

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.

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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).

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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.

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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).

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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

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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));**

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- (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));

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- (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.