The Audit Commission ("Audit") conducted a review of the Hospital Authority ("HA")'s drug management.

2. Since 2005, to ensure safety, efficacy and cost effectiveness, HA has implemented the HA Drug Formulary ("HADF") for standardizing drug policy and drug utilization in all public hospitals and clinics. HADF drugs are intended for corporate-wide use benefiting the entire local population, and most HADF drugs prescribed to patients are included in standard fees charged for services provided. To suit its specific needs, each hospital may select drugs from 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 HADF ("non-HADF drug") in emergency/life-threatening situations or specific circumstances. If a hospital intends to include the new drug in HADF, it should follow the procedure and submit an application to HA's Drug Advisory Committee which is responsible for evaluating applications for listing new drugs on HADF. As at April 2016, HADF consisted of 1 295 drugs (or 2 708 drug items).[1] In 2015-2016, the costs of drugs used by HA patients totalled $5,710 million, representing about 10% of HA total expenditure.

3. The Committee noted the following findings from the Director of Audit's Report:

- in 2015-2016, 362 non-HADF drug items were used by public hospitals and clinics, an increase of 25% from 290 items in 2013-2014. Compared to 2013-2014, the expenditure on non-HADF drugs had escalated to $249 million (increased by 180%) in 2015-2016, representing 4.4% of HA total drug expenditure. According to HA, non-HADF drugs were to cater for the clinical needs of individual patients in exceptional situations, but no mechanism was established to make them available to all patients having relevant clinical needs. Non-HADF drugs might not be registered drugs or might not fulfil the criteria for incorporation into HADF, but their use on individual basis based on clinical needs was still justifiable;

- the 362 non-HADF drug items used in 2015-2016 comprised 95 items (73 drugs) which had been registered in Hong Kong and 267 unregistered ones. For 28 of these 73 registered drugs, applications for listing on HADF had been rejected during the period

[1] 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.

January 2009 to January 2016 one to four times for various reasons, including insufficient justification of the treatment cost in relation to the benefits, in which 12 drugs had been rejected more than one time;

- HA had not provided clear written guidelines for managing the use and charging of non-HADF drugs. Different hospitals had different practices in the approval procedures for the prescription and charging of non-HADF drugs by doctors;

- while there were on average 850 new drug items registered in Hong Kong per year between 2013 and 2015, only 51 drugs were added to HADF from 2013-2014 to 2015-2016. Few HA hospitals and clinics regularly applied for new drug listing. Some non-HADF registered drugs were in regular demand and stocked, but no applications for listing on HADF had been made;

- according to HA's current drug procurement practices, bulk contracts were established for procuring some drug items with annual purchase amount exceeding $100,000. For drug items not covered by bulk contracts, hospitals could purchase them directly from suppliers. Of the 1 019 drug items purchased directly by hospitals in 2015-2016, 520 drug items had purchase amounts (aggregating all hospitals) exceeding $100,000, involving expenditure totalling $406 million. If the demands of individual hospitals could be consolidated for establishing bulk contracts, procurement costs could be saved and more economies of scale achieved. Audit also discovered that 193 (expenditure totalled $328 million) of the 520 drug items might be procured through bulk supply contracts by tender. Moreover, repeated direct purchases by hospitals had occurred within a short period, with total purchase amount exceeding $100,000;

- during 2013-2014 to 2015-2016, the number of complaints about late delivery of drugs by a supplier increased by 183% from 65 to 184. HA might convene a Performance Review Group meeting to review the supplier's performance for necessary follow-up actions, but no such meetings had been held for the abovementioned supplier;

- Audit visited four HA hospitals and 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 level of 182 items were even below the minimum levels;[2]

- the average period of time covered by a prescription had been increasing from 2010-2011 to 2014-2015, while overseas experience indicated that prescribing large quantities of drugs for a long period of time could lead to drugs being unused and wasted;

- 32 incidents of missing dangerous drugs occurred during 2011-2012 to 2015-2016, but HA could not identify the direct causes in 27 incidents, and four of these 27 incidents happened in one hospital. Five incidents had not been reported to the Department of Health after a lapse of 425 to 1 494 days since the drugs were found missing;

- HA commissioned laboratories to conduct sample testing of drugs and requested suppliers to investigate complaints about drug quality. However, there were delays in completing the tests and investigations,[3] 41% of the test reports were not submitted within the required time in 2014-2015, which might cause delay in taking necessary action to mitigate the risk of sub-standard drug items;

- to enhance the monitor of drug quality, HA commissioned a local laboratory since 2012 to inspect the premises of selected drug suppliers. From 2013-2014 to 2015-2016, HA received 51 drug quality complaints which were related to one supplier, but HA had not conducted any inspection visit to the premises of that supplier as at June 2016;

- suppliers involving drug quality complaints would be requested to investigate the issue and provide investigation reports within one month for its follow-up. HA received 343 drug quality complaints in 2015-2016. The total time taken by HA to complete investigation for 227 cases exceeded one month. Of these 227 cases, suppliers failed to report within the time frame in 138 cases;

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[2] HA's computerized Enterprise Resource Planning 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).

[3] According to the contracts signed between HA and the laboratories, the laboratories should submit reports on microbiological testing results within 20 working days, and reports on chemical testing results within 90 calendar days.

- the Government's healthcare policy was to ensure that no one was prevented, through lack of means, from obtaining adequate medical treatment. However, self-financed drugs were services that fell outside the scope of this policy. For some self-financed drugs proven to be of significant benefits but extremely expensive for HA to provide as part of its subsidized services, subsidies were provided through the Samaritan Fund ("SF") and the Community Care Fund ("CCF"). As at April 2016, SF and CCF only covered 30 self-financed drugs (hereinafter referred to as "self-financed drugs with safety net"). For another 47 self-financed drugs listed on HADF which were not covered by SF and CCF (hereinafter referred to as "self-financed drugs without safety net"), no financial assistance would be provided to patients for purchasing them. 18 of these 47 drugs were used for treatment of certain cancers. From 2013-2014 and 2014-2015, 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; and

- the subsidies under SF and CCF were provided for needy patients only. HA would conduct sample checks on the approved SF/CCF cases. During 2010-2011 to 2015-2016, under-reporting of income and/or assets were found in 591 (43%) of the 1 369 cases with post-approval checks completed. The follow-up time of some significant under-reporting cases was long.

4. The Committee did not hold any public hearing on this subject. Instead, it asked for written responses regarding the utilization of non-HADF drugs and unregistered drugs, the progress of setting up a mechanism to monitor and analyze the use of non-HADF drugs, the inclusion criteria for listing on HADF, the charging principles of non-HADF drugs, the guidelines for procuring and dispensing drugs, the report mechanism for and follow-up actions on missing dangerous drugs, measures to monitor drugs quality, and measures to improve the financial assistance programmes for purchasing self-financed drugs. The consolidated replies from **Secretary for Food and Health, Chief Executive of HA** and **Director of Health** are in ***Appendix 32***.

5. The Committee wishes to be kept informed of the progress made in implementing the various recommendations made by Audit.