Office prepares tender documents and invites tenders (see Note 16 to para. 3.5) for supplying a drug item, with a commitment to purchase a minimum quantity of the drug item in the contract period • Tender Assessment Panel (Note 1) evaluates tenders and makes recommendations to Main Tender Board (Note 2) • Upon receipt of Main Tender Board's approval of tender acceptance, HA Head Office awards the contract • During the contract period, hospitals issue purchase orders to contractor to purchase a specified quantity of the drug item at the price stated in the contract • The contractor delivers the ordered quantity of the drug item to the hospitals	Normally 36 months
Standing offer agreement	Estimated annual purchase amount over $100,000	• HA Head Office prepares quotation documents and invites at least 5 quotations for supplying a drug item, without a commitment to purchase any quantity of the drug item in the contract period • HA Head Office evaluates quotations and enters into the standing offer agreement • During the contract period, hospitals issue purchase orders to contractor to purchase a specified quantity of the drug item at the price stated in the contract • The contractor delivers the ordered quantity of the drug item to the hospitals	Normally 12 months

Source: HA records

Note 1: The Panel is chaired by the Chief Pharmacist of the HA. Its members include staff of the HA Head Office and clusters (e.g. the Chief Supplies Officer and Senior Pharmacists).

Note 2: The Main Tender Board is chaired by a member of the HA Board. Its members include two other members of the HA Board and the Chief Executive of the HA (or his nominated representative).

3.6 Table 8 shows an analysis of the drug items purchased by the HA between 2013-14 and 2015-16.

Table 8

Drug items purchased by the HA
(2013-14 to 2015-16)

Procurement method		No. of drug items	Expenditure ($ million)
2013-14			
Direct purchases by hospitals		1,086 (44%)	364 (7%)
Purchases under bulk contracts	Supply contracts	991 (40%)	4,308 (85%)
	Standing offer agreements	381 (16%)	376 (8%)
	Sub-total	1,372 (56%)	4,684 (93%)
Total		2,458 (100%)	5,048 (100%)
2014-15			
Direct purchases by hospitals		1,029 (42%)	360 (7%)
Purchases under bulk contracts	Supply contracts	1,081 (44%)	4,653 (87%)
	Standing offer agreements	357 (14%)	303 (6%)
	Sub-total	1,438 (58%)	4,956 (93%)
Total		2,467 (100%)	5,316 (100%)
2015-16			
Direct purchases by hospitals		1,019 (41%)	424 (7%)
Purchases under bulk contracts	Supply contracts	1,153 (46%)	4,991 (87%)
	Standing offer agreements	319 (13%)	325 (6%)
	Sub-total	1,472 (59%)	5,316 (93%)
Total		2,491 (100%)	5,740 (100%)

Source: *HA records*

Remarks: *The purchases of drug items shown in the Table were for dispensing to patients directly. In addition, the HA also made purchases of drug items mainly for other purposes (e.g. disinfectants used during operations). In 2015-16, purchases of such drug items totalled $516 million. The HA was unable to provide the procurement method for each purchase of such drug items.*

Establishing bulk contracts

3.7 The objectives of establishing bulk contracts for procuring drug items include saving procurement costs and achieving economies of scale (see para. 3.3). According to the HA, bulk contracts also bring about uniformity of supply source and committed supply plan. Table 8 shows that purchases under bulk contracts increased from 56% in 2013-14 to 59% in 2015-16. In 2015-16, of the 2,491 drug items purchased by the HA, 1,472 (59%) were purchased using bulk contracts. However, Audit analysis of the remaining 1,019 (41%) drug items purchased directly by hospitals revealed room for establishing more bulk contracts to further save procurement costs and achieve economies of scale. The audit findings are in paragraphs 3.8 to 3.11.

Bulk contracts not established for 520 drug items with purchase amounts totalling $406 million

3.8 According to the HA's current drug procurement practices, bulk contracts (supply contracts and standing offer agreements) are established for procuring some drug items with annual purchase amounts exceeding $100,000 (see paras. 3.4 and 3.5). Audit noted that:

(a) supply contracts, generally having a contract period of three years and a contract value exceeding $1.5 million, were established by tender (see Table 6 in para. 3.2). Given a term of three years, they were intended for drug items with an average annual purchase amount exceeding $500,000; and

(b) standing offer agreements (established by quotation) were intended for drug items with purchase amounts exceeding $100,000 for the contract term of one year.

3.9 Table 9 shows Audit analysis of the 1,019 drug items purchased directly by hospitals using quotation procedure in 2015-16.

Table 9

Audit analysis of 1,019 drug items purchased directly by all hospitals using quotation procedure (2015-16)

Purchase amount (Note)		No. of drug items		Expenditure ($ million)	
$100,000 or less		499	(49%)	18	
Over $100,000	Over $100,000 to $500,000	327	(32%)	78	
	Over $500,000 to $1,000,000	104	(10%)	73	
	Over $1,000,000 to $1,500,000	193 / 36	(4%)	43	328
	Over $1,500,000	53	(5%)	212	
	Sub-total	520	(51%)	406	
Total		1,019	(100%)	424	

Source: Audit analysis of HA records

Note: The purchase amount of each drug item was the combined total for all hospitals.

3.10 As can be seen from Table 9, 520 (51%) drug items had purchase amounts (aggregating all hospitals) exceeding $100,000, involving expenditure totalling $406 million. In Audit's view, the HA needs to review the direct purchase method for these 520 drug items to determine whether the demands of individual hospitals could be consolidated for establishing bulk contracts, with a view to saving procurement costs and achieving more economies of scale. The 520 drug items included 193 drug items each with purchase amounts in 2015-16 exceeding $500,000, involving expenditure totalling $328 million. The HA in particular needs to assess whether the purchase amounts of these 193 drug items in the coming three years would exceed $1.5 million thus requiring establishing bulk supply contracts by tender (see para. 3.8(a)).

Some direct purchases by hospitals did not follow existing procurement practices

3.11 As mentioned in paragraph 3.4(a), as a procurement practice for drugs, hospitals would request the HA Head Office to conduct quotation process for direct purchases with a value exceeding $100,000. However, in the visits to the four hospitals (see para. 1.11), Audit noted cases of repeated direct purchases by hospitals within a short period of time, with total purchase amount exceeding $100,000 (see Case 1 for an example). The HA needs to review whether additional guidelines on direct purchases by hospitals should be issued.

Case 1

Repeated direct purchases

1. In June 2015, Hospital A obtained one written quotation (Note) for the supply of a special drug on the HADF. The price offered by the supplier was $415 per vial.

2. During June to December 2015, Hospital A made 9 purchases of the drug from the same supplier at the offered price (see para. 1 above):

Purchase date		Purchase date		Purchase date	
1	17.6.2015	4	3.7.2015	7	10.8.2015
2	23.6.2015	5	21.7.2015	8	4.12.2015
3	30.6.2015	6	24.7.2015	9	9.12.2015

The purchase amount for each purchase ranged from $49,800 to $99,600, which did not exceed the $100,000 financial limit for direct purchases by hospitals.

3. The total purchase amount for the 9 purchases was $597,600.

Audit comments

4. The total purchase amount of $597,600 for the 9 repeated direct purchases (within a period of six months) was 6 times of the $100,000 financial limit for direct purchases by hospitals.

Source: Audit analysis of HA records

Note: As the drug is brand specific (i.e. the HA would only purchase this item from a specific supplier), only one quotation was obtained.

Audit recommendations

3.12 **Audit has *recommended* that the Chief Executive, HA should:**

(a) **for the 520 drug items purchased directly by hospitals using quotation procedure and with purchase amounts in 2015-16 exceeding $100,000, review the direct purchase method to determine whether the demands of individual hospitals could be consolidated for establishing bulk contracts;**

(b) **in particular, assess whether the purchase amounts of 193 of the 520 drug items (i.e. drug items with purchase amounts in 2015-16 exceeding $500,000) in the coming three years would exceed $1.5 million thus requiring establishing bulk supply contracts by tender;**

(c) **set up an effective mechanism for regularly analysing hospitals' demands for drug items not covered by bulk contracts to determine whether bulk contracts should be used to achieve the best value for money; and**

(d) **review the practice of repeated direct purchases within a short period of time mentioned in paragraph 3.11 and provide hospitals with additional guidelines on direct purchases.**

Response from the Hospital Authority

3.13 The Chief Executive, HA has said that the HA welcomes the audit recommendations. He has also said that:

(a) the recommendations are in line with the HA's on-going drug procurement strategies for optimising bulk contract arrangements to ensure supplies continuity and maximise economies of scale. There were progressive annual increases in the number of drug items procured under supply contracts between 2013-14 and 2015-16 (increased from 991 to 1,153 items — see Table 8 in para. 3.6);

(b) there is a working list of items planned for gradual inclusion as bulk contracts. The list is prioritised based on annual consumptions and the need for central quotations to support local purchases; and

(c) the HA will:

(i) compare and adjust the 193 items pointed out by Audit against its own list and speed up the bulk contract arrangements for suitable candidates among these items;

(ii) review and formalise the direct purchase practice into corresponding guidelines; and

(iii) utilise the forthcoming Pharmacy Business Intelligence System to conduct comprehensive analysis of the consumption, procurement patterns and purchase frequency to facilitate bulk contract arrangements and overall monitoring.

Managing the risk of supply interruption

Increasing complaints against a key supplier on late delivery

3.14 The HA procures drugs from many suppliers, including three key suppliers (Suppliers A, B and C — see Table 10).

Table 10

Amount of drugs procured from suppliers
(2013-14 to 2015-16)

Supplier		Amount of drugs procured ($ million)		
		2013-14	2014-15	2015-16
Suppliers A, B and C (Note)	Supplier A	1,785 (33%)	2,066 (36%)	2,325 (37%)
	Supplier B	1,525 (28%)	1,483 (25%)	1,561 (25%)
	Supplier C	717 (13%)	866 (15%)	1,036 (17%)
	Sub-total	4,027 (74%)	4,415 (76%)	4,922 (79%)
Other suppliers		1,394 (26%)	1,386 (24%)	1,334 (21%)
	Total	5,421 (100%)	5,801 (100%)	6,256 (100%)
Total no. of suppliers		151	158	158

Source: Audit analysis of HA records

Note: Suppliers A, B and C are agents of multiple pharmaceutical manufacturers.

3.15 The Drug Quality Assurance and Enterprise Resource Planning Section of the HA monitors the performance of drug suppliers, including timeliness of delivery of drugs. It may convene a Performance Review Group meeting to review in detail the performance of a drug supplier for necessary follow-up (Note 17).

Note 17: *The Performance Review Group is co-chaired by the Chief Supplies Officer and a Senior Pharmacist of the HA. Members of the Group include cluster representatives and other HA staff. The Group may make recommendations as to whether the future tender submission of a drug supplier should be rejected for a specified period, for consideration of the Tender Assessment Panel.*

3.16 From time to time, the HA Head Office received complaints from hospitals about late delivery of drugs (delivery complaints). Table 11 shows that during 2013-14 to 2015-16, the number of delivery complaints related to Supplier A had increased by 183% from 65 to 184. In contrast, the number of complaints related to other suppliers had decreased. Upon enquiry, the HA informed Audit in September 2016 that Supplier A was a logistic agent representing an increasing number of principal manufacturers over the past few years, therefore the number of drugs supplied by Supplier A had also increased, which partly accounted for the observed increase in delivery complaints.

Table 11

Drug delivery complaints
(2013-14 to 2015-16)

Year	No. of complaints				
	Supplier A	**Supplier B**	**Supplier C**	**Other suppliers**	**Overall**
2013-14	65 (23%)	33 (12%)	15 (5%)	170 (60%)	283 (100%)
2014-15	162 (41%)	34 (9%)	17 (4%)	180 (46%)	393 (100%)
2015-16	184 (57%)	26 (8%)	9 (3%)	104 (32%)	323 (100%)
Overall	411 (41%)	93 (9%)	41 (4%)	454 (46%)	999 (100%)
2015-16 vs 2013-14 (Increase +/ decrease −)	+183%	−21%	−40%	−39%	+14%

Source: *Audit analysis of HA records*

Remarks: *If late delivery of a drug from a supplier resulted in the stock level falling to less than 1.5 months' consumption, the HA would explore replenishing the stock from other sources, with any additional expenditure recovered from the supplier in accordance with the contract terms. There were 21, 27 and 43 such cases in 2013-14, 2014-15 and 2015-16 respectively. Of these cases, 2, 4 and 23 cases respectively involved Supplier A.*

3.17 Despite the increasing number of delivery complaints related to Supplier A, no Performance Review Group meetings (see para. 3.15) had been held during 2013-14 to 2015-16 to review Supplier A's performance for necessary follow-up (Note 18). Upon enquiry, the HA informed Audit in September 2016 that the Performance Review Group was activated when there were persistent unresolved issues. In Audit's view, the HA should closely monitor the performance of drug suppliers in complying with delivery schedules and take effective follow-up action on delivery complaints received from hospitals.

Room for enhancing multi-source procurement

3.18 In 2012, the HA decided that drug items meeting the following criteria would be procured from multiple sources:

(a) the drug item was used for the treatment of chronic diseases; and

(b) the drug item was used by more than 100,000 patients annually.

The objective is to ensure continuity of supply of the drug items in case problems arise with one supplier.

3.19 Audit noted that, as at July 2016, among the drug items used for the treatment of chronic diseases, 13 drug items were used by more than 100,000 patients annually (Note 19), thus meeting the criteria for multi-source procurement. However, the HA had adopted multi-source procurement for only 7 of the 13 drug items. The remaining 6 (46%) drug items were each procured from a single source, including 5 drug items whose sole supplier was Supplier A, which was associated with increasing delivery complaints (see para. 3.16). Upon enquiry, the HA informed Audit in September 2016 that:

Note 18: *Since 2012, only one Performance Review Group meeting had been held to review the performance of a supplier. The supplier was not one of the three key suppliers.*

Note 19: *This refers to the usage from April 2014 to March 2015.*

(a) of the 6 drug items, the HA had conducted multi-source tender exercises for 5 drug items but had awarded contract to a single source in each exercise due to risk benefit considerations or no other acceptable source having been identified; and

(b) for the remaining drug item, the HA would conduct a multi-source tender exercise upon expiry of the current contract.

3.20 Audit also noted that some drug items, while not meeting the current criteria for multi-source procurement, were commonly used. For example, in 2015-16, 34 drug items were each used by more than 50,000 patients. As at July 2016, the 34 drug items were each procured from a single source, including 19 drug items whose sole supplier was Supplier A. The HA needs to assess the risk and impact of supply disruption for such commonly-used drugs to determine whether multi-source procurement should also be implemented for them.

Room for improving drug re-ordering procedure

3.21 The HA requires that stock of drug items should be maintained at the lowest possible level, balancing the need for maintaining continuity of supply to meet routine and peak demands. To prevent a stock-out situation, hospitals are prompted by the HA's computerised Enterprise Resource Planning System to re-order a drug item when its stock level drops to or below the re-order level (Note 20).

3.22 During the visits to the four hospitals, Audit noted that they had not re-ordered a total of 756 drug items whose stock levels were below the re-order levels. Of these 756 drug items, the stock levels of 182 items were even below the minimum levels. Table 12 shows the details.

Note 20: *The computer system computes the re-order level for each drug item (i.e. six-week consumption) with reference to its average consumption in the preceding eight weeks. It generates management reports daily, showing drug items with balances below their re-order levels and minimum levels (i.e. four-week consumption) to alert HA staff for necessary action.*

Table 12

756 drug items with stock levels lower than the re-order levels but had not been re-ordered (23 June 2016)

Hospital	No. of drug items			
	Above minimum stock level	At minimum stock level	Below minimum stock level	Total
A	39	0	16	55
B	99	5	38	142
C	193	33	22	248
D	181	24	106	311
Total	512 (68%)	62 (8%)	182 (24%)	756 (100%)
		244 (32%)		

Source: *Audit analysis of HA records*

Remarks: *The stock levels of all the 756 drug items were below the re-order levels.*

3.23 Upon enquiry, the HA informed Audit in September 2016 that pharmacy staff did not solely rely on the re-order levels and minimum levels generated by the computer system to determine when to re-order and what quantity of drug items to be stocked. A basket of factors, including clinical needs, consumption trend and storage capacity, would also be taken into consideration to decide whether re-order is necessary.

3.24 Audit considers that there is room for improving the drug re-ordering procedure. For example, with re-order levels appropriately set to reflect all relevant factors, pharmacy staff can make better use of the HA's computerised Enterprise Resource Planning System to make re-order decisions more efficiently and effectively.

Audit recommendations

3.25 **Audit has *recommended* that the Chief Executive, HA should:**

(a) **closely monitor the performance of drug suppliers in complying with delivery schedules and take effective follow-up action on delivery complaints received from hospitals;**

(b) **remind staff of the need to hold Performance Review Group meetings to review any unsatisfactory performance of suppliers in warranted cases;**

(c) **for drug items meeting the criteria set by the HA (i.e. for treatment of chronic diseases and used by more than 100,000 patients annually) for multi-source procurement but currently procured from a single source for reasons such as risk benefit considerations, implement multi-source procurement upon expiry of the current contract where appropriate;**

(d) **assess the risk and impact of supply disruption for other commonly-used drug items to determine whether multi-source procurement should be implemented for them; and**

(e) **take measures to improve the drug re-ordering procedure.**

Response from the Hospital Authority

3.26 The Chief Executive, HA has said that the HA agrees with the audit recommendations. He has also said that the HA will:

(a) utilise the key performance indicators in the forthcoming Pharmacy Business Intelligence System to enhance monitoring of delivery performance;

(b) conduct regular Performance Review Group meetings to review the performance of manufacturers and suppliers;

(c) continue conducting multi-source tender exercises on existing and new drug items meeting the pre-set criteria, and review the current criteria for conducting multi-source tender exercises; and

(d) review and explore relevant factors to assist decision making in the drug re-ordering procedure.

PART 4: DISPENSING AND HANDLING OF DRUGS

4.1 This PART examines issues related to the dispensing and handling of drugs. Audit has found room for improvement in the following areas:

(a) dispensing of drugs (paras. 4.2 to 4.9); and

(b) handling of dangerous drugs (paras. 4.10 to 4.18).

Dispensing of drugs

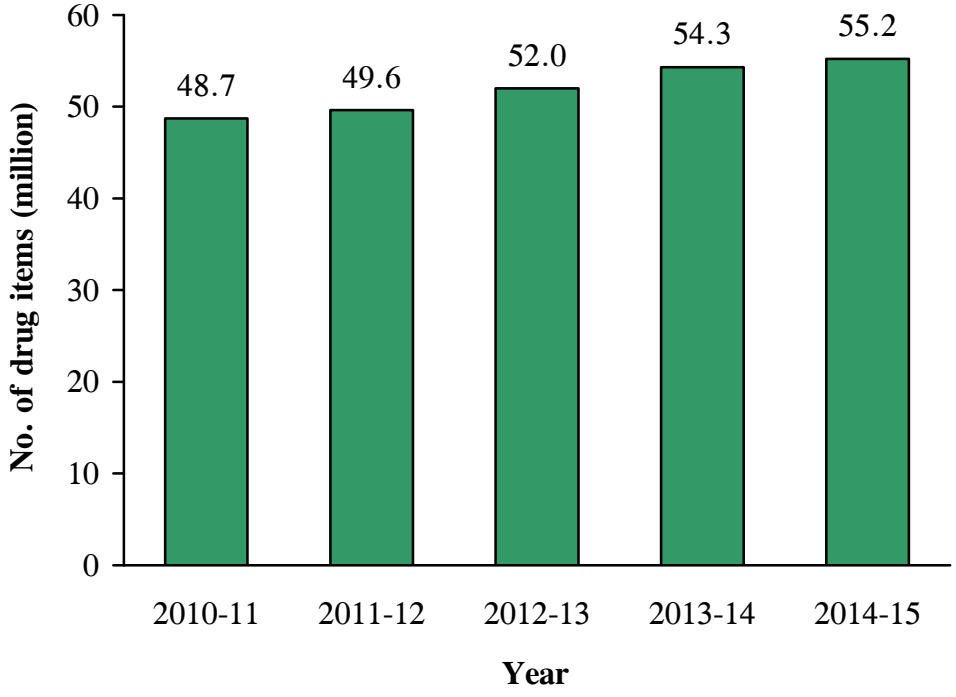
4.2 Drugs are dispensed to patients through pharmacies of each hospital/clinic (Note 21). As mentioned in paragraph 2.3, eligible persons attending specialist clinics for public services are charged $10 for each drug item on the prescription, which covers a duration up to 16 weeks. Eligible persons are not separately charged for drug items when attending general outpatient clinics or receiving treatment as inpatients. For non-eligible persons, drugs are charged at cost.

4.3 Each year, the HA dispenses a huge quantity of drugs for use by patients. During 2010-11 to 2014-15, the total number of drug items dispensed to HA patients increased by 13%, from 48.7 million to 55.2 million (see Figure 1).

Note 21: *To ensure efficiency of drug administration, drugs stocks are also kept at wards to meet the needs of individual patients.*

Figure 1

Total number of drug items dispensed to HA patients (2010-11 to 2014-15)



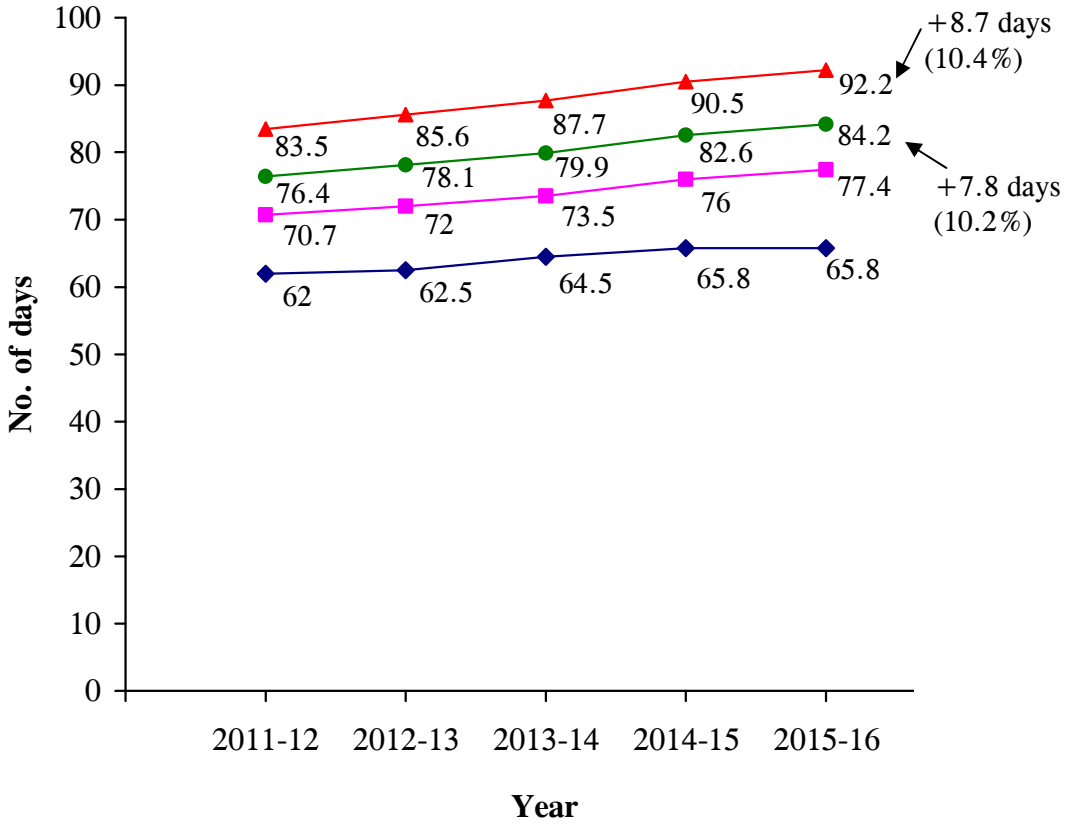
Source: *HA records*

Remarks: *For each prescription, the number of drug items dispensed referred to the number of items on the prescription that was supplied to the patient.*

4.4 Drugs are dispensed in accordance with doctors' prescriptions. HA records showed that, in general, the average period of time covered by a prescription (average prescription length) had been increasing. For example, Figure 2 shows the average prescription length for specialist out-patients. Overall, during 2011-12 to 2015-16, the average prescription length increased by 7.8 days (10.2%), from 76.4 to 84.2 days. Among the different age groups, the average prescription length for people aged over 65 showed the greatest increase of 8.7 days (10.4%), from 83.5 to 92.2 days.

Figure 2

Average prescription lengths for HA specialist out-patients (2011-12 to 2015-16)



Source: HA records

Need to assess the extent of drug wastage

4.5 In the visits to the four hospitals (see para. 1.11), Audit noted many patients collecting large quantities of drugs from the pharmacies. Overseas experience indicated that prescribing large quantities of drugs for a long period of time could lead to drugs being unused and wasted (Note 22). Locally, there were also concerns about possible drug wastage in the community. According to the results of a research submitted to the HA in 2013 (Note 23), the total drug wastage could be enormous (Note 24).

4.6 Audit noted that the HA had not taken steps (e.g. conducting regular surveys) to assess the extent of drug wastage among patients. In Audit's view, knowing the magnitude of drug wastage would help the HA take appropriate measures to tackle the problem.

4.7 In this connection, Audit noted that the HA had since October 2013 explored the feasibility of providing a new service (i.e. refill dispensing services) with a view to improving service efficiency and drug management. The initial thinking was to set up regional drug centres (e.g. in collaboration with non-governmental organisations) for patients to refill their prescribed drug items. This could enable dispensing the prescribed drugs to patients in smaller quantities by phases and thus might help reduce drug wastage, instead of dispensing a large quantity to patients in one go at hospital pharmacies. The matter was last discussed in June 2016 with no decision made.

Note 22: *For example, in a national study of 2009 in the UK by the Care Quality Commission (the independent regulator of health and adult social care services), it was estimated that among the patients with long term conditions, only half of the patients took their drugs as prescribed.*

Note 23: *The research was conducted by the Pharmaceutical Society of Hong Kong. Members of the Society include Hong Kong registered pharmacists.*

Note 24: *The research estimated that the drug wastage among some 60,000 elderly living at old aged homes in Hong Kong was about $5.8 million a year.*

Audit recommendations

4.8 **Audit has *recommended* that the Chief Executive, HA should:**

(a) **regularly assess the extent of drug wastage among patients of the HA; and**

(b) **based on the assessment in (a) above, take appropriate measures to tackle the problem of drug wastage.**

Response from the Hospital Authority

4.9 The Chief Executive, HA has said that the HA welcomes the audit recommendations. He has also said that:

(a) the increase in service demand has led to extended prescription durations. The HA is aware of the potential risk of drug wastage arising from changes in patients' clinical conditions, and has been exploring options to minimise potential drug wastage taking into consideration patients' acceptability, practicality, technology and resource requirements; and

(b) the HA will pilot the implementation of drug refill services in selected specialist out-patient clinics to break long duration prescriptions into refills and provide drug counselling for targeted patients between refills. These services will help estimate and reduce the extent of drug wastage and improve patient care, and will be rolled out upon positive evaluation of the pilot.

Handling of dangerous drugs

4.10 Dangerous drugs are drugs or substances specified in Part 1 of the First Schedule of the Dangerous Drugs Ordinance (Cap. 134). The Ordinance sets out the rules for controlling the manufacture, supply, possession and administration of dangerous drugs.

4.11 The Ordinance authorises certain persons (e.g. registered medical practitioners and nursing sisters in charge of a ward) to be in possession of dangerous drugs and to supply the drugs to persons receiving treatment. Pursuant to the Ordinance, dangerous drugs must be kept in a locked receptacle. Whenever a dangerous drug is supplied, a record shall be entered in a register kept for the purpose. All dangerous drugs which are in the possession of any authorised person shall be examined at least once in every month. The Department of Health shall be forthwith notified of any irregularity and non-compliance with the provisions of the Ordinance, including incidents of missing dangerous drugs.

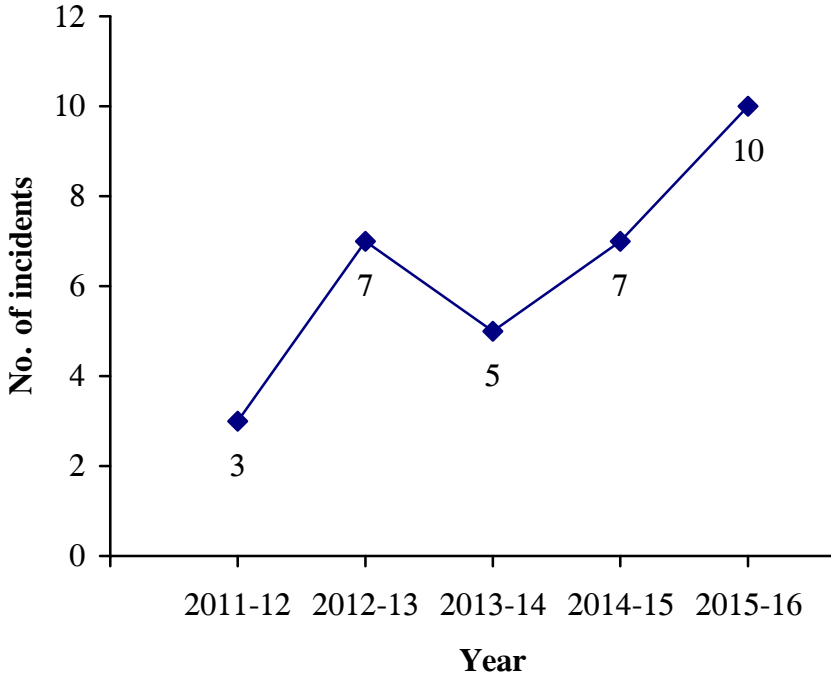
Increasing incidents of missing dangerous drugs

4.12 During 2011-12 to 2015-16, there were 32 incidents of missing dangerous drugs. In December 2012, after one of such incidents was reported by the HA to the Department of Health, the Department of Health issued a letter to the HA, urging the HA to ensure safe custody of dangerous drugs in its hospitals.

4.13 The number of incidents of missing dangerous drugs dropped from 7 incidents in 2012-13 to 5 incidents in 2013-14. However, in 2014-15 the number started to rise again. In 2015-16, there were 10 incidents of missing dangerous drugs, up from 3 incidents in 2011-12 (see Figure 3).

Figure 3

Incidents of missing dangerous drugs (2011-12 to 2015-16)



Source: *HA records*

Remarks: *In December 2012, the Department of Health urged the HA to ensure safe custody of dangerous drugs in its hospitals (see para. 4.12).*

Direct causes of many incidents of missing dangerous drugs not identified

4.14 According to the HA, it had guidelines in place on the proper handling, safe custody, record keeping and disposal of dangerous drugs in hospitals. For each incident of missing dangerous drugs, the responsible hospital conducted investigations and analysed the risk factors which might be underlying the incident and direct causes if they were identified. Table 13 shows that, of the 32 incidents between 2011-12 and 2015-16, the direct causes in 27 (84%) incidents could not be identified through the investigations.

Table 13

Results of investigations of 32 incidents of missing dangerous drugs (2011-12 to 2015-16)

Investigation result	No. of incidents
Incidents with direct causes identified:	
Mistakenly discarded by staff	3 (9.4%)
Lost during transmission	2 (6.2%)
Sub-total	5 (15.6%)
Incidents with direct causes not identified	27 (84.4%)
Total	32 (100%)

Source: Audit analysis of HA records

4.15 The Dangerous Drugs Ordinance specifies various rules to control the handling of dangerous drugs (see paras. 4.10 and 4.11). The increasing incidents of missing dangerous drugs by the HA is a cause for concern. For each incident, identifying the direct cause is important. It helps locate any staff who should be held accountable for the incident thus reinforcing accountability for the safe custody of dangerous drugs. It also helps determine what effective measures should be taken to prevent recurrence. However, as shown in Table 13, the HA investigation could not identify the direct causes in 27 (84%) incidents. Of these 27 incidents, Audit noted that 4 incidents occurred in the same hospital (see Case 2).

Case 2

Repeated occurrences of missing dangerous drug incidents with direct cause not identified

1. There were 4 incidents of missing dangerous drugs in Hospital A between 2012-13 and 2015-16, as follows:

	Date	Location	Dangerous drug missing
1.	28.4.2012	Ward of the Surgical Department	2 tablets of 1 milligram Ativan (a drug for treating conditions such as anxiety disorder)
2.	18.3.2015	Ward of the Surgical Department	1 ampoule of Pethidine 50 milligrams/millilitre injection (a drug for pain relief)
3.	21.3.2015	Ward of the Department of Obstetrics and Gynaecology	5 ampoules of Diazepam 10 milligrams/2 millilitres injection (a drug for treating conditions such as anxiety disorder)
4.	12.4.2015	Ward of the Surgical Department	1 ampoule of Pethidine 50 milligrams/millilitre injection (a drug for pain relief)

2. All 4 incidents were reported to the police. Hospital A had also conducted investigations of the incidents. Actions taken included repeated counting and verification of physical stock against inventory records, and review of dispensing and transaction records. No direct cause could be identified.

Audit comments

3. The repeated occurrences of missing dangerous drugs in Hospital A, particularly in the Ward of the Surgical Department, suggested that effective improvement measures had not been taken after each incident. Audit noted that the direct cause of the incidents could not be identified. The investigation reports for the incidents did not state whether the staff responsible for the safe custody of the drugs had been inquired of during the investigation, nor did the report state whether results of the police investigation were available and had been taken into account. In Audit's view, there was scope for improving the conduct and follow-up of the investigation.

Source: Audit analysis of HA records

Incidents of missing dangerous drugs not forthwith reported to the Department of Health

4.16 The Dangerous Drugs Ordinance stipulates that the medical officer in charge of the hospital shall forthwith notify the Department of Health of any incident of missing dangerous drugs. In May 2016, Audit analysed the time taken for reporting the 32 incidents between 2011-12 and 2015-16. Audit found that 5 incidents (16%) had not been reported, after a lapse of 425 to 1,494 days since the dangerous drugs were found missing. After Audit enquiry, in May 2016, the HA reported the 5 incidents. Overall, Audit found that a long time had been taken to report some incidents to the Department of Health (see Table 14).

Table 14

Time taken for reporting 32 incidents of missing dangerous drugs to the Department of Health (2011-12 to 2015-16)

Time taken	No. of incidents
Incidents reported before Audit enquiry in May 2016	
7 days or less	14 (44%)
8 to 14 days	8 (25%)
15 to 30 days	4 (12%)
64 days	1 (3%)
Sub-total	27 (84%)
Incidents not reported before Audit enquiry in May 2016 (Note)	
425 days	1 (3%)
1,000 to 1,494 days	4 (13%)
Sub-total	5 (16%)
Total	32 (100%)

Source: Audit analysis of HA records

Note: In May 2016, the HA reported the incidents to the Department of Health after Audit enquiry. In August 2016, the Department of Health issued a letter to the HA, reminding the HA to handle the dangerous drugs in strict compliance with the Dangerous Drugs Ordinance, and to step up security measures and develop protocols to ensure safe custody of dangerous drugs.

Audit recommendations

4.17 **Audit has *recommended* that the Chief Executive, HA should:**

(a) **monitor the number of incidents of missing dangerous drugs and conduct a comprehensive review of the handling and custody of dangerous drugs where necessary;**

(b) **regularly remind relevant staff of the importance of ensuring the proper handling and safe custody of dangerous drugs in HA hospitals and clinics;**

(c) **issue guidelines on the investigation of incidents of missing dangerous drugs, and ensure that the staff concerned comply with the guidelines and take effective improvement measures to prevent recurrence; and**

(d) **ensure that incidents of missing dangerous drugs are forthwith reported to the Department of Health.**

Response from the Hospital Authority

4.18 The Chief Executive, HA has said that the HA agrees with the audit recommendations. He has also said that the HA will:

(a) enhance staff training and conduct regular audits;

(b) enhance reporting of incidents of missing dangerous drugs to facilitate monitoring and notification, and follow-up reporting to the Department of Health; and

(c) develop a template to guide investigation of incidents of missing dangerous drugs.

PART 5: MONITORING THE QUALITY OF DRUGS

5.1 This PART examines the HA's monitoring of the quality of drugs. Audit has found room for improvement in the following areas:

(a) sample testing of drugs (paras. 5.3 to 5.8);

(b) inspection of premises of drug suppliers (paras. 5.9 to 5.13); and

(c) investigation of complaints about drug quality (paras. 5.14 to 5.18).

Quality assurance work

5.2 The Chief Pharmacist's Office of the HA is responsible for monitoring the quality of drugs procured. The work includes:

(a) regularly commissioning local laboratories to conduct sample testing of drugs procured by the HA and inspections of premises of HA drug suppliers; and

(b) regularly investigating complaints about drug quality received from frontline hospitals and clinics (Note 25).

Sample testing of drugs

Sampling methodology not laid down

5.3 The HA has commissioned local laboratories to conduct microbiological testing and chemical testing on drugs it procured. Drugs in general are tested under a sampling programme. In addition, drugs related to safety alerts issued by local or

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Note 25: *A drug quality complaint is one related to discrepancy in efficacy, appearance, packaging, possible contamination or any other circumstances observed that may jeopardise or cause reasonable doubt on the routine and intended utilisation of a drug item.*

overseas authorities (e.g. the U.S. Food and Drug Administration) and drugs related to drug quality complaints are tested as necessary. Table 15 shows that, during 2013-14 to 2015-16, the amount of drugs procured by the HA increased by 15.4%, from $5,421 million to $6,256 million. The total number of drugs selected for testing decreased by 3.1%, from 783 to 759. Moreover, excluding drugs related to safety alerts or drug quality complaints (tests on them were ad hoc and the number of tests might fluctuate from year to year), the total number of drugs selected for testing decreased by 6.1%, from 773 to 726.

Table 15

Procurement and sample testing of drugs
(2013-14 to 2015-16)

	2013-14	**2014-15**	**2015-16**	**2015-16 vs 2013-14 (Increase + / decrease −)**
Drugs procured by the HA				
Amount of drugs procured	$5,421 million	$5,801 million	$6,256 million	+15.4%
No. of drugs selected for testing				
Drugs in general	773	758	726	−6.1%
Safety alerts related	0	28	31	N/A
Quality complaints related	10	7	2	−80%
Overall	783	793	759	−3.1%

Source: Audit analysis of HA records

5.4 According to HA records, during 2013-14 to 2015-16, all selected drugs passed the testing. However, the decreasing scale of drug testing was not commensurate with the increasing scale of HA procurement. Upon enquiry, the HA informed Audit in September 2016 that:

(a) the HA had a risk-based sample testing strategy which was recommended by an Expert Panel and had taken into account risks associated with individual drug items (e.g. priorities given to drugs used on vulnerable patients) and the level of procurement activities (e.g. priorities given to drugs under supply contracts with high consumption); and

(b) the HA had a sampling methodology recommended by the Expert Panel to implement the above-mentioned strategy, in terms of the proportion of items selected for testing according to the risk category.

Audit noted that the HA had not laid down the drug testing strategy and detailed sampling methodology to justify the scale of drug testing. The HA also had not documented how the results of inspection visits (see para. 5.9) and complaint investigations (see para. 5.14) had affected the selection of drugs.

Late submission of testing reports

5.5 Testing of drugs was outsourced to local laboratories. According to the contracts, they should submit reports on microbiological testing results within 20 working days, and reports on chemical testing results within 90 calendar days. However, Audit found that for testing performed in 2014-15 (Note 26), 41% of the reports were not submitted within the required time (see Table 16).

Note 26: *Reports on testing performed in 2014-15 were the latest available information at the time of audit review.*

Table 16

Late submission of some testing reports
(2014-15)

Type of testing	No. of reports			No. of days of delay	
	Submitted within the required time	Not submitted within the required time	Total	Range	Average
Microbiological testing	318 (78%)	88 (22%)	406 (100%)	1 to 59 working days	18 working days
Chemical testing	148 (38%)	239 (62%)	387 (100%)	1 to 194 calendar days	50 calendar days
Overall	466 (59%)	327 (41%)	793 (100%)		

Source: Audit analysis of HA records

5.6 Upon enquiry, the HA informed Audit in September 2016 that there were circumstances that required extra time for testing, such as acquiring chemical reference standards and procurement of specific apparatus or equipment. In Audit's view, late reporting of testing results will cause delay in taking necessary action to mitigate the risk of sub-standard drug items.

Audit recommendations

5.7 **Audit has *recommended* that the Chief Executive, HA should:**

(a) **formulate a strategy for sample testing of drugs, taking account of relevant factors such as coverage and results of other quality assurance work, level of HA procurement activities, risk associated with individual drug items and resources available;**

(b) **lay down clearly the sampling methodology for implementing the drug testing strategy in (a) above; and**

(c) **ensure that contractors submit reports on drug testing according to the time frame set out in the contracts.**

Response from the Hospital Authority

5.8 The Chief Executive, HA has said that the HA agrees with the audit recommendations. He has also said that the HA will:

(a) formalise its strategy and methodology to become part of the standard operating procedure for sample testing of drugs; and

(b) review the contract requirements to ensure feasible and timely submission of test reports, and build in multiple time frames to address cases meeting different levels of requirements.

Inspection of premises of drug suppliers

5.9 In 2012, to enhance monitoring of the quality of drugs, the HA started to commission a local laboratory to inspect the premises of selected drug suppliers. Conditions of the premises, as well as supplier practices in production and quality control, are inspected. According to the HA:

(a) as a drug purchaser for public healthcare services and in its due diligence, the HA inspects premises to review compliance with improvement measures in response to drug product quality complaints; and

(b) the HA has an established risk-based inspection programme taking severity and frequency of complaints as the prioritisation criteria. Currently, two inspections are conducted annually on average.

5.10 HA records indicated that as at June 2016, the premises of 6 drug suppliers had been inspected, comprising 1 inspected in 2012, 1 in 2013, 2 in 2014 and 2 in 2015. For all the 6 inspections, the suppliers' premises and practices were considered as reasonable or acceptable.

5.11 Audit considers that inspection of premises of drug suppliers is useful for monitoring the quality of drugs procured from them. The HA needs to review this programme to determine whether there is room for expanding it. For example, Audit noted that all the 6 drug suppliers which had been inspected by the HA were local drug manufacturers. The HA may also inspect the premises of local drug wholesalers, especially those associated with many drug quality complaints (see Case 3 for an example).

Case 3

A drug supplier associated with many drug quality complaints not covered by the inspection programme

1. Supplier D was a local drug wholesaler.

2. During each of the past 3 years, Supplier D supplied 57 to 59 drug items to the HA in considerable quantity. In 2015-16, the amount of the 57 drug items procured from Supplier D totalled $35 million.

3. From time to time, drug quality complaints about Supplier D were lodged with the HA. During 2013-14 to 2015-16, 51 of the 940 drug quality complaints were related to Supplier D.

4. As at June 2016, the HA had not conducted any inspection visit to the premises of Supplier D.

Audit comments

5. Supplier D was one of the main suppliers. The many drug quality complaints about Supplier D might call for an inspection visit to its premises.

Source: Audit analysis of HA records

Audit recommendation

5.12 **Audit has *recommended* that the Chief Executive, HA should consider expanding the programme on inspection of premises of drug suppliers to cover more drug suppliers, particularly those associated with many drug quality complaints and supplying considerable amount of drugs to the HA.**

Response from the Hospital Authority

5.13 The Chief Executive, HA has said that the HA agrees with the audit recommendation. He has also said that the HA will review the existing programme on inspection of premises of drug suppliers to take into account the volume of supply as an additional prioritisation criterion.

Investigation of complaints about drug quality

5.14 The Chief Pharmacist's Office is responsible for reviewing and following up drug quality complaints received from frontline hospitals and clinics. It will request suppliers to investigate the issue and propose improvement measures where necessary. In 2015-16, there were 343 drug quality complaints (Note 27). As at May 2016, the investigations of 240 cases had been completed (Note 28). Audit analysis of the 240 cases revealed that in 24 cases, it took more than 6 months to complete the investigations (see Table 17).

Note 27: *There were 275 complaints in 2013-14 and 322 in 2014-15.*

Note 28: *Of the remaining 103 cases, 97 cases were still under investigation and 6 cases had been closed after concluding that no investigation was necessary. The 97 outstanding cases included 7 which had been outstanding for over 6 months.*

Table 17

Time taken to complete investigations of 240 drug quality complaints received in 2015-16

Time taken	No. of cases	
1 month or less	13 (5%)	
Over 1 to 3 months	126 (53%)	
Over 3 to 6 months	77 (32%)	227 (95%)
Over 6 months (Note)	24 (10%)	
Total	240 (100%)	

Source: Audit analysis of HA records

Note: The longest time taken to complete investigation was 13.5 months, involving one case.

5.15 Audit noted that, in requesting suppliers to investigate drug quality complaints, the HA required suppliers to provide investigation reports within one month for its follow-up. Table 17 shows that in 227 (95%) cases, the total time taken by the HA to complete investigation (including the time used by suppliers) exceeded one month. Of the 227 cases, suppliers failed to report within the one-month time frame in 138 (61%) cases. The tardiness of supplier actions could be a factor causing the long time taken to complete some investigations. Upon enquiry, the HA informed Audit in September 2016 that the course of an investigation sometimes involved logistics for returning samples to overseas manufacturers, commissioning independent tests and implementing improvement measures that required regulatory approvals. All these needed adequate time for completion.

5.16 Audit considers that sub-standard drugs could pose a significant risk to patient health and safety. Investigations of drug quality complaints should be completed as soon as possible, with a view to taking timely remedial action where necessary.

Audit recommendation

5.17 **Audit has *recommended* that the Chief Executive, HA should take effective measures to ensure that investigations of complaints about drug quality are completed as soon as possible.**

Response from the Hospital Authority

5.18 The Chief Executive, HA has said that the HA agrees with the audit recommendation. He has also said that the HA will develop performance indicators to regularly monitor the investigation of complaints and take measures to ensure timely completion of investigations.

PART 6: ADMINISTERING FINANCIAL ASSISTANCE PROGRAMMES FOR PURCHASING SELF-FINANCED DRUGS

6.1 This PART examines issues related to the HA's administration of financial assistance programmes for purchasing self-financed drugs. Audit has found room for improvement in the following areas:

(a) expanding coverage of drugs (paras. 6.7 to 6.12); and

(b) conducting post-approval checks (paras. 6.13 to 6.24).

Government's healthcare policy

6.2 The Government's healthcare policy is to ensure that no one is prevented, through lack of means, from obtaining adequate medical treatment. According to the HA:

(a) to fulfil this policy objective, the HA has been providing highly subsidised healthcare services to the public. Patients are provided with drugs in accordance with their clinical needs and available treatment guidelines in the HA at highly subsidised rates. The scope of this policy is described by services under the standard fees and charges. For general drugs and special drugs of which usage is within the specific indications, they are provided within the standard fees and charges; and

(b) guided by the principles of evidence-based medical practice, targeted subsidy and opportunity costs considerations, self-financed drugs are non-standard provisions in the HA and patients will have to purchase these drugs at their own expenses.

Financial assistance programmes for purchasing self-financed drugs

6.3 For some self-financed drugs proven to be of significant benefits but extremely expensive for the HA to provide as part of its subsidised services, subsidies are provided through the following two Government funds to needy patients to meet the drug expenses:

(a) ***Samaritan Fund (SF, established in 1950).*** The objective of the Fund is to provide subsidies to needy patients for designated privately purchased medical items including specified self-financed drugs. The HA has administered the Fund since 1990; and

(b) ***Community Care Fund (CCF, established in 2011).*** The objective of the Fund is to provide assistance to people facing economic difficulties, in particular those who fall outside the social safety net or those within the safety net but have special circumstances that are not covered. The Fund runs a number of assistance programmes. The HA is responsible for administering a medical assistance programme to provide subsidies to needy patients to purchase specified self-financed cancer drugs.

6.4 As at April 2016, the SF and the CCF covered a total of 30 self-financed drugs (referred to as self-financed drugs with safety net — Note 29). For the other 47 self-financed drugs listed on the HADF (referred to as self-financed drugs without safety net — see Table 1 in para. 2.2), no financial assistance is provided to patients for purchasing them. Upon enquiry, the HA informed Audit in September 2016 that:

(a) self-financed drugs without safety net included drugs with only preliminary medical evidence, drugs with marginal benefits over available alternatives but at significantly higher costs, as well as lifestyle drugs (e.g. anti-obesity drugs). The therapeutic objectives of these drugs fell outside the scope of highly subsidised public medical services; and

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Note 29: *The SF covered 22 drugs while the CCF covered 10 drugs. As 2 drugs were covered by both Funds (the clinical indications designated by the Funds were different), the total number of drugs covered was 30.*

(b) the provision of self-financed drugs without safety net allowed patients the choice of using drugs outside the highly subsidised healthcare system through self-financing while remaining within the highly subsidised healthcare system.

6.5 To be eligible for subsidies under the SF and the CCF for purchasing self-financed drugs with safety net, the patient must be an HA patient and fulfil all of the following requirements:

(a) ***Clinical requirement.*** The patient's clinical indications and commencement of treatment must be supported by a designated HA doctor;

(b) ***"Eligible Person" requirement.*** The patient must be an eligible person within the meaning of the latest relevant government gazette published under the Hospital Authority Ordinance; and

(c) ***Financial requirement.*** The patient must pass a household-based financial assessment conducted by the Medical Social Worker (Note 30). The financial assessment includes assessment on the patient's household income, expenditures and assets to calculate the annual disposable financial resources (Note 31).

6.6 Table 18 shows the amounts of subsidies for purchasing self-financed drugs with safety net provided by the SF and the CCF during 2010-11 to 2015-16.

Note 30: *Medical Social Workers of the Social Welfare Department or the HA are stationed in public hospitals and some specialist out-patient clinics. Comprehensive Social Security Assistance recipients do not need to go through financial assessment.*

Note 31: *If the amount of annual disposable financial resources is $20,000 or less, the subsidy is the drug cost; if the amount is $20,001 to $60,000, the subsidy is the drug cost minus $1,000 or $2,000; and if the amount is over $60,001, the subsidy is the drug cost minus 5% to 20% of the amount. No subsidy is provided if the calculated subsidy is a negative amount.*

Table 18

Subsidies for purchasing self-financed drugs with safety net provided by SF and CCF (2010-11 to 2015-16)

Year	SF		CCF	
	No. of approved cases	Amount of drug subsidies ($ million)	No. of approved cases	Amount of drug subsidies ($ million)
2010-11	1,354	144	N/A (Note)	N/A (Note)
2011-12	1,516	155	200	20
2012-13	1,745	208	829	73
2013-14	2,027	240	1,364	112
2014-15	2,230	240	1,680	109
2015-16	2,237	269	1,678	123
Total	11,109	1,256	5,751	437

Source: HA records and financial statements of the SF and the CCF

Note: The CCF's medical assistance programme commenced in August 2011.

Expanding coverage of drugs

6.7 As at April 2016, there were 30 self-financed drugs with safety net and 47 self-financed drugs without safety net (see para. 6.4). These 77 drugs have been evaluated with positive recommendations by the Drug Advisory Committee before they are listed on the HADF (see para. 2.5(a)). The 47 self-financed drugs without safety net included 18 drugs for treatment of certain cancers. Table 19 shows that during 2013-14 and 2014-15, the number of self-financed drugs without safety net prescribed to out-patients was much greater than that for self-financed drugs with safety net. This indicated that many patients needed self-financed drugs without safety net for treatment.

Table 19

Drug items prescribed to out-patients (2013-14 and 2014-15)

Category	2013-14		2014-15	
	No. of items ('000)	Percentage	No. of items ('000)	Percentage
General drugs	38,685	88.8%	38,945	87.9%
Special drugs	4,282	9.8%	4,737	10.7%
Self-financed drugs with safety net	23	0.1%	25	0.1%
Self-financed drugs without safety net	576	1.3%	589	1.3%
Total	43,566	100%	44,296	100%

Source: *HA records*

Remarks: *The 2014-15 data were the latest available data at the time of audit review.*

6.8 From time to time, there have been requests from patients and patient groups for expanding the coverage of the safety net to benefit more patients (e.g. drugs for treatment of certain cancers). The HA has an established mechanism for conducting annual exercises to prioritise new drugs to be included under the scope of the safety net, taking into account the safety, efficacy and cost-effectiveness of the new drugs and other relevant factors such as financial resources (Note 32).

Note 32: *The Drug Management Committee convenes an annual meeting to prioritise all drug-related safety net proposals. The recommended list for the SF would be sent to the Samaritan Fund Office for processing and onward prioritisation by the Samaritan Fund Management Committee. Final endorsement by the Medical Services Development Committee under the HA Board has to be obtained before implementation. Similarly, the recommended list for the CCF would be sent to the HA Community Care Fund Administration Committee, the Community Care Fund Task Force and finally the Commission on Poverty for approval.*

6.9 Audit noted that between 2013-14 and 2015-16, seven new self-financed drugs were included under the scope of the safety net. In Audit's view, given that many patients needed self-financed drugs without safety net for treatment (see para. 6.7), the HA should continue its efforts to prioritise such drugs for inclusion under the scope of the safety net.

Audit recommendation

6.10 **Audit has *recommended* that the Chief Executive, HA should continue to include appropriate new self-financed drugs under the scope of the safety net.**

Response from the Hospital Authority

6.11 The Chief Executive, HA has said that the HA agrees with the audit recommendation. He has also said that the HA will continue to include appropriate new drugs under the scope of the safety net, based on safety, efficacy and cost-effectiveness considerations and other relevant factors as described in the HADF Management Manual.

Response from the Government

6.12 The Secretary for Food and Health has said that:

(a) while the Government's healthcare policy is to ensure that no one is prevented, through lack of means, from obtaining adequate medical treatment, self-financed drugs (both with or without safety net) are services that fall outside the scope of this policy; and

(b) as can be seen from Table 19 in paragraph 6.7, in both 2013-14 and 2014-15, general drugs and special drugs, which were highly subsidised by public funding and covered by the standard fees and charges in public hospitals and clinics, accounted for 98.6% of the drug items prescribed to out-patients, which was much greater than that of the self-financed drugs (both with or without safety net). It shows that the HA has on the whole ensured equitable access by patients to cost-effective drugs of proven safety and efficacy.

Conducting post-approval checks

6.13 The subsidies under the SF and the CCF are provided only for needy patients. Acquiring a subsidy by deception is a criminal offence. In addition to the consequence of being ineligible for the subsidy, the patient/applicant/patient's household member(s) shall be liable on conviction upon indictment to imprisonment of 10 years under the Theft Ordinance (Cap. 210). To prevent and detect fraud and abuse and to take appropriate action against suspect who commits deception related offence, the HA conducts sample checks on the approved SF/CCF cases, as follows:

(a) ***Level-1 checks at cluster level.*** The Cluster Checking Units (CCUs) (Note 33) at individual clusters conduct checks on the accuracy and completeness of financial information provided by applicants for selected approved SF/CCF cases (Note 34). For all cases of under-reporting of income and/or assets (referred to as "under-reporting cases" hereinafter), the CCUs will take appropriate actions (e.g. issuing warning letters and recovering the overpaid amounts). For significant under-reporting cases (Note 35), the CCUs will also refer them to the HA Head Office for level-2 checks; and

(b) ***Level-2 checks at HA Head Office.*** The Medical Fee Assistance Section (MFA Section) reviews the under-reporting cases referred by the CCUs for taking necessary action, including reporting suspected fraud cases to the police for investigation.

Appendix C shows the workflow of post-approval checks on SF/CCF cases.

Note 33: *The CCUs report to their Cluster Chief Executives.*

Note 34: *The Medical Fee Assistance Section at the HA Head Office selects approved SF/CCF cases mainly on a random basis, and allocates them to the CCUs for level-1 checks. According to the HA, in setting the post-approval checking strategy, the HA has considered the risk level, checking processing time and resource requirements.*

Note 35: *They are cases with the amount of overpayment of subsidy not less than $16,000.*

6.14 Table 20 shows the results of post-approval checks on SF/CCF cases approved between 2010-11 and 2015-16. Table 21 shows the amounts of overpayment of subsidy in under-reporting cases.

Table 20

Results of post-approval checks on SF/CCF cases (2010-11 to 2015-16)

Year of approval	No. of cases completed			
	Under-reporting cases		Cases without under-reporting found	Total
	With overpayment of subsidy	Without overpayment of subsidy		
2010-11	37 (27%)	27 (19%)	76 (54%)	140
2011-12	41 (27%)	25 (16%)	86 (57%)	152
2012-13	42 (20%)	60 (29%)	106 (51%)	208
2013-14	24 (8%)	99 (34%)	171 (58%)	294
2014-15	16 (4%)	148 (40%)	204 (56%)	368
2015-16	2 (1%)	70 (34%)	135 (65%)	207
Overall	162 (12%)	429 (31%)	778 (57%)	1,369 (Note)
	591 (43%)			

Source: *Audit analysis of HA records*

Note: *The total number of cases selected for post-approval checks was 1,672. As at the time of audit review (March 2016), there were 1,369 cases completed, 159 cases not yet completed and 144 cases terminated due to various reasons (e.g. death of patient or patient was a Comprehensive Social Security Assistance recipient (see Note 30 to para. 6.5(c))).*

Table 21

Under-reporting cases with overpayment of subsidy (2010-11 to 2015-16)

Year of approval	SF		CCF		Total	
	No. of cases	Amount overpaid ($ '000)	No. of cases	Amount overpaid ($ '000)	No. of cases	Amount overpaid ($ '000)
2010-11	37	820	N/A (Note 1)	N/A (Note 1)	37	820
2011-12	40	1,790	1	0	41	1,790
2012-13	33	1,307	9	40	42	1,347
2013-14	16	493	8	68	24	561
2014-15	8	438	8	401	16	839
2015-16	2	33	0	0	2	33
Total	136	4,881	26	509	162	5,390 (Note 2)

Source: Audit analysis of HA records

Note 1: The CCF's medical assistance programme commenced in August 2011.

Note 2: As at July 2016, of the overpayment of $5.39 million, the HA had recovered $3.66 million (68%), had agreed with the patients to recover $1.14 million (21%) by instalments and was taking other recovery procedures (e.g. legal action) to recover the remaining $0.59 million (11%).

High percentage of under-reporting cases

6.15 It can be seen from Tables 20 and 21 that during 2010-11 to 2015-16, of the 1,369 cases with post-approval checks completed, 591 (43%) cases were under-reporting cases, involving overpayments of subsidies totalling $5.39 million. Upon enquiry, the HA informed Audit in September 2016 that:

(a) to safeguard public funds, the HA's primary strategies were to prevent and deter fraud. Between 2010 and 2015, the HA had rolled out various measures, including patient education and publicity; and

(b) the decreasing trends of under-reporting cases with overpayment of subsidy (from 27% to 1% — see Table 20) and the amount overpaid (from $820,000 to $33,000 — see Table 21) demonstrated the effectiveness of these strategies.

However, Audit found some areas for improvement in the conduct of post-approval checks (see paras. 6.16 to 6.21). In Audit's view, after implementing appropriate improvement measures, the HA needs to monitor the results of the checks, and determine whether more sample checks are required to prevent and detect fraud and abuse.

Limited scope of checks

6.16 In conducting post-approval checks on SF/CCF cases, the HA mainly used the information obtained from bank searches. The scope of checks did not include other asset searches. Audit considers that, given the limited scope of checks, the HA would not be able to detect under-reporting of assets effectively. The HA needs to explore expanding the scope of checks, particularly for cases involving a substantial amount of subsidy. For example, the Land Registry's service on owner's properties information check may be used to obtain information on properties registered in the patient's/household member's name for detecting under-reporting of properties (Note 36).

Need to consider extending the bank search period

6.17 In applying for SF/CCF financial assistance, the applicant is required to make a declaration on the information provided. After approval, if there are changes in the particulars in the application within the validity period of the assistance, the applicant is required to notify the HA immediately and provide all relevant information to the Medical Social Worker for financial reassessment as appropriate.

Note 36: *Self-use residential property is not counted as an asset in calculating the annual disposable financial resources.*

6.18 According to the current HA guidelines, for the purposes of conducting post-approval checks, bank information should be obtained for the period from 3 months before the declaration date up to the approval date or latest financial reassessment approval date, whichever is the later (Note 37). Audit notes that such practice (i.e. not obtaining bank information up to the expiry of the validity period) does not enable the HA to check whether there were unreported changes after the approval date that affected the eligibility of the patient (see para. 6.17). The HA needs to consider extending the bank search period for cases involving a substantial amount of subsidy.

Long time taken to follow up some significant under-reporting cases

6.19 As mentioned in paragraph 6.13 and shown in Appendix C, CCUs refer significant under-reporting cases (with overpaid subsidy not less than $16,000) to the MFA Section for level-2 checks. After conducting the level-2 checks and consolidating the information, the MFA Section will refer those cases to the case conference (Note 38) for discussion. The conference members will decide the appropriate actions for suspected fraud cases (e.g. reporting to the police for investigation). The MFA Section maintains central registries for both the level-1 and level-2 checking cases to ensure that all significant under-reporting cases are followed through.

6.20 As shown in Table 20 in paragraph 6.14, among the cases approved during 2010-11 to 2015-16 and with post-approval checks completed, there were 162 under-reporting cases involving overpayment of subsidy. Audit noted that 56 (35%) of the 162 cases were significant cases with overpaid subsidy ranging from $17,000 to $223,000 per case. Table 22 shows the progress of handling these 56 cases as at 31 August 2016.

Note 37: *Before 2014, the bank search period was up to the expiry of the validity period of the financial assistance. Considering that the primary focus of post-approval check was to identify under-reported financial conditions at the time of application, the bank search period was revised to the financial assistance approval date with effect from 1 January 2014.*

Note 38: *The case conference is composed of representatives from the HA Head Office, Cluster/Hospital Management, SF Office (for SF cases only), CCUs, MFA Section, Social Welfare Department, and Medical Social Services Units under the Social Welfare Department and the HA.*

Table 22

Progress of handling of significant under-reporting cases approved between 2010-11 and 2015-16 (31 August 2016)

Case status	SF		CCF		Total	
	No. of cases	Amount overpaid ($ '000)	No. of cases	Amount overpaid ($ '000)	No. of cases	Amount overpaid ($ '000)
Cases which had not been submitted by CCUs to MFA Section for level-2 checks	14	1,046	1	150	15	1,196
Cases which had been submitted to MFA Section for level-2 checks:						
• Cases which had been returned to CCUs (Note 1)	6	381	1	163	7	544
• Cases which had been reported to the police (Note 2)	12	1,211	0	0	12	1,211
• Cases which had not been reported to the police	18	1,945	4	119	22	2,064
Sub-total	36	3,537	5	282	41	3,819
Total	50	4,583	6	432	56	5,015

Source: *Audit analysis of HA records*

Note 1: *These included cases checked to be inaccurate/incomplete and returned to CCUs for further follow-up, and cases with other medical assistance application approved and assigned back to CCUs for checking.*

Note 2: *As at 31 August 2016, no case had been prosecuted.*

Remarks: *The significant under-reporting cases had overpaid subsidy ranging from $17,000 to $223,000 per case.*

6.21 Audit noted that a long time was taken to follow up some significant under-reporting cases after completion of level-1 checks. Examples are as follows:

(a) as at 31 August 2016, 15 cases had not yet been submitted by the CCUs to the MFA Section for level-2 checks. Of these 15 cases, the level-1 checks for 10 cases had been completed for over 1 to 2.9 years (averaging 1.9 years); and

(b) as at 31 August 2016, 22 cases which had been submitted to the MFA Section for level-2 checks had not been reported to the police. Of these 22 cases, the level-1 checks for 14 cases had been completed for over 1 to 2.5 years (averaging 1.6 years).

6.22 Timely follow-up of significant under-reporting cases detected during post-approval checks, including instituting prosecution action in warranted cases and publicising the outcomes, helps create a deterrent effect and prevent fraud and abuse. The HA needs to review the audit findings in paragraph 6.21 and take improvement measures.

Audit recommendations

6.23 **Audit has *recommended* that the Chief Executive, HA should:**

(a) **monitor the results of post-approval checks on SF/CCF cases to determine whether more sample checks are required to prevent and detect fraud and abuse;**

(b) **explore expanding the scope of post-approval checks on SF/CCF cases, particularly for cases involving a substantial amount of subsidy;**

(c) **consider extending the bank search period up to the expiry of the validity period of the financial assistance for cases involving a substantial amount of subsidy; and**

(d) **review the long time taken to follow up some significant cases of under-reporting of income and/or assets and take improvement measures.**

Response from the Hospital Authority

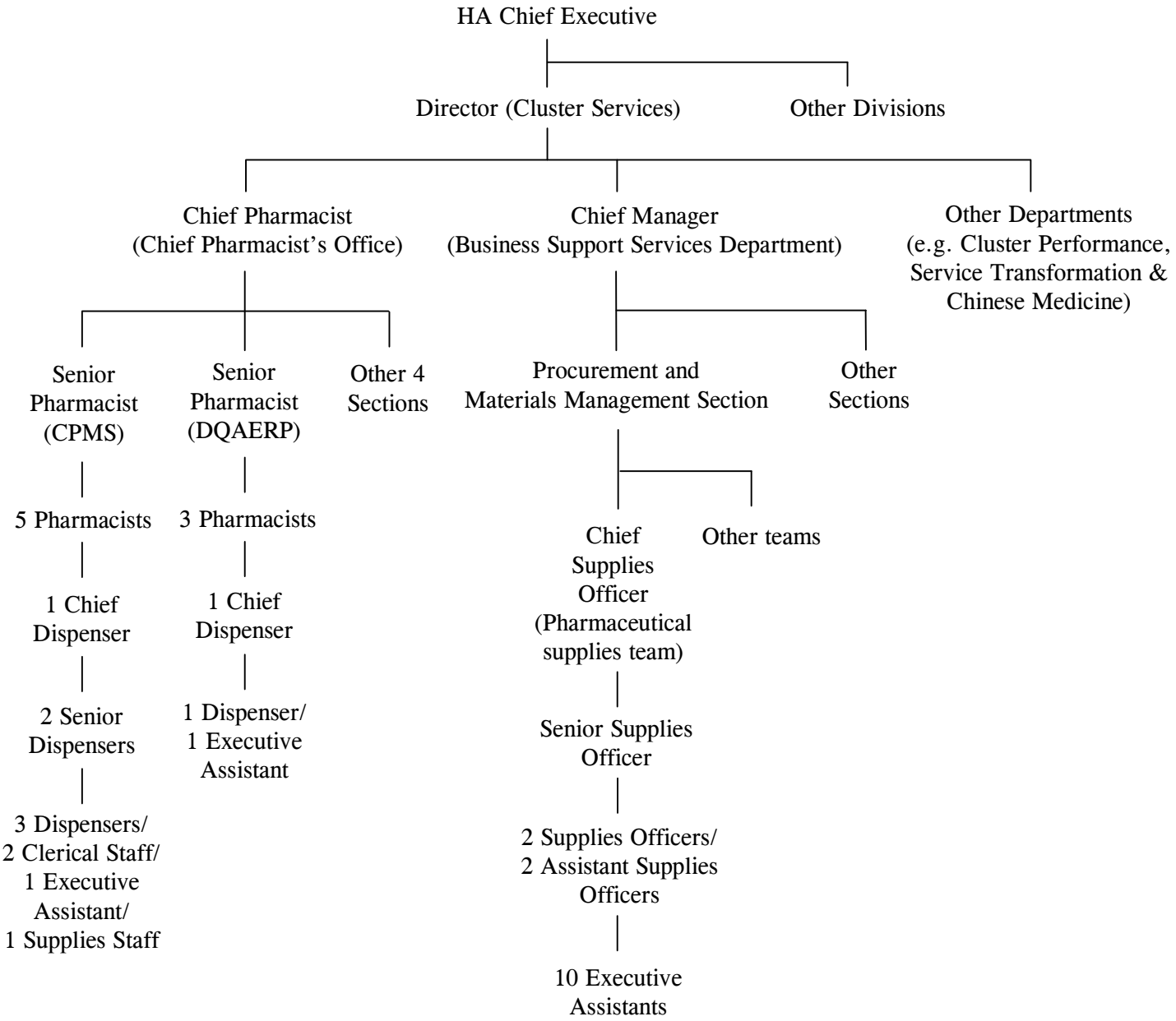
6.24 The Chief Executive, HA has said that the HA agrees with the audit recommendations. He has also said that the HA will:

(a) explore, for cases involving a substantial amount of subsidy, sampling more cases for checking, expanding the scope of checking and extending the bank search period up to the expiry of the validity period of the financial assistance; and

(b) develop performance indicators to monitor the processing time of level-1 and level-2 checks.

Appendix A
(para. 1.9 refers)

Hospital Authority Head Office
Organisation chart (extract)
(31 March 2016)

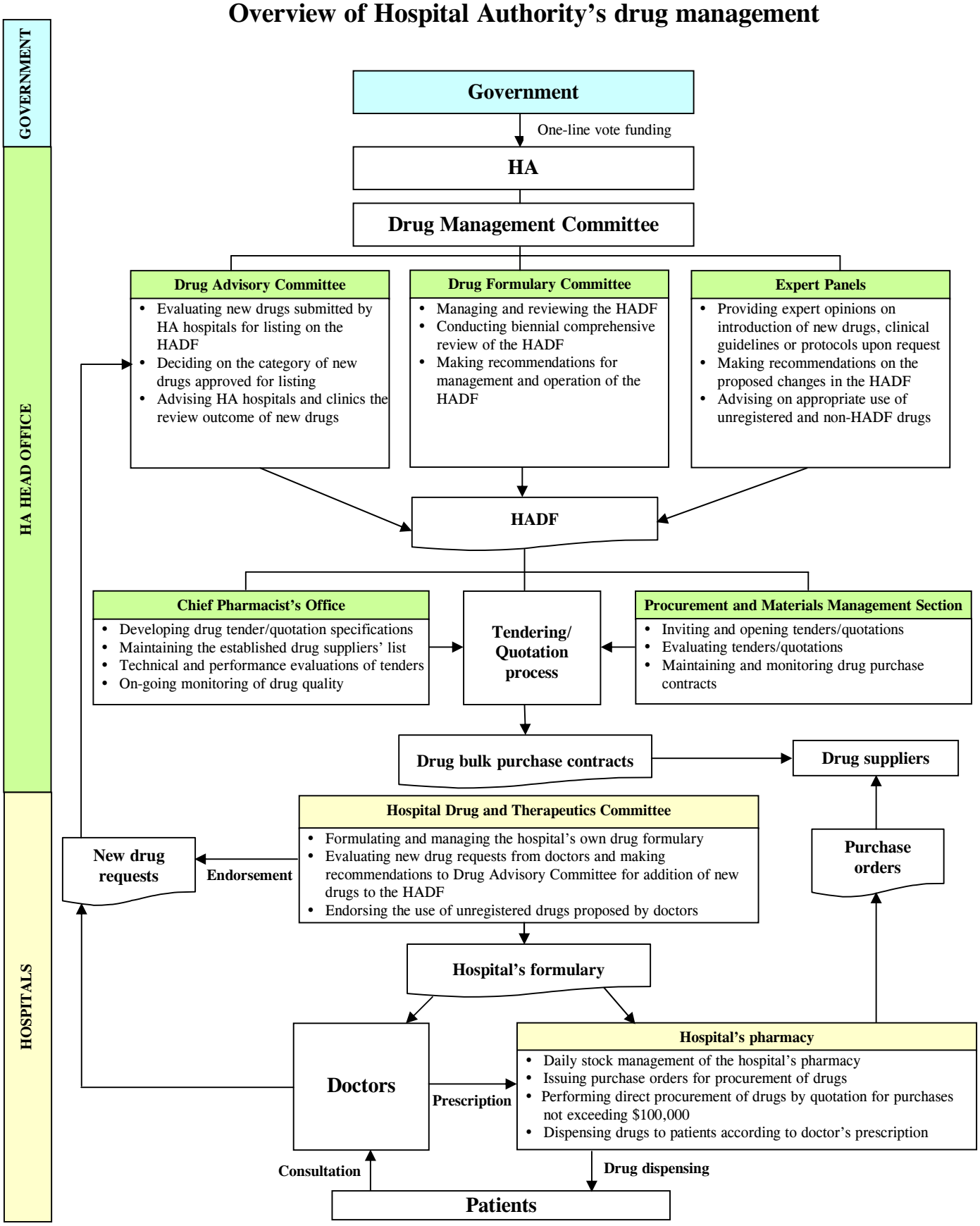


Legend: CPMS Corporate Pharmaceutical Management Section
DQAERP Drug Quality Assurance and Enterprise Resource Planning Section

Source: HA records

Appendix B
(paras. 1.9 and 2.5 refer)

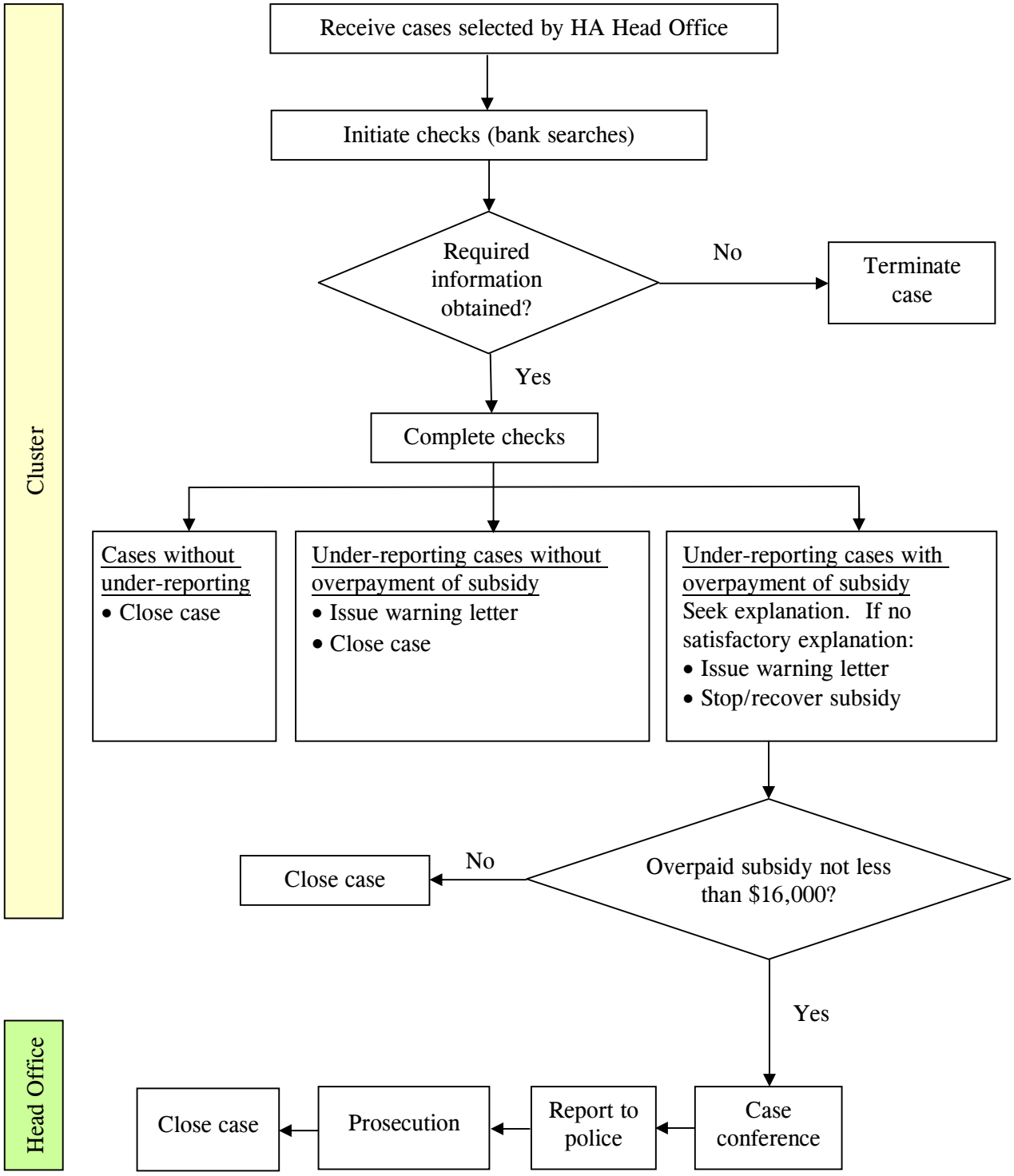
Overview of Hospital Authority's drug management



Source: Audit analysis of HA records

Appendix C
(paras. 6.13 and 6.19 refer)

Workflow of post-approval checks on financial assistance cases



Source: Audit analysis of HA records

Appendix D

Acronyms and abbreviations

Audit	Audit Commission
CCF	Community Care Fund
CCUs	Cluster Checking Units
DTCs	Drug and Therapeutics Committees
HA	Hospital Authority
HADF	Hospital Authority Drug Formulary
MFA Section	Medical Fee Assistance Section
SF	Samaritan Fund

Annex II

Action Plan

Director of Audit's Report No. 67 on

Hospital Authority's Drug Management

	Audit Recommendation	**Action Plan**
Part 2		
Paragraph 2.28	Audit has recommended that the Chief Executive, HA should: (a) review what measures need to be implemented to ensure that patients attending different public hospitals and clinics have equitable access to non-HADF drugs when they have the relevant clinical needs; (b) regularly review the need for the continued use of non-HADF drugs which had failed the Drug Advisory Committee's new drug evaluation; (c) consider drawing up a detailed manual for managing the use of non-HADF drugs, and ensure compliance with the relevant provisions including the approval procedure for prescribing non-HADF drugs; (d) issue comprehensive guidelines on the charging of non-HADF drugs covering different situations, and ensure compliance with the guidelines; and (e) ensure that the drug classifications in hospital formularies for communication uses by clinical staff tally with those specified in the HADF.	HA will: ● share information among hospitals to facilitate cross referencing in the use of non-HADF drugs; ● set up a mechanism to monitor and analyse the use of non-HADF drugs and evaluate the need for continual use; ● formulate a guideline on the use of non-HADF drugs to align their application, approval, documentation and monitoring. The existing section on non-HADF drugs in the HADF Management Manual will be expanded into a new chapter in the next revised version; ● explicitly define the charging principles through expanding the existing guideline on the use of immediate life-threatening emergency drugs to cover non-HADF drugs as well, taking into consideration whether it is clinical need or patient's choice; and ● develop a system function for auto-generation of the communication document on hospital drug formulary containing real-time information in a standard format.

Annex II

	Audit Recommendation	**Action Plan**
Paragraph 2.35	Audit has recommended that the Chief Executive, HA should: (a) given that few hospitals had applied for new drug listing, review the adequacy of the HA mechanism for listing new items on the HADF, taking account of the numerous new drugs emerging over time, and the benefits for considering their potential inclusion in the HADF in a timely manner; and (b) take measures to encourage and facilitate more HA hospitals and clinics to apply for new drug listing on the HADF.	HA will: ● request cluster and hospital DTCs to set a standing agenda item on new drug applications in their meetings; and ● share the link to the Department of Health's webpage on newly registered medicines in Hong Kong.
Paragraph 2.39	Audit has recommended that the Chief Executive, HA should review the 47 drugs with no consumption records during 2013-14 to 2015-16 to ascertain the need for deleting any of them from the HADF.	HA will review and refine the screening methodology of the computer system to ensure that all potentially obsolete drugs are identified for assessment.

Annex II

	Audit Recommendation	**Action Plan**
Part 3		
Paragraph 3.12	Audit has recommended that the Chief Executive, HA, should: (a) for the 520 drug items purchased directly by hospitals using quotation procedures and with purchase amounts in 2015-16 exceeding $100,000, review the direct purchase method to determine whether the demands of individual hospitals could be consolidated for establishing bulk contracts; (b) in particular, assess whether the purchase amounts of 193 of the 520 drug items (i.e. drug items with purchase amounts in 2015-16 exceeding $500,000) in the coming three years would exceed $1.5 million thus requiring establishing the bulk supply contracts by tender; (c) set up an effective mechanism for regularly analysing hospitals' demands for drug items not covered by bulk contracts to determine whether bulk contracts should be used to achieve the best value for money; and (d) review the practice of repeated purchases within a short period of time mentioned in paragraph 3.11 and provide hospitals with additional guidelines on direct purchases.	HA will: ● compare and adjust the 193 items pointed out by Audit against its own list and speed up the bulk contract arrangements for suitable candidates among these items; ● review and formalise direct purchase practice into corresponding guidelines; and ● utilise the forthcoming Pharmacy Business Intelligence System to conduct comprehensive analysis of the consumption, procurement patterns and purchase frequency to facilitate bulk contract arrangements and overall monitoring.

Annex II

	Audit Recommendation	**Action Plan**
Paragraph 3.25	Audit has recommended that the Chief Executive, HA, should: (a) closely monitor the performance of drug suppliers in complying with delivery schedules and take effective follow-up action on delivery complaints received from hospitals; (b) remind staff of the need to hold Performance Review Group meetings to review any unsatisfactory performance of suppliers in warranted cases; (c) for drug items meeting the criteria set by the HA (i.e. for treatment of chronic diseases and used by more than 100,000 patients annually) for multi-source procurement but currently procured from a single source for reasons such as risk-benefit considerations, implement multi-source procurement upon expiry of the current contract where appropriate; (d) assess the risk and impact of supply disruption for other commonly-used drug items to determine whether multi-source procurement should be implemented for them; and (e) take measures to improve the drug re-ordering procedure.	HA will: ● utilise the key performance indicators in the forthcoming Pharmacy Business Intelligence System to enhance monitoring of delivery performance; ● conduct regular Performance Review Group meetings to review the performance of manufacturers and suppliers; ● continue conducting multi-source tender exercises on existing and new drug items meeting the pre-set criteria, and review the current criteria for conducting multi-source tender exercises; and ● review and explore relevant factors to assist decision making in the drug re-ordering procedure.

Annex II

	Audit Recommendation	**Action Plan**
Part 4		
Paragraph 4.8	Audit has recommended that the Chief Executive, HA, should: (a) regularly assess the extent of drug wastage among patients of the HA; and (b) based on the assessment in (a) above, take appropriate measures to tackle the problem of drug wastage.	HA will pilot the implementation of drug refill services in selected specialist out-patient clinics to break long duration prescriptions into refills and provide drug counselling for targeted patients between refills. These services will help estimate and reduce the extent of drug wastage and improve patient care, and will be rolled out upon positive evaluation of the pilot.
Paragraph 4.17	Audit has recommended that the Chief Executive, HA, should: (a) monitor the number of incidents of missing dangerous drugs and conduct a comprehensive review of the handling and custody of dangerous drugs where necessary; (b) regularly remind relevant staff of the importance of ensuring the proper handling and safe custody of dangerous drugs in HA hospitals and clinics; (c) issue guidelines on the investigation of incidents of missing dangerous drugs, and ensure that the staff concerned comply with the guidelines and take effective improvement measures to prevent recurrence; and (d) ensure that incidents of missing dangerous drugs are forthwith reported to the Department of Health.	HA will ● enhance staff training and conduct regular audits; ● enhance reporting of incidents of missing dangerous drug to facilitate monitoring and notification, and follow-up reporting to the Department of Health; and ● develop a template to guide investigation of incidents of missing dangerous drugs.

Annex II

	Audit Recommendation	**Action Plan**
Part 5		
Paragraph 5.7	Audit has recommended that the Chief Executive, HA, should: (a) formulate a strategy for sample testing of drugs, taking account of relevant factors such as coverage and results of other quality assurance work, level of HA procurement activities, risk associated with individual drug items and resources available; (b) lay down clearly the sampling methodology for implementing the drug testing strategy in (a) above; and (c) ensure that contractors submit reports on drug testing according to the time frame set out in the contracts.	HA will ● formalise its strategy and methodology to become part of the standard operating procedure for sample testing of drugs; and ● review the contract requirements to ensure feasible and timely submission of test reports, and build in multiple timeframes to address cases meeting different levels of requirements.
Paragraph 5.12	Audit has recommended that the Chief Executive, HA should consider expanding the programme on inspection of premises of drug suppliers to cover more drug suppliers, particularly those associated with many drug quality complaints and supplying considerable amount of drugs to the HA.	HA will review the existing programme on inspection of premises of drug suppliers to take into account the volume of supply as an additional prioritisation criterion.
Paragraph 5.17	Audit has recommended that the Chief Executive, HA should take effective measures to ensure that investigations of complaints about drug quality are completed as soon as possible.	HA will develop performance indicators to regularly monitor the investigation of complaints and take measures to ensure timely completion of investigations.

Annex II

	Audit Recommendation	**Action Plan**
Part 6		
Paragraph 6.10	Audit has recommended that the Chief Executive, HA should continue to include appropriate new self-finnaced drugs under the scope of the safety net.	HA will continue to include appropriate new drugs under the scope of the safety net, based on safety, efficacy and cost-effectiveness considerations and other relevant factors as described in the HADF Management Manual.
Paragraph 6.23	Audit has recommended that the Chief Executive, HA should: (a) monitor the result of post-approval checks on SF/CCF cases to determine whether more sample checks are required to prevent and detect fraud and abuse; (b) explore expanding the scope of post-approval checks on SF/CCF cases, particularly for cases involving a substantial amount of subsidy; (c) consider extending the bank search period up to the expiry of the validity period of the financial assistance for cases involving a substantial amount of subsidy; and (d) review the long time taken to follow up some significant cases of under-reporting of income and/or assets and take improvement measures.	HA will: ● explore, for cases involving a substantial amount of subsidy, sampling more cases for checking, expanding the scope of checking and extending the bank search period up to the expiry of the validity period of the financial assistance; and ● develop performance indicators to monitor the processing time of level-1 and level-2 checks.