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Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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11 January 2017

Mr Anthony Chu
Clerk to Legislative Council Public Accounts Committee
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong
(Fax No.：2543 9197)

Dear Mr Chu,

**Public Accounts Committee**
**Consideration of Chapter 5 of the Director of Audit's Report No. 67**
**Hospital Authority's Drug Management**

Thank you for your letter of 20 December 2016 on the above subject.

We provide at Annex a coordinated response to your questions raised for the Public Accounts Committee on issues related to the Food and Health Bureau, Hospital Authority and Department of Health. The Management Manual of the Hospital Authority Drug Formulary is also enclosed for reference.

Yours sincerely,

(Charvis Li)
for Secretary for Food and Health

***Note by Clerk, PAC:** ***Please refer to Hospital Authority Website for the Management Manual of the Hospital Authority Drug Formulary.***

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**Coordinated Responses to PAC's Questions on**
**Chapter 5 of the Director of Audit's Report No. 67**
**Hospital Authority's drug management**

**For the Hospital Authority ("HA")**

1) Regarding the situation mentioned in paragraph 2.10 of the Audit Report, can HA inform this Committee:

a) of a breakdown of the unregistered drugs used in all specialist clinics and general outpatient clinics;

b) why unregistered drugs can be used in Hong Kong;

c) whether HA has overseen the corporate-wide use of unregistered drugs; if so, of the details; if not, the reasons for that;

d) whether HA or its healthcare staff have to bear the risk of being held responsible for the use of unregistered drugs, if any; if so, of the details; and

e) of the criteria for incorporating drugs into HADF?

a) As at April 2016, the number of unregistered drugs in use in the seven clusters under the management of the Hospital Authority ("HA") is set out below:

| Cluster | Number of Unregistered Drugs in Use |
|---|---|
| Hong Kong East | 133 |
| Hong Kong West | 197 |
| Kowloon Central | 162 |
| Kowloon East | 125 |
| Kowloon West | 165 |
| New Territories East | 171 |
| New Territories West | 138 |

b) Not every clinical condition has a corresponding registered drug readily available for treatment in Hong Kong. Clinicians may need to prescribe unregistered drugs based on their clinical expertise and professional judgment, taking into consideration the clinical conditions of individual

patients. When a specific patient demonstrates a clinical need, clinicians may follow the established mechanism to apply for the approval of the Department of Health for use of unregistered drugs in Hong Kong.

c) It is HA's established policy that only new drug entities and new indications registered in Hong Kong would be considered for listing in the HA Drug Formulary ("HADF"). However, clinicians may need to prescribe unregistered drugs based on their clinical expertise and professional judgment, taking into consideration the clinical conditions of individual patients. The use of non-HADF drugs (including unregistered drugs) is an integral part of medical care catering for the clinical needs of individual patients in exceptional situations. The inclusion of non-HADF drugs in HA's drug policy is to bridge the gap between population and individual needs and to manage urgent situations to ensure that patients are provided with appropriate clinical care. There are established mechanism and procedures in place in respect of the application and endorsement for use of unregistered drugs in HA.

   If an unregistered drug is required for use on a specific patient, the concerned clinician must obtain prior endorsement of the Cluster / Hospital Drug & Therapeutic Committee ("DTC") via the Chief of Service before the procurement procedure can be initiated. The HA Head Office ("HAHO") would evaluate the request and, subject to the approval of the Department of Health for importation, individual hospitals can place order for the concerned unregistered drug.

d) HA clinicians would ensure that the prescribed drugs are clinically safe and appropriate for use on patients. Under the established mechanism for use of unregistered drugs, the concerned clinicians must obtain prior endorsement from the Cluster / Hospital DTC via the Chief of Service. The use of unregistered drugs, where necessary, is an integral part of medical care catering for the clinical needs of individual patients in exceptional situations. As a whole, HA would take on full responsibility for provision of care for all its patients.

e) HA embarked on developing the HADF in 2003 along the core values of evidence-based medical practice, rational use of public resources, targeted subsidy, opportunity cost consideration and facilitation of patients' choice. HA follows an evidence-based approach in evaluating new drugs for listing

on the HADF, having regard to the three principal considerations of safety, efficacy and cost-effectiveness while taking into account other 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 views of professionals and patient groups. These considerations are described in the HADF Management Manual which was promulgated to all internal and external stakeholders upon its publication in July 2015 and has since been available in HA's internet website for public reference.

2) Has HA explained the drug policy mentioned in paragraph 2.10(b) to the public and the Legislative Council? What measures HA has put in place to ensure that individual patients attending different public hospitals and clinics have equitable access to non-HADF drugs when they have clinical needs?

There is an established mechanism for use of non-HADF drugs (including unregistered drugs) on specific patients in HA. Under this mechanism, a hospital may, at its discretion, acquire a non-HADF drug that is required for use in emergency / life-threatening situations or specific circumstances through urgent request. When the clinical need is identified for use of non-HADF drugs on a specific patient, the concerned clinician may follow the established procedures to apply for prior endorsement of the Cluster / Hospital DTC via the Chief of Service. HAHO will then evaluate the request before individual hospitals can place order for the concerned non-HADF drug. If an unregistered drug is involved, prior approval from the Department of Health would be obtained before placing the order.

The procedure for use of non-formulary drugs was well promulgated to all clinical units in HA vide an internal memorandum; and a standardised form for requisition of non-HADF drugs has been put into use across all HA institutions since 2006. The use of non-HADF drugs is described in Chapter 3 of the HADF Management Manual, which was promulgated to all internal and external stakeholders upon its publication in July 2015 and has since been available in HA's internet website for public reference.

In response to the audit recommendations, HA will further formulate a detailed 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 also be expanded into a new chapter in the

next revised version.

3) Can HA inform this Committee of the timetable for and progress of setting up the mechanism mentioned in paragraph 2.29(b)? Since there is an increase in the use of non-HADF drug items in public hospitals and clinics, coupled with various factors such as the advance of medical technologies, will the Drug Advisory Committee also set up a mechanism to conduct regular reviews as to whether those drugs which have been rejected from being incorporated into HADF previously may, with the advance of times, fulfil the criteria for being incorporated into HADF?

As mentioned in the preceding reply, the use of non-HADF drugs (including unregistered drugs) is an integral part of medical care catering for the clinical needs of individual patients in exceptional situations. The inclusion of non-HADF drugs in HA's drug policy is to bridge the gap between population and individual needs and to manage urgent situations to ensure that patients are provided with appropriate clinical care.

In response to the audit recommendations, HA will set up a mechanism within the coming 12 months to strengthen the monitoring and analyse the frequency and duration of use of individual non-HADF drugs within and across hospitals. If required, Hospital DTCs will be requested to review if there is a continual need for using certain non-HADF drugs and to consider submitting new drug applications to the HA Drug Advisory Committee for evaluation and listing on the HADF where appropriate.

4) Regarding the phrase "the treatment cost in relation to the benefits" in paragraph 2.13(c), can HA explain its meaning?

As stated in Section 3.4 of the HADF Management Manual, HA follows an evidence-based approach in evaluating new drug applications for listing on the HADF, having regard to three principal considerations of safety, efficacy and cost-effectiveness while taking into account other 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 views of professionals and patient groups.

***Safety***

HA evaluates the safety profile of a new drug by weighing its clinical benefits against its risks, and compares the adverse effect profiles between the new drug and its alternatives. Short and long-term safety profiles and potential for serious adverse effects are also considered with reference to any black box warning, post-marketing surveillance reports and safety alerts issued by overseas health authorities. Special attention would be given to drugs that have potential risks of causing serious harm to patients when used in therapeutic doses or after inadvertent use.

***Efficacy***

The efficacy of a new drug is compared with that of other existing treatment alternatives in the HADF for the same disease condition where appropriate. Head-to-head, direct comparative randomised trials which offer the highest level of evidence are preferred over indirect comparisons. However, if a treatment alternative is not available, properly designed and conducted indirect comparison using a common comparator in practice or placebo-controlled trial would be adopted in order to quantify the clinical benefits of the new drug. The weighting would follow the normal hierarchy of clinical evidence as advocated by evidence-based medicine.

Regarding the choice of endpoints, clinical trials which measure hard clinically important primary outcome endpoints are preferred over those using surrogate endpoints that only demonstrate strong correlation with the true clinical endpoint. Long-term outcome endpoints are always preferred. If these are not available, the limitation would be taken into account. Other elements of clinical study design that may affect data reliability, significance and relevance of trial results are also considered, such as precautions to minimise bias, randomisation, statistical methodology, trial size, duration of study, generalisability of trial population and relevance to the local target patient population, etc.

***Cost Effectiveness***

The cost-effectiveness of a new drug is evaluated by assessing its total cost impacts and making reference to related overseas pharmacoeconomic evaluation studies. The total impacts of a new drug on direct healthcare costs, including costs of drug acquisition and administration, treatment-associated in-/out-patient

service utilisation and monitoring of adverse reactions, are taken into account in order to determine whether listing of the new drug on the HADF would be cost saving, cost neutral or would pose a significantly higher cost to HA. The budget impact is assessed in the light of total service needs under the new drug's prescribing criteria and according to the estimated disease incidence / prevalence, cost of drug treatment and associated healthcare costs as opposed to those of existing treatments. The potential cumulative impacts on HA's budget arising from drug initiation for new cases and continuation of treatment for existing patients, together with the opportunity cost of using the new drug, would also be assessed. New drugs having significant budget impacts on HA would be addressed through the annual planning process with a view to soliciting additional funding allocation to list the new drugs on the HADF.

HA also makes reference to pharmacoeconomic evaluation studies in technology assessments conducted by overseas health authorities, in particular those with national reimbursement schemes comparable to the fees and charges for medical services provided by HA in Hong Kong, e.g. the United Kingdom, Australia and some Asian countries. It is well recognised that each healthcare jurisdiction has its unique system and no international studies and recommendations of overseas health authorities can be fully applicable. HA may make reference to local pharmacoeconomic evaluation studies, if available, and may consider commissioning such studies, if required, for evaluation of a new drug.

5) It is pointed out in paragraph 2.14 that the Drug Advisory Committee approved HADF drugs that were intended for corporate-wide use for the benefit of the general patient population. In this connection, will the authorities inform this Committee:

a) whether such practice is an express rule or a customary practice of HA, and of the justifications for so doing; and

b) why HA cannot procure a small amount of certain drugs to address the needs of a few patients?

a) As mentioned in the preamble of the HADF Management Manual (which is a public document accessible in HA's internet website), provision of sustainable and quality public healthcare services for residents of Hong Kong is the overarching mandate of HA. To this end, HA embarked on developing its Drug Formulary in 2003 along the core values of

evidence-based medical practice, rational use of public resources, targeted subsidy, opportunity cost considerations and facilitation of patients' choice. In July 2005, HADF was formally launched and uniform principles of managing the HADF were adopted by all HA institutions. Since then, new drugs of proven safety and efficacy have been introduced and the prevailing list of drugs has been regularly reviewed under the established mechanisms. Patients thus have equitable access to cost-effective drug treatments under the highly subsidised public healthcare system.

In the face of rising and competing demands for providing new drug treatments that vary widely in cost, therapeutic effectiveness, side effects and health outcome, it is imperative for HA, as a publicly-funded organisation, to ensure rational use of limited resources in order to provide adequate medical care and optimise the health benefits for the society.

b) With reference to the considerations for new drug evaluation for listing on the HADF, as mentioned in Section 3.4.3 of the HADF Management Manual, HA places high emphasis on maximising health benefits for the community while balancing the interests between different patient groups and individuals. For non-HADF drugs, there are established procedures to facilitate their use to cater for individual patient's needs in exceptional situations.

6) According to paragraphs 2.20 and 2.21, patients prescribed with non-HADF drugs in different public hospitals and clinics might be charged differently. Can the authorities explain why there is a situation where "the same drugs are charged differently"? And what criteria are used for determining the relevant fees and charges adopted by public hospitals and clinics and who made such decisions? Does HA have plans to enhance its transparency by keeping the public well informed of the relevant fees and charges adopted by various public hospitals and clinics? If HA does not have such plans, what are the reasons? Has HA established the charging principle for non-HADF drugs as mentioned in paragraph 2.29(d)? If HA has done so, what are the details and when will it be implemented? If HA has not done so, what are the implementation timetable and progress?

Clinically it is common that a drug may be indicated for use in more than one disease such that different patients using the same drug may have different underlying clinical conditions. In this connection, the use of drugs on different

patients cannot be compared directly.

HA has issued an internal operations circular setting out the charging policy for use of drugs (including both HADF and non-HADF drugs) in immediate life threatening emergency situations. Under these circumstances, drug treatments will be provided at standard fees and charges. If the use of non-HADF drugs is involved, clinicians will need to follow the established procedures to obtain prior endorsement of the Hospital DTC via the Chief of Service, and recommend if charging is required. The local DTCs would use the operations circular as a reference to guide them to decide on the charging. As mentioned in the audit report, 96.5% of prescriptions involving non-HADF drugs in 2015-16 were provided at standard fees and charges, meaning that the use of non-HADF drugs was essential for treatment in the majority of cases.

In view of the audit recommendations, HA will further elaborate the charging principles within the next 12 months by expanding the existing guideline to cover the general use of non-HADF drugs, taking into consideration whether the use is essential for treatment or patient's choice. Moreover, HA will expand the existing section on non-HADF drugs in the HADF Management Manual into a new chapter in the next revised version.

7) What is HA's response to the views of many patients and patient groups that non-HADF drugs are unaffordable by the general public?

HA has implemented the HADF since July 2005 with a view to ensuring equitable access by patients to cost effective drugs of proven safety and efficacy through standardisation of drug policy and drug utilisation in all public hospitals and clinics. At present, there are approximately 1,300 drugs listed on the Drug Formulary which are categorised into the following four groups:

a) General Drugs – These are drugs with well-established indications and cost-effectiveness which are available for general use as indicated by patients with relevant clinical indications and provided at standard fees and charges in public hospitals and clinics.

b) Special Drugs – These are drugs used under specific clinical conditions with specific specialist authorisation. Special drugs are provided at standard fees and charges in public hospitals and clinics when prescribed under specific clinical conditions. Patients who do not meet the specified

clinical conditions but choose to use Special drugs are required to pay for the drugs.

c) Self-financed Items ("SFIs") with Safety Net – These are drugs which are proven to be of significant clinical benefits but are extremely expensive for HA to provide as part of its standard services. These drugs are not covered by the standard fees and charges in public hospitals and clinics. Patients who require these drugs and can afford the costs have to purchase the drugs at their own expense. A safety net is provided through relevant funds to subsidise the drug expenses of patients who have financial difficulties.

d) SFIs without Safety Net – These include drugs with preliminary medical evidence only, drugs with marginal benefits over available alternatives but at significant higher costs, and lifestyle drugs (e.g. anti-obesity drugs). These drugs are not provided as part of HA's standard services nor covered by the standard fees and charges in public hospitals and clinics. Patients who choose to use these drugs must purchase them at their own expense.

Over 93% of drugs in the HADF are currently provided at standard fees and charges while the provision of SFI drugs without safety net in HADF is to provide patients with an additional choice of using such drugs at their own expense while continuing their treatment in the highly subsidised public healthcare system.

As mentioned in the audit report, 96.5% of prescriptions involving non-HADF drugs in 2015-16 were provided by HA at standard fees and charges. Hence, HA has mostly covered the clinical needs of individual patients for use of non-HADF drugs at a highly subsidised rate in public hospitals.

8) According to paragraph 2.31, there were on average 850 new drug items registered in each of the years between 2013 and 2015 in Hong Kong, but few HA hospitals and clinics had applied for new drug listing. Would there be a chance that new drugs were not given timely consideration for incorporation into HADF? Has HA found out the reasons why only a few HA hospitals, mainly the leading ones, have regularly applied for new drug listing? Is it because applications by other hospitals for new drug listing were not given due consideration or because of other reasons? Has HA encouraged and urged more hospitals and clinics to apply for new drug listing? If so, what are the details? If not, what are the reasons?

There are approximately 1,300 drugs listed on the HADF which covers a wide range of disease treatments. At present, even hospitals providing quaternary services have a range of approximately 1,100 drugs only in their hospital drug lists, demonstrating that the existing pool of drugs in the HADF is in general sufficient to meet the demand for public medical services.

A new drug entity or indication would be considered for listing if (a) it is registered in Hong Kong, (b) it is indicated for prevention or treatment of conditions which are not covered by drugs in the existing HADF, (c) it has an advantage in terms of efficacy and adverse effects over the existing agents in the HADF for the same indication; or (d) it is equivalent in terms of safety and efficacy as compared to the existing agents in the HADF for the same indication and of lower treatment costs. HA follows an evidence-based approach in evaluating new drug applications for listing on the HADF, having regard to three principal considerations of safety, efficacy and cost-effectiveness while taking into account other 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 views of professionals and patient groups.

There are currently over 20,000 registered drugs in Hong Kong. Among the new product registrations every year, the majority are related to new sources or formulations of existing drugs in the market. It would be unrealistic or impracticable for HA, as a publicly-funded organisation, to provide all registered drugs in the market through public funding. There is a continual need to review the development of the HADF under the established mechanisms.

HA has an establish mechanism for listing new drugs on the HADF. New drug applications are initiated by clinicians who are aware of international practices and market availabilities of new drugs relevant to their services. New technologies generally target advanced and complex clinical cases which are predominantly treated in hospitals with teaching and quaternary services. Hence new drug applications are usually submitted by hospitals engaged in teaching and quaternary services or serving as a specialised centre for certain diseases. All Hospital DTCs may submit new drug applications. However, Cluster DTCs would usually cover the need of their affiliated hospitals / clinics for new drug applications. Once a new drug application has been successfully

listed on the HADF, all hospitals may use the drug and there is no need to submit an application for the same drug / indication again.

In view of the audit recommendations, HA has requested Cluster and Hospital DTCs to set a standing agenda item on new drug applications in their DTC meetings, and has shared the link to the Department of Health's webpage on newly registered medicines in Hong Kong in the HADF website.

9) Based on paragraphs 2.33 and 2.34, will HA please explain why drugs in regular demand cannot be included in HADF? Was drug costs a consideration or were there other reasons?

HADF drugs are intended for corporate-wide use benefitting the entire local population while non-HADF drugs are to cater for the clinical needs of individual patients in exceptional situations. As stated in paragraph 2.10(b) of the audit report, the use of non-HADF drugs is an integral part of medical care, and accounts for only 0.3% of the total number of drug items dispensed in HA in 2015-16. The very low percentage of use is in line with the principle of using non-HADF drugs in exceptional situations.

In view of the audit recommendations, HA will set up a mechanism to strengthen the monitoring and analyse the frequency and duration of use of individual non-HADF drugs within and across hospitals, and evaluate the need for continual use. Hospital DTCs will be requested to review if there is a continual need for using certain non-HADF drugs and to consider submitting new drug applications to the HA Drug Advisory Committee for evaluation and listing on the HADF where appropriate.

10) Has HA reviewed whether it can establish bulk contracts for 520 drug items or some of them as mentioned in paragraph 3.10 and Table 9? If it has not, what are the reasons? If it has, why did it eventually fail to establish bulk contracts? Can HA assess the resource savings that can be achieved if bulk contracts for these drugs are established?

In HA, supply contracts are generally established for purchases exceeding $1.5 million. Out of those 520 drug items mentioned in the audit report, some are not suitable for supply contract arrangement, such as drug items that have extremely small patient pools and those which have unstable consumption patterns.

In fact, in line with HA's on-going drug procurement strategy, there have been progressive annual increases in the number of drug items procured under supply contracts in recent years, i.e. from 991 in 2013-14 to 1,153 in 2015-16 representing an overall increase by 16.3% in 3 years. HA has a working list of drug items planned for gradual inclusion in the bulk contract arrangement. The list is prioritised according to the annual consumption of different drugs and the need for central quotations to support purchases by local hospitals.

In response to the audit recommendations, HA will compare those 193 drug items against HA's working list and assess whether any of these items are suitable for bulk contract arrangements. However, since a significant portion of these items are proprietary products with patent protection, it is anticipated that the workflow for procuring these drug items will be streamlined but there would not be substantial savings through bulk contract arrangement.

11) Has HA investigated whether the situation mentioned in paragraph 3.11 has arisen because the hospitals concerned deliberately refrained from establishing bulk contracts or due to other reasons?

According to HA's Procurement and Materials Management Manual, hospitals are given the authority to make direct purchase at a value not exceeding $1.5 million while purchases exceeding $1.5 million should be centrally arranged through bulk contracts established by the HAHO. The case mentioned in Paragraph 3.11 of the audit report is within the approved purchase limits for direct purchase by hospitals. On the other hand, the recommended practice on procurement of drugs is that hospitals should enlist HAHO's support to seek quotations for direct purchase with a total value exceeding $100,000.

In response to the audit recommendations, HA will formalise the direct purchase practice into corresponding guidelines.

12) In connection with the aforesaid two questions, in cases where hospitals do not follow the existing procurement practices for drugs, has HA taken any follow-up actions and what are the outcomes?

As explained in the preceding reply, hospitals are given the authority to make direct purchase at a value not exceeding $1.5 million. The concerned hospitals have been reminded to follow the recommended practice to enlist HAHO's

support to seek quotations for direct purchase with a total value exceeding $100,000.

In response to the audit recommendations, HA will formalise the direct purchase practice into corresponding guidelines.

13) Has HA taken any follow-up actions against Supplier A in respect of the situation mentioned in paragraph 3.16? Has HA conducted any study on the procurement of drugs through other channels? If it has, why has it not adopted other channels to procure drugs? If not, what are the reasons?

HA has a well-established centralised procedure for handling drug delivery complaints. Every delivery complaint is centrally followed up by HAHO with the concerned supplier. In most cases, the drug suppliers are able to improve their delivery performance for the concerned products. If a particular delivery problem persisted and the supplier was not able to perform according to the contract, HA may convene a Performance Review Group meeting to review in detail the performance of the drug supplier for necessary follow-up action, which would include making recommendations to the tender assessment panel as to whether future tender submissions of the drug supplier would be considered.

Each of the delivery complaints against supplier A mentioned in the audit report had been followed up and necessary improvements were made. In response to the audit recommendation, HA will conduct regular Performance Review Group meetings to review the performance of manufacturers and suppliers.

14) What is the original intent of HA in setting the re-order levels and the minimum levels for drug items as mentioned in paragraph 3.22? What impacts will the situation mentioned in the paragraph probably have on medical services?

It is mentioned in paragraph 3.21 of the Director of Audit's Report that 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. HA's computerised Enterprise Resource Planning System would generate individual prompts to hospitals to consider re-ordering a drug item when its stock level drops to or below the re-order level which is calculated according to the consumption of the drug item and the stock on hand. These are reference prompts only to remind pharmacy staff that a particular product

may need re-ordering. However, the pharmacy staff would need to consider a basket of factors, including clinical needs, consumption trend and storage capacity, in determining whether re-ordering is necessary. There is another mechanism in place to prompt for regular checking of stock level such that the concerned drugs would not go out of stock and drug supply would not be discontinued even if the pharmacy staff does not follow the prompts.

15) In connection with the aforesaid question and according to HA's response in paragraph 3.23, pharmacy staff did not solely rely on the re-order levels and minimum levels generated by the computer system to determine when and the quantity to re-order. When did the aforesaid criteria for re-ordering drugs come into effect? Are these criteria implemented in all hospitals? Does HA know that the computer system has failed to effectively assist pharmacy staff in making drug re-ordering decisions? If not, what are the reasons that HA was not aware of the situation? If yes, how will HA improve the drug re-ordering procedure?

Since the pharmacy computer system was implemented in all hospitals in 1994, the same re-ordering prompt has been put into use across all hospitals for consideration of re-ordering individual drug items. Since then, the system prompt had undergone refinements on both the calculation and the re-ordering level. The system prompt has all along been providing useful information and remains a reference prompt for pharmacy staff to determine when to re-order, having regard to a basket of factors mentioned in the preceding reply.

In response to the audit recommendations, HA will continue to review and explore relevant factors to assist decision making in the drug re-ordering process.

16) Will HA please set out in a table the respective average periods of time covered by prescriptions (drug supply durations) dispensed to the following categories of patients from 2011-2012 to 2015-2016:

a) chronic disease patients at General Outpatient Clinics ("GOPCs");

b) other patients at GOPCs;

c) all patients at GOPCs;

d) chronic disease patients at Specialist Outpatient Clinics ("SOPCs");

e) other patients at SOPCs; and

f) all patients at SOPCs ?

HA does not maintain statistics of drug supply duration for patients with different diseases. The average drug supply durations, stratified into General Outpatient Clinics ("GOPCs") and Specialist Outpatient Clinics ("SOPC") patients, are set out below:

| HA GOPC Patients | | | | |
|---|---|---|---|---|
| Year | Average Drug Supply (in Days) | | | |
| | 0-18 Year Old | 19-65 Year Old | Over 65 Year Old | HA Overall |
| 2011-12 | 8.9 | 37.5 | 54.6 | 43.0 |
| 2012-13 | 8.9 | 38.4 | 56.9 | 44.3 |
| 2013-14 | 9.0 | 40.4 | 60.0 | 46.8 |
| 2014-15 | 9.0 | 42.9 | 63.1 | 49.8 |
| 2015-16 | 8.7 | 43.9 | 65.1 | 51.3 |

| HA SOPC Patients | | | | |
|---|---|---|---|---|
| Year | Average Drug Supply (in Days) | | | |
| | 0-18 Year Old | 19-65 Year Old | Over 65 Year Old | HA Overall |
| 2011-12 | 62.0 | 70.7 | 83.5 | 76.4 |
| 2012-13 | 62.5 | 72.0 | 85.6 | 78.1 |
| 2013-14 | 64.5 | 73.5 | 87.7 | 79.9 |
| 2014-15 | 65.8 | 76.0 | 90.5 | 82.6 |
| 2015-16 | 65.8 | 77.4 | 92.2 | 84.2 |

17) In connection with the aforesaid question, will a comparison between the current figures and the figures five years ago project a different picture? If so, what are the details and the reasons?

With the ageing of local population, the demand for general and specialist outpatient services in public hospitals has been increasing over the years. To cope with the increasing service demand, the intervals between follow-up medical appointments, hence the duration of drug supply to individual patients, have been lengthened.

Over the past five years, there had been a consistent increase in the duration of drug supply to individual patients with similar gradients of increase for all age groups of both GOPC and SOPC patients. In 2015-16, the average duration of SOPC prescriptions (84.2 days) was 32.9 days longer than that of the GOPC prescriptions (51.3 days). The drug supply duration for patients aged over 65 also ranked top among all age groups.

18) Can HA draw up guidelines on drug supply durations according to such factors as the nature or severity of different diseases?

The interval between outpatient medical appointments depends on the clinical conditions of individual patients, compounded by the increase in demand for public healthcare services which has resulted in extended intervals of medical appointments. Patients, even with the same disease, would have varied clinical conditions which warrant different intervals of follow-up appointments. It is therefore not appropriate to set the duration of drug supply for different diseases.

19) Regarding the pilot scheme mentioned by HA in paragraph 4.9(b), will HA provide the details and arrangement of the pilot scheme, including when and in which specialist outpatient clinics it will be tried out, the expected duration of the pilot scheme, as well as the timetable for the formal and full implementation of drug refill services, etc.?

At present, HA is actively planning the implementation of drug refill services for selected groups of specialist outpatients in phases. HA will prepare relevant technologies and strengthen resource provisions to facilitate service implementation. HA aims to launch a pilot programme for selected high-risk patients by the end of 2017-18, taking into consideration patients' age, poly-pharmacy and chronic medications with long duration of drug supply. HA will split their prescriptions and provide necessary support and drug counselling for targeted patients between refills through enhanced pharmacy services. Upon positive evaluation of the pilot programme, HA will consider extending the services to other SOPCs.

20) Has HA taken any follow-up actions against the hospitals mentioned in paragraphs 4.14 and 4.15? If HA has done so, what are the details? If it has not done so, what are the reasons?

HA has established operational guidelines on proper handling, safe custody, record keeping and disposal of dangerous drugs. The guidelines are reviewed and updated on a regular basis. In the event of missing dangerous drugs, the hospital concerned would conduct investigation and analyse the potential risk factors and possible root causes so as to prevent recurrence of similar incidents in future. Regarding the four incidents of missing dangerous drugs that occurred in the same hospital, the concerned hospital had conducted prompt investigations and took necessary follow-up actions, including review of drug administration and dangerous drug register records, interviewing the concerned staff to obtain further details of the incidents, reporting the incidents to the Police and introducing necessary improvement measures. As the four incidents happened in different wards and involved different personnel over a period of three years, HAHO concurred that they were isolated incidents. The concerned hospital had been asked to reinforce among its frontline staff the importance of strict adherence to relevant guidelines on handling of dangerous drugs.

21) According to paragraph 4.16, five incidents (16%) of missing dangerous drugs had not been reported to the Department of Health after a lapse of 425 to 1 494 days since they were found missing, why did the authorities fail to practically implement the relevant reporting mechanism? Does such situation reflect that there are inadequacies in the mechanism for reporting incidents of missing dangerous drugs? What are the follow-up actions taken by the authorities in respect of cases involving delayed reporting of missing dangerous drugs?

In the past, there was not a standardised workflow among HA hospitals on reporting of missing dangerous drug incidents to the Department of Health. As a result of miscommunication between clinical departments and pharmacy and the lack of a standardised workflow, five incidents of delayed reporting on missing dangerous drugs occurred.

HA has reviewed the situation and formulated a standardised workflow across HA hospitals. From now on, hospital pharmacy would take up to report dangerous drug irregularities to the Department of Health. Furthermore, the concerned departments are required to report the incidents to the hospital management and HAHO via the Advance Incident Reporting System such that the incidents will be duly monitored and followed-up.

22) Regarding the situation mentioned in paragraph 5.5, will HA inform this Committee whether laboratories had explained the reasons to HA on each occasion of late submission of reports? What were the respective numbers of reports that were not submitted within the required time in each of the past five years? Have the authorities taken any follow-up actions against the laboratories concerned? What are the progress and specific details of HA's actions in following up on its response set out in paragraph 5.8(b), including how contract terms will be refined to reduce the occurrence of delayed submission of test reports?

The terms of the testing contract stipulate that a test report should be submitted to HA within 90 calendar days and the laboratory may request for extension of the submission deadline with justifications, which may be granted by HA when deemed necessary. It is not uncommon that extra time would be required for conducting sample drug tests, for reasons including the need for acquiring chemical reference standards and procuring specific apparatus or equipment. In each case where extra time was required, the laboratory had communicated with HA to explain the situation and request for extension. HA maintained communication with the testing laboratories until the report was submitted. In the past 3 years, the proportion of sample drug tests that required extra time for completion amounted to 52%, 41% and 65% respectively.

In response to the audit recommendations, HA will 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.

23) Can HA explain in detail the reasons for failing to conduct any inspection visit to Supplier D as mentioned in Case 3 of paragraph 5.11? In such a case, how can HA ensure that the drugs supplied comply with the expected quality standards and the safety of those members of the public who take the drugs concerned?

The Department of Health is the regulatory body responsible for ensuring the quality and safety of drug products used in Hong Kong, and would inspect premises of drug manufacturers and suppliers for overall compliance with applicable laws and regulations. HA, as the major purchaser of drugs for delivering quality public healthcare services in Hong Kong and in exercising its due diligence, has an established risk-based inspection programme taking

severity and frequency of complaints as the priortisation criteria. HA would inspect the premises of drug manufacturers and suppliers to review their compliance with the contract requirements as well as improvement measures with respect to drug product quality complaints.

In response to the audit recommendation, HA will review the existing programme on inspection of premises of drug suppliers.

24) Regarding the situation mentioned in paragraph 5.15, why did HA not strictly enforce the requirement for those suppliers who had failed to report within the one-month time frame? In respect of the suppliers' late submission of reports, have the authorities required suppliers to give an explanation or take follow-up actions? In such a case, how can HA ensure the safety of those members of the public who take the drugs concerned?

In its initial correspondence with the supplier / manufacturer on investigating a drug quality complaint, HA would request for submission of an investigation report within one month. In the course of following up individual complaints, HA would maintain close communication with the supplier on the progress of investigation. However, certain investigations may involve time-consuming logistics such as returning samples to overseas manufacturers, commissioning independent tests and implementing improvement measures that require regulatory approvals. All these actions require ample time for completion and HA would keep on reviewing the progression of individual investigations.

For high-risk cases with potential impacts on patient safety, the concerned drug products would be withheld from use in HA while the investigation result is pending to ensure that patient safety is not compromised. HA will also notify the Department of Health of such high-risk cases if necessary.

25) Regarding its response set out in paragraph 5.18, will HA please inform this Committee of the specific measures taken by HA to monitor the progress of investigation of complaints, as well as the details and progress of and the timetable for formulating performance indicators?

HA will categorise the investigation process requirements in the light of the complaint nature, and analyse the distribution of cases in order to develop key performance indicators for monitoring the investigation of drug product quality complaints. The key performance indicators will be established within 12

months and the mechanism will be reviewed periodically to ensure effective and quality investigation of drug product quality complaints.

26) What were the respective numbers of patients who had been approved and had been rejected to receive subsidies under the Samaritan Fund and the Community Care Fund?

The table below sets out the application statistics for drug items for the Samaritan Fund ("SF") and the Community Care Fund ("CCF") Medical Assistance Programme for the past five years:

| Year | Samaritan Fund | | CCF Medical Assistance Programme | |
|---|---|---|---|---|
| | Number of applications approved for subsidy | Number of applications rejected | Number of applications approved for subsidy | Number of applications rejected |
| 2011-12 | 1,516 | 3 | 200 | 1 |
| 2012-13 | 1,745 | 0 | 829 | 0 |
| 2013-14 | 2,027 | 0 | 1,364 | 0 |
| 2014-15 | 2,230 | 0 | 1,680 | 0 |
| 2015-16 | 2,237 | 0 | 1,678 | 0 |

27) Regarding the situation mentioned in paragraph 6.7, can HA inform this Committee:

a) whether HA has reflected such situation to the Government, and regarding the aspirations of many patients and patient groups for expanding the coverage of the safety net, whether it has conducted studies on how to make improvement in this respect and respond to such aspirations; if so, of the outcome and the specific enhancement measures; if not, the reasons for that;

b) whether the authorities have reviewed if the threshold for including drugs under the safety net is excessively high; and

c) of the assistance that can be provided by HA for patients who cannot afford self-financed drugs without safety net for treatment of cancers?

a) The Government's healthcare policy is to ensure that no one is prevented, through lack of means, from obtaining adequate medical treatment. To fulfil

this policy objective, 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 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 guided by the principles of evidence-based medical practice, targeted subsidy and opportunity costs considerations, SFI drugs (both with or without safety net) are non-standard provisions in HA and fall outside the scope of this policy. Patients will have to purchase these drugs at their own expenses.

SFIs with Safety Net are drugs which are proven to be of significant clinical benefits but are extremely expensive for HA to provide as part of its standard services. These drugs are not covered by the standard fees and charges in public hospitals and clinics. Patients who require these drugs and can afford the costs have to purchase the drugs at their own expense. A safety net is provided through relevant funds to subsidise the drug expenses of patients who have financial difficulties.

SFIs without Safety Net include drugs with preliminary medical evidence only, drugs with marginal benefits over available alternatives but at significant higher costs, and lifestyle drugs (e.g. anti-obesity drugs). These drugs are not provided as part of HA's standard services nor covered by the standard fees and charges in public hospitals and clinics. Patients who choose to use these drugs must purchase them at their own expense.

The therapeutic objectives of these drugs fell outside the scope of highly subsidised public medical services. Nevertheless, the provision of SFI 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.

HA has always valued views from patients and patient groups for expanding the coverage of safety nets, and 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, etc.

Over the years, HA has expanded the coverage of the SF and the CCF Medical Assistance Programme to cover more SFI drugs and repositioned certain SFI drugs covered by the SF and the CCF Medical Assistance Programme as Special drugs in the HADF which are provided at standard fees and charges in public hospitals. From 2010-11 to 2015-16, 16 SFI drugs had been introduced to the SF, and 9 SFI drugs / indications under the coverage of the SF repositioned as Special Drugs. As for the CCF Medical Assistance Programme, since its commencement in August 2011 to 2015-16, 12 SFI drugs has been introduced to its coverage, and 2 SFI drugs / indications originally covered by CCF Medical Assistance Programme has been included in the coverage of the SF. Furthermore, since 2010-11, there are 22 SFI drugs without safety net repositioned as Special Drugs.

b) Guided by the principles of evidence-based medical practice, targeted subsidy and opportunity costs considerations, HA has already included those SFI drugs which are proven to be of significant clinical benefits but are extremely expensive for HA to provide as part of its standard services in the SF safety net.

As for those SFI drugs which have not yet fulfilled the criteria for inclusion in the safety net coverage of SF, the HA, since August 2011, administers the CCF medical assistance programme under the supervision of the Food and Health Bureau, and included those SFI cancer drugs which have been rapidly accumulating medical scientific evidence and with relatively higher efficacy in the coverage of the programme to provide subsidy for needy patients who require those drugs.

c) SFI drugs without safety net include drugs with preliminary medical evidence only, drugs with marginal benefits over available alternatives but at significant higher costs, and 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 SFI 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.

For those patients who choose not to use those SFI drugs without safety net, HA would continue to provide them with other medical services under the prevailing scope of services such as appropriate alternate drugs, operation and radiation therapy.

28) As it is pointed out in paragraph 6.15 that the percentage of cases of under-reporting of assets and/or income was high and in paragraph 6.21 that a long time was taken to follow up on some significant under-reporting cases, does this reflect that there are inadequacies in the relevant follow-up mechanism? What specific measures (including the number of manpower deployed) has HA put in place to curb abuse or deceptive fraud cases?

HA started to conduct post-approval check of the SF and CCF applications since 2010. The under-reporting cases with overpayment of subsidy were found to decrease from 27% in 2010/11 to 1% in 2015/16. And the amount overpaid was also reduced from $820,000 in 2010/11 to $33,000 in 2015/16. The decreasing trend demonstrates the effectiveness of the HA's measures on preventing and deterring fraud.

For the significant under-reporting cases, the Cluster Checking Units ("CCUs") will first collate the relevant documents and information of cases and then refer them to the Head Office Medical Fee Assistance ("MFA") Section for level-2 checks. Upon receiving CCU's referrals, the MFA will review and check if there is other approved application under the same patient. If other applications are found, MFA will wait for CCUs to complete checking of these applications before referring the case to case conference for deciding the appropriate follow up actions. Therefore, some of the cases with multiple applications might take longer processing time. On the other hand, in 2016, HA launched an electronic system to conduct post-approval checks. The system will help to streamline checking process, enhance checking efficiency and monitor checking processing time. HA will also develop performance indicators to monitor the processing times of level-1 and level-2 checks.

To safeguard public funds, HA has been implementing multiple measures to prevent and deter fraud. Measures for the public include educating public the importance of honesty through posters, leaflets, education video, media briefing and patient forum. Measures for the subsidy applicants include specifying the consequence of acquiring subsidy by deception in the subsidy briefs and the application forms. The patient and his household members are also required to the declaration confirming their understanding on the consequences. For the post-approval checking, HA is exploring to sample more cases with substantial amount of subsidy for checking, to expand the scope of checking and extend the bank search period up to the expiry of the validity period of the financial assistance so as to enhance the detection of fraud and abuse.

**Response from Department of Health**

1) According to paragraph 4.16, five incidents (16%) of missing dangerous drugs had not been reported to DH after a lapse of 425 to 1 494 days since they were found missing, why did the authorities fail to practically implement the relevant reporting mechanism? Does such situation reflect that there are inadequacies in the mechanism for reporting incidents of missing dangerous drugs? What are the follow-up actions that will be taken by the authorities in respect of cases involving delayed reporting of missing dangerous drugs?

   According to the Dangerous Drugs Ordinance, hospitals authorized to possess dangerous drugs shall forthwith notify the Director of Health once they found that the proper quantity of any dangerous drug is not in their possession. Any person who fails to notify the Director of Health in accordance with the provisions shall be guilty of an offence and shall be liable on conviction to a fine of $5000.

   When DH received notifications of incidents of missing dangerous drugs from HA in May 2016, the DH immediately sought advice from the Department of Justice (DOJ) on the cases of suspected delayed notifications, and issued an advisory letter to the HA in August 2016, upon DOJ's advice, reminding the HA to handle 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.

**Response from Food and Health Bureau**

1) Why do self-financed drugs fall outside the scope of the Government's healthcare policy mentioned in paragraph 6.12(a)? If there are patients who cannot afford certain types of self-financed drugs without safety net for treatment of cancers, while the drugs concerned are of prime importance to the treatments they need, and yet self-financed drugs fall outside the scope of the prevailing healthcare policy, does it contrary to the Government's objective of "ensuring that no one is prevented, through lack of means, from obtaining adequate medical treatment"? Has the Administration ever consulted the Legislative Council and the public on the issue of self-financed drugs falling outside the scope of the prevailing healthcare policy, and explained to them the relevant reasons and details?

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.

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).

In both 2013-14 and 2014-15, general drugs and special drugs, which were highly subsidized 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.

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.

**Abbreviation**

| | |
|---|---|
| CCF | Community Care Fund |
| CCU | Cluster Checking Unit |
| DTC | Drug and Therapeutics Committee |
| DH | Department of Health |
| GOPC | General Outpatient Clinic |
| HA | Hospital Authority |
| HADF | Hospital Authority Drug Formulary |
| HAHO | Hospital Authority Head Office |
| MFA | Medical Fee Assistance |
| SFI | Self-financed Item |
| SF | Samaritan Fund |
| SOPC | Specialist Outpatient Clinic |