Report No. 53 of the Director of Audit — Chapter 4

CONTROL OF CHINESE MEDICINES

Summary

1. In 1999, the Chinese Medicine Ordinance (CMO — Cap. 549) was enacted to provide a statutory framework for the regulation of Chinese medicines (namely Chinese herbal medicines and proprietary Chinese medicines — pCms) to safeguard public health. In September 1999, the Chinese Medicine Council (CMC) was set up to develop and implement regulatory measures. In 2003, a registration system for pCms and a licensing system for Chinese medicines traders came into operation. The Department of Health (DH) is responsible for providing executive and technical support to the CMC, and enforcing the CMO. The Audit Commission (Audit) has recently conducted a review of the implementation of the CMO. The review also covered the DH's work on regulation of undesirable medical advertisements.

Registration of proprietary Chinese medicines

2. The CMO provides for two types of registration, namely non-transitional registration of pCms manufactured or sold in Hong Kong and transitional registration for those manufactured or sold on 1 March 1999. For registration of a pCm, the Chinese Medicines Board (CMB) of the CMC requires an applicant to submit supporting documents to prove the safety, quality and efficacy of the pCm.

3. ***Slow progress in processing the applications for pCm registration.*** In 2002, the DH informed the Legislative Council Panel on Health Services (Health Panel) that it would take two to three years for all pCms to be registered. As at 31 July 2009, 652 (4.6% of 14,092) transitional registration applications and 1,861 (77.9% of 2,389) non-transitional registration applications were still under processing. *Audit has recommended that the Director of Health should inform the Health Panel if the actual implementation time of a public health related service turns out to be later than expected.*

4. ***Estimation of registration applications.*** In September 2006, the DH informed the Food and Health Bureau that one of the major difficulties encountered in the pCm registration process was that the applications received had exceeded the original estimate by 60%. According to the DH, the estimate was made after consulting the pCm trade

associations but no supporting documents were maintained. *Audit has recommended that the Director of Health should keep supporting documents used for planning the manpower requirement of a new service to facilitate a post-implementation review.*

5. ***Limitations before implementing section 119 of CMO.*** Section 119 provides that no person shall sell, import or manufacture any pCm unless it is registered. Because of the slow progress in processing the pCm registration applications, as at September 2009, there was no scheduled date for implementing section 119. At present, the DH cannot take enforcement action against the manufacture and sale of unregistered pCms. The DH has worked out a plan for commencing section 119 and would consult relevant parties in due course. *Audit has recommended that the Director of Health should expedite action to complete the pCm registration so that section 119 of the CMO can be implemented early.*

6. ***Incomplete registration documents.*** According to the registration procedures, all the registration documents for non-transitional registration must be submitted at the time when an application is made. Although most of the applications had been received by 30 June 2004, there were still 817 applications with incomplete registration documents as at 31 July 2009. *Audit has recommended that the Director of Health should expedite the checking of the completeness of registration documents at the time of receipt of an application.*

7. ***Submission of supporting documents.*** According to the timetable for submitting supporting documents (by phases) under transitional registration, the Third Phase documents were due on 30 June 2009. As at 27 August 2009, the DH received submissions for 6,991 (80%) of the 8,765 pCms. However, 76% of these 6,991 submissions were incomplete. *Audit has recommended that the Director of Health should closely monitor the submission of supporting documents under the transitional registration.*

Licensing of Chinese Medicines Traders

8. According to the CMO, four types of traders (namely retailers and wholesalers of Chinese herbal medicines, and wholesalers and manufacturers of pCms) must apply for a formal licence under the non-transitional licensing arrangement. Those traders already in business on 3 January 2000 might apply within a specified period (5 May to 15 July 2003) for a transitional certificate under the transitional licensing arrangement. As at 31 July 2009, 7,174 trader licences were issued (2,717 transitional certificates and 4,457 formal licences).

9. ***Need to expedite formal licensing of transitional certificate holders.*** In accordance with the transitional licensing arrangement, the DH had not inspected traders' business premises before issuing transitional certificates to them. The DH usually inspects

their premises when processing their applications for formal licences. To safeguard public health, the DH aimed to complete the pre-licensing inspections of all transitional certificate holders by March 2011. *Audit has recommended that the Director of Health should: (a) expedite the pre-licensing inspections of transitional certificate holders; and (b) closely monitor the progress of the inspections to meet the target completion date*.

10. ***Licensing inspections.*** Audit staff attended as observers in four of the DH's licensing inspections of traders. For one of the inspections, Audit noted that there was inadequate checking of the trader's compliance with the Chinese Medicines Regulation (CMR — Cap. 549F) requirements on record keeping. *Audit has recommended that the Director of Health should step up the checking of traders' compliance with the CMR requirements on record keeping*.

11. ***Unlicensed pCm manufacturers and wholesalers.*** While the CMO provisions prohibiting the manufacture and import of pCms by unlicensed traders have been implemented since January 2008, Audit noted in June 2009 that there were 82 pCms registered under the transitional arrangement relating to 30 unlicensed traders. *Audit has recommended that the Director of Health should: (a) urge the 30 unlicensed traders to obtain relevant trader licences as early as possible; and (b) conduct inspections to ensure that these traders do not supply the pCms for sale before obtaining the licences*.

12. ***Illegal sale of Chinese herbal medicines.*** In June and July 2009, Audit found that 19 retailers of Chinese herbal medicines were operating without a licence. While 6 of these retailers were applying for a licence, they commenced operation before the issue of the licence. *Audit has recommended that the Director of Health should: (a) remind trader licence applicants not to commence operation before obtaining a licence; and (b) take proactive action to detect illegal sale of Chinese herbal medicines*.

Surveillance of Chinese medicines

13. ***Market surveillance.*** The DH has put in place a surveillance system to monitor the safety and quality of Chinese medicines for sale in the market. In 2008, 31 sampled products were found adulterated with either western medicines or excessive heavy metals, and 6 of them had pCm registration records. The CMB was not informed of these 6 cases although in 2005, the CMB decided that an applicant for pCm registration should be required to submit explanations if his pCm was found to have safety problem. Audit also noted that among the samples purchased in 2008 for market surveillance, there were 9 pCms for which their registration applications had been rejected or withdrawn. *Audit has recommended that the Director of Health should: (a) ensure that the regulatory procedure laid down by the CMB for dealing with pCms found to have safety and quality problems is strictly followed; and (b) make use of the market surveillance programme to monitor the sale of unregistered pCms in the market*.

14. ***Web surveillance.*** In 2008, the DH identified, through its web surveillance, some 660 news items relating to pCms with quality or safety problems in other places. Four problematic pCms were found to have registration records in Hong Kong. Audit found that there was room for improvement in the DH's follow-up action on these cases. For example, there was no documentation of the reason for not taking follow-up action on two of these cases after ascertaining that they had import licence records. *Audit has recommended that the Director of Health should ensure that proper follow-up action is taken on Chinese medicines identified to have quality or safety problem by web surveillance.*

Regulation of undesirable medical advertisements

15. Advertisements of medicines (whether western or Chinese) are governed by the Undesirable Medical Advertisements Ordinance (UMAO — Cap. 231). The aim is to protect the public from being misled into improper self-medication.

16. ***Screening of medical advertisements.*** For enforcing the UMAO, the DH screens advertisements on different media. For the three years from 2006 to 2008, less than 1% of the advertisements screened were on the Internet. *Audit has recommended that the Director of Health should consider increasing the screening of advertisements on the Internet.*

17. ***Undesirable Medical Advertisements (Amendment) Ordinance 2005 not yet commenced.*** In June 2005, the Undesirable Medical Advertisements (Amendment) Ordinance was enacted to restrict 6 types of undesirable health claims. For products making certain permissible claims, a disclaimer must be put in the advertisement to inform consumers that they are not products registered under the CMO or the Pharmacy and Poisons Ordinance (Cap. 138). As the registration of pCms was still in progress, up to September 2009, a day for commencing the Amendment Ordinance has therefore not yet been appointed. *Audit has recommended that the Director of Health should expedite action to complete the pCm registration so that the Amendment Ordinance can be put into operation as soon as possible.*

Response from the Administration

18. The Administration agrees with the audit recommendations.

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